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

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 747

RIN 3133–AF40

Civil Monetary Penalty Inflation Adjustment

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The NCUA Board (Board) is amending its regulations to adjust the maximum amount of each civil monetary penalty (CMP) within its jurisdiction to account for inflation. This action, including the amount of the adjustments, is required under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: This final rule is effective January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Gira Bose, Senior Staff Attorney, at 1775 Duke Street, Alexandria, VA 22314, or telephone: (703) 518–6562.

SUPPLEMENTARY INFORMATION:

I. Legal Background
II. Regulatory Procedures

I. Legal Background

A. Statutory Requirements

Every Federal agency, including the NCUA, is required by law to adjust its maximum CMP amounts each year to account for inflation. Prior to this being an annual requirement, agencies were required to adjust their CMPs at least once every four years. The previous four-year requirement stemmed from the Debt Collection Improvement Act of 1996,[1] which amended the Federal Civil Penalties Inflation Adjustment Act of 1990.[2]

The current annual requirement stems from the Bipartisan Budget Act of 2015,[3] which contains the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 amendments).[4] This legislation provided for an initial ''catch-up'' adjustment of CMPs in 2016, followed by annual adjustments. The catch-up adjustment reset CMP maximum amounts by setting aside the inflation adjustments that agencies made in prior years and instead calculated inflation with reference to the year when each CMP was enacted or last modified by Congress. Agencies were required to publish their catch-up adjustments in an interim final rule by July 1, 2016, and make them effective by August 1, 2016.[5] The NCUA complied with these requirements in a June 2016 interim final rule, followed by a November 2016 final rule to confirm the adjustments as final.[6]

The 2015 amendments also specified how agencies must conduct annual inflation adjustments after the 2016 catch-up adjustment. Following the catch-up adjustment, agencies must make the required adjustments and publish them in the **Federal Register** by January 15 each year.[7] For 2017, the NCUA issued an interim final rule on January 6, 2017,[8] followed by a final rule issued on June 23, 2017.[9] For 2018, 2019, 2020, and 2021 the NCUA issued a final rule in each year to satisfy the agency's annual requirements.[10] This final rule satisfies the agency's requirement for the 2022 annual adjustment.

The law provides that the adjustments shall be made notwithstanding the section of the Administrative Procedure Act (APA) that requires prior notice and public comment for agency rulemaking.[11] The 2015 amendments also specify that each CMP maximum must be increased by the percentage by which the consumer price index for urban consumers (CPI–U)[12] for October of the year immediately preceding the year the adjustment is made exceeds the CPI–U for October of the prior year.[13] Thus, for the adjustment to be made in 2022, an agency must compare the October 2020 and October 2021 CPI–U figures.

An annual adjustment under the 2015 amendments is not required if a CMP has been amended in the preceding 12 months pursuant to other authority. Specifically, the statute provides that an agency is not required to make an annual adjustment to a CMP if in the preceding 12 months it has been increased by an amount greater than the annual adjustment required by the 2015 amendments.[14] The NCUA did not make any adjustments in the preceding 12 months pursuant to other authority. Therefore, this rulemaking adjusts the NCUA's CMPs pursuant to the 2015 amendments.

B. Application to the 2022 Adjustments and Office of Management and Budget Guidance

This section applies the statutory requirements and the Office of Management and Budget's (OMB) guidance to the NCUA's CMPs and sets forth the Board's calculation of the 2022 adjustments.

The 2015 amendments directed OMB to issue guidance to agencies on implementing the inflation adjustments.[15] OMB is required to issue its guidance each December and, with respect to the 2022 annual adjustment, did so on December 15, 2021.[16] For 2022, Federal agencies must adjust the maximum amounts of their CMPs by the percentage by which the October 2021

[1] Public Law 104–134, Sec. 31001(s), 110 Stat. 1321–373 (Apr. 26, 1996). The law is codified at 28 U.S.C. 2461 note.

[2] Public Law 101–410, 104 Stat. 890 (Oct. 5, 1990), codified at 28 U.S.C. 2461 note.

[3] Public Law 114–74, 129 Stat. 584 (Nov. 2, 2015).

[4] 129 Stat. 599.

[5] Public Law 114–74, Sec. 701(b)(1), 129 Stat. 584, 599 (Nov. 2, 2015).

[6] 81 FR 40152 (June 21, 2016); 81 FR 78028 (Nov. 7, 2016).

[7] Public Law 114–74, Sec. 701(b)(1), 129 Stat. 584, 599 (Nov. 2, 2015).

[8] 82 FR 7640 (Jan. 23, 2017).

[9] 82 FR 29710 (June 30, 2017).

[10] 83 FR 2029 (Jan. 16, 2018); 84 FR 2052 (Feb. 6, 2019); 85 FR 2009 (Jan. 14, 2020); 86 FR 933 (Jan. 7, 2021).

[11] Public Law 114–74, Sec. 701(b)(1), 129 Stat. 584, 599 (Nov. 2, 2015).

[12] This index is published by the Department of Labor, Bureau of Labor Statistics, and is available at its website: *https://www.bls.gov/cpi/*.

[13] Public Law 114–74, Sec. 701(b)(2)(B), 129 Stat. 584, 600 (Nov. 2, 2015).

[14] Public Law 114–74, Sec. 701(b)(1), 129 Stat. 584, 600 (Nov. 2, 2015).

[15] Public Law 114–74, Sec. 701(b)(4), 129 Stat. 584, 601 (Nov. 2, 2015).

[16] See OMB Memorandum M–22–07, Implementation of Penalty Inflation Adjustments for 2022, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (December 15, 2021).

CPI–U (276.589) exceeds the October 2020 CPI–U (260.388). The resulting increase can be expressed as an inflation multiplier (1.06222) to apply to each current CMP maximum amount to determine the adjusted maximum. The OMB guidance also addresses rulemaking procedures and agency reporting and oversight requirements for CMPs.[17]

The table below presents the adjustment calculations. The current maximums are found at 12 CFR 747.1001, as adjusted by the final rule that the Board approved in January 2021. This amount is multiplied by the inflation multiplier to calculate the new maximum in the far-right column. Only these adjusted maximum amounts, and not the calculations, will be codified at 12 CFR 747.1001 under this final rule. The adjusted amounts will be effective upon publication in the **Federal Register** and can be applied to violations that occurred on or after November 2, 2015, the date the 2015 amendments were enacted.[18]

TABLE—CALCULATION OF MAXIMUM CMP ADJUSTMENTS

Citation	Description and tier[19]	Current maximum ($)	Multiplier	Adjusted maximum ($) (Current maximum × multiplier, rounded to nearest dollar)
12 U.S.C. 1782(a)(3)	Inadvertent failure to submit a report or the inadvertent submission of a false or misleading report.	4,146	1.06222	4,404.
12 U.S.C. 1782(a)(3)	Non-inadvertent failure to submit a report or the non-inadvertent submission of a false or misleading report.	41,463	1.06222	44,043.
12 U.S.C. 1782(a)(3)	Failure to submit a report or the submission of a false or misleading report done knowingly or with reckless disregard.	Lesser of 2,073,133 or 1% of total credit union (CU) assets.	1.06222	Lesser of 2,202,123 or 1% of total CU assets.
12 U.S.C. 1782(d)(2)(A).	Tier 1 CMP for inadvertent failure to submit certified statement of insured shares and charges due to the National Credit Union Share Insurance Fund (NCUSIF), or inadvertent submission of false or misleading statement.	3,791	1.06222	4,027.
12 U.S.C. 1782(d)(2)(B).	Tier 2 CMP for non-inadvertent failure to submit certified statement or submission of false or misleading statement.	37,901	1.06222	40,259.
12 U.S.C. 1782(d)(2)(C).	Tier 3 CMP for failure to submit a certified statement or the submission of a false or misleading statement done knowingly or with reckless disregard.	Lesser of 1,895,095 or 1% of total CU assets.	1.06222	Lesser of 2,013,008 or 1% of total CU assets.
12 U.S.C. 1785(a)(3)	Non-compliance with insurance logo requirements.	129	1.06222	137.
12 U.S.C. 1785(e)(3)	Non-compliance with NCUA security requirements.	301	1.06222	320.
12 U.S.C. 1786(k)(2)(A).	Tier 1 CMP for violations of law, regulation, and other orders or agreements.	10,366	1.06222	11,011.
12 U.S.C. 1786(k)(2)(B).	Tier 2 CMP for violations of law, regulation, and other orders or agreements and for recklessly engaging in unsafe or unsound practices or breaches of fiduciary duty.	51,827	1.06222	55,052.
12 U.S.C. 1786(k)(2)(C).	Tier 3 CMP for knowingly committing the violations under Tier 1 or 2 (natural person).	2,073,133	1.06222	2,202,123.
12 U.S.C. 1786(k)(2)(C).	Tier 3 (same) (CU)	Lesser of 2,073,133 or 1% of total CU assets.	1.06222	Lesser of 2,202,123 or 1% of total CU assets.
12 U.S.C. 1786(w)(5)(A)(ii).	Non-compliance with senior examiner post-employment restrictions.	341,000	1.06222	362,217.
15 U.S.C. 1639e(k)	Non-compliance with appraisal independence standards (first violation).	11,906	1.06222	12,647.
15 U.S.C. 1639e(k)	Subsequent violations of the same	23,811	1.06222	25,293.
42 U.S.C. 4012a(f)(5)	Non-compliance with flood insurance requirements.	2,252	1.06222	2,392.

II. Regulatory Procedures

A. Final Rule Under the APA

In the 2015 amendments, Congress provided that agencies shall make the required inflation adjustments in 2017 and subsequent years notwithstanding 5 U.S.C. 553,[20] which generally requires agencies to follow notice-and-comment procedures in rulemaking and to make rules effective no sooner than 30 days after publication in the **Federal Register**. The 2015 amendments provide a clear exception to these requirements.[21] In addition, as an

[17] *Id.*

[18] Public Law 114–74, 129 Stat. 600 (Nov. 2, 2015).

[19] The table uses condensed descriptions of CMP tiers. Refer to the U.S. Code citations for complete descriptions.

[20] Public Law 114–74, Sec. 701(b)(1), 129 Stat. 584, 599 (Nov. 2, 2015).

[21] See 5 U.S.C. 559; *Asiana Airlines* v. *Fed. Aviation Admin.,* 134 F.3d 393, 396–99 (D.C. Cir. 1998).

independent basis, the Board finds that notice-and-comment procedures would be impracticable and unnecessary under the APA because of the largely ministerial and technical nature of the rule, which affords agencies limited discretion in promulgating the rule, and the statutory deadline for making the adjustments.[22] In these circumstances, the Board finds good cause to issue a final rule without issuing a notice of proposed rulemaking or soliciting public comments. The Board also finds good cause to make the final rule effective upon publication because of the statutory deadline. Accordingly, this final rule is issued without prior notice and comment and will become effective immediately upon publication.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that when an agency issues a proposed rule or a final rule pursuant to the APA [23] or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**.[24] Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. For purposes of the RFA, the Board considers federally insured credit unions (FICUs) with assets less than $100 million to be small entities.[25]

As discussed previously, consistent with the APA,[26] the Board has determined for good cause that general notice and opportunity for public comment is unnecessary, and therefore the Board is not issuing a notice of proposed rulemaking. Rules that are exempt from notice and comment procedures are also exempt from the RFA requirements, including conducting a regulatory flexibility analysis, when among other things the agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest. Accordingly, the Board has concluded that the RFA's requirements relating to initial and final regulatory flexibility analysis do not apply.

Nevertheless, the Board notes that this final rule will not have a significant economic impact on a substantial number of small credit unions because it affects only the maximum amounts of CMPs that may be assessed in individual cases, which are not numerous and generally do not involve assessments at the maximum level. In addition, several of the CMPs are limited to a percentage of a credit union's assets. Finally, in assessing CMPs, the Board generally must consider a party's financial resources.[27] Because this final rule will affect few, if any, small credit unions, the Board certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency creates a new paperwork burden on regulated entities or modifies an existing burden.[28] For purposes of the PRA, a paperwork burden may take the form of either a reporting or a recordkeeping requirement, both referred to as information collections. This final rule adjusts the maximum amounts of certain CMPs that the Board may assess against individuals, entities, or credit unions but does not require any reporting or recordkeeping. Therefore, this final rule will not create new paperwork burdens or modify any existing paperwork burdens.

D. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, the NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the Executive order. This final rule adjusts the maximum amounts of certain CMPs that the Board may assess against individuals, entities, and federally insured credit unions, including state-chartered credit unions. However, the final rule does not create any new authority or alter the underlying statutory authorities that enable the Board to assess CMPs. Accordingly, this final rule will not have a substantial direct effect on the states, on the connection between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. The Board has determined that this final rule does not constitute a policy that has federalism implications for purposes of the Executive order.

E. Assessment of Federal Regulations and Policies on Families

The Board has determined that this final rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.[29]

F. Congressional Review Act

For purposes of the Congressional Review Act,[30] the OMB makes a determination as to whether a final rule constitutes a ''major'' rule. If OMB deems a rule to be a ''major rule,'' the Congressional Review Act generally provides that the rule may not take effect until at least 60 days following its publication.

The Congressional Review Act defines a ''major rule'' as any rule that the Administrator of the Office of Information and Regulatory Affairs of the OMB finds has resulted in or is likely to result in (A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or 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.[31]

For the same reasons set forth above, the Board is adopting the final rule without the delayed effective date generally prescribed under the Congressional Review Act. The delayed effective date required by the Congressional Review Act does not apply to any rule for which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.[32]

The Board believes this final rule is not a major rule. As required by the Congressional Review Act, the Board will submit the final rule and other appropriate reports to OMB, Congress, and the Government Accountability Office for review.

[22] 5 U.S.C. 553(b)(3)(B); see *Mid-Tex Elec. Co-op., Inc.* v. *Fed. Energy Regulatory Comm'n,* 822 F.2d 1123 (D.C. Cir. 1987). For the same reasons, this final rule does not include the usual 60-day comment period under NCUA Interpretive Ruling and Policy Statement (IRPS) 87–2, as amended by IRPS 03–2 and 15–1 (Sept. 24, 2015).

[23] 5 U.S.C. 553(b).

[24] 5 U.S.C. 603, 604.

[25] NCUA IRPS 15–1.

[26] 5 U.S.C. 553(b)(3)(B).

[27] 12 U.S.C. 1786(k)(2)(G)(i).

[28] 44 U.S.C. 3507(d); 5 CFR part 1320.

[29] Public Law 105–277, 112 Stat. 2681 (Oct. 21, 1998).

[30] 5 U.S.C. 801–808.

[31] 5 U.S.C. 804(2).

[32] 5 U.S.C. 808.

List of Subjects in 12 CFR Part 747

Civil monetary penalties, Credit unions.

By the National Credit Union Administration Board on December 30, 2021.

Melane Conyers-Ausbrooks,

Secretary of the Board.

For the reasons stated in the preamble, the Board amends 12 CFR part 747 as follows:

PART 747—ADMINISTRATIVE ACTIONS, ADJUDICATIVE HEARINGS, RULES OF PRACTICE AND PROCEDURE, AND INVESTIGATIONS

■ 1. The authority for part 747 continues to read as follows:

Authority: 12 U.S.C. 1766, 1782, 1784, 1785, 1786, 1787, 1790a, 1790d; 15 U.S.C. 1639e; 42 U.S.C. 4012a; Pub. L. 101–410; Pub. L. 104–134; Pub. L. 109–351; Pub. L. 114–74.

■ 2. Revise § 747.1001 to read as follows:

§ 747.1001 Adjustment of civil monetary penalties by the rate of inflation.

(a) The NCUA is required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note)), to adjust the maximum amount of each civil monetary penalty (CMP) within its jurisdiction by the rate of inflation. The following chart displays those adjusted amounts, as calculated pursuant to the statute:

U.S. Code citation	CMP description	New maximum amount
(1) 12 U.S.C. 1782(a)(3)	Inadvertent failure to submit a report or the inadvertent submission of a false or misleading report.	$4,404.
(2) 12 U.S.C. 1782(a)(3)	Non-inadvertent failure to submit a report or the non-inadvertent submission of a false or misleading report.	$44,043.
(3) 12 U.S.C. 1782(a)(3)	Failure to submit a report or the submission of a false or misleading report done knowingly or with reckless disregard.	$2,202,123 or 1 percent of the total assets of the credit union, whichever is less.
(4) 12 U.S.C. 1782(d)(2)(A)	Tier 1 CMP for inadvertent failure to submit certified statement of insured shares and charges due to the National Credit Union Share Insurance Fund (NCUSIF), or inadvertent submission of false or misleading statement.	$4,027.
(5) 12 U.S.C. 1782(d)(2)(B)	Tier 2 CMP for non-inadvertent failure to submit certified statement or submission of false or misleading statement.	$40,259.
(6) 12 U.S.C. 1782(d)(2)(C)	Tier 3 CMP for failure to submit a certified statement or the submission of a false or misleading statement done knowingly or with reckless disregard.	$2,013,008 or 1 percent of the total assets of the credit union, whichever is less.
(7) 12 U.S.C. 1785(a)(3)	Non-compliance with insurance logo requirements	$137.
(8) 12 U.S.C. 1785(e)(3)	Non-compliance with NCUA security requirements	$320.
(9) 12 U.S.C. 1786(k)(2)(A)	Tier 1 CMP for violations of law, regulation, and other orders or agreements.	$11,011.
(10) 12 U.S.C. 1786(k)(2)(B)	Tier 2 CMP for violations of law, regulation, and other orders or agreements and for recklessly engaging in unsafe or unsound practices or breaches of fiduciary duty.	$55,052.
(11) 12 U.S.C. 1786(k)(2)(C)	Tier 3 CMP for knowingly committing the violations under Tier 1 or 2 (natural person).	$2,202,123.
(12) 12 U.S.C. 1786(k)(2)(C)	Tier 3 CMP for knowingly committing the violations under Tier 1 or 2 (insured credit union).	$2,202,123 or 1 percent of the total assets of the credit union, whichever is less.
(13) 12 U.S.C. 1786(w)(5)(A)(ii).	Non-compliance with senior examiner post-employment restrictions	$362,217.
(14) 15 U.S.C. 1639e(k)	Non-compliance with appraisal independence requirements	First violation: $12,647; Subsequent violations: $25,293.
(15) 42 U.S.C. 4012a(f)(5)	Non-compliance with flood insurance requirements	$2,392.

(b) The adjusted amounts displayed in paragraph (a) of this section apply to civil monetary penalties that are assessed after the date the increase takes effect, including those whose associated violation or violations pre-dated the increase and occurred on or after November 2, 2015.

[FR Doc. 2021–28555 Filed 1–4–22; 8:45 am]

BILLING CODE 7535–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

RIN 3245–AG94

Consolidation of Mentor-Protégé Programs and Other Government Contracting Amendments; Correction

AGENCY: U.S. Small Business Administration.

ACTION: Correcting amendment.

SUMMARY: The U.S. Small Business Administration (SBA) is correcting a final rule that was published in the **Federal Register** on October 16, 2020. The rule merged the 8(a) Business Development (BD) Mentor-Protégé Program and the All Small Mentor-Protégé Program to eliminate confusion and remove unnecessary duplication of functions within SBA. This document is making a correction to the final regulations.

DATES: Effective January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Mark Hagedorn, U.S. Small Business Administration, Office of General Counsel, 409 Third Street SW, Washington, DC 20416; (202) 205–7625; *mark.hagedorn@sba.gov.*

SUPPLEMENTARY INFORMATION: On October 16, 2020, SBA published a final rule revising the regulations pertaining to the 8(a) BD and size programs in order to further reduce unnecessary or excessive burdens on small businesses and to more clearly delineate SBA's

intent in certain regulations (85 FR 66146). This is the fifth set of corrections. The first set of corrections was published in the **Federal Register** on November 16, 2020 (85 FR 72916). The second set of corrections was published in the **Federal Register** on January 14, 2021 (86 FR 2957). The third set of corrections was published in the **Federal Register** on February 23, 2021 (86 FR 10732). The fourth set of corrections was published in the **Federal Register** on July 22, 2021 (86 FR 38538). This document augments those corrections.

It is well established that business concerns are not affiliates of joint ventures of which they are members for size purposes. However, SBA regulations have long provided that when determining a concern's size SBA will consider all revenue in whatever form received or accrued from whatever source. Therefore, since 2004 SBA regulations have required a joint venture partner to include its proportionate share of joint venture receipts and employees in its own receipts and employee count, respectively. (69 FR 29192). The final rule of October 16, 2020, revised § 121.103(h) to clarify how a joint venture partner must calculate its proportionate share of joint venture receipts and employees for purposes of determining its own size status. Specifically, the final rule provided that the joint venture partner must include its percentage share of joint venture receipts and employees in its own receipts or employees. The appropriate percentage share is the same percentage figure as the percentage figure corresponding to the joint venture partner's share of work performed by the joint venture. For employee-based size standards, the appropriate way to apportion individuals employed by the joint venture is the same percentage of employees as the joint venture partner's percentage ownership share in the joint venture, after first subtracting any joint venture employee already accounted for in the employee count of one of the partners.

It has come to SBA's attention that some have misinterpreted the intent of the final rule. Specifically, because the regulations no longer allow joint ventures to be populated with individuals intended to perform small business set-aside contracts awarded to the joint venture, some have reasoned that a joint venture populated with its own separate contracting-performing employees does not qualify as a joint venture for all SBA program purposes. From this logic it ostensibly follows that a joint venture partner need not include in its own receipts its proportionate share of receipts and employees from populated joint ventures. This was not SBA's intent.

When SBA revised its regulations to 2016 to prohibit populated joint ventures on small business contracts, it did so in response to programmatic concerns that allowing populated joint ventures between a mentor and its protégé would not ensure that the protégé firm and its employees benefit by developing new expertise, experience, and past performance. (81 FR 48558). As SBA explained, if the individuals hired by the joint venture to perform the work under the contract did not come from the protégé firm, there is no guarantee that they would ultimately end up working for the protégé firm after the contract is completed. In such a case, the protégé firm would have gained nothing out of that contract. The protégé itself did not perform work under the contract and the individual employees who performed work did not at any point work for the protégé firm. Additionally, SBA believed that requiring joint ventures to be unpopulated ensures that the lead small business partner to the joint venture will meet its performance of work requirements and will actually benefit from the joint venture arrangement. This is especially important for joint ventures between a mentor and its protégé as well as joint ventures to perform socio-economic set-aside contracts, where the lead joint venture partner has the necessary size or socio-economic status and the non-lead partner does not. Nothing, however, in the final rule or the 2016 rulemaking signaled a change in policy concerning the treatment of receipts and employees from populated joint ventures for purposes of determining a joint venture partner's size. SBA never intended to change how revenues earned by a joint venture should be counted for size purposes. As noted above, a joint venture partner of any kind must include its proportionate share of joint venture receipts and employees in its own receipts and employee count to ensure that all its revenues and employees are properly considered in determining that partner's size. In this context it is irrelevant whether the joint venture partner's proportionate share of receipts and employees are from populated or unpopulated joint ventures. Thus, while populated joint ventures are no longer eligible to submit offers for small business contracts, receipts and employees from populated joint ventures are still attributable to the underlying joint venture partners for size purposes. This rule corrects the above misconception by clarifying that a concern must include in its receipts and employee count its proportionate share of joint venture receipts and joint venture employees, respectively, regardless of whether the joint venture is populated or unpopulated.

List of Subjects in 13 CFR Part 121

Administrative practice and procedure, Government procurement, Government property, Grant programs—business, Individuals with disabilities, Loan programs—business, Small businesses.

Accordingly, 13 CFR part 121 is corrected by making the following correcting amendment:

PART 121—SMALL BUSINESS SIZE REGULATIONS

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

Authority: 15 U.S.C. 632, 634(b)(6), 636(a)(36), 662, and 694a(9); Pub. L. 116–136, Section 1114.

■ 2. Amend § 121.103 by revising the paragraph heading and the first and second sentences of paragraph (h) introductory text to read as follows:

§ 121.103 How does SBA determine affiliation?

* * * * *

(h) *Receipts/employees attributable to joint venture partners.* For size purposes, a concern must include in its receipts its proportionate share of joint venture receipts (whether that joint venture is populated or unpopulated), unless the proportionate share already is accounted for in receipts reflecting transactions between the concern and its joint ventures (*e.g.,* subcontracts from a joint venture entity to joint venture partners). In determining the number of employees, a concern must include in its total number of employees its proportionate share of joint venture employees (whether the joint venture is populated or unpopulated). * * *

* * * * *

Antonio Doss,

Deputy Associate Administrator, Office of Government Contracting and Business Development.

[FR Doc. 2021–28256 Filed 1–4–22; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0873; Project Identifier MCAI–2021–00336–R; Amendment 39–21873; AD 2021–26–14]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2018–11–01, which applied to certain Airbus Helicopters Model AS332L2 and EC225LP helicopters. AD 2018–11–01 required installing a cut-out for the left-hand (LH) and right-hand (RH) rail support junction profiles and repetitively inspecting splices, frame 5295, and related equipment for a crack. Since the FAA issued AD 2018–11–01, the manufacturer has developed a modification for in-service helicopters for replacing aluminum splices with steel splices on frame 5295. This AD retains the requirements of AD 2018–11–01 and requires a modification for replacing aluminum splices with steel splices on frame 5295 if cracking is found. This AD also provides terminating action for the repetitive inspections. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 9, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of February 9, 2022.

ADDRESSES: For service information identified in this final rule, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. Service information that is incorporated by reference is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0873.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0873; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the European Union Aviation Safety Agency (EASA) AD, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2018–11–01, Amendment 39–19289 (83 FR 23778, May 23, 2018), (AD 2018–11–01). AD 2018–11–01 applied to Airbus Helicopters Model AS332L2 and EC225LP helicopters with an extended aluminum splice installed on frame 5295, except helicopters with steel splice kit part number 332A08–2649–3072 installed. AD 2018–11–01 required installing a cut-out for the LH and RH rail support junction profiles and repetitively inspecting splices, frame 5295, and related equipment for a crack. AD 2018–11–01 was prompted by reports of cracks on frame 5295 and on splices installed to prevent those cracks. The FAA issued AD 2018–11–01 to address a crack in frame 5295, which if not detected and corrected, could lead to loss of structural integrity of the helicopter frame and subsequent loss of control of the helicopter.

The NPRM published in the **Federal Register** on October 22, 2021 (86 FR 58600). In the NPRM, the FAA proposed to retain the requirements of AD 2018–11–01 and require a modification for replacing aluminum splices with steel splices on frame 5295 if cracking is found. The NPRM was prompted by EASA AD 2021–0075, dated March 16, 2021 (EASA AD 2021–0075), which supersedes EASA Emergency AD 2014–0098–E, dated April 25, 2014 (EASA Emergency AD 2014–0098–E), issued by EASA, which is the Technical Agent for the Member States of the European Union.

EASA advises that since EASA Emergency AD 2014–0098–E was issued, Airbus Helicopters developed MOD 0728463, available for helicopters in service through the applicable modification service bulletin, providing instructions to replace aluminum splices with steel splices on frame 5295. Airbus Helicopters also issued the applicable inspection alert service bulletins, as defined in EASA AD 2021–0075. Accordingly, EASA AD 2021–0075 retains the requirements of EASA Emergency AD 2014–0098–E, which is superseded, and requires a modification, replacing aluminum splices with steel splices on helicopters on which any cracked aluminum splice has been detected. EASA AD 2021–0075 also advises that the modification is terminating action for the repetitive inspections.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following Airbus Helicopters service information.

- Alert Service Bulletins Nos. AS332–05.00.97, Revision 1; and EC225–05A038, Revision 1; both dated February 9, 2021; which specify procedures for, among other actions, installing a cut-out for the LH and RH rail support junction profiles and inspecting splices, frame 5295, and related equipment for a crack. These documents are distinct since they apply to different helicopter models.
- Service Bulletins Nos. AS332–53.01.97, Revision 0; and EC225–53–061, Revision 0; both dated February 9, 2021; which specify procedures for modifying the helicopter by replacing the aluminum LH and RH splices with

steel splices under the plates and the brackets of the main gear box (MGB) bars. The modification includes taking reference readings of the brackets of the MGB bars, removing the MGB brackets and plates, removing the aluminum splices and inspecting the joggling areas for scratches or other damage, inspecting frame 5295 for cracking (including a dye penetrant inspection if the inspection results are not conclusive), identifying the current measurements (values) of the rivet and attachment plate holes for installation of the steel splice (including determining the values of the rivet holes and attachment plate holes on frame 5295 with a calibrated pad and determining the elongations of the holes and the lengths of the straps), modifying the door hinge rail brackets on the LH and RH sides, and installing the steel splices. These documents are distinct since they apply to different helicopter models.

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

Other Related Service Information

The FAA reviewed Eurocopter Helicopters (now Airbus Helicopters) Service Bulletin No. 53–003, Revision 4, for Model EC225LP helicopters and Service Bulletin No. 53.01.52, Revision 5, for Model AS332L2 helicopters, both dated July 23, 2010. The service bulletins specify procedures to reinforce frame 5295 by installing a new titanium plate underneath the fitting and a new widened aluminum splice below the upper corner of the door.

The FAA also reviewed Airbus Helicopters Service Bulletin No. 05–019, Revision 4, dated September 22, 2014, for Model EC225 LP helicopters. This service information specifies procedures for cutting out the junction profiles.

The FAA also reviewed Airbus Helicopters Alert Service Bulletins Nos. AS332–05.00.97, Revision 0; and EC225–05A038, Revision 0; both dated April 15, 2014; which specify procedures for, among other actions, installing a cut-out for the LH and RH rail support junction profiles and inspecting splices, frame 5295, and related equipment for a crack.

Redesignation of AD 2018–11–01 Paragraph Identifier

Since AD 2018–11–01 was issued, the AD format has been revised, and certain paragraphs have been rearranged. As a result, the corresponding paragraph identifiers have been redesignated in this AD, as listed in the following table:

REVISED PARAGRAPH IDENTIFIER

Requirement in AD 2018–11–01	Corresponding requirement in this AD
paragraph (e)	paragraph (g)
paragraph (f)	paragraph (j)(1)

Differences Between This AD and the EASA AD 2021–0075

EASA AD 2021–0075 requires contacting Airbus Helicopters for approved repair instructions if any crack is found during an inspection. This AD would not require that action.

Costs of Compliance

The FAA estimates that this AD would affect 38 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained installation of cut-outs on frame 5295 from AD 2018–11–01.	40 work-hours × $85 per hour = $3,400	$5,000	$8,400	$319,200
Retained inspection of frame 5295 from AD 2018–11–01.	2 work-hours × $85 per hour = $170, per inspection cycle.	0	170, per inspection cycle	6,460, per inspection cycle.

The FAA estimates the following costs to do any necessary repairs that would be required based on the results of the inspection. The agency has no way of determining the number of aircraft that might need these repairs:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Action	Labor cost	Parts cost	Cost per product
Repair	40 work-hours × $85 per hour = $3,400	$5,000	$8,400
New modification (replacement of aluminum splices with steel splices).	830 work-hours × $85 per hour = $70,550	35,000	105,550

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2018–11–01, Amendment 39–19289 (83 FR 23778, May 23, 2018); and

■ b. Adding the following new airworthiness directive:

2021–26–14 Airbus Helicopters: Amendment 39–21873; Docket No. FAA–2021–0873; Project Identifier MCAI–2021–00336–R.

(a) Effective Date

This airworthiness directive (AD) is effective February 9, 2022.

(b) Affected ADs

This AD replaces AD 2018–11–01, Amendment 39–19289 (83 FR 23778, May 23, 2018) (AD 2018–11–01).

(c) Applicability

This AD applies to Airbus Helicopters Model AS332L2 and Model EC225LP helicopters, certificated in any category, as specified in paragraphs (c)(1) and (2) of this AD.

(1) Model AS332L2 helicopters equipped with extended aluminum splices on frame 5295 installed in accordance with Airbus Helicopters (AH) Modification (MOD) 0726517, Eurocopter (EC) AS332 Service Bulletin (SB) 53.01.52, or AH repair design 332–53–507–06, 332–53–21–07, or 332–53–82–06; except helicopters embodying AH MOD 0728463, AH SB AS 332–53.01.97, or repair design 332–53–409–12, 332–53–1284–13, 332–53–1079–16, or 332–53–1358–16.

Note 1 to paragraph (c)(1): As referenced in paragraphs (c)(1) and (2) of this AD, helicopters with AH MOD 0728463 installed have replaced the aluminum splices with steel splices.

(2) Model EC225LP helicopters equipped with extended aluminum splices on frame 5295 installed in accordance with AH MOD 0726517, or EC EC225 SB 53–003 (pre AH MOD 0726493 and post AH MOD 0726517), except helicopters embodying AH MOD 0728463, or SB EC225–53–061.

Note 2 to paragraph (c)(2): Helicopters with AH MOD 0726493 have installed steel splice kit part number 332A08–2649–3072.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of cracks on frame 5295 and on aluminum splices installed to prevent those cracks. The FAA is issuing this AD to address cracking on frame 5295 and on the inner skins. The unsafe condition, if not addressed, could result in loss of structural integrity of the helicopter frame and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Retained Installation and Inspections With New Service Information and Corrective Actions (Modification)

This paragraph retains the requirements of paragraph (e) of AD 2018–11–01, with new service information and corrective actions (modification).

(1) Before a splice reaches 1,700 hours time-in-service (TIS), within 50 hours TIS, or before the helicopter reaches 11,950 hours TIS, whichever occurs latest, do the following.

(i) Install the rail support cut-out and identify the left-hand (LH) and right-hand (RH) junction profile, in accordance with the Accomplishment Instructions, paragraph 3.B.2., of Airbus Helicopters Alert Service Bulletin (ASB) No. EC225–05A038, Revision 1, dated February 9, 2021 (Airbus Helicopters ASB No. EC225–05A038, Revision 1); or Airbus Helicopters ASB No. AS332–05.00.97, Revision 1, dated February 9, 2021 (Airbus Helicopters ASB No. AS332–05.00.97, Revision 1); whichever is applicable to your helicopter.

(ii) Inspect each splice for a crack in the area depicted as Area Y in Figure 3 of Airbus Helicopters ASB No. EC225–05A038, Revision 1; or Airbus Helicopters ASB No. AS332–05.00.97, Revision 1; whichever is applicable to your helicopter. If a crack exists, do the applicable action required by paragraph (g)(1)(ii)(A) or (B) of this AD.

(A) For any cracking found before the effective date of this AD: Repair or replace the splice before further flight.

(B) For any cracking found on or after the effective date of this AD: Before further flight, modify the helicopter in accordance with paragraph 3.B.2. of the Accomplishment Instructions of Airbus Helicopters Service Bulletin (SB) No. AS332–53.01.97, Revision 0, dated February 9, 2021 (Airbus Helicopters SB No. AS332–53.01.97, Revision 0); or Service Bulletin No. EC225–53–061, Revision 0, dated February 9, 2021 (Airbus Helicopters SB No. EC225–53–061, Revision 0); as applicable to your helicopter; except as specified in paragraph (h) of this AD.

(2) Thereafter at intervals not to exceed 110 hours TIS, inspect each splice for a crack in the area depicted as Area Y in Figure 3 of Airbus Helicopters ASB No. EC225–05A038, Revision 1; or Airbus Helicopters ASB No. AS332–05.00.97, Revision 1; whichever is applicable to your helicopter. If a crack exists, do the applicable actions required by paragraph (g)(2)(i) or (ii) of this AD. Accomplishing the modification specified in paragraph (g)(1)(ii)(B) and (g)(2)(ii) of this AD terminates the inspections required by this paragraph.

(i) For any cracking found before the effective date of this AD: Repair or replace the splice before further flight.

(ii) For any cracking found on or after the effective date of this AD: Before further flight, modify the helicopter in accordance with paragraph 3.B.2. of the Accomplishment Instructions of Airbus Helicopters SB No. AS332–53.01.97, Revision 0; or Airbus Helicopters SB No. EC 225–53–061, Revision 0; as applicable to your helicopter; except as specified in paragraph (h) of this AD.

(h) Service Information Exceptions

(1) Where Airbus Helicopters ASB No. EC225–05A038, Revision 1; Airbus Helicopters ASB No. AS332–05.00.97, Revision 1; Airbus Helicopters SB No. AS332–53.01.97, Revision 0; and Airbus Helicopters SB No. EC 225–53–061, Revision 0; specify to perform dye-penetrant inspections ''if in doubt'' or ''if any doubt,'' this AD requires performing a dye-penetrant inspection during inspections done on or after the effective date of this AD.

(2) Where Airbus Helicopters SB No. AS332–53.01.97, Revision 0; and Airbus Helicopters SB No. EC 225–53–061, Revision 0; specify discarding parts, this AD requires removing those parts from service.

(3) Where Airbus Helicopters SB No. AS332–53.01.97, Revision 0; and Airbus Helicopters SB No. EC 225–53–061, Revision 0, specify contacting Airbus Helicopter for corrective action or further procedures, this AD requires repair done in accordance with a method approved by the Manager, General Aviation & Rotorcraft Section, International Validation Branch, FAA; or EASA; or Airbus Helicopters' EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(4) Airbus Helicopters SB No. AS332–53.01.97, Revision 0; and Airbus Helicopters SB No. EC 225–53–061, Revision 0, specify a visual check and dye penetrant inspection for cracks on the inside and outside of frame 5295. For this AD, if any cracking is found during any visual check or dye penetrant inspection on the inside and outside of frame 5295, before further flight, repair in accordance with a method approved by the Manager, General Aviation & Rotorcraft Section, International Validation Branch, FAA; or EASA; or Airbus Helicopters' EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(i) Reporting Not Required

Although Airbus Helicopters SB No. AS332–53.01.97, Revision 0; and Airbus

Helicopters SB No. EC 225–53–061, Revision 0; specify to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Credit for Previous Actions

(1) This paragraph provides credit for the installation of the rail support cut-out required by paragraph (g)(1)(i) of this AD, if that action was performed before June 27, 2018 (the effective date of AD 2018–11–01) using Airbus Helicopters MOD 0728090 or Airbus Helicopters SB No. 05–019, Revision 4, dated September 22, 2014.

(2) This paragraph provides credit for the actions required by paragraphs (g)(1) and (2) of this AD, if the actions were performed before the effective date of this AD using Airbus Helicopters ASB No. EC225–05A038, Revision 0, dated April 15, 2014; or Airbus Helicopters ASB No. AS332–05.00.97, Revision 0, dated April 15, 2014.

(k) Special Flight Permits

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter to a location where the actions can be performed, provided no passengers are onboard.

(l) 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 (m)(1) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(m) Related Information

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

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

(3) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD 2021–0075, dated March 16, 2021. You may view the EASA AD at *https://www.regulations.gov* in Docket No. FAA–2021–0873.

(n) Material Incorporated by Reference

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

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

(i) Airbus Helicopters Alert Service Bulletin No. AS332–05.00.97, Revision 1, dated February 9, 2021.

(ii) Airbus Helicopters Alert Service Bulletin No. EC225–05A038, Revision 1, dated February 9, 2021.

(iii) Airbus Helicopters Service Bulletin No. AS332–53.01.97, Revision 0, dated February 9, 2021.

(iv) Airbus Helicopters Service Bulletin No. EC225–53–061, Revision 0, dated February 9, 2021.

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

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

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

Issued on December 10, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–28469 Filed 1–4–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0839; Project Identifier MCAI–2020–01697–R; Amendment 39–21877; AD 2021–26–18]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–21–01 for certain Airbus Helicopters Model AS–365N2, AS 365N3, EC 155B, EC155B1, and SA–365N1 helicopters. AD 2020–21–01 required modifying the main gearbox (MGB) tail rotor (T/R) drive flange installation. This AD was prompted by several reported occurrences of loss of tightening torque of the Shur-Lok nut, which serves as a retainer of the MGB T/R drive flange. This AD continues to require modifying the MGB T/R drive flange installation, and includes additional helicopters in the applicability for the required actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 9, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of February 9, 2022.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of November 12, 2020 (85 FR 63440, October 8, 2020).

ADDRESSES: For service information identified in this final rule, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax: (972) 641–3775; or at *https://www.airbus.com/helicopters/services/support.html.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0839.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0839; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the European Union Aviation Safety Agency (EASA) AD, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; phone: (516) 228–7330; email: *andrea.jimenez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2020–21–01,

Amendment 39–21274 (85 FR 63440, October 8, 2020) (AD 2020–21–01). AD 2020–21–01 applied to certain Airbus Helicopters Model AS–365N2, AS 365N3, EC 155B, EC155B1, and SA–365N1 helicopters. The NPRM published in the **Federal Register** on September 30, 2021 (86 FR 54139). In the NPRM, the FAA proposed to continue to require modifying the MGB T/R drive flange installation, and also proposed to include additional helicopters in the applicability for the required actions. The NPRM was prompted by several reported occurrences of loss of tightening torque of the Shur-Lok nut, which serves as a retainer of the MGB T/R drive flange.

EASA AD 2020–0287, dated December 21, 2020 (EASA AD 2020–0287), was issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for certain AS 365 N2, AS 365 N3, SA 365 C1, SA 365 C2, SA 365 C3, SA 365 N and SA 365 N1 helicopters; and all EC 155 B and EC 155 B1 helicopters. Model SA 365 C3 helicopters are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those helicopters in the applicability. EASA AD 2020–0287 supersedes EASA AD 2020–0212, dated October 5, 2020, which required modification of the MGB T/R drive flange installation. EASA advises of reported occurrences of loss of tightening torque of the Shur-Lok nut, which serves as a retainer of the T/R drive flange of the MGB. EASA also advises of subsequent investigation that determined that these occurrences were the result of failure of the Shur-Lok nut locking function, which is normally ensured by two antirotation tabs engaged into two slots at the end of the MGB output shaft pinion. EASA states this condition could lead to the loosening of the Shur-Lok nut and disengagement of the Shur-Lok nut threads, possibly resulting in reduction of T/R drive control, rear transmission vibrations, and subsequent reduced control of the helicopter.

Accordingly, EASA AD 2020–0287 retains the modification of the MGB T/R drive flange installation. EASA AD 2020–0287 also includes additional helicopters in the applicability for the required actions (Model SA–365C1, SA–365C2, and SA–365N helicopters on which Airbus Helicopters modification 0763B64 has been embodied; and Model EC 155B and EC155B1 helicopters without modification 0763B64 embodied).

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from three commenters. The commenters were an individual who made a statement about the applicability; an individual who expressed support and favor for the NPRM; and an anonymous commenter, who had a question about the applicability. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request for Clarification of Applicability

An individual stated the opinion that all helicopters should be subject to the same rules, a preference for unity under the law, and that it is unfair to have different rules for different helicopters. An anonymous commenter asked why the NPRM is only applicable to Airbus Helicopters and not other current and modern models of helicopters. The FAA infers that the commenters may be suggesting that this AD should apply to all helicopter models. No further justification was given.

The FAA agrees to clarify the applicability. Each FAA AD has a specific applicability, and this FAA AD reflects the applicability of EASA AD 2020–0287. This AD only addresses the models specified in the EASA AD that are affected by the unsafe condition. Helicopters and the systems that support the design are varied, and because of design variances between manufacturers, may or may not be subject to an unsafe condition. Therefore, in crafting a rule, the FAA specifically works to apply rulemaking only to the models and systems that are affected. Otherwise, the FAA may be creating arbitrary regulations, unnecessary work, and burdensome costs for the operators of the unaffected helicopters. There is no further need to expand the applicability of this AD to other helicopter models due to the likelihood that the type designs are different and therefore not subject to the unsafe condition. If information is received indicating other models are affected by the unsafe condition, the FAA will consider further rulemaking. The FAA has made no changes to this AD.

Conclusion

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following service information.

Airbus Helicopters Alert Service Bulletin (ASB) No. AS365–63.00.26, Revision 0, dated July 22, 2020, for Model AS365N helicopters and non FAA-type certificated military Model AS365Fs helicopters; and Airbus Helicopters ASB No. SA365–65.52, Revision 1, dated July 22, 2020, for Model SA–365C1 and SA–365C2 helicopters and non FAA-type certificated Model SA–365C3 helicopters. This service information specifies procedures for modifying the MGB T/R drive flange installation, which include installing a rear (aft) output stop between the T/R drive flange and T/R drive shaft. These documents are distinct since they apply to different helicopter models.

This AD also requires Airbus Helicopters ASB No. AS365–63.00.19, Revision 1, dated January 31, 2019; and Airbus Helicopters ASB No. EC155–63A013, Revision 1, dated January 31, 2019; which the Director of the Federal Register approved for incorporation by reference as of November 12, 2020 (85 FR 63440, October 8, 2020).

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

Differences Between This AD and the EASA AD

EASA AD 2020–0287 specifies compliance times of 600 flight hours or a certain time frame (months). However, this AD only requires the compliance time of 600 hours time-in-service.

Costs of Compliance

The FAA estimates that this AD affects 53 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modification (46 helicopters) (retained actions from AD 2020-21-01).	14 work-hours × $85 per hour = $1,190.	$2,704	$3,894	$179,124
Modification (new action)	14 work-hours × $85 per hour = $1,190.	Up to 18,474	Up to 19,664	Up to 1,042,192

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2020–21–01, Amendment 39–21274 (85 FR 63440, October 8, 2020); and

■ b. Adding the following new airworthiness directive:

2021–26–18 Airbus Helicopters: Amendment 39–21877; Docket No. FAA–2021–0839; Project Identifier MCAI–2020–01697–R.

(a) Effective Date

This airworthiness directive (AD) is effective February 9, 2022.

(b) Affected ADs

This AD replaces AD 2020–21–01, Amendment 39–21274 (85 FR 63440, October 8, 2020) (AD 2020–21–01).

(c) Applicability

This AD applies to the Airbus Helicopters model helicopters, certificated in any category, as identified in paragraphs (c)(1) through (3) of this AD.

(1) Model AS–365N2, AS 365 N3, and SA–365N1, all serial numbers on which Airbus Helicopters modification 0763B64 has been embodied, except those on which Airbus Helicopters modification 0763C81 has been embodied.

(2) Model SA–365C1, SA–365C2, and SA–365N, all serial numbers on which Airbus Helicopters modification 0763B64 has been embodied.

(3) Model EC 155B and EC155B1, all serial numbers, except those on which Airbus Helicopters modification 0763C81 has been embodied.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by several reported occurrences of loss of tightening torque of the Shur-Lok nut, which serves as a retainer of the main gear box (MGB) tail rotor (T/R) drive flange. The FAA is issuing this AD to detect and address loss of tightening torque of the Shur-Lok nut. The unsafe condition, if not addressed, could result in loosening of the Shur-Lok nut, possibly resulting in disengagement of the Shur-Lok nut threads, reduction of T/R drive control, rear transmission vibrations, and subsequent reduced control of the helicopter.

(f) Compliance

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

(g) Required Actions

This paragraph restates the requirements of paragraph (e) of AD 2020–21–01 with no changes. Within 600 hours time-in-service after November 12, 2020 (the effective date of AD 2020–21–01):

(1) For Model AS–365N2, AS 365N3, and SA–365N1 helicopters:

(i) Without removing the tail drive shaft flange (a), remove the sliding flange (b) from the flexible coupling (c) as shown in Detail ''B'' of Figure 1, PRE MOD, of Airbus Helicopters Alert Service Bulletin (ASB) No. AS365–63.00.19, Revision 1, dated January 31, 2019 (ASB AS365–63.00.19, Revision 1); replace the 3 bolts (d) and remove from service the 3 washers (e).

(ii) Install the sliding flange (b) with aft output stop (1) part number (P/N) 365A32–7836–20 as shown in Detail ''B'' of Figure 1, POST MOD, of ASB AS365–63.00.19, Revision 1, and by following the Accomplishment Instructions, paragraph 3.B.2.b, of ASB AS365–63.00.19, Revision 1.

(2) For Model EC 155B and EC155B1 helicopters with modification 0763B64 embodied:

(i) Without removing the Shur-Lok nut (a), remove the sliding flange (b) from the flexible coupling (c) as shown in Detail ''B'' of Figure 1, PRE MOD, of Airbus Helicopters ASB No. EC155–63A013, Revision 1, dated January 31, 2019 (ASB EC155–63A013, Revision 1); replace the 3 bolts (d) and remove from service the 3 washers (e).

(ii) Install the sliding flange (b) with aft output stop (1) P/N 365A32–7836–20 as shown in Detail ''B'' of Figure 1, POST MOD, of ASB EC155–63A013, Revision 1, and by following the Accomplishment Instructions, paragraph 3.B.2.b, of ASB EC155–63A013, Revision 1.

Note 1 to paragraph (g)(2)(ii): ASB EC155–63A013, Revision 1 refers to the ''aft output stop'' as ''rear output stop.''

(h) New Required Actions

For Model SA–365C1, SA–365C2, and SA–365N helicopters; and Model EC 155B and EC155B1 helicopters without modification 0763B64 embodied: Within 600 hours time-in-service after the effective date of this AD, modify the MGB T/R drive flange installation, in accordance with paragraph

3.B.2., ''Procedure,'' of the Accomplishment Instructions of the applicable service information specified in paragraphs (h)(1) through (3) of this AD, except as specified in paragraph (i) of this AD.

(1) Airbus Helicopters ASB SA365–65.52, Revision 1, dated July 22, 2020.

(2) Airbus Helicopters ASB AS365–63.00.26, Revision 0, dated July 22, 2020.

(3) ASB EC155–63A013, Revision 1.

(i) Exceptions to Service Information

Where the service information identified in paragraph (h) of this AD specifies to discard certain parts, this AD requires removing those parts from service.

(j) Special Flight Permits

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

(k) 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 (l)(1) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(l) Related Information

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

(2) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD 2020–0287, dated December 21, 2020. You may view the EASA AD at *https://www.regulations.gov* in Docket No. FAA–2021–0839.

(m) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on February 9, 2022.

(i) Airbus Helicopters Alert Service Bulletin (ASB) No. AS365–63.00.26, Revision 0, dated July 22, 2020.

(ii) Airbus Helicopters ASB No. SA365–65.52, Revision 1, dated July 22, 2020.

(4) The following service information was approved for IBR on November 12, 2020 (85 FR 63440, October 8, 2020).

(i) Airbus Helicopters ASB No. AS365–63.00.19, Revision 1, dated January 31, 2019.

(ii) Airbus Helicopters ASB No. EC155–63A013, Revision 1, dated January 31, 2019.

(5) For Airbus Helicopters service information identified in this AD, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax: (972) 641–3775; or at *https://www.airbus.com//services/support.html.*

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

(7) 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 December 15, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–28471 Filed 1–4–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31408; Amdt. No. 563]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: Effective 0901 UTC, January 27, 2022.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg 29 Room 104, Oklahoma City, OK 73125. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

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

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC, on December 27, 2021.

Thomas J Nichols,

Aviation Safety, Flight Standards Service Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, January 27, 2022.

■ 1. The authority citation for part 95 continues to read as follows:

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

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT

[Amendment 563 effective date January 27, 2022]

From	To	MEA	MAA
§ 95.3000 Low Altitude RNAV Routes			
§ 95.3348 RNAV Route T348 Is Amended by Adding			
LESNR, SD WP	TECUD, SD WP	*4000	17500
TECUD, SD WP	SIOUX FALLS, SD VORTAC	*4100	17500
SIOUX FALLS, SD VORTAC	GRSIS, MN WP	*3500	17500
§ 95.3409 RNAV Route T409 Is Added To Read			
LLUKY, NE WP	ADEDY, SD WP	*4000	17500
ADEDY, SD WP	LESNR, SD WP	*4000	17500
LESNR, SD WP	PIERRE, SD VORTAC	*4200	17500
§ 95.4000 High Altitude RNAV Routes			
§ 95.4013 RNAV Route Q13 Is Amended To Read in Part			
SKANN, NV WP *18000—GNSS MEA *DME/DME/IRU MEA	SHUFL, NV WP	#*25000	45000
SHUFL, NV WP *18000—GNSS MEA *DME/DME/IRU MEA	LOMIA, NV WP	#*25000	45000
§ 95.4015 RNAV Route Q15 Is Amended To Read in Part			
SKANN, NV WP *18000—GNSS MEA *DME/DME/IRU MEA	SHUFL, NV WP	#*25000	45000
SHUFL, NV WP *18000—GNSS MEA *DME/DME/IRU MEA	LOMIA, NV WP	#*25000	45000

From	To	MEA
§ 95.6001 Victor Routes—U.S.		
§ 95.6001 VOR Federal Airway V1 Is Amended To Read in Part		
COYLE, NJ VORTAC *3800—MCA DIXIE, NJ FIX, SW BND	*DIXIE, NJ FIX	3800
DIXIE, NJ FIX *1700—MOCA	KENNEDY, NY VOR/DME	*2500
§ 95.6016 VOR Federal Airway V16 Is Amended To Read in Part		
COYLE, NJ VORTAC *3800—MCA DIXIE, NJ FIX, SW BND	*DIXIE, NJ FIX	3800
DIXIE, NJ FIX *1700—MOCA	KENNEDY, NY VOR/DME	*2500
§ 95.6031 VOR Federal Airway V31 Is Amended To Read in Part		
ROCHESTER, NY VOR/DME	AIRCO, NY FIX	4000
§ 95.6036 VOR Federal Airway V36 Is Amended To Delete		
U.S. CANADIAN BORDER *3000—MOCA	U.S. CANADIAN BORDER	*8000

From	To	MEA
SAULT STE MARIE, MI VOR/DME *2800—MOCA	U.S. CANADIAN BORDER	*5000
BUFFALO, NY VOR/DME *11000—MCA BURST, NY WP, NW BND **4000—GNSS MEA	*BURST, NY WP	**11000
BURST, NY WP	THINK, NY WP	4000
THINK, NY WP	ELMIRA, NY VOR/DME	3500
§ 95.6045 VOR Federal Airway V45 Is Amended To Read in Part		
NEW BERN, NC VOR/DME #KINSTON R-130 UNUSABLE USE NEWBERN R-313	KINSTON, NC VORTAC	#2900
KINSTON, NC VORTAC	BRADE, NC FIX	UNUSABLE
BRADE, NC FIX	RALEIGH/DURHAM, NC VORTAC	2600
§ 95.6063 VOR Federal Airway V63 Is Amended To Read in Part		
RAZORBACK, AR VORTAC *3200—MOCA	BILIE, MO FIX	*4000
§ 95.6070 VOR Federal Airway V70 Is Amended To Read in Part		
GRAND STRAND, SC VORTAC	WILMINGTON, NC VORTAC	UNUSABLE
WILMINGTON, NC VORTAC	BEULA, NC FIX	UNUSABLE
BEULA, NC FIX	KINSTON, NC VORTAC	UNUSABLE
KINSTON, NC VORTAC	PEARS, NC FIX	UNUSABLE
§ 95.6071 VOR Federal Airway V71 Is Amended To Read in Part		
SPRINGFIELD, MO VORTAC *2500—MOCA	BUTLER, MO VORTAC	*3000
§ 95.6072 VOR Federal Airway V72 Is Amended To Read in Part		
RAZORBACK, AR VORTAC *3200—MOCA	EDUGE, AR FIX	*4000
§ 95.6084 VOR Federal Airway V84 Is Amended To Delete		
BUFFALO, NY VOR/DME	GENESEO, NY VOR/DME	4000
§ 95.6088 VOR Federal Airway V88 Is Amended To Read in Part		
TULSA, OK VORTAC *6200—MCA VINTA, OK FIX, NE BND	*VINTA, OK FIX	2700
VINTA, OK FIX *3100—MOCA *4000—GNSS MEA	SPRINGFIELD, MO VORTAC	*6200
§ 95.6132 VOR Federal Airway V132 Is Amended To Read in Part		
NALLY, KS FIX *2800—MOCA *3000—GNSS MEA	SPRINGFIELD, MO VORTAC	*4500
§ 95.6140 VOR Federal Airway V140 Is Amended To Read in Part		
TULSA, OK VORTAC *2900—MRA **2300—MOCA	*PRYOR, OK FIX	**3400
PRYOR, OK FIX *2900—MOCA	RAZORBACK, AR VORTAC	*3400
RAZORBACK, AR VORTAC *2900—MOCA	SPRAY, AR FIX	*4000
§ 95.6159 VOR Federal Airway V159 Is Amended To Read in Part		
SPRINGFIELD, MO VORTAC	TRALE, MO FIX	3000
TRALE, MO FIX *2400—MOCA	HODEN, MO FIX	*4000
§ 95.6180 VOR Federal Airway V180 Is Amended To Delete		
INTERNATIONAL FALLS, MN VOR/DME	U.S. CANADIAN BORDER	2900

From	To	MEA
§ 95.6190 VOR Federal Airway V190 Is Amended To Read in Part		
OSWEGO, KS VOR/DME *3100—MOCA *4000—GNSS MEA	SPRINGFIELD, MO VORTAC	*6200
§ 95.6213 VOR Federal Airway V213 Is Amended To Read in Part		
GRAND STRAND, SC VORTAC	WILMINGTON, NC VORTAC	UNUSABLE
WILMINGTON, NC VORTAC	WALLO, NC FIX	UNUSABLE
§ 95.6229 VOR Federal Airway V229 Is Amended To Read in Part		
DIXIE, NJ FIX *1700—MOCA	KENNEDY, NY VOR/DME	*2500
§ 95.6252 VOR Federal Airway V252 Is Amended To Read in Part		
AIRCO, NY FIX *2800—MOCA	GENESEO, NY VOR/DME	*4000
95.6316 VOR Federal Airway V316 Is Amended To Delete		
SAULT STE MARIE, MI VOR/DME *2800—MOCA	U.S. CANADIAN BORDER	*5000
§ 95.6510 VOR Federal Airway V510 Is Amended To Delete		
BUFFALO, NY VOR/DME *11000—MCA EHMAN, NY FIX, SW BND **3000—GNSS MEA	*EHMAN, NY FIX	**11000
EHMAN, NY FIX	ROCHESTER, NY VOR/DME	2400
§ 95.6527 VOR Federal Airway V527 Is Amended To Read in Part		
RAZORBACK, AR VORTAC *3200—MOCA	BILIE, MO FIX	*4000
§ 95.6424 Hawaii VOR Federal Airway V24 Is Amended To Read in Part		
#*LANAI, HI VORTAC *5100—MCA LANAI, HI VORTAC, NE BND **7800—MOCA #6700—MCA MAUI, HI VORTAC, SW BND	MAUI, HI VORTAC	**9000

Airway Segment		Changeover Points	
From	To	Distance	From
§ 95.8003 VOR Federal Airway Changeover Point V159 Is Amended To Add Changeover Point			
SPRINGFIELD, MO VORTAC	NAPOLEON, MO VORTAC	57	SPRINGFIELD.

[FR Doc. 2021–28504 Filed 1–4–22; 8:45 am]
BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–11016; 34–93827; 39–2542; IC–34444]

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is adopting amendments to Volume 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 December 20, 2021.

DATES: *Effective date:* January 5, 2022. The incorporation by reference of the Filer Manual is approved by the Director of the Federal Register as of January 5, 2022.

FOR FURTHER INFORMATION CONTACT: For questions regarding the amendments to Volume II of the Filer Manual and related rules, please contact Rosemary Filou, Deputy Director and Chief Counsel, or Jane Patterson, Senior Special Counsel, in the EDGAR Business Office at (202) 551–3900. For questions concerning Inline XBRL tagging requirements for Business Development Companies, please contact Heather Fernandez in the Division of Investment Management at (202) 551–6708. For questions concerning form types SBSE–CCO–RPT and SBSE–CCO–RPT/A, please contact Kelly Shoop, Branch Chief, and Katherine Lesker, Special Counsel, in the Division of Trading and Markets at (202) 551–5550. For questions regarding the DEI Taxonomy additions for auditor information, please contact Chris Windsor, Senior Special Counsel, in the

Division of Corporation Finance at (202) 551–3419. For questions regarding a validation added to EDGAR for Form ATS–N, please contact Tyler Raimo, Assistant Director, in the Division of Trading and Markets at (202) 551–6227. For questions concerning 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 Filer Manual, Volume II: ''EDGAR Filing,'' Version 60 (December 2021) and amendments to 17 CFR 232.301 (''Rule 301''). The updated Filer Manual is 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]

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

EDGAR is being updated in Release 21.4, and was previously updated in Release 21.3.1, and corresponding amendments to Volume II of the Filer Manual will be made to reflect these changes, as described below.[2]

On April 14, 2016, the Commission adopted rules to implement provisions of Title VII of the Dodd-Frank Act. Rule 15Fk–1(c) under the Securities Exchange Act of 1934 requires security-based swap dealers and security-based swap participants (''SBS Entities'') to submit an annual report to the Commission, prepared and signed by the chief compliance officer, containing prescribed information concerning the SBS Entities' compliance programs.[3] Release 21.4 introduces two new submission types for SBS Entities' chief compliance officer to submit the annual compliance report and any subsequent amendments to the report on EDGAR: SBSE–CCO–RPT and SBSE–CCO–RPT/A.

On April 8, 2020, the Commission adopted rule and form amendments that modify the registration, communications, and offering processes for business development companies (''BDCs'') and registered closed-end investment companies (collectively, ''funds'') under the Securities Act of 1933, Regulations S–K and S–T, the Securities Exchange Act of 1934, and the Investment Company Act of 1940 (''Offering Reform Rules'').[4]

The Offering Reform Rules include new structured data requirements for BDCs, which will be required to use Inline XBRL to tag their financial statements. In addition, all funds that file on Form N–2 will be required to use Inline XBRL to tag Form N–2 cover page information.[5] Funds must also tag information provided in response to Items 3.1, 4.3, 8.2.b, 8.2.d, 8.3.a, 8.3.b, 8.5.b, 8.5.c, 8.5.e, 10.1.a–d, 10.2.a–c, 10.2.e, 10.3, and 10.5 (''specified prospectus disclosures'') that is included in any registration statement or post-effective amendment filed on Form N–2, or for any forms of prospectus filed pursuant to Rule 424 under the Securities Act of 1933 that include or amend such information. The Offering Reform Rules also require funds that file a short-form shelf registration statement on Form N–2 (''seasoned issuers'') to use Inline XBRL to tag any specified prospectus disclosures that appear in Exchange Act reports that are incorporated by reference into their registration statement (*e.g.,* Forms 10–K, 10–Q, 8–K, N–CSR).

In conjunction with the Offering Reform Rules, EDGAR will be updated to support the 2021Q4 Closed-End Funds (CEF) Taxonomy, and the EDGAR Filer Manual will be revised to update the submission types that will accept XBRL and to describe certain validations specific to the CEF Taxonomy.

Further, on October 13, 2021, the Commission adopted rules and form amendments to modernize filing fee disclosure and payment methods for operating companies, BDCs, and most registered closed-end funds.[6] Effective January 31, 2022, such filers will be required to disclose their filing fee calculation table(s) and related information in a new filing fee exhibit for most fee bearing forms within the scope of the rules. The new exhibit, which will be titled ''EX–FILING FEES,'' will initially be filed in an unstructured format. Filing instructions for the new filing fee exhibits are included in Volume II of the Filer Manual with a note to filers that the instructions are effective on January 31, 2022.

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

- A validation will be added within EDGAR to ensure that if a filer indicates that certain information can be found on a website URL that is listed in Item 6 of Form ATS–N, the website URL has, in fact, been included. If the filer has not included the website, EDGAR will suspend the filing and send a suspension message to the filer.
- On December 18, 2020, Congress enacted the ''Holding Foreign Companies Accountable Act'' (''HFCAA''), which includes submission and disclosure requirements for registrants that the Commission identifies as having filed an annual report on Forms 20–F, 40–F, 10–K, and N–CSR with an audit report issued by a registered public accounting firm that is located in a foreign jurisdiction and that the Public Company Accounting Oversight Board (''PCAOB'') has determined it is unable to inspect or investigate completely because of a position taken by an authority in that jurisdiction.[7] On December 2, 2021, the Commission adopted amendments[8] to finalize interim final rules[9] that revised Forms 20–F, 40–F, 10–K, and N–CSR to implement the disclosure and submission requirements of the HFCAA. The final amendments, among other things, mandated that filers provide certain XBRL information about firms providing audit reports for financial statements included in annual reports filed on Forms 20–F, 40–F, 10–K, and N–CSR for fiscal years ending on or after December 18, 2021, which will begin to be made in early 2022.[10] In order for registrants to comply with the final amendments, EDGAR will be updated to support the latest version of DEI–2021Q4 Taxonomy, and all registrants will be required to use the updated taxonomy, or a subsequently adopted version of the taxonomy, for any annual

[1] *See* Rule 301 of Regulation S–T.

[2] Release 21.4 will be deployed on or about December 20, 2021.

[3] *See* Rule 15Fk–1(c) under the Exchange Act [17 CFR 240.15Fk–1(c)].

[4] *See* Securities Offering Reform for Closed-End Investment Companies, Release 33–10771 (Apr. 8, 2020) [85 FR 33290 (June 1, 2020)]. The compliance dates for the new structured data requirements of the rulemaking are August 1, 2022 (for funds that file a short-form shelf registration statement on Form N–2), and February 1, 2023 (for all other funds).

[5] BDCs and registered closed-end funds that file on Forms 10–K, 10–Q, or 8–K must also tag the cover page of such filings pursuant to the requirements of Rule 406 of Regulation S–T.

[6] *See* Filing Fee Disclosure and Payment Methods Modernization, Release 33–10997 (Oct. 13, 2021) [86 FR 70166 (Dec. 9, 2021)].

[7] Holding Foreign Companies Accountable Act, Public Law 116–222 (Dec. 18, 2020).

[8] Holding Foreign Companies Accountable Act Disclosure, Release 34–93701 (Dec. 2, 2021) [86 FR 70027 (Dec. 9, 2021)].

[9] Holding Foreign Companies Accountable Act Disclosure, Release No. 34–91364 (Mar. 18, 2021) [86 FR 17528 (Apr. 5, 2021)].

[10] Holding Foreign Companies Accountable Act Disclosure, Release 34–93701 (Dec. 2, 2021) [86 FR 70027 (Dec. 9, 2021)].

report filed for a period ended after December 15, 2021.

Release 21.4 also introduces, and Release 21.3.1 introduced, additional changes in EDGAR that do not require corresponding amendments to the Filer Manual. See the ''Updates'' section of Volume II of the Filer Manual.

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 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, the related 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'').[11] It follows that the amendments do not require analysis under requirements of the Regulatory Flexibility Act [12] or a report to Congress under the Small Business Regulatory Enforcement Fairness Act of 1996.[13]

The effective date for the updated Filer Manual and related rule amendments is January 5, 2022. In accordance with the APA,[14] 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 under the authority in Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,[15] Sections 3, 12, 13, 14, 15, 15B, 23, and 35A of the Securities Exchange Act of 1934,[16] Section 319 of the Trust Indenture Act of 1939,[17] and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[18]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

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), 78*l,* 78m, 78n, 78o(d), 78w(a), 78*ll,* 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 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 60 (December 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.*

By the Commission.

Dated: December 20, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–28445 Filed 1–4–22; 8:45 am]

BILLING CODE 8011–01–P

[11] 5 U.S.C. 553(b)(A).

[12] 5 U.S.C. 601 through 612.

[13] 5 U.S.C. 804(3)(C).

[14] 5 U.S.C. 553(d)(3).

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

[16] 15 U.S.C. 78c, 78*l,* 78m, 78n, 78*o,* 78o–4, 78w, and 78*ll.*

[17] 15 U.S.C. 77sss.

[18] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2014–0471; FRL–5562–08–OAR]

RIN 2060–AS26

Clean Air Act Section 112 List of Hazardous Air Pollutant: Amendments to the List of Hazardous Air Pollutants (HAP)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is amending the list of hazardous air pollutants (HAP) under Clean Air Act (CAA) to add 1-bromopropane (1-BP) in response to public petitions previously granted by the EPA. This action amends the list of hazardous air pollutants initially listed under the CAA.

DATES: This final rule is effective on February 4, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2014–0471. All documents in the docket are listed in *https://www.regulations.gov/.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information 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. With the exception of such material, publicly available docket materials are available electronically in *https://www.regulations.gov/.* Out of an

abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are open to the public by appointment only to reduce the risk of transmitting COVID–19. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention, local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets* or call the Public Reading Room at (202) 566–1744 or the EPA Docket Center at (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Susan Miller, Sector Policies and Programs Division (D205–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number: (919) 541–2443; fax number: (919) 541–4991; email address: *miller.susan@epa.gov.* You may also consult your state or local permitting representative or the appropriate EPA Regional office representative.

SUPPLEMENTARY INFORMATION:

Organization of this document. The information in this preamble is organized as follows:

I. General Information
II. Background
III. What does this final rule do?
IV. Statutory and Executive Order Reviews

I. General Information

A. Why is the EPA issuing this final rule?

Having previously granted petitions to add 1-BP to the CAA HAP list, this current action is the final step in granting petitioners' request. Per CAA section 112(b)(3)(B), the Administrator ''shall add a substance to the list upon a showing by the petitioner or on the Administrator's own determination that the substance is an air pollutant, and that emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects.'' On June 18, 2020, the EPA published its final decision to grant the petitions from two entities to list 1-BP. See 85 FR 36851. This final rule completes the listing action required when a petition is granted.

Having previously published the rationale for the decision to grant these petitions and provided an opportunity for public review and comment, the EPA has determined that there is good cause for amending the CAA HAP list without additional need for public review and comment. This final rule merely codifies a decision that was made in the June 2020 granting notice; therefore, we believe any additional public notice and comment is duplicative, unnecessary, and would serve no useful purpose.

B. Judicial Review

Under CAA section 112(e)(4), the Administrator's decision to add a pollutant to the CAA HAP list is not a final Agency action subject to judicial review, except that any such action may be reviewed when the Administrator promulgates emission standards for the pollutant. Accordingly, the decision to add 1-BP to the HAP list is not subject to judicial review until the Administrator promulgates applicable CAA section 112(d) standards that address emissions of 1-BP.

II. Background

A. What is the statutory authority for this action?

The CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP contained in CAA section 112(b)(1), otherwise known as the CAA HAP list,[1] by adding or deleting a substance. CAA section 112(b)(3)(B) sets out the substantive criteria for granting a petition. It calls for the Administrator to add a substance to the CAA section 112(b)(1) list, ''upon a showing by the petitioner or on the Administrator's own determination that the substance is an air pollutant and that emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects.'' The Administrator is required under the CAA section 112(b)(3)(A) to either grant or deny a petition within 18 months of the receipt of a complete petition by publishing a written explanation of the reasons for the Administrator's decision. The Administrator may not deny a petition based solely on inadequate resources or time for review.

This is the first occasion on which the EPA is adding a substance to the CAA HAP list that Congress created in 1990. Since 1990, the EPA has amended the CAA HAP list four times to remove or delist a HAP. They are caprolactam (61 FR 30816; June 18, 1996); ethylene glycol monobutyl ether (69 FR 69320; November 29, 2004); surfactant alcohol ethoxylates and their derivatives (these are compounds that were considered to be included in glycol ethers, which is a listed HAP); (65 FR 47342; August 2, 2000); and methyl ethyl ketone (MEK) (70 FR 75047; December 19, 2005)). The EPA has also denied a petition to remove methanol from the CAA HAP list (66 FR 21929; May 2, 2001).

B. What is the history of the listing process for 1-BP?

The Halogenated Solvents Industry Alliance (HSIA) and New York State Department of Environmental Conservation (NYSDEC) submitted petitions requesting that the EPA add 1-BP to the CAA section 112(b)(1) HAP list on October 28, 2010, and November 24, 2011, respectively.[2] On November 28, 2012, in response to the EPA's requests for additional data, HSIA supplemented its petition. Following the receipt of these petitions and supplemental data, the EPA conducted a review to determine whether the petitions were complete according to Agency criteria for the CAA section 112(b)(3) actions, which we explained in the February 6, 2015, document (80 FR 6676). Specifically, the EPA determined that these petitions and supplemental data addressed all the necessary subject areas for the Agency to assess whether emissions, ambient concentrations, bioaccumulation, or deposition of 1-BP are known to cause or may reasonably be anticipated to cause adverse human health effects or adverse environmental effects. On February 6, 2015, the EPA determined these petitions to be complete and published a notification of receipt of a complete petition in the **Federal Register** (80 FR 6676), that invited the public to comment on the technical merits of these petitions and to submit any information relevant to the technical review of these petitions. Further, on March 11, 2015 (80 FR

[1] The CAA HAP list is a list or organic and inorganic substances that Congress identified as HAP in the 1990 CAA Amendments. CAA section 112(b)(1). These HAP are associated with a wide variety of adverse health effects, including, but not limited to cancer, neurological effects, reproductive effects, and developmental effects. The health effects associated with various HAP differ depending upon the toxicity of the individual HAP and the particular circumstances of exposure, such as the amount of chemical present, the length of time a person is exposed and the stage of life at which the person is exposed.

[2] Both the Halogenated Solvents Industry Alliance and the New York State Department of Environmental Conservation petitions referred to the chemical as n-propyl bromide and 1-bromopropane.

12794), the EPA extended the comment period for the notification of receipt of complete petitions to May 7, 2015. Subsequently, on January 9, 2017, the EPA published a draft notice in the **Federal Register** (82 FR 2354) containing the Agency's intended rationale for granting these petitions and solicited public comments on the rationale. In the draft notice, the EPA determined that these petitions met criteria specified in the CAA section 112(b)(3)(B): *i.e.,* 1-BP is an air pollutant and its emissions and ambient concentrations ''may reasonably be anticipated to cause adverse effects to human health.'' Further, on June 6, 2017, the EPA extended the comment period until October 1, 2017, in response to the request by Albemarle Corporation, a U.S.-based manufacturer of 1-BP, that the Agency provide an opportunity for prospective commenters to review the 2017 Toxics Release Inventory (TRI), which included newly required reporting of 1-BP emissions. (82 FR 26091). On June 18, 2020, the EPA granted these petitions after reviewing and addressing public comments received on the draft notice containing the Agency's intended rationale for granting them. (85 FR 36851).[3] Finally, on June 11, 2021, the EPA published an advanced notice of proposed rulemaking (ANPRM), Addition of 1-Bromopropane to Clean Air Act Section 112 HAP List, that solicited data and comments on the potential regulatory impacts of the addition of a HAP to the Section 112 HAP list. (86 FR 31225).

Based on the information and comments received in response to the ANPRM, the Agency determined that a separate regulation is needed to ensure the effective and efficient implementation of requirements triggered by the addition of a new HAP. The Agency has thus begun working on a separate regulatory ''infrastructure'' to address the impacts, implications, and requirements associated with the addition of a new HAP to the HAP list. In the meantime, the Agency has also determined that additional guidance may be needed on the listing of 1-BP and intends to publish such guidance upon promulgation of this rule.

[3] On August 17, 2020, California Communities Against Toxics, Sierra Club and Gasp filed a petition for judicial review of the agency's decision to grant petitions that did not list 1-BP as a HAP under CAA section 112(b)(1). *California Communities Against Toxics* v. *EPA,* Case No. 20–1311 (D.C. Circuit). The State of New York is an intervenor on behalf of petitioners. This case is currently being held in abeyance and motions to govern further proceedings are now due on February 7, 2022.

C. What is 1-BP?

The compound 1-BP or n-propyl bromide (nPB),[4] CAS #106–94–5, is a brominated organic colorless liquid that is insoluble in water but soluble in ethanol and ether. Both petitioners and public commenters provided background information regarding 1-BP's chemical properties, physical properties, production, and usage as a part of the 1-BP petition granting process. [See Docket ID No. EPA–HQ–OAR–2014–0471]. Applications of 1-BP include solvent cleaning in electronic, metal, and precision cleaning operations; aerosols; adhesives; and as an intermediate chemical in the manufacture of pharmaceuticals and agricultural products.

III. What does this final rule do?

This final rule will amend 40 CFR part 63, subpart C, to add 1-BP to the list of CAA section 112 HAP. The effective date of the addition is February 4, 2022. Once added to the HAP list, 1-BP will become subject to regulation under CAA section 112. (''EPA has a clear statutory obligation under the statute to set emission standards for each listed HAP.'' *National Lime Association* v. *EPA,* 233 F.3d 625, 634 (D.C. Cir. 2000)). There is no specific period for promulgating standards for newly listed HAPs under CAA section 112(b)(1).

IV. Statutory and Executive Order Reviews

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it was determined that it raised ''novel legal or policy issues.'' Any changes made in response to OMB recommendations have been documented in the docket. This action will have no direct immediate impacts under 40 CFR part 63 on emissions of 1-BP, but the addition of 1-BP to the HAP list could have immediate impacts to facilities that emit 1-BP (*e.g.,* the operating permits program under title V of the CAA).

[4] For this action and for future regulations under the CAA, the EPA will refer to the chemical identified by CAS No. 106–94–5 as 1-bromopropane or 1-BP. The EPA notes that in an action published on November 23, 2015, the EPA added the chemical by the name 1-BP to the Community Right-to-Know Toxic Chemical Release Reporting requirements. In addition, the chemical is listed in the EPA's Substance Registry Services, EPA's authoritative resource for basic information about chemicals, as 1-BP. Finally, the chemical's final risk evaluation is currently undergoing reconsideration pursuant to Toxic Substances Control Act Section 6(a), under Docket ID No. EPA– HQ–OPPT–2015–0084 as 1-BP.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the EPA concludes that the impact of concern is any significant adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities if the rule has no net burden on the small entities subject to the rule. This regulatory action is ministerial in nature as it codifies a decision to list 1-BP as a HAP that was made when the petitions to list were granted. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action 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.

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

This action does not have tribal implications as specified in Executive Order 13175. The action presents no additional burden on implementing authorities beyond existing requirements. Thus, Executive Order 13175 does not apply to this action. However, the EPA held two meetings with tribes to explain this action. The first meeting occurred on June 29, 2020, immediately after the petitions to add 1-BP were granted. The second meeting followed the June 11, 2021, publication of the ANPRM for 1-BP (86 FR 31225).

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action 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. This action codifies a decision to list 1-BP as a HAP that was made when petitions were granted in 2020.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

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

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629; February 16, 1994) because it does not establish an environmental health or safety standard. This regulatory action is ministerial in nature as it codifies a decision to list 1-BP as a HAP that was made when petitions were granted in 2020 and does not have any direct impact on human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule in section I of this preamble, including the basis for that finding.

List of Subjects for 40 CFR Part 63

Environmental protection, Administrative practice and procedures, General Provisions, Hazardous substances.

Michael S. Regan,

Administrator.

For the reasons discussed in the preamble, the Environmental Protection Agency amends 40 CFR part 63 as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

■ 2. Add § 63.64 to subpart C to read as follows:

§ 63.64 Additions of substances to the list of hazardous air pollutants.

(a) The substance 1-bromopropane, or 1-BP, also known as n-propyl bromide or nPB (CAS No. 106–94–5) is added to the list of hazardous air pollutants established by Clean Air Act (CAA) section 112(b)(1), 42 U.S.C. 7412(b)(1).

(b) [Reserved]

[FR Doc. 2021–28315 Filed 1–4–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[DA 21–1631; FR ID 65075]

Annual Adjustment of Civil Monetary Penalties To Reflect Inflation

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Inflation Adjustment Act) requires the Federal Communications Commission (Commission) to amend its forfeiture penalty rules to reflect annual adjustments for inflation in order to improve their effectiveness and maintain their deterrent effect. The Inflation Adjustment Act provides that the new penalty levels shall apply to penalties assessed after the effective date of the increase, including when the penalties whose associated violation predate the increase.

DATES:

Effective date: The rule is effective January 5, 2022.

Applicability date: The civil monetary penalties are applicable beginning January 15, 2022.

FOR FURTHER INFORMATION CONTACT: Lisa Gelb, Deputy Chief, Enforcement Bureau, at *Lisa.Gelb@fcc.gov* or 202–418–2019.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, DA 21–1631, adopted and released on December 22, 2021. The complete text of this document is available for download at *https://www.fcc.gov/document/2022-annual-adjustment-civil-monetary-penalties-reflect-inflation.* The complete text of this document is also available for inspection and copying during normal business hours in the FCC Reference Information Center, 45 L Street NE, Washington, DC 20554. To request this document in accessible formats for people with disabilities (*e.g.,* Braille, large print, electronic files, audio format, etc.) or to request reasonable accommodations (*e.g.,* accessible format documents, sign language interpreters, CART, etc.), send an email to *fcc504@fcc.gov* or call the FCC's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

The Bipartisan Budget Act of 2015 included, as section 701 thereto, the Inflation Adjustment Act, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410), to improve the effectiveness of civil monetary penalties and maintain their deterrent effect. Under the Inflation Adjustment Act, agencies are required to make annual inflationary adjustments by January 15 each year, beginning in 2017. The adjustments are calculated pursuant to Office of Management and Budget (OMB) guidance. OMB issued guidance on December 15, 2021, and this Order follows that guidance. The Commission therefore updates the civil monetary penalties for 2022, to reflect an annual inflation adjustment based on the percent change between each published October's CPI–U; in this case, October 2021 CPI–U (276.589)/October 2020 CPI–U (260.388) = 1.06222. The Commission multiplies 1.06222 by the most recent penalty amount and then rounds the result to the nearest dollar.

For 2022, the adjusted penalty or penalty range for each applicable penalty is calculated by multiplying the most recent penalty amount by the 2022 annual adjustment (1.06222), then rounding the result to the nearest dollar. The adjustments in civil monetary

penalties that we adopt in this Order apply only to such penalties assessed on and after January 15, 2022.

Paperwork Reduction Act

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

Congressional Review Act

The Commission has determined, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, concurs that this rule is non-major under the Congressional Review Act, 5 U.S.C. 804(2). The Commission will send a copy of this Order to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 1

Administrative practice and procedure, Penalties.

Federal Communications Commission.

Lisa Gelb,

Deputy Chief, Enforcement Bureau.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 1 as follows:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 47 U.S.C. chs. 2, 5, 9, 13; 28 U.S.C. 2461 note, unless otherwise noted.

■ 2. Amend § 1.80 by revising paragraphs (b)(1) through (9), Table 4 to paragraph (b)(10), and paragraph (b)(11)(ii) to read as follows:

§ 1.80 Forfeiture proceedings.

* * * * *

(b) * * * (1) *Forfeiture penalty for a broadcast station licensee, permittee, cable television operator, or applicant.* If the violator is a broadcast station licensee or permittee, a cable television operator, or an applicant for any broadcast or cable television operator license, permit, certificate, or other instrument of authorization issued by the Commission, except as otherwise noted in this paragraph (b)(1), the forfeiture penalty under this section shall not exceed $55,052 for each violation or each day of a continuing violation, except that the amount assessed for any continuing violation shall not exceed a total of $550,531 for any single act or failure to act described in paragraph (a) of this section. There is no limit on forfeiture assessments for EEO violations by cable operators that occur after notification by the Commission of a potential violation. See section 634(f)(2) of the Communications Act. Notwithstanding the foregoing in this section, if the violator is a broadcast station licensee or permittee or an applicant for any broadcast license, permit, certificate, or other instrument of authorization issued by the Commission, and if the violator is determined by the Commission to have broadcast obscene, indecent, or profane material, the forfeiture penalty under this section shall not exceed $445,445 for each violation or each day of a continuing violation, except that the amount assessed for any continuing violation shall not exceed a total of $4,111,796 for any single act or failure to act described in paragraph (a) of this section.

(2) *Forfeiture penalty for a common carrier or applicant.* If the violator is a common carrier subject to the provisions of the Communications Act or an applicant for any common carrier license, permit, certificate, or other instrument of authorization issued by the Commission, the amount of any forfeiture penalty determined under this section shall not exceed $220,213 for each violation or each day of a continuing violation, except that the amount assessed for any continuing violation shall not exceed a total of $2,202,123 for any single act or failure to act described in paragraph (a) of this section.

(3) *Forfeiture penalty for a manufacturer or service provider.* If the violator is a manufacturer or service provider subject to the requirements of section 255, 716, or 718 of the Communications Act, and is determined by the Commission to have violated any such requirement, the manufacturer or service provider shall be liable to the United States for a forfeiture penalty of not more than $126,463 for each violation or each day of a continuing violation, except that the amount assessed for any continuing violation shall not exceed a total of $1,264,622 for any single act or failure to act.

(4) *Forfeiture penalty for a 227(e) violation.* Any person determined to have violated section 227(e) of the Communications Act or the rules issued by the Commission under section 227(e) of the Communications Act shall be liable to the United States for a forfeiture penalty of not more than $12,646 for each violation or three times that amount for each day of a continuing violation, except that the amount assessed for any continuing violation shall not exceed a total of $1,264,622 for any single act or failure to act. Such penalty shall be in addition to any other forfeiture penalty provided for by the Communications Act.

(5) *Forfeiture penalty for a 227(b)(4)(B) violation.* Any person determined to have violated section 227(b)(4)(B) of the Communications Act or the rules in 47 CFR part 64 issued by the Commission under section 227(b)(4)(B) of the Communications Act shall be liable to the United States for a forfeiture penalty determined in accordance with paragraphs (A)–(F) of section 503(b)(2) plus an additional penalty not to exceed $10,748.

(6) *Forfeiture penalty for pirate radio broadcasting.* (i) Any person who willfully and knowingly does or causes or suffers to be done any pirate radio broadcasting shall be subject to a fine of not more than $2,149,551; and

(ii) Any person who willfully and knowingly violates the Act or any rule, regulation, restriction, or condition made or imposed by the Commission under authority of the Act, or any rule, regulation, restriction, or condition made or imposed by any international radio or wire communications treaty or convention, or regulations annexed thereto, to which the United States is party, relating to pirate radio broadcasting shall, in addition to any other penalties provided by law, be subject to a fine of not more than $107,478 for each day during which such offense occurs, in accordance with the limit described in this section.

(7) *Forfeiture penalty for a section 6507(b)(4) Tax Relief Act violation.* If a violator who is granted access to the Do-Not-Call registry of public safety answering points discloses or disseminates any registered telephone number without authorization, in violation of section 6507(b)(4) of the Middle Class Tax Relief and Job Creation Act of 2012 or the Commission's implementing rules in 47 CFR part 64, the monetary penalty for such unauthorized disclosure or dissemination of a telephone number from the registry shall be not less than $118,430 per incident nor more than $1,184,300 per incident depending upon whether the conduct leading to the violation was negligent, grossly negligent, reckless, or willful, and depending on whether the violation was a first or subsequent offense.

(8) *Forfeiture penalty for a section 6507(b)(5) Tax Relief Act violation.* If a

violator uses automatic dialing equipment to contact a telephone number on the Do-Not-Call registry of public safety answering points, in violation of section 6507(b)(5) of the Middle Class Tax Relief and Job Creation Act of 2012 or the Commission's implementing rules in 47 CFR part 64, the monetary penalty for contacting such a telephone number shall be not less than $11,843 per call nor more than $118,430 per call depending on whether the violation was negligent, grossly negligent, reckless, or willful, and depending on whether the violation was a first or subsequent offense.

(9) *Maximum forfeiture penalty for any case not previously covered.* In any case not covered in paragraphs (b)(1) through (8) of this section, the amount of any forfeiture penalty determined under this section shall not exceed $22,021 for each violation or each day of a continuing violation, except that the amount assessed for any continuing violation shall not exceed a total of $165,159 for any single act or failure to act described in paragraph (a) of this section.

(10) * * *

TABLE 4 TO PARAGRAPH (b)(10)—NON-SECTION 503 FORFEITURES THAT ARE AFFECTED BY THE DOWNWARD ADJUSTMENT FACTORS [1]

Violation	Statutory amount after 2022 annual inflation adjustment
Sec. 202(c) Common Carrier Discrimination	$13,213, $661/day.
Sec. 203(e) Common Carrier Tariffs	$13,213, $661/day.
Sec. 205(b) Common Carrier Prescriptions	$26,425.
Sec. 214(d) Common Carrier Line Extensions	$2,642/day.
Sec. 219(b) Common Carrier Reports	$2,642/day.
Sec. 220(d) Common Carrier Records & Accounts	$13,213/day.
Sec. 223(b) Dial-a-Porn	$136,924/day.
Sec. 227(e) Caller Identification	$12,646/violation. $37,937/day for each day of continuing violation, up to $1,264,622 for any single act or failure to act.
Sec. 364(a) Forfeitures (Ships)	$11,011/day (owner).
Sec. 364(b) Forfeitures (Ships)	$2,203 (vessel master).
Sec. 386(a) Forfeitures (Ships)	$11,011/day (owner).
Sec. 386(b) Forfeitures (Ships)	$2,203 (vessel master).
Sec. 511 Pirate Radio Broadcasting	$2,149,551, $107,478/day.
Sec. 634 Cable EEO	$976/day.

[1] Unlike section 503 of the Act, which establishes maximum forfeiture amounts, other sections of the Act, with two exceptions, state prescribed amounts of forfeitures for violations of the relevant section. These amounts are then subject to mitigation or remission under section 504 of the Act. One exception is section 223 of the Act, which provides a maximum forfeiture per day. For convenience, the Commission will treat this amount as if it were a prescribed base amount, subject to downward adjustments. The other exception is section 227(e) of the Act, which provides maximum forfeitures per violation, and for continuing violations. The Commission will apply the factors set forth in section 503(b)(2)(E) of the Act and this table 4 to determine the amount of the penalty to assess in any particular situation. The amounts in this table 4 are adjusted for inflation pursuant to the Debt Collection Improvement Act of 1996 (DCIA), 28 U.S.C. 2461. These non-section 503 forfeitures may be adjusted downward using the "Downward Adjustment Criteria" shown for section 503 forfeitures in table 3 to this paragraph (b)(10).

(11) * * *

(ii) The application of the annual inflation adjustment required by the foregoing Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 results in the following adjusted statutory maximum forfeitures authorized by the Communications Act:

TABLE 5 TO PARAGRAPH (b)(11)(ii)

U.S. Code citation	Maximum penalty after 2022 annual inflation adjustment
47 U.S.C. 202(c)	$13,213 661
47 U.S.C. 203(e)	13,213 661
47 U.S.C. 205(b)	26,425
47 U.S.C. 214(d)	2,642
47 U.S.C. 219(b)	2,642
47 U.S.C. 220(d)	13,213
47 U.S.C. 223(b)	136,924
47 U.S.C. 227(e)	12,646 37,937 1,264,622
47 U.S.C. 362(a)	11,011
47 U.S.C. 362(b)	2,203
47 U.S.C. 386(a)	11,011

TABLE 5 TO PARAGRAPH (b)(11)(ii)—Continued

U.S. Code citation	Maximum penalty after 2022 annual inflation adjustment
47 U.S.C. 386(b)	2,203
47 U.S.C. 503(b)(2)(A)	55,052 550,531
47 U.S.C. 503(b)(2)(B)	220,213 22,202,123
47 U.S.C. 503(b)(2)(C)	445,445 4,111,796
47 U.S.C. 503(b)(2)(D)	22,021 165,159
47 U.S.C. 503(b)(2)(F)	126,463 1,264,622
47 U.S.C. 507(a)	2,181
47 U.S.C. 507(b)	320
47 U.S.C. 511	2,149,551 107,478
47 U.S.C. 554	976

* * * * *

[FR Doc. 2021–28310 Filed 1–4–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 52

[WC Docket No. 18–336; FCC 21–119; FR 61458]

Implementation of the National Suicide Hotline Improvement Act of 2018

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission or FCC) requires all covered text providers to support text messaging to 988, the 3-digit dialing code to reach the National Suicide Prevention Lifeline, by July 16, 2022. Given the popularity of text messaging, particularly among at-risk populations, it is essential for Americans to be able to text the Lifeline with the same short, easy-to-remember code by which they will be able to call the Lifeline.

DATES: This rule is effective February 4, 2022.

FOR FURTHER INFORMATION CONTACT: Michelle Sclater, Competition Policy Division, Wireline Competition Bureau, at (202) 418–0388, *Michelle.Sclater@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Second Report and Order* (SRO) in WC Docket No. 18–336, adopted on November 18, 2021and released on November 19, 2021. The document is available for download at *https://docs.fcc.gov/public/attachments/FCC-21-119A1.pdf.* To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Synopsis

I. Second Report and Order

A. Text-to-988 Will Save Lives

1. We conclude that requiring covered text providers to support text-to-988 will save lives. No commenter in the record opposes adoption of a text-to-988 requirement. As Americans become more reliant on texting to communicate, the need to access mental health assistance and resources by text is essential. Text messaging to the Lifeline will facilitate access to critical mental health resources for all, and particularly for at-risk populations who tend to prefer communicating through text rather than phone calls.

2. The record reflects overwhelming support for the conclusion that text-to-988 functionality will greatly improve consumer access to the Lifeline. Over 14 National Alliance on Mental Illness (NAMI) offices across the United States filed in support of text messaging to 988. Substance Abuse and Mental Health Services Administration (SAMHSA), the Government agency responsible for overseeing the Lifeline, states that texting capability would improve equitable access to the Lifeline, especially for at-risk communities; and Vibrant, the administrator of the Lifeline, also notes that ''text-to-988 capability would improve consumer accessibility to the Lifeline and save lives.'' Mental Health America suggests that ''[i]f 988 is implemented without support for text messaging, individuals in need of mental health crisis services, particularly youth and adolescents, will remain unanswered.'' A bipartisan group of U.S. Representatives from Colorado express their support, stating that ''[b]y allowing a text-to-988 option in addition to voice call, the Commission can lower the bar to entry and improve access to crisis counseling and mental health services.'' Text-to-988 will provide greater access to anyone who is not comfortable calling the Lifeline or cannot make a phone call. For instance, individuals who are in abusive or controlling situations may feel safer texting than making a verbal call when in a crisis. Similarly, for individuals who are helping someone who is experiencing symptoms such as paranoia or delusions and appears threatening, texting offers greater safety when reaching out for crisis assistance.

3. The record also demonstrates that requiring covered text providers to support text-to-988 functionality will provide significant benefits to at-risk populations, particularly to young Americans who are disproportionately at risk for mental health crises. Research shows that serious psychological distress, major depression, and suicidal thoughts and attempts among adolescents and young adults have increased significantly in recent years. SAMHSA explains that individuals who send texts or online chats to the Lifeline both skew younger and are more likely to experience current suicidal ideation relative to the categories of individuals who typically access the Lifeline via phone. Nearly 95% of teens have access to smart phones and report that texting is the primary way by which they connect. According to Mental Health America, ''[m]ultiple sources of data demonstrate youth prefer communicating by text rather than calls,'' including a study finding that young people ''were more likely to forgo psychological support than talk in person or over the phone.'' Nevada, which conducted one of the country's first text messaging for crisis response pilot programs, TextToday, found an increase in help-seeking behaviors by youth as a result of the program and a preference for texting among the youth age cohort. Some members of at-risk populations may prefer or find it easier to access the Lifeline via text as compared to the online chat portal, which requires people to have internet access, find the website, and locate the chat portal. A survey addressing how teens are coping and connecting during COVID–19 reported that 65% of teens used texting to communicate with friends and family more than usual in response to the pandemic.

4. In addition to young Americans, text-to-988 will help other American communities that are disproportionately impacted by suicide, including Veterans, LGBTQ+ individuals, racial and ethnic minorities, and rural Americans. Death by suicide amongst Veterans has steadily increased over the past several years. Furthermore, the suicide rate has risen faster among Veterans than it has for non-Veteran adults. LGBTQ+ youth are nearly five times as likely to have attempted suicide compared to heterosexual youth, and the suicide rate for Black children ages 5–12 is about two times higher compared to white children. The record indicates that these at-risk communities may use text services at higher rates than other communities. For example, NAMI reports that people of color text at a higher rate than white individuals, and lower-income households send twice as many texts than households with higher incomes. Mental Health America notes that data they collected demonstrate that individuals ''who identify as Black or African American are more likely to report that they would like to receive a phone number they can immediately call or text for help'' than members of any other race or ethnicity. Individuals from communities, religious groups, or ethnic backgrounds that have been found to have lower professional help-seeking behaviors or whose communities are less typically accepting of mental health treatment will also benefit from the added privacy of seeking crisis support via text.

5. Text messaging has also become a crucial form of communication for people who are deaf, hard of hearing, or have other disabilities that impact communication. Studies find an increased risk of suicide among deaf and hard of hearing people when compared to those without hearing loss. These individuals have increasingly adopted widely available text messaging platforms in lieu of specialized legacy devices, such as text telephones (TTY), because of the ease of access, wide availability, and practicability of modern text-capable devices. Some individuals with disabilities find it more effective to access mental health support through text messaging over other means of communications. Vibrant notes that for individuals in the disability community, the ability to text crisis services directly, without need for an intermediary interpreter or service, provides ''substantial benefit.'' SAMHSA highlights the convenience texting would provide to people with autism spectrum disorder (ASD), who are at an increased risk for suicide, yet may have ''difficulties with back and forth conversations, and may therefore prefer to text rather than call the Lifeline.'' Access to communications capabilities for individuals with disabilities is a longstanding Commission priority and statutory obligation. Our requirement to support

text-to-988 broadens access to 988 and helps ensure individuals with disabilities that impact communication can more easily reach lifesaving resources.

6. The Commission's designation of 988 as the 3-digit telephone number for the Lifeline reflected its expectation that a simple, easy-to-remember, 3-digit dialing code for suicide prevention and mental health crisis counseling would ''help increase the effectiveness of suicide prevention efforts, ease access to crisis services, reduce the stigma surrounding suicide and mental health conditions, and ultimately save lives.'' We conclude that providing text access at the same short code number will generate synergies that enhance the value of efforts to promote 988. We are also mindful that the promotion and availability of the 988 short code for telephone calls to the Lifeline crisis hotline, and by extension the Veterans Crisis Line, could create confusion as to whether that number is available for, and capable of, receiving text messages. We find that requiring providers to implement text-to-988 will also help to avoid confusion or putting lives at risk.

B. Designating a Wholly Unique 3-Digit Dialing Code vs. an Existing N11

7. We adopt our proposed two-step process to establish the scope of text messages that fall within our text-to-988 requirement (86 FR 31404, June 11, 2021). While we acknowledge the importance of testing and coordination between covered text providers and the Lifeline, we decline at this time to adopt the Department of Veterans Affairs' (VA's) proposed ''third-step'' to our scope of text messages because the proposed testing and validation process is not germane to *ex ante* defining the scope of covered text providers. First, we establish an outer bound definition of ''988 text message'' that sets the maximum possible scope of text formats which covered text providers may be obligated to support for delivery to 988, based on the definition of ''text message'' that Congress enacted in 2018 in the Truth in Caller ID context. Second, we establish a process to ensure that covered text providers only must enable transmission of text messages in formats that the Lifeline can actually receive. We also define the scope of entities subject to our text-to-988 requirements—*i.e.,* ''covered text providers''—to be consistent with our text-to-911 rules, which include Commercial Mobile Radio Services (CMRS) providers and providers of interconnected text messaging services. We find that this approach, in combination, provides a forward-looking, flexible scope that will expand with the capabilities of the Lifeline without unnecessarily obligating covered text providers to support formats that the Lifeline cannot yet receive.

1. Scope of Covered Text Formats

8. *Outer Bound Definition.* Consistent with our proposal in the further notice of proposed rulemaking (FNPRM) (86 FR 31404, June 11, 2021), we adopt the Truth in Caller ID definition of ''text message''—including the definitions for ''short message service'' (SMS) and, as a requirement when Lifeline is able to support it, ''multimedia message service'' (MMS)—as the outer bound scope of text messages that covered text providers may be obligated to transmit to 988, which provides that the term (1) means a message consisting of text, images, sounds, or other information that is transmitted to or from a device that is identified as the receiving or transmitting device by means of a 10-digit telephone number or N11 service code; (2) includes a SMS message and a multimedia message service (commonly referred to as 'MMS') message; and (3) does not include—(i) a real-time, two-way voice or video communication; or (ii) a message sent over an internet protocol (IP)-enabled messaging service to another user of the same messaging service, except a message described in clause (2).

9. We find that there are several advantages to adopting the Truth in Caller ID definition in the text-to-988 context. The definition encompasses, but is not exclusive to, SMS and MMS messages without limiting the outer bounds of supported text formats to specific technologies, thus providing flexibility for inclusion of future text message formats under the rules. It also represents a recent definition provided by Congress, albeit in a different policy context. We slightly modify the Truth in Caller ID definition to account for the 988 context by adopting our proposal to add ''or 988'' to the phrase from the Truth in Caller ID definition ''10-digit telephone number or N11 service code.'' This modification will ensure that covered text providers' obligations encompass those text messages sent to the Lifeline via the 3-digit code 988. We also add language clarifying that the definition we adopt ''includes and is not limited to'' SMS and MMS messages. This addition clarifies that the word ''includes,'' within the definition we adopt, does not limit the scope of messages meeting the first prong of the definition and instead merely eliminates doubt as to whether SMS and MMS meet that definition. This clarification advances our policy goal of promoting availability of a broad range of communications methodologies for individuals reaching the Lifeline. Further, we think this clarification follows the canon of avoiding rendering language a nullity—if the definition included only SMS and MMS, the first provision would be unnecessary.

10. We decline to adopt the text-to-911 text message definition, as recommended by CTIA and T-Mobile. The Truth in Caller ID definition is more recent than the text-to-911 text message definition, and it derives from Congress. The Truth in Caller ID definition expressly identifies that it includes images and sound. Allowing the parties that operate the Lifeline to incorporate graphics or other rich media in addition to textual communications, if they choose to do so, offers members of at-risk communities the means to communicate flexibly and fully with the Lifeline. Furthermore, the limitation of the initial implementation requirement to SMS messages, as discussed below, addresses CTIA and T-Mobile's concerns about meeting the implementation deadline if the Commission were to immediately require implementation of other text formats. The annual review process we establish below, through which the Wireline Competition Bureau (Bureau) will require covered text providers to implement only those texting formats within the outer bound definition that the Lifeline can actually receive, will ensure that covered text providers are not burdened with unnecessary work, and will avoid any consumer confusion that would arise from implementing formats that cannot go through.

11. We clarify that the exclusions we adopt from the ''988 text message'' definition match those exclusions contained in the Truth in Caller ID ''text message'' definition. We therefore exclude ''real-time, two-way voice or video communication[s],'' as well as messages sent over ''IP-enabled messaging service[s] to another user of the same messaging service'' that are not SMS or MMS messages. Similar to the Commission's interpretation in the *Truth in Caller ID Second Report and Order* (84 FR 45669, August 30, 20219), we conclude that ''real-time, two-way voice or video communication'' includes voice calling service. We find that the plain language of the Truth in Caller ID exclusion indicates that Congress explicitly intended to exclude real-time, two-way video communication from the definition of ''text message. We further ''interpret the latter exclusion to include non-MMS or SMS messages sent using IP-enable

messaging services'' between users of the same service. For example, a message transmitted via an application delivered over IP-based networks, such as Twitter or LinkedIn, to another user of the same messaging service would be excluded from the outer bound definition.

12. We decline the Consumer Electronics Association's (CEA's) request to affirmatively determine at this time what particular text messaging formats fit within the outer bound definition. We direct the Bureau to resolve questions concerning the scope of the outer bound during the annual review process by applying the statutory Truth in Caller ID definition and Commission precedent regarding that definition. We clarify that should the Bureau find in the future based on the record before it that rich communications service (RCS), real-time text (RTT), or other formats do not fall within the exclusions from the 988 text message definition, then they may be acceptable formats within the outer bound scope. We anticipate that addressing scope issues as they arise, in the context of specific technologies, will lead to better decisions based on more detailed information than trying to decide well ahead of any specific issue arising.

13. *Limitation to Currently-Employed Technology.* As proposed in the FNPRM, we initially require that covered text providers only support transmission of SMS messages to 988. We adopt the proposed procedure delegating to the Bureau future determinations to require covered text providers to support additional text formats within the outer bound definition, in consultation with our Federal partners and in consideration of what text formats the Lifeline is capable of receiving. We therefore define ''covered 988 text message'' as a 988 text message in SMS format and any other format that the Wireline Competition Bureau has determined must be supported by covered text providers.

14. The record supports requiring transmission of texts to 988 in SMS format. Vibrant indicates that the Lifeline can currently receive and respond to SMS messages sent to the 10-digit number. Furthermore, representatives of covered text providers and public interest groups express support for requiring transmission of SMS messages to 988. In their support for adoption of requirements based on the Commission's text-to-911 rules, CTIA and T-Mobile note the technical feasibility of supporting SMS messages to 988, given that that format is currently supported in texting to 911. CEA also argues that the Commission should, at a minimum, require transmission of text messages in SMS within its broader outer bound definition. Because there is no technical or operational impediment to transmitting SMS messages to 988 expressed by covered text providers, and the Lifeline is currently able to receive and respond to SMS messages, we require covered text providers to support SMS messages to 988.

15. We decline at this time to require covered text providers to support other text message formats, such as MMS, RCS, and RTT, because the Lifeline cannot currently receive texts in these formats. The Bureau will consider requiring covered text providers to support these or other additional formats through the Public Notice process we discuss below, should the Lifeline indicate it can receive such formats. While commenters note that rich media communications and next-generation text formats may offer benefits to individuals attempting to access the Lifeline, requiring covered text providers to transmit messages in these formats is premature because we do not know if or when the Lifeline will accept these formats. In addition, as CTIA states, including additional text formats such as RTT and RCS in the scope of our text-to-988 requirements ''would cause consumer confusion when the Lifeline is only capable of *receiving* SMS messages today'' and, due to technical and engineering obstacles, would likely delay implementation of text-to-988 service. Finally, with respect to multimedia messages, both the Alliance for Telecommunications Industry Solutions (ATIS) and CTIA note that including media in text messages, a feature not currently supported in text-to-911 service, would present technical obstacles that could impede implementation by the July 16, 2022, deadline that we adopt. Although Vibrant indicates that the Lifeline is technically capable of receiving MMS formats, it clarifies that Lifeline policy and clinical standards ''currently block[ ] images and video from being seen by the counselor.'' Because of the impediments to transmitting media such as images and video with text to 988, we decline to require covered text providers to support MMS messages to 988.

16. Just as our Federal partners recently added a texting capability to the Lifeline, they may choose to expand the functionality of their texting service over time. It is important for the requirements we establish to keep pace flexibly and readily rather than resorting to a Commission-level proceeding every time the Lifeline can accept a new text format. We therefore direct the Bureau to routinely consult with our Federal partners at SAMHSA and the VA to determine when the Lifeline has implemented a new text message format to 988. We further direct the Bureau, on or before June 30, 2023, and no less frequently than annually thereafter, to propose and seek comment on implementation parameters for covered text providers to transmit any additional text message formats to 988 that the Lifeline is capable of receiving and that are within the scope of the outer bound message definition adopted herein. The Bureau shall identify the additional text messaging format(s) that the Lifeline is capable of receiving, if any; propose and seek comment on an interpretive determination as to whether the additional text message format(s) fall within the outer bound definition; and propose and seek comment on implementation deadline(s) for those additional text message formats. If the Bureau finds after this process that the Lifeline is capable of receiving an additional text format that is within the scope of the outer bound definition that we have established, it shall release a second Public Notice requiring covered text providers to implement text-to-988 using that new format and setting an implementation date that is as prompt as reasonably practical. If the Bureau instead finds that, notwithstanding its initial proposal, the Lifeline is not capable of receiving an additional text format that is within the scope of the outer bound that we have established, it shall issue a Public Notice declining to adopt its initial proposal. The Bureau may set one implementation deadline or staggered implementation deadlines for different classes of providers, and it shall identify all implementation deadlines with certainty (*i.e.,* by a specified calendar date). In setting a deadline or deadlines for compliance, the Bureau shall assess factors such as technical and financial challenges with respect to implementation, the status of the Lifeline, and the public interest. We find our two-step approach allows us to ensure rapid support for additional texting formats as technology evolves, while providing certainty to the industry and the public. Further, we find this approach facilitates further updates when the Lifeline implements a new texting format without requiring a Commission rulemaking, which often requires more time than Bureau-level action. Accordingly, we direct the Bureau to implement the approach we describe above, including through prescribing implementation deadlines.

17. CEA supports the Commission's proposal but asks for the Bureau to conduct annual public hearings rather than develop a written record. We find the proposed Public Notice procedure achieves the same purpose as a public hearing—providing a forum to establish a record regarding expansion of the covered 988 text message definition—while imposing fewer administrative burdens and costs on the public and the Commission. We expect the Bureau to meet with interested parties, as permitted by the Commission's *ex parte* rules.

18. We decline to adopt CEA's proposals to bypass our Public Notice procedure and automatically include MMS, RCS, or RTT within the scope of covered 988 text messages if and when the Lifeline is ready to accept those new texting formats. We think the Public Notice process is valuable because it will allow the Bureau to gather information to set appropriate technology-specific implementation deadlines and to evaluate whether a given technology fits within the outer scope of the definition of 988 text message we adopt herein. It also provides the Bureau time to facilitate dialogue between parties should any complications arise. We are concerned that automatic inclusion of certain formats in the future could lead to avoidable problems, and we therefore decline CEA's suggestion.

19. We also decline CEA's proposal that, should the Bureau or Commission require inclusion of RCS, RTT, or any other format, covered text providers would be required to support the new format ''by the later of (i) three months after the Lifeline states that it is ready to receive such format; or (ii) the date upon which the affected covered text provider begins providing such texting format to its customers generally.'' We find it best to grant the Bureau flexibility to determine an implementation timeframe appropriate to each technology the Lifeline may implement. We prefer this approach because the Bureau will be able to make a decision based on a thorough record focused on the Lifeline's actual implementation of the technology. We anticipate that some technologies such as RTT that are already generally in use may be easier for covered text providers, especially larger providers, to support if implemented by the Lifeline, and we encourage the Bureau to take ease of implementation and availability of the technology into account when reaching a determination.

20. We decline requests from CEA and ZP Better Together (ZP) to require direct video communication (DVC) and direct dialing from video relay service (VRS) to 988. With respect to VRS, ZP believes that by dialing 988 directly, both a Lifeline counselor and a VRS communications assistant would show up simultaneously. We are not addressing ZP's VRS request at this time because direct 988 dialing for VRS is beyond the scope of this item, which is focused on text-to-988. With respect to DVC, we strongly encourage the development and implementation of direct communications solutions for individuals with disabilities. However, the Lifeline does not receive direct communications via video. Requiring providers to support communications that the Lifeline is not currently capable of receiving would cause consumer confusion, as individuals in crisis may attempt to access the Lifeline via direct video communications without realizing that the Lifeline cannot answer. We are pleased that the Lifeline is available to users of telecommunications relay services, including via 988, and the Lifeline maintains a separate TTY number, and we encourage our Federal partners to continue to consider additional alternative means by which individuals with disabilities may contact the Lifeline. Users of speech-to-speech services and TTY-based TRS dial 711 first to connect to a communications assistant who will complete the call to the Lifeline.

2. Definition of ''Covered Text Provider''

21. We adopt our proposed definition of ''covered text providers'' as that term is defined in the Commission's text-to-911 rules, to include ''all CMRS providers, as well as providers of interconnected text messaging services that enable consumers to send text messages to and receive text messages from all or substantially all text-capable U.S. telephone numbers, including through the use of applications downloaded or otherwise installed on mobile phones.'' We find that the straightforward and well-established definition from the 911 context best delineates the scope of covered text providers obligated to support text-to-988 service.

22. The record supports our proposal to adopt the text-to-911 definition of ''covered text provider'' here. CTIA encourages us to keep the text-to-988 scope consistent with the scope of covered text providers in the text-to-911 context in order to ''identify a well-known and experienced scope of providers who will need to work collaboratively with the Lifeline to achieve the aggressive deadline that CTIA and others have suggested.'' T-Mobile similarly agrees with CTIA that the Commission should look to its text-to-911 rules when establishing the scope of covered text providers in the text-to-988 context. And, as CTIA notes, no commenter suggests an alternative definition to our proposal.

23. We require interconnected text messaging service providers, which enable customers to ''send text messages to all or substantially all text-capable U.S. telephone numbers and receive text messages from the same,'' to support text-to-988 service. We decline to apply our requirements to non-interconnected text providers, as CEA suggests. By definition, non-interconnected text providers cannot send text messages to and receive text messages from all or substantially all text-capable U.S. telephone numbers, meaning they are unlikely to be able to transmit texts to and receive texts from 988. Even non-interconnected text providers that use telephone numbers—for instance where an application uses telephone numbers to identify users relative to each other rather than for routing—may nonetheless be unable to send text messages to users of other services or to all or substantially all telephone numbers. Obligating non-interconnected text providers to attempt to route texts to 988 via telephone numbers when physical routing is beyond such providers' control could increase customer confusion or diminish public trust in texting as a means to reach the Lifeline.

24. Voice on the Net (VON) and Mitel request that we exempt covered text providers in Wi-Fi only locations because ''there remain challenges to the reliability of routing text messages to interconnected networks without the benefit of a CMRS provider.'' We decline at this time to adopt a blanket exemption for covered text providers in Wi-Fi only locations. While we anticipate interconnected text messaging service providers will typically use CMRS-based solutions to support text-to-988, CMRS networks are not the only means of interconnection, and covered text providers may use any reliable method or methods to support text routing and transmission to 988. Furthermore, neither VON nor Mitel elaborate on or provide evidence to support their claims of technical challenges associated with routing without access to a CMRS network, or that such challenges cannot be bypassed by adopting a non-CMRS solution. While we agree with Mitel that ''[r]outing messages to the interconnected network often requires access to an underlying wireless network or provider,'' commenters have not provided sufficient support for us to

conclude that covered text providers in Wi-Fi only locations are never able to use a CMRS-based or alternative method to reliably support text routing and transmission to 988. We reiterate that our requirements exclude providers that are unable to allow consumers to send text messages to and receive text messages from all or substantially all text-capable U.S. telephone numbers.

C. Routing Texts to 988

25. We adopt our proposal to require covered text providers to route covered 988 text messages to the Lifeline's current 10-digit number, 1–800–273–8255 (TALK). Our decision is consistent with the Commission's approach in the *988 Report and Order* (85 FR 57767, September 16, 2020) to require service providers to ''transmit all calls initiated by an end user dialing 988 to the current toll free access number for the Lifeline.'' Most commenters support centralized routing for text-to-988.

26. We find our centralized routing rule will allow for swift implementation of text-to-988 to the Lifeline's 10-digit number by lowering technical requirements and costs for covered text providers to route texts to the Lifeline. As Vibrant states, our centralized routing solution for text-to-988 will ''allow[] for a seamless delivery of crisis intervention services that is consistent with clinical standards, best practices, and national guidelines overseen by the administrator and SAMHSA.'' CTIA notes that by requiring centralized routing, ''the Commission can significantly lower technical hurdles to enable wireless providers to deploy text-to-988 as soon as possible.'' ATIS ''has not identified any technical challenges associated with'' routing covered 988 texts to the Lifeline 10-digit number. We note that several wireless providers were able to implement routing calls to 988 within six months of adoption, and we anticipate that similarly swift implementation may be possible here.

27. We also find that adopting our proposal will provide our Federal partners with the flexibility to develop and expand routing solutions to meet the Lifeline's needs. Once text messages are routed to the Lifeline's 10-digit number, the Lifeline can then ''forward those messages to the appropriate local crisis center,'' similar to the current mechanism for voice call routing to 988. Currently, the Lifeline's network consists of over 180 crisis centers, with 33 centers providing text service. SAMHSA has identified resource strain and capacity issues experienced during its rollout of text service to the Lifeline's 10-digit number and, as a result, indicates its intention to explore working with existing crisis text and chat services outside the Lifeline as well as expanding text capacity within the network. We encourage SAMHSA and the VA to work with outside entities as needed to meet increased demand, and we believe our centralized routing rule will better allow for the Lifeline's network to adapt, evolve, and expand as necessary to meet capacity and technological needs.

28. We decline to require covered text providers to route covered 988 text messages directly to a Lifeline local crisis center or Veterans Crisis Line crisis center. While text-to-911 uses such direct routing, we believe that approach would be counterproductive for text-to-988. We disagree with Intrado's proposal to leverage the existing text-to-911 infrastructure by using Intrado's Text Control Center (TCC) services to transmit texts to 988 directly to an individual local crisis center, once the crisis center has made a valid request for text-to-988 service. This proposal mirrors the text-to-911 rules, where a covered text provider must enable text-to-911 service within six months of a local Public Safety Answering Point's (PSAP's) valid request for service. We are concerned that implementation of a localized routing model would be time-consuming, contrary to our goal of making text-to-988 rapidly available to all Americans. CTIA and T-Mobile point to specific technical and administrative challenges should the Commission require covered text providers to route texts to 988 to local crisis centers, which would compromise swift implementation by the July 16, 2022, date. ATIS, T-Mobile, and VON also note routing to the local crisis centers would require the adoption of new technical standards and specifications, including the development of intermediate gateway providers at regional centers, which could increase costs and delay launch of text-to-988. Requiring delivery of texts to 988 to individual crisis centers could impede the Lifeline network's future expansion, as covered text providers would need to implement text routing to each new center to ensure that the community served by that center can communicate via text if desired, as opposed to immediate nationwide access through centralized routing. Furthermore, as CTIA points out, ''Intrado fails to explain why texts to 9–8–8 should be routed differently from voice calls to 9–8–8.'' We see no difference between voice and text service to the Lifeline presented in the record that would justify adopting alternate routing infrastructures for either service. In contrast, there are significant differences between 988 and 911, chief among them the nationwide Lifeline voice and text service routed through a centralized, toll free 10-digit number as opposed to the localized PSAP network.

29. We find that it is premature to require covered text providers to enable covered 988 text messages to include location information. As instructed by Congress in the National Suicide Hotline Designation Act of 2020, in April 2021 the Bureau released a report on the costs and feasibility of providing location information with calls to 988. In the report, the Bureau recommended the establishment of a multi-stakeholder advisory committee to develop detailed recommendations on how to address several challenges presented in the record, including privacy considerations, technical implementation, and cost recovery. NAMI and Vibrant reiterate arguments raised in the *988 Geolocation Report* that requiring geolocation information with calls and texts to local crisis centers will improve accuracy in connecting individuals in crisis with counselors who are in the best position to provide localized care. Yet, as the Bureau identified in the *988 Geolocation Report,* requiring providers to transmit location information to 988 ''raises important privacy and legal issues, is technically complex, and could impose significant costs.'' Several commenters, including ATIS and CTIA, highlight the challenges identified in the *988 Geolocation Report* and oppose a location information requirement for text-to-988, indicating it would be premature for the Commission to adopt such a mandate without further study and standards development. Given the similar complexity and interrelation between call and text routing to 988, we decline, at this time, NAMI and Vibrant's requests to require location information with texts transmitted to 988. Commenters also raise privacy concerns should the Commission require the transmission of location information without the texter's consent. Given the Bureau's recommendation and the similar concerns raised in the record regarding technical limitations of providing location information, we decline, at the present time, to require covered text providers to include location information with texts to 988.

30. We also decline to require covered text providers to take action to route texts to 988 to the Veterans Crisis Line, and we instead defer to our Federal partners to determine whether and how to make it possible to text 988 for the

Veterans Crisis Line's text service. Telephone callers to the Lifeline's 10-digit number can press ''1'' to connect directly with a crisis counselor at the Veterans Crisis Line. Texting, on the other hand, is not presently integrated—texters who wish to reach the Veterans Crisis Line contact a text short code (838255) rather than the Lifeline's toll free 10-digit number. We recognize that there would be significant benefits to enabling texters to reach the Veterans Crisis Line by texting 988. At the same time, we recognize the critical need for carefully developing a pilot program and extensively testing the transfer of texts between 988 and the Veterans Crisis Line to ensure that no Service Member, Veteran, or family member is left without access to lifesaving resources. Any rush to enable texting 988 for the Veterans Crisis Line's text service before sufficient implementation work and testing would raise safety concerns, should any text conversations be dropped or lost in transfer. We believe our Federal partners at the VA and SAMHSA are best positioned to evaluate the benefits, challenges, and costs of transferring texts and to pursue a solution, if desirable. We agree with ATIS that use of 988 ''makes it infeasible to automatically route calls to one service or the other'' without additional information, such as through a secondary input exchange, to enable providers to correctly route the text to the proper recipient. There is no record support for Commission action to require providers to selectively route texts to 988 to the Veterans Crisis Lifeline's text service. Nor does the record reveal any solutions for requiring providers to implement texting to 988 for the Veterans Crisis Line's text service that we could effectuate in conjunction with requiring providers to implement texting to 988 for the Lifeline. After evaluation and testing, our Federal partners may be able to pursue a workable, reliable approach to enabling texts to 988 to reach the Veterans Crisis Line. At the present time, Service Members, Veterans, and their families may reach the Veterans Crisis Line by calling 1–800–273–8255 and pressing 1, by texting 838255, or by chat through the Veterans Crisis Line's website, *https://www.veteranscrisisline.net.* We recognize that during the rollout and launch of 988, our Federal partners at the VA will face challenges in promoting widespread public awareness that the Veterans Crisis Line is reachable by text through a short code that is separate from 988. We direct Commission staff to work cooperatively with our Federal partners to promote awareness of how Service Members, Veterans, and their families can reach the Veterans Crisis Line.

D. Implementation Timeframe

31. We adopt our proposal to set a uniform nationwide implementation deadline for text-to-988 of July 16, 2022—concurrent with 988's voice implementation deadline—for all covered text providers to support transmission of all covered 988 text messages. As stated above, this deadline applies only to texts the user sends to 988. It does not apply to texts to the Veterans Crisis Line using its existing short code. Guiding our decision is the need to minimize the time needed to implement text-to-988 so as to help address the growing epidemic of suicide as quickly as possible. By setting a uniform deadline, rollout of text-to-988 will be most effective, enabling stakeholders to clearly and consistently communicate when the public can access texting services universally, while avoiding any confusion stemming from a different deadline than voice implementation. Although a phased-in approach may enable us to set a shorter deadline for some providers, this approach risks confusion not just among those ''unaware of the details of staggered regulatory deadlines,'' but also among those who may seek to call rather than text. Such a scenario ''could be disastrous for individuals and, in the aggregate, could erode trust in the Lifeline.'' Further, we find that a July 16, 2022, deadline provides the Lifeline adequate time to prepare for additional texting volume, with Vibrant expressing confidence following its successful 2021 pilot program that ''the Lifeline has the capability to receive text-to-988 messages on the first day of 988 operation.'' And as ATIS highlights, because we only require that covered text providers send text messages to the Lifeline's 10-digit number, the need for a phased approach is eliminated.

32. We specifically set a deadline of July 16, 2022, which nearly all commenters who address timing support. Just as we concluded previously with respect to 988 implementation for voice calls, we set as early of a deadline as possible because of the numerous benefits of swift implementation in preventing suicide. As explained above, providers need not route calls to individual call centers, eliminating the need for lengthy development of new technical standards and specifications. Some providers themselves also support a July 16, 2022, deadline as providing sufficient time for implementation. Setting a deadline for text-to-988 that matches the existing deadline for implementing calls to 988 also avoids public confusion and enhances the efficacy of marketing campaigns promoting 988. As the Mental Health Associations state, ''[d]elaying an implementation deadline [beyond July 2022] will not prevent people in crisis from reaching out to 988 through text,'' and such individuals will find their ''[r]equest for help will go unanswered'' without action in this proceeding.

33. We reject VON's arguments that we should set a deadline of 12 months following the effective date of the order due to ''[t]he need to develop and implement new routing and technical standards'' that may pose challenges to meeting the voice deadline of July 16, 2022. Specifically, VON compares the Lifeline's call centers to PSAPs, explaining how in the context of text-to-911, a new joint standard needed to be created in order to direct texts to the latter. However, as explained above, we do not require that providers route texts to individual call centers, but instead to the Lifeline's toll free 10-digit number. Additionally, VON cites these potential challenges only in vague terms, and claims only that they ''might'' serve as obstacles to ''meeting the *voice* deadline of July 16, 2022.'' Moreover, as explained below, the flexible text-to-988 rules we adopt in this document do not generate significant technical obstacles, and the record's support for a July 16, 2022, deadline suggests that the issues pertinent to a texting solution specifically can be overcome in the given timeframe. For example, ATIS supports a July 16, 2022, deadline as ''reasonable'' given that ''it is already possible to text the existing Lifeline toll-free number,'' highlighting that ''texting to the new three-digit short code (988) would create no new technical challenges.''

E. Technical Considerations

34. We adopt our proposal to allow covered text providers to use any reliable method or methods to support text routing and transmission to 988. We reiterate that covered text providers may use any reliable method or methods to support text routing and transmission to 988, and emphasize our neutrality on the technologies that covered text providers use to support text messaging to 988. We find that this approach accounts for currently-available text messaging formats and technologies and also provides the flexibility to adapt to future availability. No commenter opposed our proposal. As ATIS explains, texting to 988 ''can and should be implemented in a timely manner[,]''

and should ''create no technical challenges.''

35. *Network Upgrades.* Based on the record, we do not expect that covered text providers will need to install significant network upgrades to implement the texting to 988 requirements adopted herein. Though covered text providers must determine how to support texting to 988 as adopted, the rules we adopt in this document provide the flexibility to choose the most effective method for doing so. For example, covered text providers may choose to route text messages to 988 over their mobile-switched networks or use an IP-based method to deliver text messages to the Lifeline. We are encouraged that many providers have implemented voice calling to 988 a year or more before the implementation deadline, and we envision that covered text providers can also easily implement texting to 988.

36. *Equipment Upgrades.* We find, based on the record, that no significant software or equipment upgrades will be necessary to implement texting to 988. We agree with ATIS, one of the organizations that set the standards for texting to 911, that ''[a] focus on functionality rather than technical standards is required to meet the needs of those who communicate primarily via texting.'' We are not persuaded by VON's argument that, like implementing text-to-911, industry needs to develop new routing and technical standards that may delay text-to-988's implementation. VON generically states that 911 networks and the Lifeline are ''two distinct infrastructures'' that will require new standards, but does not explain why these infrastructural differences merit developing new standards. We find more convincing ATIS's assertion that changes to industry standards will ''be minimal if, as expected, no changes are required to consumer devices to support text-to-988 requirements'' because the bulk of the record indicates that texting to 988's centralized routing solution, limited scope of text messaging service technologies, and other adopted requirements are straightforward to implement by our adoption deadline.

37. We exempt legacy devices that are incapable of sending text messages via 3-digit codes from the text-to-988 requirements, provided the software for these devices cannot be upgraded over the air to allow text-to-988. In the *Text-to-911* proceeding, the Commission did not require certain legacy devices to comply with the text-to-911 requirements because ''the messaging application or interface on the mobile device will likely provide an error message indicating an invalid destination number, reducing user confusion somewhat'' that the legacy device could not support texting to 911. No commenter discussed legacy devices nor indicated that circumstances have changed since the Commission adopted this exemption in the *Text-to-911* proceeding. Accordingly, we find that the same exemption is appropriate here.

38. *Network Access.* We require CMRS providers to allow access to their SMS networks by any other covered text provider for the capabilities necessary to transmit 988 text messages originating on such other covered text providers' networks, similar to the text-to-911 rules. We find this rule is necessary to implement our text to 988 requirement as we anticipate that many interconnected text providers will choose CMRS network-based solutions to implement texting to 988. No commenter opposed providing this network access. Mitel explains that, like in the texting to 911 context, routing messages to interconnected networks often requires access to an underlying wireless network and provider. Similar to the text-to-911 rules, we adopt this requirement to ''respond to consumers' reasonable expectations and reduce consumer confusion'' regarding text-to-988's availability.

39. Similar to the Commission's position in the *Text-to-911 Second Report and Order* (79 FR 55367, September 14, 2014), we conclude that it is the responsibility of the covered text provider using the CMRS-based solution to ensure that its text messaging service is technically compatible with the CMRS providers' SMS-based network and devices and in conformance with any applicable technical standards. As in the text-to-911 context, we further require CMRS providers to make any necessary specifications for accessing their SMS networks available to other covered text providers upon request, and to inform such covered text providers in advance of any changes to these specifications. We clarify, however, that we do not intend to use these requirements to establish an open-ended obligation for CMRS providers to maintain underlying SMS network support merely for the use of other providers, nor do we require CMRS providers to reconfigure any SMS text-to-988 platforms in order to facilitate the ability of other covered text providers to access the CMRS providers' networks. Further, as with the text-to-911 rules, CMRS providers' obligation to allow access to CMRS networks ''is limited to the extent that the CMRS providers offers SMS.'' While we expect that adopting these rules will similarly encourage ''interconnected text providers to actively develop solutions to support [text-to-988] without reliance on CMRS providers' underlying networks,'' we nonetheless encourage providers to enact solutions to carry other covered text providers' text messages to 988 over their networks.

F. Other Issues

40. *Cost Recovery.* We adopt our proposal to require all covered text providers to bear their own costs to implement text-to-988. We find that this approach promotes efficiency in implementation and avoids unnecessary administrative costs. In the *988 Report and Order,* we observed that ''[u]nlike previous numbering proceedings in which the Commission established a cost recovery mechanism,'' implementation of 988 itself does not involve ''shared industry costs such as central or regional numbering databases or third-party administrators.'' Similarly, we conclude that implementation of a text-to-988 solution requires no shared industry costs, with costs being provider-specific and solutions unique to each. As such, as proposed in the FNPRM we find that the requirements in section 251(e)(2) of the Act that ''[t]he cost of establishing telecommunications numbering administration arrangements and number portability shall be borne by all telecommunications carriers on a competitively neutral basis'' does not apply.

41. *Bounce-back Messages.* We decline to require covered text providers to send an automatic bounce-back message specifically designed to address where text-to-988 service is unavailable for several reasons. First, the record indicates that failed messages are likely to be rare. CTIA explains that network failures are ''rare due to redundancies in the SMS network'' and Vibrant indicates that to date the Lifeline's text messaging service has not experienced any downtime. Second, in the rare instance that covered text providers fail to deliver a text message to the Lifeline, current notice practices are sufficient. Individuals texting the Lifeline currently receive a bounce-back message under a variety of circumstances. CTIA explains that covered text providers usually send customers a notification from a device or network when a CMRS provider cannot deliver a text message due to a network failure. Vibrant also indicates that the Lifeline currently sends individuals scheduled text messages approximately every 10 minutes if there is a wait to reach a crisis counselor that informs them they are in the queue, offers access to other

resources while they wait, and provides the option to call the Lifeline. Consequently, we further agree with commenters that to the extent operational concerns, network congestion, or outsized demand prevent texters from reaching a crisis counselor, the parties that operate the Lifeline are in the best position to send a message to texters because covered text providers do not have visibility into the Lifeline's operations. Third, we decline to require 988-specific bounce-back messages because such a mandate risks delay of text-to-988 implementation. We recognize comments from CTIA which state that developing a bounce-back messaging capability ''would require substantial additional time and complexity, as well as the development of standards and requirements for implementation, and would significantly delay the July 16, 2022 implementation target.'' T-Mobile further asserts that when a CMRS provider has not delivered a text message to the Lifeline due to network congestion, sending a Lifeline-specific automatic bounce-back message could be technically infeasible because ''[c]arriers cannot determine if a text sent to the 10-digit Lifeline number has not been delivered due to network congestion or other factors related to nature of SMS generally.''

42. Finally, a key circumstance that prompted the Commission to require automatic bounce-back messaging for text-to-911 are not present for text-to-988. In the *Text-to-911* proceeding, the Commission adopted an automatic bounce-back messaging requirement because texting was and is only available to some PSAPs, and Americans in many parts of the country could not text 911 at all. In contrast, our centralized routing approach ensures that texting to 988 will be uniformly available nationwide. The unique geographic gaps that the bounce-back requirement addresses in the 911 context are not present here. It is possible that, as in the text-to-911 context, requiring a bounce-back message for text-to-988 could help ''persons in emergency situations being able to know immediately if a text message has been delivered to the proper authorities'' in the limited situations when consumers cannot send text messages to the Lifeline. However, given the urgency of improving access to lifesaving suicide prevention resources, and in light of existing protections against and in the event of a delivery failure, we decline to a bounce-back messaging requirement for text-to-988 at this time. We will monitor the operation of texting to 988 post-implementation and will not hesitate to revisit the issue of requiring a bounce-back if warranted.

43. *Federal Coordination.* We direct the Bureau to continue to coordinate implementation of 988 with SAMHSA, including any issues pertaining to the delivery of text messages to 988. We direct the Bureau and Commission staff to support the VA in promoting awareness of texting options for Service Members, Veterans, and their families, and to support the VA and SAMHSA in piloting, testing, and implementing any solution our Federal partners may choose to pursue to allow texting to 988 for the Veterans Crisis Line's text service. We also encourage SAMHSA to continue to work to expand the Lifeline's texting infrastructure. We will continue to work with and support our Federal partners in their efforts to assist Americans in crisis.

44. *Future Technical Corrections to Lifeline 10-Digit Number.* In our rules, we identify the current 10-digit telephone number of the Lifeline, 1–800–273–8255 (TALK). We direct the Bureau, after notice and comment, to update this reference to the correct number if the Lifeline ever changes telephone numbers. This direction applies to the text-to-988 rules we adopt in this document and to our previously-adopted 988 telephone rules.

G. Legal Authority

45. We conclude that Title III of the Act and the Twenty-First Century Communications and Video Accessibility Act (CVAA) provide us with authority for the rules we adopt in this document. No commenter opposes these conclusions. With respect to CMRS providers, we find that Title III provides us the authority to require wireless carriers to enable and support text-to-988 service. Consistent with the U.S. Supreme Court's recognition that Title III provides the Commission a ''broad mandate'' to manage spectrum usage in the public interest, we find that significant public interest benefits will likely inure from broadly enabling access to lifesaving services through texting. Further, the rules adopted here are analogous to those the Commission adopted to facilitate text-to-911, which relied in part on the Commission's Title III authority. Therefore, with respect to CMRS providers, we conclude that Title III provides sufficient authority for the rules we adopt in this document.

46. As to interconnected text messaging service providers, the CVAA granted us authority to adopt ''other regulations . . . as are necessary to achieve reliable, interoperable communication that ensures access by individuals with disabilities to an internet protocol-enabled emergency network.'' We conclude that the Lifeline constitutes an ''emergency network'' within the meaning of the CVAA. The CVAA does not define what an ''emergency network'' is, nor does it elaborate on what qualifies as ''emergency services.'' However, Congress, through the National Suicide Hotline Designation Act, deemed ''life-saving resources'' such as the Lifeline and the Veterans Crisis Line ''essential'' and recognized the need for an ''easy-to-remember, 3-digit phone number''—that is, one readily available in an emergency situation. As CTIA argues, it is therefore reasonable to conclude that such services should be considered ''emergency services'' and that the Lifeline and Veterans Crisis Line act as an ''emergency network'' within the meaning of the CVAA. Moreover, texting capabilities provide ''easy access to emergency services for people with disabilities,'' including those with hearing and speech disabilities. Such individuals may not be able to take advantage of 988's voice service, necessitating that an alternative means of communicating be provided. We therefore conclude that the CVAA provides authority for the rules we adopt in this document, and the record reflects agreement with our analysis. Because we find that Title III and the CVAA provide sufficient authority for the rules we adopt in this document, we find it unnecessary to address other possible sources of authority to adopt these rules.

H. Benefits and Costs of Text-to-988

47. Consistent with our proposal in the FNPRM, we find that benefits of requiring service providers to support text-to-988 far exceed the costs of implementation. The loss of victims' lives to suicide cannot be adequately captured by any pecuniary measure; the principal benefit of text-to-988 is that it will reduce suicide risk by providing an additional means of reaching help for the most vulnerable. Text-to-988 will reduce the risk of suicide mortality, primarily among those who would either send a text to 988 or forgo a lifesaving intervention altogether. Three vulnerable communities, in particular, face this stark choice: Youth, who rely heavily on text messages for their general communications needs; the deaf, deafblind, hard of hearing, and speech disabled; and those who are reluctant to dial 988 because they feel unsafe, ashamed or embarrassed, including many LGBTQ+ youth and victims of domestic abuse. As outlined

above, the ability to text to the short and easy-to-remember 988 code will make the lifesaving interventions of the Lifeline crisis centers even more accessible than dialing alone. As no commenter in the record disputes, we find that the benefits of implementing text-to-988 will quickly exceed costs, and dwarf them over time.

48. In the FNPRM, we estimated the cost of implementing text to 988 would be nearly $27 million over five years. We based our estimate on Intrado's existing estimates of the costs of upgrading 911 call centers to receive text messages. Although one commenter asserts that the costs of implementation are likely to be ''substantially lower'' than our estimate, no commenters provided any individual estimates or disputed our underlying approach or our estimate of the combined total cost of nearly $27 million with an alternate figure. We agree that implementation costs may be lower than we projected. However, since no commenter provided an estimate of the impact of these potential reductions, we find it prudent to rely on our original estimate.

49. Commenters suggest quantifiable benefits that would greatly exceed these costs. For example, the Mental Health Associations emphasize that improved access to ''mental health response to mental health crises'' will result in cost savings for communities and individuals. These ''[e]mergency department visits for mental health and substance use disorders cost an average of $520 across 10.7 million visits in 2017, for a total cost nationwide of nearly $5.6 billion.'' Any reduction in these visits and resulting cost savings are benefits of implementing text-to-988. In addition, the Center for Law and Social Policy (CLASP) points to an evaluation of Nevada's TextToday pilot program, one of the country's first crisis response lines that accepted text messages. The evaluation found an increase in help-seeking by youth and a preference for texting. Groups that would be especially likely to benefit from text-to-988 are members of the LGBTQ+ community, and deaf, deafblind, hard of hearing, and speech-disabled adults. Between 2015 and 2019, we estimate there were more than 39,000 suicides among youth 10–19, LGBTQ+ adults, and deaf, deafblind, hard of hearing, and speech-disabled adults. If text-to-988 reduces the annual risk of suicide mortality among these groups and others by even a very small amount, the benefits would easily outweigh the costs of implementing text-to-988.

II. Final Regulatory Flexibility Analysis

1. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated into the FNPRM, released April 2021. The Commission sought written public comments on the proposals in the FNPRM, including comment on the IRFA. No comments were filed addressing the IRFA. Because the Commission amends its rules in the Second Report and Order, the Commission has included this Final Regulatory Flexibility Analysis (FRFA). This present FRFA conforms to the RFA.

A. Need for, and Objectives of, the Rules

2. In the Second Report and Order, the Commission adopts rules requiring CMRS providers and providers of interconnected text messaging services that enable consumers to send text messages to, and receive text messages from, all or substantially all text-capable U.S. telephone numbers, including through the use of applications downloaded or otherwise installed on mobile phones (covered text providers) to enable delivery of text messages to 988. The Commission further requires that covered text providers route 988 text messages to the National Suicide Prevention Lifeline's (Lifeline) 10-digit number, currently 1–800–273–8255 (TALK). The Commission believes these rules will expand the availability of mental health and crisis counseling resources to Americans who suffer from depressive or suicidal thoughts, by allowing individuals in crisis to reach the Lifeline by texting 988.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

3. There were no comments filed that specifically addressed the proposed rules and policies presented in the IRFA.

C. Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

4. Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed rules as a result of those comments.

5. The Chief Counsel did not file any comments in response to the proposed rules in this proceeding.

D. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

6. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the final rules adopted pursuant to the Second Report and Order. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. A ''small-business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

7. *Small Businesses, Small Organizations, Small Governmental Jurisdictions.* Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the SBA's Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 30.7 million businesses.

8. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' The Internal Revenue Service (IRS) uses a revenue benchmark of $50,000 or less to delineate its annual electronic filing requirements for small exempt organizations. Nationwide, for tax year 2018, there were approximately 571,709 small exempt organizations in the U.S. reporting revenues of $50,000 or less according to the registration and tax data for exempt organizations available from the IRS.

9. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2017 Census of Governments indicate that there were 90,075 local governmental jurisdictions consisting of general purpose

governments and special purpose governments in the United States. Of this number there were 36,931 general purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,040 special purpose governments—independent school districts with enrollment populations of less than 5ll governmental jurisdictions.

10. *Wired Telecommunications Carriers.* The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including [voice over internet protocol] VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. U.S. Census Bureau data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this size standard, the majority of firms in this industry can be considered small.

11. *Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. The closest applicable North American Industry Classification System (NAICS) Code category is Wired Telecommunications Carriers. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 show that there were 3,117 firms that operated for the entire year. Of that total, 3,083 operated with fewer than 1,000 employees. Thus under this category and the associated size standard, the Commission estimates that the majority of local exchange carriers are small entities.

12. *Incumbent Local Exchange Carriers (Incumbent LECs).* Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent local exchange services. The closest applicable NAICS Code category is Wired Telecommunications Carriers. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 indicate that 3,117 firms operated the entire year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by our actions. According to Commission data, one thousand three hundred and seven (1,307) Incumbent Local Exchange Carriers reported that they were incumbent local exchange service providers. Of this total, an estimated 1,006 have 1,500 or fewer employees. Thus, using the SBA's size standard the majority of incumbent LECs can be considered small entities.

13. *Competitive Local Exchange Carriers (Competitive LECs). Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate NAICS Code category is Wired Telecommunications Carriers and under that size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 indicate that 3,117 firms operated during that year. Of that number, 3,083 operated with fewer than 1,000 employees. Based on these data, the Commission concludes that the majority of Competitive LECS, CAPs, Shared-Tenant Service Providers, and Other Local Service Providers, are small entities. According to Commission data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,442 carriers, an estimated 1,256 have 1,500 or fewer employees. In addition, 17 carriers have reported that they are Shared-Tenant Service Providers, and all 17 are estimated to have 1,500 or fewer employees. Also, 72 carriers have reported that they are Other Local Service Providers. Of this total, 70 have 1,500 or fewer employees. Consequently, based on internally researched FCC data, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and Other Local Service Providers are small entities.

14. *Interexchange Carriers (IXCs).* Neither the Commission nor the SBA has developed a small business size standard specifically for Interexchange Carriers. The closest applicable NAICS Code category is Wired Telecommunications Carriers. The applicable size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 indicate that 3,117 firms operated for the entire year. Of that number, 3,083 operated with fewer than 1,000 employees. According to internally developed Commission data, 359 companies reported that their primary telecommunications service activity was the provision of interexchange services. Of this total, an estimated 317 have 1,500 or fewer employees. Consequently, the Commission estimates that the majority of interexchange service providers are small entities.

15. *Local Resellers.* The SBA has not developed a small business size standard specifically for Local Resellers. The SBA category of Telecommunications Resellers is the closest NAICS code category for local resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. Under the SBA's size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data from 2012 show that 1,341 firms provided resale services during that year. Of that number, all operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these resellers can be considered small entities. According to Commission data, 213 carriers have reported that they are engaged in the provision of local resale services. Of these, an estimated 211 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of local resellers are small entities.

16. *Toll Resellers.* The Commission has not developed a definition for Toll Resellers. The closest NAICS Code Category is Telecommunications

Resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. MVNOs are included in this industry. The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. 2012 U.S. Census Bureau data show that 1,341 firms provided resale services during that year. Of that number, 1,341 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these resellers can be considered small entities. According to Commission data, 881 carriers have reported that they are engaged in the provision of toll resale services. Of this total, an estimated 857 have 1,500 or fewer employees. Consequently, the Commission estimates that the majority of toll resellers are small entities.

17. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a definition for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. The applicable SBA size standard consists of all such companies having 1,500 or fewer employees. U.S. Census Bureau data for 2012 indicates that 3,117 firms operated during that year. Of that number, 3,083 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of Other Toll Carriers can be considered small. According to internally developed Commission data, 284 companies reported that their primary telecommunications service activity was the provision of other toll carriage. Of these, an estimated 279 have 1,500 or fewer employees. Consequently, the Commission estimates that most Other Toll Carriers are small entities.

18. *Prepaid Calling Card Providers.* Neither the Commission nor the SBA has developed a small business definition specifically for prepaid calling card providers. The most appropriate NAICS code-based category for defining prepaid calling card providers is Telecommunications Resellers. This industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. MVNOs are included in this industry. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 show that 1,341 firms provided resale services during that year. Of that number, 1,341 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these prepaid calling card providers can be considered small entities. According to the Commission's Form 499 Filer Database, 86 active companies reported that they were engaged in the provision of prepaid calling cards. The Commission does not have data regarding how many of these companies have 1,500 or fewer employees, however, the Commission estimates that the majority of the 86 active prepaid calling card providers that may be affected by these rules are likely small entities.

19. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The appropriate size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census Bureau data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms employed fewer than 1,000 employees and 12 firms employed of 1000 employees or more. Thus under this category and the associated size standard, the Commission estimates that the majority of Wireless Telecommunications Carriers (except Satellite) are small entities.

20. The Commission's own data—available in its Universal Licensing System—indicate that, as of August 31, 2018, there are 265 Cellular licensees that will be affected by our actions. The Commission does not know how many of these licensees are small, as the Commission does not collect that information for these types of entities. Similarly, according to internally developed Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service (PCS), and Specialized Mobile Radio (SMR) Telephony services. Of this total, an estimated 261 have 1,500 or fewer employees, and 152 have more than 1,500 employees. Thus, using available data, we estimate that the majority of wireless firms can be considered small.

21. *Cable and Other Subscription Programming.* The U.S. Census Bureau defines this industry as establishments primarily engaged in operating studios and facilities for the broadcasting of programs on a subscription or fee basis. The broadcast programming is typically narrowcast in nature (*e.g.,* limited format, such as news, sports, education, or youth-oriented). These establishments produce programming in their own facilities or acquire programming from external sources. The programming material is usually delivered to a third party, such as cable systems or direct-to-home satellite systems, for transmission to viewers. The SBA size standard for this industry establishes as small any company in this category with annual receipts less than $41.5 million. Based on U.S. Census Bureau data for 2012, 367 firms operated for the entire year. Of that number, 319 firms operated with annual receipts of less than $25 million a year and 48 firms operated with annual receipts of $25 million or more. Based on this data, the Commission estimates that a majority of firms in this industry are small.

22. *Cable Companies and Systems (Rate Regulation).* The Commission has also developed its own small business size standards, for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers nationwide. Industry data indicate that there are 4,600 active cable systems in the United States. Of this total, all but five cable operators nationwide are small under the 400,000-subscriber size standard. In addition, under the Commission's rate regulation rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Commission records show 4,600 cable systems nationwide. Of this total, 3,900 cable systems have fewer than 15,000 subscribers, and 700 systems have

15,000 or more subscribers, based on the same records. Thus, under this standard as well, we estimate that most cable systems are small entities.

23. *Cable System Operators (Telecom Act Standard).* The Communications Act of 1934, as amended, also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than one percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' As of 2019, there were approximately 48,646,056 basic cable video subscribers in the United States. Accordingly, an operator serving fewer than 486,460 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, we find that all but five cable operators are small entities under this size standard. We note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million. Therefore, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

24. *All Other Telecommunications.* The ''All Other Telecommunications'' category is comprised of establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing internet services or VoIP services via client-supplied telecommunications connections are also included in this industry. The SBA has developed a small business size standard for ''All Other Telecommunications'', which consists of all such firms with annual receipts of $35 million or less. For this category, U.S. Census Bureau data for 2012 show that there were 1,442 firms that operated for the entire year. Of those firms, a total of 1,400 had annual receipts less than $25 million and 15 firms had annual receipts of $25 million to $49,999,999. Thus, the Commission estimates that the majority of ''All Other Telecommunications'' firms potentially affected by our action can be considered small.

25. *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.* This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, Global Positioning System (GPS) equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment. The SBA has established a small business size standard for this industry of 1,250 employees or less. U.S. Census Bureau data for 2012 show that 841 establishments operated in this industry in that year. Of that number, 828 establishments operated with fewer than 1,000 employees, 7 establishments operated with between 1,000 and 2,499 employees and 6 establishments operated with 2,500 or more employees. Based on this data, we conclude that a majority of manufacturers in this industry are small.

26. *Semiconductor and Related Device Manufacturing.* This industry comprises establishments primarily engaged in manufacturing semiconductors and related solid state devices. Examples of products made by these establishments are integrated circuits, memory chips, microprocessors, diodes, transistors, solar cells and other optoelectronic devices. The SBA has developed a small business size standard for Semiconductor and Related Device Manufacturing, which consists of all such companies having 1,250 or fewer employees. U.S. Census Bureau data for 2012 show that there were 862 establishments that operated that year. Of this total, 843 operated with fewer than 1,000 employees. Thus, under this size standard, the majority of firms in this industry can be considered small.

27. *Software Publishers.* This industry comprises establishments primarily engaged in computer software publishing or publishing and reproduction. Establishments in this industry carry out operations necessary for producing and distributing computer software, such as designing, providing documentation, assisting in installation, and providing support services to software purchasers. These establishments may design, develop, and publish, or publish only. The SBA has established a size standard for this industry of annual receipts of $41.5 million or less per year. U.S. Census data for 2012 indicates that 5,079 firms operated for the entire year. Of that number 4,691 firms had annual receipts of less than $25 million and 166 firms had annual receipts of $25,000,000 to $49,999,999. Based on this data, we conclude that a majority of firms in this industry are small.

28. *Internet Service Providers (Broadband).* Broadband internet service providers include wired (*e.g.,* cable, digital subscriber line (DSL)) and VoIP service providers using their own operated wired telecommunications infrastructure fall in the category of Wired Telecommunication Carriers. Wired Telecommunications Carriers are comprised of establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies. The SBA size standard for this category classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, under this size standard the majority of firms in this industry can be considered small.

29. *Internet Service Providers (Non-Broadband).* internet access service providers such as dial-up internet service providers (ISPs), VoIP service providers using client-supplied telecommunications connections and internet service providers using client-supplied telecommunications connections (*e.g.,* dial-up ISPs) fall in the category of All Other Telecommunications. The SBA has developed a small business size standard for All Other Telecommunications which consists of all such firms with gross annual receipts of $35 million or less. For this category, U.S. Census Bureau data for 2012 show that there were 1,442 firms that operated for the entire year. Of these firms, a total of 1,400 had gross annual receipts of less than $25 million. Consequently, under this size standard a majority of firms in this industry can be considered small.

30. *All Other Information Services.* The U.S. Census Bureau has determined that this category ''comprises establishments primarily engaged in providing other information services (except news syndicates, libraries, archives, internet publishing and

broadcasting, and Web search portals).'' The SBA has developed a small business size standard for this category, which consists of all such firms with annual receipts of $30 million or less. U.S. Census Bureau data for 2012 show that there were 512 firms that operated for the entire year. Of those firms, a total of 498 had annual receipts less than $25 million and 7 firms had annual receipts of $25 million to $49,999,999. Consequently, we estimate that the majority of these firms are small entities that may be affected by our action.

E. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

31. The Second Report and Order modifies the Commission's rules to require covered text providers to support text messaging to 988. It concludes that text-to-988 functionality will greatly improve consumer access to the Lifeline, particularly for at-risk populations and thereby save lives. The final rules adopted in the Second Report and Order require CMRS providers and interconnected text messaging service providers to route texts sent to 988 to the 10-digit Lifeline number, presently 1–800–273–8255 (TALK). The Second Report and Order (1) establishes a definition that sets the outer bound of text messages sent to 988 that covered text providers may be required to support; (2) directs the Wireline Competition Bureau (Bureau) to identify text formats within the scope of that definition that the Lifeline can receive and thus covered text providers must support by routing to the 10-digit Lifeline number; and (3) requires CMRS providers that offer SMS to allow access by any other covered text provider to the capabilities necessary for transmission of 988 text messages originating on such other covered text providers' application services.

F. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

32. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

33. In the Second Report and Order, the Commission adopts a uniform implementation deadline for all covered text providers to route covered 988 text messages to 988 to the Lifeline's 10-digit number by July 16, 2022. The Commission believes that applying the same rules equally to all entities in this context is necessary to alleviate potential consumer confusion from adopting different rules, at different times, for different covered text providers. However, the Commission does not believe that the actions in the Second Report and Order will overly burden small carriers or providers. Further, the Commission believes that by its actions, all entities, including small carriers or providers, will benefit from reduced costs. For example, the Commission believes that adopting our proposal to require all covered text providers to bear their own costs to implement text-to-988 will avoid any unnecessary administrative costs. Further, the Commission provides covered text provider flexibility in how they support texting to 988, allowing them to choose the most effective method for doing so.

G. Report to Congress

34. The Commission will send a copy of the Second Report and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the Second Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Second Report and Order and FRFA (or summaries thereof) will also be published in the **Federal Register**.

III. Procedural Matters

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

36. *Final Regulatory Flexibility Analysis.* As required by the Regulatory Flexibility Act of 1980,103 the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) of the possible significant economic impact on small entities of the policies and rules, as proposed, addressed in the *Second Report and Order.* The FRFA is set forth in Appendix B of the Second Report and Order. The Commission will send a copy of the *Second Report and Order,* including the FRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

37. *Congressional Review Act.* The Commission has determined, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, concurs that this rule is non-major under the Congressional Review Act, 5 U.S.C. 804(2). The Commission will send a copy of the Second Report and Order to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A).

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

39. *Contact Person.* For further information about this rulemaking proceeding, please contact Michelle Sclater, Competition Policy Division, Wireline Competition Bureau, at (202) 418–0388 or *michelle.sclater@fcc.gov.*

IV. Ordering Clauses

40. Accordingly, *it is ordered*, pursuant to sections 201, 251(e)(4), 301, 303, 307, 309, 316, and 615c of the Communications Act of 1934, as amended, 47 U.S.C. 201, 251(e)(4), 301, 303, 307, 309, 316, 615c, that the Second Report and Order in WC Docket No. 18–336 *is adopted.*

41. *It is further ordered* that, pursuant to §§ 1.4(b)(1) and 1.103(a) of the Commission's rules, 47 CFR 1.4(b)(1), 1.103(a), the Report and Order *shall be effective* 30 days after publication in the **Federal Register**.

42. *It is further ordered* that part 52 of the Commission's rules *is amended* as set forth in Appendix A of the Second Report and Order.

43. *It is further ordered* that the Commission *shall send* a copy of the Second Report and Order to Congress and to the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

44. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of the Second Report and Order, including the Final Regulatory Flexibility Analysis (FRFA), to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 52

Communications common carriers, Telecommunications, Telephone.

(47 U.S.C. 201, 251, 301, 303, 307, 309, 316)

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

Final Rules

For the reasons stated in the preamble, the Federal Communications Commission amends 47 CFR part 52 as follows:

PART 52—NUMBERING

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

Authority: 47 U.S.C. 151, 152, 153, 154, 155, 201–205, 207–209, 218, 225–227, 251–252, 271, 303, 332, unless otherwise noted.

Subpart E—Universal Dialing Code for National Suicide Prevention and Mental Health Crisis Hotline System

■ 2. Add § 52.201 to read as follows:

§ 52.201 Texting to the National Suicide Prevention and Mental Health Crisis Hotline.

(a) *Support for 988 text message service.* Beginning July 16, 2022, all covered text providers must route a covered 988 text message to the current toll free access number for the National Suicide Prevention Lifeline, presently 1–800–273–8255 (TALK).

(b) *Access to SMS networks for 988 text messages.* To the extent that Commercial Mobile Radio Services (CMRS) providers offer Short Message Service (SMS), they shall allow access by any other covered text provider to the capabilities necessary for transmission of 988 text messages originating on such other covered text providers' application services.

(c) *Definitions.* For purposes of this section:

988 text message. (i) Means a message consisting of text, images, sounds, or other information that is transmitted to or from a device that is identified as the receiving or transmitting device by means of a 10-digit telephone number, N11 service code, or 988;

(ii) Includes and is not limited to a SMS message and a multimedia message service (MMS) message; and

(iii) Does not include—

(A) A real-time, two-way voice or video communication; or

(B) A message sent over an IP-enabled messaging service to another user of the same messaging service, except a message described in paragraph (b) of this section.

Covered 988 text message means a 988 text message in SMS format and any other format that the Wireline Competition Bureau has determined must be supported by covered text providers.

Covered text provider includes all CMRS providers as well as all providers of interconnected text messaging services that enable consumers to send text messages to and receive text messages from all or substantially all text-capable U.S. telephone numbers, including through the use of applications downloaded or otherwise installed on mobile phones.

Multimedia message service (*MMS*) shall have the same definition as the term in § 64.1600(k) of this chapter.

Short message service (*SMS*) shall have the same definition as the term in § 64.1600(m) of this chapter.

[FR Doc. 2021–27878 Filed 1–4–22; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR 679

[Docket No. 211221–0266]

RIN 0648–BL04

Fisheries of the Exclusive Economic Zone off Alaska; Reclassifying Sculpin Species in the Groundfish Fisheries of the Bering Sea and Aleutian Islands and the Gulf of Alaska; Correcting Amendment

Correction

In rule document 2021–28232, appearing on pages 74386 thru 74389, in the issue of Thursday, December 30, 2021, make the following correction:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA [CORRECTED]

■ On page 74388, at the bottom of the page, immediately following Table 10, insert the following amendatory instruction:

''3. Revise Table 11 to Part 679—BSAI Retainable Percentage, to read as follows:''

[FR Doc. C1–2021–28232 Filed 1–4–22; 8:45 am]

BILLING CODE 0099–10–P

Proposed Rules

Federal Register
Vol. 87, No. 3
Wednesday, January 5, 2022

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 THE INTERIOR

National Park Service

36 CFR Part 7

[NPS–OZAR–29687; PPMWOZARS0/PPMPSPD1Z.YM0000]

RIN 1024–AE62

Ozark National Scenic Riverways; Motorized Vessels

AGENCY: National Park Service, Interior

ACTION: Proposed rule.

SUMMARY: The National Park Service proposes to amend special regulations governing the use of motorized vessels within Ozark National Scenic Riverways. The changes would allow the use of 60/40 horsepower motors in the middle sections of the Current and Jacks Fork Rivers. The proposed rule would establish seasonal closures in the upper sections of the rivers and limit the maximum horsepower of motorized vessels in other locations. These changes would be slight modifications to restrictions on motorized vessels that have been in place since 1991.

DATES: Comments must be received by 11:59 p.m. EST on March 7, 2022.

ADDRESSES: You may submit comments, identified by the Regulation Identifier Number (RIN) 1024–AE62, by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail or Hand Deliver to:* Superintendent, Ozark National Scenic Riverways, 404 Watercress Drive, P.O. Box 490, Van Buren, MO 63965.

Instructions: Comments will not be accepted by fax, email, or in any way other than those specified above. All submissions must include the words ''National Park Service'' or ''NPS'' and must include the docket number or RIN for this rulemaking (1024–AE62). Bulk comments in any format (hard copy or electronic) submitted on behalf of others will not be accepted. Comments received may be posted without change to *www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Lindel Gregory, Chief Ranger, Ozark National Scenic Riverways; (573) 323–4923; *lindel_gregory@nps.gov.*

SUPPLEMENTARY INFORMATION:

Background

Purpose and Significance of Ozark National Scenic Riverways

Congress established Ozark National Scenic Riverways (the Riverways) in 1964 to conserve and interpret the scenic, natural, scientific, ecological, and historic values and resources within the Riverways, and to provide for public outdoor recreational use and enjoyment of those resources. 16 U.S.C 460m. The Riverways includes portions of the Current and Jacks Fork Rivers, encompassing 134 miles of clear, free-flowing, spring-fed waterways. The impressive hydrogeological character of the Riverways' karst landscape supports an amazing variety of natural features, including a spring system unparalleled in North America. The cave system is equally impressive with one of the highest densities of caves in any unit of the National Park System.

The Riverways lies within the Ozark Highlands, an important center of biodiversity in North America. The Ozark Highlands are home to a rich array of wildlife and plants, including endemic species that exist nowhere else in the world. The Current and Jacks Fork Rivers have been designated as Outstanding National Resource Waters in Missouri. The Riverways features archeological and historic structures, landscapes, and objects, reflecting ancient life in the Ozark Highlands. The extraordinary resources of the Riverways provide outstanding recreational opportunities and experiences on and along free-flowing rivers.

Use of Motorized Vessels at the Riverways

One of the recreational opportunities at the Riverways is the use of motorboats on the Current and Jacks Fork Rivers. When the Riverways was created in 1964, the only outboard motorboats operating on the rivers were conventional propeller-driven motors with elongated shafts. The propellers of these motors could hit bottom in shallow water, resulting in propeller damage. As a result, operators outfitted their motors with a lever that would lift the propeller out of the water when the vessel skimmed across shallow areas. This naturally limited the size of most motorboats operating on the rivers to 20 horsepower (hp) or less because heavier motors were too difficult to lift. The only exception was the lower Current River that is broader and deeper than the upper reaches of the Current and Jacks Fork Rivers. In this lower section of the Current River, motorboats up to 40 hp could operate.

The status quo changed in 1976 when operators began to refit outboard motors with jet propulsion systems that could operate in inches of water. This eliminated the need to have the skills and experience to lift the propeller out of shallow water. As a consequence, the number of motorboats in the Riverways increased dramatically. The smaller, traditional motor and shaft propellers were replaced with large outboard jet motors, some exceeding 250 hp. These larger motors generated greater speed (some in excess of 50 mph) and larger wakes, and required more space to operate. This resulted in safety concerns and conflicts with other users of the rivers, including canoers, tube floaters, swimmers, and anglers.

In order to address these concerns, in 1991 the NPS revised the special regulations for the Riverways at 36 CFR 7.83(a) to designate zones for motorboat operation, restrict horsepower, and limit the use of motorboats during certain seasons (56 FR 30694). The use of motorboats was also limited to vessels equipped with outboard motors. The nature of the shallow, narrow rivers precludes the safe use of inboard motors. These motors are capable of much greater speeds but need more water depth to operate due to increased weight.

Motor boating continues to be a popular activity and means of travel on the Current and Jacks Fork Rivers. Visitors use motorboats to access fishing areas, cruise the river, and enjoy scenic views. Despite the existing regulations that manage motorboats within the Riverways, there are concerns about motorboats in certain sections of river. One concern is the effect of noise on

visitors seeking a quiet experience. Another concern arises during the summer, when the number of motorboats on the rivers pose a safety hazard due to conflicts between different user groups competing for the same resources. Many access points along the rivers have become popular for concessioners and private individuals to launch nonmotorized watercraft, such as tubes, rafts, canoes, and kayaks. Often, groups of visitors seeking motorized and nonmotorized access enter the river at the same time and place, which can lead to congestion and conflicts. Once in the water, people in tubes, rafts, kayaks, and canoes can be overwhelmed by the wake of motorized vessels. Over the past 20 years, the number of visitors using nonmotorized vessels on the rivers has steadily increased. If this number continues to increase, so too will crowding and conflicts among user groups.

Proposed Rule

Summary

This proposed rule would help accommodate a variety of desired river conditions and recreational uses, promote high quality visitor experiences, promote visitor safety, and minimize conflicts among different user groups. It would do this by making the following changes to existing regulations.

Measuring Horsepower

Existing regulations, established in 1991, limit the horsepower of motorized vessels for the purpose of limiting the size and speed of motorized vessels to help ensure a safe and enjoyable experience for all types of visitors. Larger motors generate greater speed, larger wakes, and require more space in proportion to their speed. The very nature of the shallow, narrow rivers, and channel and flow characteristics preclude the safe operation and navigation of oversized motorboats around obstacles and other users in certain sections of the Current and Jacks Fork Rivers. Various combinations of channel depth and stream velocity sometimes require boaters to maintain sufficient momentum to get across the shallows, and into deeper waters, which poses a particular safety hazard to other visitors such as floaters and swimmers. Additionally, most boats used on the Current and Jacks Forks Rivers are not equipped with speedometers and are therefore unable to gauge their own speeds. Further, depending on whether a boat is traveling downstream or upstream, speedometers may not accurately gauge speed of travel. For these reasons, horsepower limits on outboard motors are the most effective means to ensure safety and achieve compliance.

Horsepower can be measured at the engine powerhead and at the final output. These measurements are virtually the same for outboard motors equipped with propellers. For motors equipped with jet propulsion systems, horsepower is approximately 30 percent less at the final output than at the powerhead. For purposes of complying with the horsepower limits, the existing regulations state that horsepower will be based upon power output at the propeller shaft as established by the manufacturer. 36 CFR 7.83(a)(2). This method of measuring power works well for motors with propellers that have not be modified to change final power output. This method is problematic, however, for motors that were manufactured with propellers but then retrofitted with jet propulsion systems that lower the final power output below the maximum horsepower that was established by the manufacturer at the propeller shaft. These types of motors are popular with visitors to the Riverways because they can operate in shallow waters and enable the use of longer and wider boats capable of transporting four or more adults against the current of the rivers. The problem is that the existing regulations prohibit many of these motors even though they have a final power output less than or equal to the maximum horsepower that the NPS has determined is appropriate. In this way, the regulations are overinclusive.

For example, the existing regulations prohibit the use of motors that exceed 40 hp in the middle sections of the Current and Jacks Fork Rivers. 36 CFR 7.83(a)(3)(i). The most popular type of motors in these sections are known as 60/40 hp motors. This indicates that the motors produce 60 hp at the powerhead but only 40 hp at the final output because they are equipped with a jet propulsion system. Some of these motors were manufactured with propellers and rated at 60 hp by the manufacturer, only to be retrofitted with jets. Others were manufactured with jet propulsion systems and for this reason could be rated at either 60 hp or 40 hp depending upon where the manufacturer measured the power. Under the existing regulations, retrofitted motors rated by the manufacturer at 60 hp are prohibited even though they now only have 40 hp of usable power. The method of measurement in the existing regulations is impracticable for vessels manufactured with jet propulsion systems because there was never a propeller shaft. In order to address this unintended outcome, the NPS has allowed 60/40 hp motors in the Riverways since 1999 under a Superintendent's memorandum.

This proposed rule would officially allow these popular motors in the middle sections of river. The proposed rule would clarify that, for purposes of complying with the regulations, maximum horsepower means the maximum horsepower produced by the engine's powerhead.[1] The proposed rule would state that this measurement may be different than the maximum power measured at the final output or the maximum power rated by the manufacturer. The proposed rule would then add tables that include maximum horsepower limits on each river that differ depending upon whether the motor has a jet propulsion system or a propeller. For the middle sections, 60 hp would be allowed for jet motors but only 40 hp would be allowed for propeller motors.

In the upper sections of the rivers, existing regulations prohibit the use of motors that exceed 25 hp measured at the propeller shaft by the manufacturer. 36 CFR 7.83(a)(3)(ii). In practice, the NPS has allowed 25 hp motors in the upper sections only if they are equipped with jet propulsion systems that lower the effective horsepower to 18 hp at the final output. The narrow and shallow nature of the upper sections make motors with more powerful outputs unsafe throughout the year. The proposed rule would change the regulations to be consistent with this practice by allowing 25 hp motors with an attached jet unit and 18 hp motors fitted with a propeller.

Seasonal Closures on the Upper Sections of River

Existing regulations allow 10 hp motors in the upper section of the Current River from May 1 through September 15, and in the upper section on the Jacks Fork river from March 1 to the Saturday before Memorial Day. 36 CFR 7.83(a)(3)(iii)–(iv). This proposed rule would prohibit motorized vessels in these sections during peak season. This would include vessels using only a trolling motor. This closure would apply to the full extent of the upper sections of each river, from the northern boundary downstream to Round Spring on the Current River, and from the western boundary downstream to the boundary at West Eminence on the Jacks

[1] This is consistent with the International Council of Marine Industry Association's Standard 28–83.

Fork River. Existing regulations apply the seasonal 10 hp limit above Akers Ferry on the Current River and above Bay Creek on the Jacks Fork River, even though during off-peak seasons the 25 hp limits on the upper sections of each river apply downstream to Round Spring on the Current River, and from the western boundary downstream to the boundary at West Eminence on the Jacks Fork River.

Peak season would be defined as beginning on the day after the last day of beaver trapping season (usually around April 1) and ending on the day before the first day of gigging season for nongame fish (usually around September 15). These dates are determined annually by the Missouri Department of Conservation. Defining peak season in this manner, rather than using fixed dates, would allow visitors to use motorboats for lawful trapping and gigging activities without interfering with nonmotorized vessels (*e.g.,* tubes, rafts, kayaks and canoes) when they are most popular. These upper sections of river are very narrow and shallow and do not receive heavy use from motorized vessels even during trapping and gigging seasons. A nonmotorized season would provide opportunities for solitude and connection with nature that are not currently available during weekends and holidays in the summer. Visitors would be able to intimately experience conditions reminiscent of those that existed when the Riverways was established. The seasonal closures would also eliminate safety concerns and conflicts that arise when motorized and nonmotorized user groups are both present in these areas.

Maximum Horsepower Limit on the Lower Section of River

Existing regulations do not impose a horsepower limit on the lower section of the Current River. The proposed rule would establish new horsepower limits in this section. The proposed rule would allow motors with propellers up to 105 hp. For the same reason that 60 hp motors would be allowed in the middle sections of the Current and Jacks Fork Rivers if they are equipped with jet propulsion systems, the proposed rule would allow 150 hp motors in the lower section of the Current River if they are similarly equipped. These limits are higher than the limits that would apply in the upper and middle sections of the rivers because the river below Big Spring is much broader and deeper. Currently, vessels with 225–300 hp motors are operating in this section of river. Motors such as these that are larger than the proposed limits of 150/105 hp generate greater speed (some in excess of 50 mph), larger wakes, and require more space to operate. This results in serious safety concerns and conflicts with other users of the river, including canoers, tube floaters, swimmers, and anglers.

Other Changes

The proposed rule would revise § 7.83(a)(1) of the existing special regulations to clarify that only motorized vessels with one outboard motor are allowed in the Riverways. The proposed rule would clarify that the motor count does not include electric trolling motors, which could accompany a vessel with a single outboard motor. For clarity, the revisions would define the terms ''inboard motor'' and ''outboard motor'' and state that the use of inboard engines and personal watercraft are prohibited.

The proposed rule would allow the Superintendent to issue a permit for the operation of vessels with motors more powerful than the horsepower limits established by the proposed rule. This would allow the Superintendent to make exceptions in limited circumstances, such as when the NPS issues permits to the Missouri Department of Fish and Game for research activities on the rivers that, for safety or other reasons, require more power than is allowed by the proposed rule.

The proposed rule would also include a provision establishing the Superintendent's authority to restrict or impose conditions on the use of motorized vessels, or close any portion of the Riverways to motorized vessels, after taking into consideration public safety, protection or park resources, weather conditions and park management objectives, provided public notice is given using one or more of the methods identified in 36 CFR 1.7. This would clarify the Superintendent's authority to respond to emerging technologies or other unforeseen circumstances in order to help maintain a safe and enjoyable experience for visitors to the Riverways.

Notice of Horsepower Restrictions

Maps indicating the horsepower limits in the various portions of the rivers would be located at Riverways headquarters in Van Buren, MO and on the Riverways' website (*www.nps.gov/ozar*). The Superintendent would notify the public of the start and end dates for peak season through one or more of the methods listed in 36 CFR 1.7. The proposed rule would also add a table to the special regulations that identifies each section of river and the applicable horsepower restrictions for that section during peak and non-peak seasons.

Compliance With Other Laws, Executive Orders, and Department Policy

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this proposed rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The NPS has developed this proposed rule in a manner consistent with these requirements.

Regulatory Flexibility Act (RFA)

This proposed rule will not have a significant economic effect on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This certification is based on the cost-benefit and regulatory flexibility analyses found in the report entitled ''Draft Cost-Benefit and Regulatory Flexibility Threshold Analyses: Proposed Special Regulations Governing the Use of Motorized Vessels within Ozark National Scenic Riverways'' that can be found on the Riverways' planning website at *http://parkplanning.nps.gov/ozar,* by clicking the link entitled ''Archived Projects,'' and the clicking on the link entitled ''General Management Plan, Wilderness Study, Environmental Impact Statement'' and then clicking the link entitled ''Document List.''

Congressional Review Act (CRA)

This proposed rule is not a major rule under 5 U.S.C. 804(2), the CRA. This proposed rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers,

individual industries, federal, state, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act (UMRA)

This proposed rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The proposed rule does not have a significant or unique effect on state, local or tribal governments or the private sector. It addresses public use of NPS-administered waters, and imposes no requirements on other agencies or governments. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

This proposed rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12630. Access to private property adjacent to the recreation area will not be affected by this proposed rule. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, this proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. The proposed rule is limited in effect to federal lands managed by the NPS and would not have a substantial direct effect on state and local government. A Federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This proposed rule complies with the requirements of Executive Order 12988. Specifically, this proposed rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Paperwork Reduction Act (44 U.S.C. 3501 et seq.)

This proposed rule does not contain any new collections of information that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. 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.

National Environmental Policy Act of 1969 (NEPA)

The proposed rule would implement a portion of the preferred alternative (Alternative B) for the Riverways described in the Final General Management Plan/Wilderness Study/Environmental Impact Statement (GMP/EIS), which constitutes a major Federal action significantly affecting the quality of the human environment. The NPS prepared the GMP/EIS under the NEPA. The NPS released a Draft GMP/EIS that was available for public review and comment from November 8, 2013 through February 7, 2014. The NPS released the final GMP/EIS in December 2014. On January 22, 2015, the Regional Director of the Department of the Interior Unified Regions 3, 4, and 5 (formerly the Midwest Region) signed a Record of Decision (ROD) identifying the preferred alternative as the selected action. The GMP/EIS describes the purpose and need for the plan, the alternatives considered, the scoping process and public participation, the affected environment and environmental consequences, and consultation and coordination. Copies of the GMP/EIS and ROD can be found on the Riverways' planning website at *http://parkplanning.nps.gov/ozar,* by clicking the link entitled ''Archived Projects,'' and the clicking on the link entitled ''General Management Plan, Wilderness Study, Environmental Impact Statement'' and then clicking the link entitled ''Document List.''

Consultation With Indian Tribes (Executive Order 13175 and Department Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and tribal sovereignty. The NPS has evaluated this proposed rule under the Department's consultation policy and under the criteria in Executive Order 13175 and has determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's tribal consultation policy is not required.

The NPS consulted with culturally affiliated American Indian tribes on the development of the GMP/EIS, including meetings in Oklahoma and Missouri in 2003, 2006, 2010. The NPS invited all tribal representatives to visit the Riverways and to actively participate in the GMP/EIS planning process. As part of ongoing government-to-government relations, NPS staff will continue to consult with affiliated tribes about planning and other actions in the Riverways that could affect the tribes. NPS staff will further consult with regard to specific actions and undertakings arising from the GMP/EIS that are proposed for future implementation. When appropriate, NPS staff provide technical assistance to the tribes, including sharing information and resources, to address problems and issues of mutual concern.

Effects on the Energy Supply (Executive Order 13211)

This proposed rule is not a significant energy action under the definition in Executive Order 13211. The proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy, and the Administrator of OIRA has not designated the proposed rule as a significant energy action. A Statement of Energy Effects is not required.

Clarity of This Proposed Rule

The NPS is required by Executive Orders 12866 (section 1(b)(12)), 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each proposed rule the NPS publishes must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that the NPS has not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section above. To better help us revise the proposed rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your

personal identifying information—may be made publicly available at any time.

List of Subjects in 36 CFR Part 7

National Parks, Reporting and recordkeeping requirements.

In consideration of the foregoing, the National Park Service proposes to amend 36 CFR part 7 as follows:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

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

Authority: 54 U.S.C. 100101, 100751, 320102; Sec. 7.96 also issued under D.C. Code 10–137 and D.C. Code 50–2201.07.

■ 2. In § 7.83:

■ a. Redesignate paragraphs (a), (b), (c), (d) and (e) as paragraphs (b), (c), (d), (e) and (f).

■ b. Add a new paragraph (a).

■ c. Revise newly designated paragraph (b) to read as follows:

§ 7.83 Ozark National Scenic Riverways.

(a) *Definitions.* The following definitions apply to this section only:

Inboard motor means a marine propulsion system that is enclosed within the hull of the vessel.

Maximum horsepower means the maximum horsepower produced by the engine's powerhead. This measurement may be different than the maximum horsepower at the final output or the maximum horsepower rated by the manufacturer.

Off-peak season means anytime that is not during peak season.

Outboard motor means a marine propulsion system that is mounted on the exterior of the vessel's hull.

Peak season means a period of time:

(i) Beginning on the day after the last day of beaver trapping season, as determined by the Missouri Department of Conservation; and

(ii) Ending on the day before the first day of gigging season for nongame fish, as determined by the Missouri Department of Conservation.

(b) *Restrictions for motorized vessels.* (1) On waters situated within the boundaries of Ozark National Scenic Riverways, the use of motorized vessels is limited to vessels equipped with one outboard motor, not including an electric trolling motor. The use of inboard engines and personal watercraft are prohibited.

(2) The use of a motorized vessel is allowed on the Current River according to the seasonal restrictions and maximum horsepower limits set forth in Table 1 to paragraph (b)(2).

TABLE 1 TO PARAGRAPH (b)(2)

Section of river	Maximum horsepower during peak season	Maximum horsepower during off-peak season
Current River:		
Upper Section: Northern boundary downstream to Round Spring.	Motorized vessels prohibited	25 hp (motor with jet unit); 18 hp (motor with propeller).
Middle Section: Round Spring downstream to Big Spring.	60 hp (motor with jet unit); 40 hp (motor with propeller).	60 hp (motor with jet unit); 40 hp (motor with propeller).
Lower Section: Big Spring downstream to southern boundary.	150 hp (motor with jet unit); 105 hp (motor with propeller).	150 hp (motor with jet unit); 105 hp (motor with propeller).

(3) The use of a motorized vessel is allowed on the Jacks Fork River according to the seasonal restrictions and maximum horsepower limits set forth in Table 1 to paragraph (b)(3):

TABLE 1 TO PARAGRAPH (b)(3)

Section of river	Maximum horsepower during peak season	Maximum horsepower during off-peak season
Jacks Fork River:		
Upper Section: Western boundary downstream to the boundary at West Eminence.	Motorized vessels prohibited	25 hp (motor with jet unit); 18 hp (motor with propeller).
Middle Section: Boundary at East Eminence downstream to Two Rivers.	60 hp (motor with jet unit); 40 hp (motor with propeller).	60 hp (motor with jet unit); 40 hp (motor with propeller).

(4) The maximum horsepower limits in this section may be exceeded pursuant to a written permit issued by the Superintendent.

(5) Maps indicating the horsepower limits in the various portions of the rivers are located at park headquarters in Van Buren, MO and on the Ozark National Scenic Riverways website. Designated access points will mark the boundaries of the upper, middle, and lower sections of river. The Superintendent will notify the public of the designated access points through one or more of the methods listed in § 1.7 of this chapter.

(6) Operating a motorized vessel in a manner not allowed by this paragraph (b) is prohibited.

(7) The Superintendent may restrict or impose conditions on the use of motorized vessels, or close any portion of the Riverways to motorized vessels, after taking into consideration public safety, protection or park resources, weather conditions and park management objectives. The Superintendent will provide notice of any such action by one or more of the methods listed in § 1.7(a) of this chapter.

* * * * *

Shannon A. Estenoz,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2021–28509 Filed 1–4–22; 8:45 am]

BILLING CODE 4312–EJ–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ30

Modifying Copayments for Veterans at High Risk for Suicide

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its medical regulations that govern copayments for VA outpatient medical care and medications (to include outpatient medical care and medications provided by VA directly or community care obtained by VA through contracts, provider agreements or sharing agreements) by effectively eliminating the copayment for outpatient care and reducing the copayment for medications dispensed to veterans identified by VA as being at high risk for suicide. These copayment changes would be applied until VA determines that the veteran is no longer at high risk for suicide.

DATES: Comments must be received by VA on or before March 7, 2022.

ADDRESSES: Comments may be submitted through *www.Regulations.gov.* Comments received will be available at *regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: David Carroll, Ph.D., Executive Director, Office of Mental Health and Suicide Prevention (11MHSP), Department of Veterans Affairs, Veterans Health Administration, 810 Vermont Ave. NW, Washington, DC 20420; (202) 461–4058. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Background

Under 38 U.S.C. 1710(g), VA is required to set the copayment amount for outpatient medical care provided to veterans who are eligible for such care by reason of 38 U.S.C. 1710(a)(3). In general, this applies to veterans enrolled in priority groups 7 and 8, which includes veterans with no compensable service-connected disability and veterans who have an annual income exceeding the applicable threshold. 38 CFR 17.36. VA regulates the copayment amount for outpatient medical care in 38 CFR 17.108(c). Under existing regulations, VA charges certain veterans $15.00 for each primary care outpatient visit and $50.00 for each specialty care outpatient visit. 38 CFR 17.108(c)(2). Across the broad continuum of mental health services, mental health care may be classified for billing purposes as primary care, such as an outpatient general mental health appointment, or as specialty care, such as a neuropsychological assessment.

Section 1722A(a)(1) of title 38 of the U.S. Code states that the Secretary shall require a veteran to pay the United States $2 for each 30-day supply of medication furnished to such veteran under this chapter on an outpatient basis for the treatment of a non-service-connected disability or condition. In general, this applies to veterans enrolled in priority groups 2 through 8 (38 CFR 17.36) and excludes veterans with a service-connected disability rated 50 percent or more, veterans who are former prisoners of war, veterans whose annual income does not exceed the applicable threshold, and veterans awarded the medal of honor. VA regulates the copayment amount for medications in 38 CFR 17.110(c). Section 1722A(a)(1) also states that if the amount supplied is less than a 30-day supply, VA may not reduce the copayment amount. While VA is not permitted to require a veteran to pay an amount in excess of the cost to VA, 38 U.S.C. 1722A(b) authorizes the Secretary to increase the copayment amount in effect under subsection (a) to cover the agency's costs for medications by regulation. However, the Secretary is not authorized to reduce the medication copayment below $2 for each 30-day supply.

VA regulations set forth the categories of veterans who are exempt from copayment requirements as required by law for inpatient and outpatient medical care (38 CFR 17.108(d)–(f)), as well as medication (38 CFR 17.110(c)).

II. Need for the Proposed Rule

VA has identified suicide prevention as a top clinical priority. Implementation of evidence-based clinical practice guidelines is one strategy VA has embraced to improve mental health care and access to suicide prevention resources available to veterans by reducing variation in practice and systematizing best practices. Jointly issued by VA and the Department of Defense (DoD), the VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide (2019) (CPG) recommends health care professionals increase the frequency of outpatient mental health encounters to provide more intense care and preventive services for veterans who are determined to be at high risk for suicide, as these evidence-based enhancements have shown to reduce the risk of suicide. *See, e.g.,* CPG pp. 23–25. *https://www.healthquality.va.gov/guidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf.*

However, VA understands that the increase in outpatient visits may be a financial burden and a detriment to certain veterans who must pay a copayment, as an increase in outpatient visits results in increased numbers of copayments. Healthcare research has provided extensive evidence that copayments can be barriers to healthcare for vulnerable patients. For example, as summarized in the CPG, scientific and clinical literature supports the principle that copayment rates can be barriers to medication adherence and access to clinical services. *See, e.g.,* (No author listed). Impact of Copays in Vulnerable Populations, American Journal of Managed Care, Vol. 12 No. 13 Nov. 2006, S359–363; and, Simon GE, VonKorff M, Durham ML. Predictors of outpatient mental health utilization by primary care patients in a health maintenance organization, American Journal of Psychiatry, Vol. 151 No. 6 Jun. 1994, 908–913. Currently, there is no exemption from outpatient care copayments for veterans who are at risk for suicide, and such veterans have to pay a $15.00 or $50.00 copayment for each outpatient visit (depending on whether the visit qualifies as primary care or specialty care).

In addition, VA internal reporting documents, such as issue briefs, have revealed that there are substantial numbers of suicides and suicide attempts among veterans that result from overdoses of medications that are prescribed by VA providers on an outpatient basis. The CPG includes a strong recommendation to prescribe medication in less than 30-day supplies for veterans at high risk of suicide in order to prevent fatal or medically serious overdoses. *See* CPG p. 24. The clinical necessity to prescribe medication in less than 30-day supplies for veterans who are at high risk for suicide would likely arise, for medications that are potentially dangerous or lethal in the event of overdose, either by themselves or in combination with other medications being used by a veteran. VA understands that providing less than a 30-day supply would necessarily require more prescriptions, which may cause an economic burden to veterans who must pay a copayment for each prescription. In order to address both the necessity of prescribing medication in less than 30-day supplies for veterans at high risk of suicide and the consequent financial burden of issuing

multiple prescriptions, each with fewer doses, for the same 30-day period, VA believes that current 38 CFR 17.110 should be amended to allow for lesser copayment amounts for medications prescribed for a veteran at high risk of suicide.

III. Provisions of the Proposed Rule

VA seeks to revise two sections of our medical regulations, § 17.108 regarding copayments for inpatient hospital care and outpatient medical care and § 17.110 regarding copayments for medication to modify copayments for veterans who are determined by VA to be at high risk of suicide. As §§ 17.108 and 17.110 apply to care and medication obtained by VA through contracts, providers agreements, and sharing agreements, not just care and medication provided directly by VA, the proposed revisions below would apply to outpatient care and medication provided directly by VA as well as outpatient care and medication provided by community providers. The determination of whether a veteran is at high risk of suicide is a clinical decision made by VA clinicians that is based upon the following essential features: (1) A recent suicide attempt or preparatory behaviors, (2) suicidal ideation with intent to die resulting in inpatient hospitalization, or (3) active threats to harm oneself, seeking access to means, or talking or writing about death, dying, or suicide when the actions are out of character for the person.

In general, electronic flags and triggers are used in the electronic health record to alert a provider to a variety of clinical needs and prevention opportunities. VA restricts the use of the alert to address immediate clinical safety issues. VA has implemented such tools in several areas, including alerting VA providers through patient record flags to a veteran's suicide risk. For purposes of readability, we will use the term ''alert'' in this document rather than referring to an electronic flag or trigger. The CPG at Sidebar 2a. Essential Features from Risk Stratification Table—Acute Risk (p. 23) lists essential features for a high acute risk of suicide as: Suicidal ideation with intent to die by suicide; and an inability to maintain safety, independent of external support/help. The CPG lists common warning signs such as: A plan for suicide; recent attempt and/or ongoing preparatory Behaviors; acute major mental illness (*e.g.,* major depressive episode, acute mania, acute psychosis, recent/current drug relapse); and, exacerbation of a personality disorder (*e.g.,* increased borderline symptomatology). In addition, various psychosocial factors are associated with risk for suicide and suicide attempts. These include recent life events such as losses (especially employment, careers, finances, housing, marital relationships, physical health, and a sense of a future), and chronic or long-term problems such as relationship difficulties, unemployment, and ongoing or pending legal issues.

In addition, there are warning signs that empirically have been shown to be temporally related to the acute onset of suicidal behaviors (*e.g.,* within hours to a few days). These signs should warn the clinician of acute risk for the expression of suicidal behaviors, especially in those individuals with other risk factors. *See, e.g.,* Rudd MD, Berman AL, Joiner TE, et al. Warning signs for suicide: Theory, research and clinical applications. Suicide and Life Threatening Behavior; Volume 36 Issue 3, 255–62 (2006). Three of these warning signs carry the highest likelihood of short-term onset of suicidal behaviors and require immediate attention, evaluation, referral, or consideration of hospitalization. These warning signs are: (1) Threatening to hurt or kill self; (2) looking for ways to kill self; seeking access to pills, weapons or other means; and, (3) talking or writing about death, dying or suicide. See VA Suicide Risk Assessment Guide. *https://www.mentalhealth.va.gov/docs/suicide_risk_assessment_reference_guide.pdf.*

Once a veteran is determined to be at high risk for suicide by a VA clinician, VA suicide prevention staff, as a matter of VA policy, places an alert in the veteran's electronic health record indicating that the veteran is at high risk for suicide. VA suicide prevention staff then conducts a periodic review in all cases where a high-risk of suicide alert has been added to the electronic health record to determine whether the alert will remain active or be discontinued.

We note that community care providers do not have direct access to the veteran's electronic health record, which is maintained by VA, and therefore cannot add an alert into that record. VA intends to engage community care providers and urge them to communicate to VA any finding that a veteran patient is believed to be at high risk of suicide so that VA can determine if a veteran is at high risk of suicide, as appropriate.

A. § 17.108 Copayments for Inpatient Hospital Care and Outpatient Medical Care

Section 17.108 establishes the copayment amounts for inpatient hospital care and outpatient medical care. Paragraph (c) of that section lists the copayments for outpatient care. We propose to add a new paragraph (c)(5), which would reduce to zero the outpatient copayment amount for veterans that VA determines to be at high risk for suicide.

We propose that this copayment level would align with the use of the high risk of suicide alert in the veteran's electronic health record. Therefore, it would begin once the veteran is determined to be at high risk for suicide by a VA clinician and an alert is placed in the veteran's electronic health record. This copayment level would remain in place until the veteran is no longer at high risk for suicide. VA would no longer consider a veteran to be at high risk for suicide when an alert in the veteran's electronic health record indicating that the veteran is at high risk for suicide has been inactivated or removed by VA suicide prevention staff.

VA has interpreted 38 U.S.C. 1710(g)(1) to mean that VA has the discretion to establish the applicable outpatient visit copayment amount by regulation, even if such amount is zero. 77 FR 13195, 13196. Therefore, if finalized as proposed, VA would effectively eliminate the outpatient visit copayment for veterans when veterans are at high risk for suicide by establishing the outpatient visit copayment amount as zero. This copayment level would begin once the veteran is determined to be at high risk for suicide and would remain in place until the veteran is no longer at high risk for suicide. By proposing elimination of copayments for all outpatient care it is VA's intent to remove any financial deterrents or barriers that a veteran may have against agreeing to an increase in the frequency of outpatient care when they are at high risk of suicide. VA believes this proposed change will assist VA in preventing suicide among veterans who are at high risk for suicide by providing a CPG-informed intervention without introducing new barriers to care, such as financial burdens. See, *e.g.,* National Academy of Science, Institute of Medicine. Reducing Suicide: A National Imperative (2002).

The proposed copayment reduction would be for all outpatient care, and not just limited to mental health care, for these veterans who are at high risk of suicide. VA believes that active and increased engagement in all medical care, not just mental health care, is a protective factor against suicide. See Department of Veterans Affairs, Veterans Health Administration. National Veteran Suicide Prevention Annual Report (2002); National

Academy of Science, Institute of Medicine. Reducing Suicide: A National Imperative (2002). Mental health care is integrated into health care provided across the full range of VA medical services, and mental health care cannot reasonably and accurately be parsed out by provider type (*e.g.,* some oncologists, who ordinarily screen for and treat cancer, also screen for depression and suicide risk) or setting type (*e.g.,* some patients receive the bulk of their mental health care, including risk assessments and medication adjustments, in primary care settings). VA believes that eliminating copayments for all outpatient care supports provision of ongoing mental health screenings in clinical settings by various VA health care professionals.

In addition, we propose revising paragraph (c)(1) by adding a reference to new proposed paragraph (c)(5). Current paragraph (c)(1) states that ''[e]xcept as provided in paragraphs (d), (e), or (f) of this section, a veteran, as a condition for receiving outpatient medical care provided by VA (provided either directly by VA or obtained by VA by contract, provider agreement, or sharing agreement), must agree to pay VA (and is obligated to pay VA) a copayment as set forth in paragraph (c)(2) or (c)(4) of this section.'' We would revise this paragraph to instead refer to ''a copayment as set forth in paragraph (c)(2), (c)(4) or (c)(5) of this section.''

B. § 17.110 Copayments for Medication

Section 17.110 establishes the copayment amounts for medications. Under this proposed rule, a veteran would pay the copayment amount of only $2 for a 30-day or less supply of medication while such veteran is determined to be at high risk for suicide. We propose to add a new paragraph (b)(6) to Section 17.110 to state that veterans who VA determines to be at high risk for suicide will pay a $2 medication copayment for all medications for each 30-day or less supply of a medication. We also propose that the initiation and duration of this medication copayment level would be the same as that established for outpatient copayments in proposed § 17.108(c)(5). In other words, this copayment level would begin when the veteran is determined to be at high risk for suicide and would remain in place until the veteran is no longer considered to be at high risk for suicide. Also, VA would no longer consider a veteran to be at high risk for suicide when the alert in the veteran's electronic health record indicating that the veteran is at high risk for suicide is inactivated or removed.

VA has three classes of medications, identified as Tier 1, Tier 2, and Tier 3. Copayment amounts are fixed and vary depending upon the class of medication as follows: $5 for a 30-day or less supply of a Tier 1 medication, $8 for a 30-day or less supply of a Tier 2 medication, and $11 for a 30-day or less supply of a Tier 3 medication. Currently, there is no exemption from medication copayments for veterans who are at high risk for suicide, and such veterans would have to pay a much higher amount in copayments if they are being prescribed medication more frequently but with less supply (*e.g.,* in increments of two weeks or less) and still paying a full copayment for each prescription filled. However, VA has consistently interpreted 38 U.S.C. 1722A(a) to mean that VA has discretion to determine the appropriate copayment amount for medication furnished on an outpatient basis, as long as that amount is at least $2. *See, e.g.,* 74 FR 69283 (December 31, 2009); 75 FR 32668 (June 9, 2010); 81 FR 88117 (December 7, 2016).

Under this proposed regulation, if VA were to prescribe a veteran medication on, for example, a weekly basis, the veteran would pay a $2 copayment every week and would ultimately pay a total of $8 in copayments for a month's supply of medication regardless of tier. By contrast, under the current regulations and in the same scenario, for a Tier 1 medication (pursuant to 38 CFR 17.110(b)(1)), the veteran would pay $5 in copayment every week and would ultimately pay a total of $20 in copayments for a month's supply of medication, or $44 for a Tier 3 medication.

Under the proposed rule, VA would adjust the copayment for medications once the veteran is determined to be at high risk for suicide and would remain in place until the veteran is no longer at high risk for suicide. The copayment reduction would be for all medications, regardless of tier, for these veterans who are at high risk of suicide. This is because many medications, psychiatric or non-psychiatric, may be non-lethal when taken alone, but lethal when combined with other medication in an overdose. Also, it would be impractical for VA to identify every potentially dangerous medication combination for purposes of this copayment reduction.

VA believes that establishing a flat $2 medication copayment, regardless of tier, for veterans determined to be at high risk for suicide serves several purposes. Applying a flat copayment amount to all prescribed medications means that there is no financial disincentive to the veteran continuing with medications that are prescribed to treat medical conditions other than for mental health, such as ongoing chronic medical conditions. In addition, veterans sometimes request that a clinician prescribe a Tier 1 or 2 medication to treat a diagnosed condition rather than a Tier 3 medication recommended by the clinician in order to decrease medication copayments. Adopting a flat medication copayment regime ensures that therapeutic options are not limited by concerns for medication copayment amounts for these veterans determined to be at high risk of suicide. Finally, as noted, a flat medication copayment of $2 helps ensure that veterans determined to be at high risk for suicide are not financially penalized because medications are prescribed in less than 30-day increments.

Therefore, if finalized as proposed, VA would reduce the copayment amount for medications for veterans at a high risk for suicide as a way to remove any deterrents or barriers that a veteran may have to agreeing to an increased number of prescriptions when providers find it clinically necessary to reduce the amount of certain medications prescribed at one time (*i.e.,* from a 30-day supply to a less than 30-day supply). This will better enable VA to reduce lethality of medications at hand and reduce the risk of medication-related suicide attempts among veterans who are at high risk for suicide.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This proposed rule would only affect individual veterans who receive VA health care. The proposed rule focuses on the copayment amount that must be paid by a veteran who has been determined to be at high risk of suicide. It does not impact payments made to non-VA entities or health care providers, and does not create any administrative or transition burdens for third parties that might qualify as a small entity under the Regulatory Flexibility Act. Billing for copayment amounts is administered solely by VA. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility

analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the 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 effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Assistance Listing

The Assistance Listing program numbers and titles for this proposed rule are as follows: 64.009, Veterans Medical Care Benefits; 64.012, Veterans Prescription Service; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.041, VHA Outpatient Specialty Care; 64.045, VHA Outpatient Ancillary Services; 64.047, VHA Primary Care; 64.048, VHA Mental Health Clinics.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on June 8, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 17 as set forth below:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

* * * * *

■ 2. Amend § 17.108 by revising paragraph (c)(1) and adding paragraph (c)(5) to read as follows:

§ 17.108 Copayments for inpatient hospital care and outpatient medical care.

* * * * *

(c)(1) Except as provided in paragraphs (d), (e), or (f) of this section, a veteran, as a condition for receiving outpatient medical care provided by VA (provided either directly by VA or obtained by VA by contract, provider agreement, or sharing agreement), must agree to pay VA (and is obligated to pay VA) a copayment as set forth in paragraph (c)(2), (c)(4) or (c)(5) of this section.

* * * * *

(5) The copayment for outpatient medical care furnished to a veteran who VA determines to be at high risk for suicide is zero dollars ($0). This copayment level will begin once the veteran is determined to be at high risk for suicide and will remain in place until the veteran is no longer at high risk for suicide.

* * * * *

■ 3. Amend § 17.110 by adding paragraph (b)(6) to read as follows:

§ 17.110 Copayments for medication.

* * * * *

(b) * * *

(6) *Veterans at high risk for suicide.* Veterans who VA determines to be at high risk for suicide will be charged a $2 medication copayment amount for all medications for each 30-day or shorter supply of a medication. The initiation and duration of this medication copayment level are the same as those established for outpatient copayments in § 17.108(c)(5).

* * * * *

[FR Doc. 2021–28049 Filed 1–4–22; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2005–0155; FRL–8391–03–OAR]

RIN 2060–AV44

National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities Technology Review; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; correction.

SUMMARY: On December 27, 2021, the U.S. Environmental Protection Agency (EPA) proposed amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for dry cleaning facilities using perchloroethylene (PCE) as the cleaning solvent (PCE Dry Cleaning NESHAP). The proposed amendments addressed the results of the technology review for the PCE Dry Cleaning NESHAP, in accordance with section 112 of the Clean Air Act (CAA). This action is being issued to correct a typographical error which stated that we would hold a virtual public hearing if anyone contacted us requesting a public hearing on or before January 11, 2022 (*i.e.,* 15 days after publication of the proposed rule). However, that same notice also said that if requested, the virtual hearing would be held on January 11, 2022. Logistically, we cannot have the same date for both actions because we need to know several days ahead of time whether stakeholders request a hearing so that we have sufficient time to plan accordingly and make all the necessary arrangements. For most proposed rules, the EPA states that if anyone contacts us requesting a public hearing on or before a date five days after publication of the proposed rule, that the EPA will hold such public hearing on a date 15 days after publication of such rule. To correct this error, in this correction notice, EPA states that if anyone contacts us requesting a public hearing on or before January 10, 2022 the virtual hearing will be held on January 20, 2022. As

described below, several other dates regarding the preparations for such hearing and the deadline for submitting public comments have also been revised accordingly.

DATES: Comments on the proposed rule that was published in the **Federal Register** on December 27, 2021 (86 FR 73207) must be received on or before February 22, 2022.

Public hearing: If anyone contacts us requesting a public hearing on or before January 10, 2022, we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2005–0155, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2005–0155 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2005–0155.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2005–0155, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions about this correction, contact Brian Storey, Sector Policies and Programs Division (Mail Code D243–04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1103; fax number: (919) 541–4991; and email address: *brian.storey@epa.gov.*

SUPPLEMENTARY INFORMATION: For the sake of clarity, the EPA is reiterating information concerning the public hearing and comment processes, with the correct dates provided below.

Participation in virtual public hearing. Please note that because of current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, the EPA cannot hold in-person public meetings at this time.

To request a virtual public hearing, contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* If requested, the virtual hearing will be held on January 20, 2022. The hearing will convene at 9:00 a.m. Eastern Time (ET) and will conclude at 3:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/dry-cleaning-facilities-national-perchloroethylene-air-emission.*

If a public hearing is requested, the EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/dry-cleaning-facilities-national-perchloroethylene-air-emission* or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* The last day to pre-register to speak at the hearing will be January 18, 2022. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/dry-cleaning-facilities-national-perchloroethylene-air-emission.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to *brian.storey@epa.gov.* The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/dry-cleaning-facilities-national-perchloroethylene-air-emission.* While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your needs by January 12, 2022. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2005–0155. All documents in the docket are listed in *https://www.regulations.gov/.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. With the exception of such material, publicly available docket materials are available electronically in *Regulations.gov.*

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2005–0155. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points

you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Due to public health concerns related to COVID–19, the Docket Center and Reading Room are open to the public by appointment only. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

The EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID–19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2005–0155. Note that written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Joseph Goffman,

Principal Deputy Assistant Administrator.

[FR Doc. 2021–28544 Filed 1–4–22; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 87, No. 3
Wednesday, January 5, 2022

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

Rural Utilities Service

[Docket No. RUS–21–ELECTRIC–0022]

Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request; Settlement of Debt Owed by Electric Borrowers

AGENCY: Rural Utilities Service, USDA.

ACTION: 60-Day notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the United States Department of Agriculture (USDA) Rural Utilities Service (RUS) announces its' intention to request an extension of a currently approved information collection and invites comments on this information collection.

DATES: Comments on this notice must be received by March 7, 2022 to be assured of consideration.

ADDRESSES: Comments may be submitted by the Federal eRulemaking Portal: Go to *https://www.regulations.gov* and, in the lower ''Search Regulations and Federal Actions'' box, select ''Rural Utilities Service'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select RUS–21–ELECTRIC–0022 to submit or view public comments and to view supporting and related materials available electronically. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.

FOR FURTHER INFORMATION CONTACT: MaryPat Daskal, Chief, Branch 1, Rural Development Innovation Center—Regulations Management Division, United States Department of Agriculture, 1400 Independence Avenue SW, South Building, Washington, DC 20250–1522. Telephone: (202) 720–7853. Email *MaryPat.Daskla@usda.gov.*

SUPPLEMENTARY INFORMATION:

The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies the following information collection that RUS is submitting to OMB as extension to an existing collection with Agency adjustment.

Title: 7 CFR Part 1717, Subpart Y, Settlement of Debt Owed by Electric Borrowers.

OMB Control Number: 0572–0116.

Expiration Date of Approval: March 31, 2022.

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

Estimate of Burden: Public reporting for this collection of information is estimated to average 1,000 hours per response.

Respondents: Not-for-profit institutions and other businesses.

Estimated Number of Respondents: 1.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 1,000 hours.

Abstract: The Rural Utilities Service makes mortgage loans and loan guarantees to electric systems to provide and improve electric service in rural areas pursuant to the Rural Electrification Act of 1936, as amended (7 U.S.C. 901 *et seq.*) (RE Act). This information collection requirement stems from passage of Public Law 104–127, on April 4, 1996, which amended section 331(b) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1921 *et seq.*) to extend to RUS the Secretary of Agriculture's authority to settle debts with respect to loans made or guaranteed by RUS. Only those electric borrowers that are unable to fully repay their debts to the Government and who apply to RUS for relief will be affected by this information collection. The collection will require only that information which is essential for determining: The need for debt settlement; the amount of relief that is needed; the amount of debt that can be repaid; the scheduling of debt repayment; and the range of opportunities for enhancing the amount of debt that can be recovered. The information to be collected will be similar to that which any prudent lender would require to determine whether debt settlement is required and the amount of relief that is needed. Since the need for relief is expected to vary substantially from case to case, so will the required information collection.

Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) the accuracy of the agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used;

(c) ways to enhance the quality, utility and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Copies of this information collection can be obtained from Kimble Brown, Rural Development Innovation Center—Regulations Management Division, at (202) 720–6780. Email: *Kimble.Brown@usda.gov.*

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Christopher McLean,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2021–28541 Filed 1–4–22; 8:45 am]

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DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–61–2021]

Foreign-Trade Zone (FTZ) 261—Alexandria, Louisiana, Authorization of Production Activity, Avant Organics LLC (Specialty Chemicals), Alexandria, Louisiana

On September 1, 2021, Avant Organics LLC submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 261, in Alexandria, Louisiana.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (86 FR 50324, September 8, 2021). On December 30, 2021, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: December 30, 2021.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2021–28557 Filed 1–4–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–093]

Refillable Stainless Steel Kegs From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020

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

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that certain producers and/or exporters made sales of refillable stainless steel kegs (kegs) at less than normal value and that one company had no shipments of subject merchandise during the period of review (POR) December 13, 2019, through November 30, 2020. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Michael Romani and Konrad Ptaszynski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0198 or (202) 482–6187, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 16, 2019, we published in the **Federal Register** an antidumping duty order on kegs from the People's Republic of China (China).[1] On December 2, 2020, we published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order*.[2] On February 4, 2021, based on timely requests for an administrative review, Commerce initiated the administrative review of the antidumping duty order on kegs.[3] The administrative review covers 30 companies, which includes the mandatory respondent, Guangzhou Ulix Industrial & Trading Co., Ltd. (Ulix).[4]

Scope of the Order

The products covered by this *Order* are refillable stainless steel kegs. A full description of the scope of the *Order* is provided in the Preliminary Decision Memorandum.[5]

Preliminary Determination of No Shipments

One company that received a separate rate in previous segments of the proceeding and is subject to this review did not have any exports of subject merchandise during the POR.[6] Based on information on the record, we preliminarily determine that Guangzhou Jingye Machinery Co., Ltd. (Jingye)'s had no shipments of subject merchandise during the POR. Consistent with our practice in non-market economy (NME) cases, we are not rescinding this review with respect to these companies but, rather, intend to complete the review and issue appropriate instructions to CBP based on the final results of the review.[7] For additional information regarding these preliminary determinations, *see* the Preliminary Decision Memorandum.

China-Wide Entity

Under Commerce's policy regarding the conditional review of the China-wide entity,[8] the China-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 China-wide entity in this review, the entity is not under review, and the entity's rate (*i.e.,* 77.13 percent) is not subject to change.[9] Aside from the no-shipment companies discussed above, Commerce considers all other companies for which a review was requested (none of which filed a separate rate application) listed in Appendix II to this notice, to be part of the China-wide entity.[10]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act).

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. 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 *https://access.trade.gov.* A list of topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. In addition,

[1] *See Refillable Stainless Steel Kegs from the Federal Republic of Germany and the People's Republic of China: Antidumping Duty Orders,* 84 FR 68405 (December 2, 2020) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 85 FR 77431 (December 2, 2020).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 8166 (February 4, 2021) (*Initiation Notice*).

[4] *See* Memorandum, ''Administrative Review of Refillable Stainless Steel Kegs from the People's Republic of China: Respondent Selection,'' dated May 12, 2021.

[5] *See* Memorandum, ''Refillable Stainless Steel Kegs from the People's Republic of China: Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* Memorandum ''U.S. Customs and Border Protection (CBP) Data Release,'' dated February 19, 2021 at Attachment 1; *see also* Memorandum ''U.S. Customs and Border Protection (CBP) Data Release,'' dated May 12, 2021 at Attachment 1.

[7] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011); *see also* the ''Assessment Rates'' section, below.

[8] *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).

[9] *See Order.*

[10] *See Initiation Notice,* 86 FR 8166, 8167 (January 11, 2018) (''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.''). *See* Appendix II for the list of companies that are subject to this administrative review that are considered to be part of the China-wide entity.

a complete version of the Preliminary Decision Memorandum can be found at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of the Administrative Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the administrative review covering the period December 13, 2019, through November 30, 2020:

Exporters	Weighted-average dumping margin (percent)
Guangzhou Ulix Industrial & Trading Co., Ltd	0.00

Disclosure

Commerce intends to disclose to parties to the proceeding the calculations performed for these preliminary results of review within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Public Comment

Because Commerce intends to request additional information after these preliminary results, interested parties will be provided an opportunity to submit written comments (case briefs) at a date to be determined by Commerce and rebuttal comments (rebuttal briefs) within seven days after the time limit for filing case briefs.[11] Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs.[12] Commerce modified certain of its requirements for serving documents containing business proprietary information until further notice.[13] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[14]

Unless the deadline is extended, Commerce intends to issue the final results of this review, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

Upon issuing the final results, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[15] If the preliminary results are unchanged for the final results, we will instruct CBP to apply an *ad valorem* assessment rate of 77.13 percent to all entries of subject merchandise during the POR which were exported by the companies listed in Appendix II of this notice. If Commerce determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the China-wide rate.[16]

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 will be effective upon publication of the final results of this review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For the subject merchandise exported by the company listed above that has a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this administrative review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice 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 these PORs. 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

Commerce is issuing and publishing the preliminary results of this review in accordance with sections 751(a)(1)(B), 751(a)(3) and 777(i) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: December 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, Performing the Non-Exclusive Functions and Duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Preliminary Determination of No Shipments
V. Discussion of the Methodology
VI. Adjustment Under Section 777A(f) of the Act
VII. Recommendation

Appendix II

Companies that are subject to this administrative review that are considered to be part of the China-wide entity are:

1. Equipmentimes (Dalian) E-Commerce Co., Ltd.
2. Jinan HaoLu Machinery Equipment Co., Ltd.
3. NDL Keg Qingdao Inc.
4. Ningbo BestFriends Beverage Containers Industry Co., Ltd.
5. Ningbo Chance International Trade Co., Ltd.

[11] *See* 19 CFR 351.309(c)(l)(ii) and 351.309(d)(l). Interested parties will be notified through ACCESS regarding the deadline for submitting case briefs; *see also* 19 CFR 351.303 (for general filing requirements); *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020)).

[12] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[13] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[14] *See* 19 CFR 351.309(c)(2) and (d)(2) and 19 CFR 351.303 (for general filing requirements).

[15] *See* 19 CFR 351.212(b)(1).

[16] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65695 (October 24, 2011).

6. Ningbo Direct Import & Export Co., Ltd.
7. Ningbo Haishu Direct Import and Export Trade Co., Ltd.
8. Ningbo Haishu Xiangsheng Metal Factory
9. Ningbo Hefeng Container Manufacturer Co., Ltd.
10. Ningbo Hefeng Kitchen Utensils Manufacture Co., Ltd.
11. Ningbo HGM Food Machinery Co., Ltd.
12. Ningbo Jiangbei Bei Fu Industry and Trade Co., Ltd.
13. Ningbo Kegco International Trade Co., Ltd.
14. Ningbo Minke Import & Export Co., Ltd.
15. Ningbo Sanfino Import & Export Co., Ltd.
16. Ningbo Shimaotong International Co., Ltd.
17. Ningbo Sunburst International Trading Co., Ltd.
18. Orient Equipment (Taizhou) Co., Ltd.
19. Penglai Jinfu Stainless Steel Products
20. Qingdao Henka Precision Technology Co., Ltd
21. Rain Star International Trading Dalian Co., Ltd.
22. Shandong Tiantai Beer Equipment Co., Ltd.
23. Shandong Tonsen Equipment Co., Ltd.
24. Sino Dragon Group, Ltd.
25. Wenzhou Deli Machinery Equipment Co.
26. Wuxi Taihu Lamps and Lanterns Co., Ltd.
27. Yantai Toptech Ltd.
28. Yantai Trano New Material Co., Ltd

[FR Doc. 2021–28558 Filed 1–4–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

United States-Mexico-Canada Agreement (USMCA), Article 10.12: Binational Panel Review: Notice of Request for Panel Review

AGENCY: United States Section, USMCA Secretariat, International Trade Administration, Department of Commerce.

ACTION: Notice of USMCA request for panel review.

SUMMARY: A Request for Panel Review was filed on behalf of the Government of Canada, the Governments of Alberta, British Columbia, New Brunswick, Ontario, Québec; Alberta Softwood Lumber Trade Council, British Columbia Lumber Trade Council, Conseil de l'Industrie Forestiere du Québec, Ontario Forest Industries Association; Canfor Corporation, Fontaine, Inc., J.D. Irving, Limited, Resolute FP Canada Inc., Tolko Marketing and Sales Ltd. and Tolko Industries Ltd., Gilbert Smith Forest Products, and West Fraser Mills Ltd. with the United States Section of the USMCA Secretariat on December 28, 2021, pursuant to USMCA Article 10.12. Panel Review was requested of the U.S. International Trade Administration's Final Results of the Countervailing Duty Administrative Review (2019) in Certain Softwood Lumber from Canada, which was published in the **Federal Register** on December 2, 2021. The USMCA Secretariat has assigned case number USA–CDA–2021–10.12–03 to this request.

FOR FURTHER INFORMATION CONTACT: Vidya Desai, Acting United States Secretary, USMCA Secretariat, Room 2061, 1401 Constitution Avenue NW, Washington, DC 20230, 202–482–5438.

SUPPLEMENTARY INFORMATION: Article 10.12 of Chapter 10 of USMCA provides a dispute settlement mechanism involving trade remedy determinations issued by the Government of the United States, the Government of Canada, and the Government of Mexico. Following a Request for Panel Review, a Binational Panel is composed to review the trade remedy determination being challenged and issue a binding Panel Decision. There are established USMCA *Rules of Procedure for Article 10.12 (Binational Panel Reviews),* which were adopted by the three governments for panels requested pursuant to Article 10.12(2) of USMCA which requires Requests for Panel Review to be published in accordance with Rule 40. For the complete Rules, please see *https://can-mex-usa-sec.org/secretariat/agreement-accord-acuerdo/usmca-aceum-tmec/rules-regles-reglas/article-article-articulo_10_12.aspx?lang=eng.*

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 44 no later than 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is January 27, 2022);

(b) A Party, an investigating authority or other interested person who does not file a Complaint but who intends to participate in the panel review shall file a Notice of Appearance in accordance with Rule 45 no later than 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is February 11, 2022);

(c) The panel review will be limited to the allegations of error of fact or law, including challenges to the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and to the procedural and substantive defenses raised in the panel review.

Dated: December 30, 2021.

Garrett Peterson,

International Trade Specialist, USMCA Secretariat.

[FR Doc. 2021–28581 Filed 1–4–22; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–985]

Xanthan Gum From the People's Republic of China: Amended Final Results of the Antidumping Duty Administrative Review; 2017–2018

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

SUMMARY: The Department of Commerce (Commerce) finds that the collapsed entity, Neimenggu Fufeng Biotechnologies Co., Ltd. (aka Inner Mongolia Fufeng Biotechnologies Co., Ltd.)/Shandong Fufeng Fermentation Co., Ltd./Xinjiang Fufeng Biotechnologies Co., Ltd. (collectively, Fufeng) is eligible for separate rate status. The period of review (POR) is July 1, 2017, through June 30, 2018.

DATES: Applicable January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Thomas Hanna, 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) 482–0835.

SUPPLEMENTARY INFORMATION:

Background

On September 3, 2021, Commerce published the amended preliminary results of this administrative review of the antidumping duty order on xanthan gum from the People's Republic of China (China).[1] This review covers the POR, July 1, 2017, through June 30, 2018.[2] No parties commented on the *Amended Preliminary Results.*

Scope of the Order

The product covered by the *Order* is dry xanthan gum, whether or not coated or blended with other products, from China (xanthan gum).[3]

[1] *See Xanthan Gum from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 78 FR 43143 (July 19, 2013) (*Order*).

[2] *See Xanthan Gum from the People's Republic of China: Amended Preliminary Results of the Antidumping Duty Administrative Review; 2017–2018,* 86 FR 49512 (September 3, 2021) (*Amended Preliminary Results*).

[3] For a complete description of the scope of the Order, see the Memorandum, ''Xanthan Gum from

Continued

Analysis

In the *Amended Preliminary Results,* Commerce determined that Fufeng was eligible for separate rate status and assigned it a dumping margin of zero percent, which is the dumping margin that Commerce calculated for both of the respondents individually examined in the review. As noted above, no parties commented on the *Amended Preliminary Results.* In these amended final results of review, we are making no change to and are adopting the decisions in the Preliminary Decision Memorandum. Specifically, we continue to find that Fufeng is eligible for separate rate status and that it is appropriate to assign Fufeng the zero percent dumping margin that Commerce calculated for both of the respondents that it individually examined in the review.

Assessment

Pursuant to section 751(a)(2)(C) of the Tariff Act of 1930 as amended (the Act), and 19 CFR 351.212(b), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by the amended final results of this review. Because Fufeng's weighted average dumping margin is zero percent, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[4] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these amended final results of review in the **Federal Register**.[5] 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 cash deposit rate for Fufeng is zero percent, which will be effective for shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as provided for by section 751(a)(2)(C) of the Act. For information regarding the cash deposit requirements established for other companies in this segment of the proceeding, *see* the *Final Results.*[6] This cash deposit requirement, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) 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 Orders

This notice also serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. 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 violation which is subject to sanction.

Notification to Interested Parties

These amended final results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1) and 19 CFR 351.221(b)(5).

Dated: December 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–28508 Filed 1–4–22; 8:45 am]

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the People's Republic of China: Decision Memorandum for the Amended Preliminary Results of the 2017–2018 Antidumping Duty Administrative Review'' (Preliminary Decision Memorandum).

[4] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[5] *See Notice of Discontinuation of Policy to Issue Liquidation Instructions After 15 Days in Applicable Antidumping and Countervailing Duty Administrative Proceedings,* 86 FR 3995 (January 15, 2021).

[6] *See Xanthan Gum from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2017–2018,* 84 FR 64831 (November 25, 2019).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–884]

Certain Hot-Rolled Steel Flat Products From the Republic of Korea: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

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

SUMMARY: The Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Korea (Korea) would be likely to lead to the continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Nathan James, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5305.

SUPPLEMENTARY INFORMATION:

Background

On October 3, 2016, Commerce published in the **Federal Register** the CVD order on hot-rolled steel from Korea.[1] On September 1, 2021, Commerce published the notice of initiation of the first sunset review of the CVD order on hot-rolled steel from Korea, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] Commerce received timely notices of intent to participate from Cleveland-Cliffs Inc. (Cleveland-Cliffs), United States Steel Corporation (U.S. Steel), California Steel Industries (CSI), Steel Dynamics Inc. (SDI), and Nucor Corporation (Nucor) (collectively, domestic interested parties).[3] The

[1] *See Certain Hot-Rolled Steel Flat Products from Brazil and the Republic of Korea: Amended Final Affirmative Countervailing Duty Determinations and Countervailing Duty Orders,* 81 FR 67960 (October 3, 2016).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 86 FR 48983 (September 1, 2021).

[3] *See* Cleveland-Cliffs' Letter, ''Five-Year ('Sunset') Review Of Countervailing Duty Order On Certain Hot-Rolled Steel Flat Products from the Republic of Korea: Notice Of Intent To Participate In Sunset Review,'' dated September 16, 2021; U.S. Steel's Letter, ''Five-Year ('Sunset') Review of Antidumping and Countervailing Duty Orders on Certain Hot-Rolled Steel Flat Products from the Republic of Korea: Notice of Intent to Participate,'' dated September 16, 2021; CSI/SDI's Letter, ''Notice of Intent to Participate in the First Five-Year Review of the Countervailing Duty Order on Hot-Rolled

domestic interested parties claimed interested party status under section 771(9)(C) of the Act, as domestic producers of hot-rolled steel.

On September 30, 2021, Commerce received a timely and adequate substantive response from the domestic interested parties.[4] We received no substantive responses from any other interested parties, including the Government of Korea, nor was a hearing requested. On October 20, 2021, Commerce notified the U.S. International Trade Commission that we did not receive an adequate substantive response from any respondent interested parties.[5] As a result, pursuant to 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the CVD order on hot-rolled steel from Korea.

Scope of the Order

The product covered by this order is hot-rolled steel. For a full description of the scope, *see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

All issues raised in this sunset review are addressed in the accompanying Issues and Decision Memorandum, which is hereby adopted by this notice. A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice.

The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, Commerce determines that revocation of the order would be likely to lead to the continuation or recurrence of countervailable subsidies at the rates listed below:

Producer/exporter	Subsidy rate (percent)
POSCO	41.64
Hyundai Steel Co., Ltd	3.98
All Others	3.89

Notification Regarding Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. 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 these results in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: December 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, Performing the Non-Exclusive Functions and Duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Issues Addressed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. History of the Order
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Countervailable Subsidies
  2. Net Countervailable Subsidy Rates Likely to Prevail
  3. Nature of the Subsidies
VII. Final Results of Review
VIII. Recommendation

[FR Doc. 2021–28556 Filed 1–4–22; 8:45 am]

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Steel Flat Products from Korea,'' dated September 16, 2021; and Nucor's Letter, ''Hot-Rolled Steel Flat Products from the Republic of Korea: Notice of Intent to Participate in Sunset Review,'' dated September 16, 2021.

[4] *See* Domestic Interested Parties' Letter, ''Substantive Response to Notice of Initiation of Sunset Review,'' dated September 30, 2021.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on September 1, 2021,'' dated October 20, 2021.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Countervailing Duty Order on Certain Hot-Rolled Steel Flat Products from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

DEPARTMENT OF COMMERCE

International Trade Administration

United States-Mexico-Canada Agreement (USMCA), Article 10.12: Binational Panel Review: Notice of Request for Panel Review

AGENCY: United States Section, USMCA Secretariat, International Trade Administration, Department of Commerce.

ACTION: Notice of USMCA Request for Panel Review.

SUMMARY: A Request for Panel Review was filed on behalf of the Government of Canada; Conseil de l'Industrie Forestiere du Québec, Ontario Forest Industries Association; Canfor Corporation, Fontaine, Inc., Resolute FP Canada Inc., Tolko Marketing and Sales Ltd., Tolko Industries Ltd., Gilbert Smith Forest Products, and West Fraser Mills Ltd. with the United States Section of the USMCA Secretariat on December 28, 2021, pursuant to USMCA Article 10.12. Panel Review was requested of the U.S. International Trade Administration's Final Results of the Antidumping Duty Administrative Review (2019) in Certain Softwood Lumber from Canada, which was published in the **Federal Register** on December 2, 2021. The USMCA Secretariat has assigned case number USA–CDA–2021–10.12–04 to this request.

FOR FURTHER INFORMATION CONTACT: Vidya Desai, Acting United States Secretary, USMCA Secretariat, Room 2061, 1401 Constitution Avenue NW, Washington, DC 20230, 202–482–5438.

SUPPLEMENTARY INFORMATION: Article 10.12 of Chapter 10 of USMCA provides a dispute settlement mechanism involving trade remedy determinations issued by the Government of the United States, the Government of Canada, and the Government of Mexico. Following a Request for Panel Review, a Binational Panel is composed to review the trade remedy determination being challenged and issue a binding Panel Decision. There are established USMCA *Rules of Procedure for Article 10.12 (Binational Panel Reviews),* which were adopted by the three governments for panels requested pursuant to Article 10.12(2) of USMCA which requires Requests for Panel Review to be published in accordance with Rule 40. For the complete Rules, please see *https://can-mex-usa-sec.org/secretariat/agreement-accord-acuerdo/usmca-aceum-tmec/rules-regles-reglas/article-article-articulo_10_12.aspx?lang=eng.*

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 44 no later than 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is January 27, 2022);

(b) A Party, an investigating authority or other interested person who does not

file a Complaint but who intends to participate in the panel review shall file a Notice of Appearance in accordance with Rule 45 no later than 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is February 11, 2022);

(c) The panel review will be limited to the allegations of error of fact or law, including challenges to the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and to the procedural and substantive defenses raised in the panel review.

Dated: December 30, 2021.

Garrett Peterson,

International Trade Specialist, USMCA Secretariat.

[FR Doc. 2021–28587 Filed 1–4–22; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB690]

Pacific 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 Pacific Fishery Management Council's (Pacific Council) Groundfish Management Team (GMT) will hold a work session that is open to the public.

DATES: The online meeting will be held Tuesday, January 18, 2022, through Friday, January 21, 2022, starting at 8 a.m. Pacific Standard Time and ending when business has been completed for each day.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Todd Phillips, Staff Officer, Pacific Council; telephone: (503) 820–2426.

SUPPLEMENTARY INFORMATION: The primary purpose of the GMT meeting is to develop and review analyses for the 2023–24 harvest specifications and routine management measures for consideration by the Pacific Council at its March and April 2022 meetings. The GMT will also consider new management measures proposed by the Pacific Council at their November 2021 meeting, such as potential changes to shortbelly rockfish management and reconfiguration of Groundfish Conservation Area boundaries. The GMT may also address other groundfish, Pacific halibut, and administrative agenda items scheduled for the March Pacific Council meeting. A detailed agenda will be available on the Pacific Council's website prior to the meeting. No management actions will be decided by the GMT.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document 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

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

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

Dated: December 30, 2021.

Diane M. DeJames-Daly,

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

[FR Doc. 2021–28592 Filed 1–4–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB693]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of webconference.

SUMMARY: The North Pacific Fishery Management Council (Council) Bering Sea Fishery Ecosystem Plan Climate Change Taskforce will meet January 18, 2022 through January 20, 2022.

DATES: The meeting will be held on Tuesday, January 18, 2022, through Thursday, January 20, 2022, from 8 a.m. to 4 p.m., Alaska Time.

ADDRESSES: The meeting will be a webconference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/2734.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Dr. Diana Stram, Council staff; phone: (907) 271–2809 and email: *diana.stram@noaa.gov.* For technical support, please contact our administrative staff; email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, January 18, 2022 Through Thursday, January 20, 2022

The agenda will include: (a) Key risks; (b) adaptation tools—feasibility and effectiveness evaluation; (c) conceptual model update; (d) continued indicator development; (e) status and development of climate ready-assessment; and (f) other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2734* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2734.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2734.*

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

Dated: December 30, 2021.

Diane M. DeJames-Daly,

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

[FR Doc. 2021–28593 Filed 1–4–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB692]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of webconference.

SUMMARY: The North Pacific Fishery Management Council (Council) Bering Sea Fishery Ecosystem Plan Local Knowledge, Traditional Knowledge, and Subsistence Taskforce (LKTKS) will be held January 20, 2022 through January 21, 2022.

DATES: The meeting will be held on Thursday, January 20, 2022, and on Friday, January 21, 2022, from 9 a.m. to 3 p.m., Alaska Time.

ADDRESSES: The meeting will be a webconference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/2735.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Kate Haapala Council staff; phone: (907) 271–2809 and email: *kate.haapala@noaa.gov.* For technical support, please contact our administrative staff; email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Thursday, January 20, 2022 and Friday, January 21, 2022

The LKTKS will discuss tools for identifying and cataloging LK, TK, and subsistence information like a search engine and futher develop the protocol. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2735* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2735.* If you are attending the meeting in-person please note that all attendees will be required to wear a mask.

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2735* by 5 p.m. Alaska time on Wednesday, January 19, 2022. An opportunity for oral public testimony will also be provided during the meeting.

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

Dated: December 30, 2021.

Diane M. DeJames-Daly,

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

[FR Doc. 2021–28602 Filed 1–4–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–T–2021–0055]

Trademarks Administrative Sanctions Process

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: As part of the United States Patent and Trademark Office's (USPTO or Office) continuing efforts to protect the integrity of the U.S. trademark register, the Commissioner for Trademarks (Commissioner) has established an administrative process for investigating submissions filed with the USPTO in trademark matters that appear to violate the Trademark Rules of Practice, including the rules concerning signatures, certificates, and representation of others in trademark matters before the USPTO (collectively, the USPTO rules), and/or the USPTO website's Terms of Use; and imposing sanctions, as appropriate.

DATES: Comments must be received by January 20, 2022 to ensure consideration.

ADDRESSES: Comments regarding this notice should be sent to *TMFRNotices@uspto.gov* with the subject line ''Trademarks Administrative Sanctions Process.'' If a submission by email is not feasible (*e.g.,* due to a lack of access to a computer and/or the internet), please contact the USPTO for special instructions using the contact information provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

FOR FURTHER INFORMATION CONTACT: Robert Lavache, Office of the Deputy Commissioner for Trademark Examination Policy, at 571–272–5881 or *TMFRNotices@uspto.gov.*

SUPPLEMENTARY INFORMATION: As part of the USPTO's continuing efforts to protect the integrity of the U.S. trademark register, the Commissioner has established an administrative process to investigate improper submissions filed with the USPTO in trademark matters. The USPTO Director has the authority to investigate submissions that appear to violate the USPTO rules and/or the USPTO website's Terms of Use and impose sanctions or actions as deemed appropriate. *See* 37 CFR 11.18. Sanctions may include terminating proceedings. *See* 37 CFR 11.18(c)(5). Pursuant to 35 U.S.C. 3(a)–(b), the Director has explicitly delegated to the Commissioner for Trademarks the authority to impose such sanctions or actions permitted under 37 CFR 11.18(c), as deemed appropriate in trademark matters, and to otherwise exercise the Director's authority in trademark-related matters. The Director has also provided that such authority may be further delegated by the Commissioner. *See generally* Delegation of Authority to Issue Sanctions in Trademark Proceedings (January 14, 2020) [1] and Trademark Manual of Examining Procedure § 1701.

To promote transparency regarding the sanctions process for applicants or registrants who may be impacted by sanctions, as well as third parties who may be concerned about a particular application or registration, the USPTO will place documents associated with the process, including administrative orders to show cause and orders for sanctions regarding particular applications or registrations, in the electronic file record, which can be viewed by the public in the USPTO Trademark Status and Document Retrieval (TSDR) database. Further, examination may be suspended while the application is subject to a pending administrative investigation or order, and, if so, the TSDR record will reflect that as well.

I. Reporting and Investigation of Suspicious Filings

The administrative process begins when the USPTO identifies or otherwise learns of a suspicious submission in connection with a trademark application or registration, based on information communicated by internal sources, such as examining attorneys and data analytics personnel, or through external sources, such as Letters of

[1] A copy of the January 14, 2020 delegation of authority is available upon request. Please contact the USPTO using the contact information provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Protest, the *TMScams@uspto.gov* mailbox, law enforcement, or media reports.

The USPTO will investigate suspicious submissions, and any related submissions, to determine whether they: (1) Appear to violate the USPTO rules and/or the USPTO website's Terms of Use, and (2) are part of an improper filing scheme. These determinations are made using filing data from the suspicious submissions and any related submissions, as well as any other information and evidence available to the USPTO.

Once the USPTO initiates an investigation, the relevant application(s) may be removed from examination status to ensure that it does not move forward to approval for publication or registration while the administrative process is ongoing. In such cases, the USPTO will update the prosecution history to indicate that the application is suspended pending administrative review. In addition, a suspension letter will issue to all correspondence email addresses in the electronic record, as appropriate. When an application is suspended on this basis, any associated deadlines are also suspended, and the applicant will not be able to make any electronic submissions other than: (1) An express abandonment, (2) a withdrawal of attorney, or (3) a petition to the Director under Rule 2.146. 37 CFR 2.146. Thus, an applicant would be able to request permission to make a further submission by filing a petition to the Director under Rule 2.146. If an investigation ends without the issuance of an administrative order, the suspension will be lifted, and the application will then be assigned to an examining attorney for examination in the normal course or, if examination had begun prior to suspension, returned to the assigned examining attorney, who will issue a new Office action resetting any response deadline.

II. Show Cause Order

If, upon investigation, the USPTO identifies conduct that illustrates violations of the USPTO rules and/or the USPTO website's Terms of Use, particularly conduct that indicates an intent to circumvent the USPTO rules, the Office may issue an order to show cause why sanctions should not be imposed on individuals or entities involved, which may include the applicants or registrants themselves, or third parties involved in an improper filing scheme. A copy of the order to show cause will be placed in the electronic records of the affected applications or registrations.

The show cause order will inform the relevant parties of the conduct that indicates violations of the USPTO rules and/or the USPTO website's Terms of Use, identify the affected application(s) or registration(s), and specify the proposed action or sanction the USPTO deems appropriate, which may include terminating all involved applications, striking a submission, precluding a party from appearing before the USPTO in trademark matters, and/or deactivating all relevant *uspto.gov* accounts. The order will require the parties to respond by a certain date to explain why the USPTO should not impose the proposed sanctions. The USPTO will consider any timely response in determining whether to impose sanctions. Resubmitting documents or appointing a new attorney will not avoid the imposition of sanctions. Petitions such as those filed under 37 CFR 2.146 are not appropriate during the investigation or response period unless the USPTO made a mistake in including a specific application or registration in the show cause order. Furthermore, applicants and registrants are reminded that they are responsible for actions or omissions made by their representatives on their behalf. Moreover, any misrepresentation or deceit on the part of a representative does not necessarily constitute an ''extraordinary circumstance'' under 37 CFR 2.146 or 2.148.

III. Order for Sanctions

The USPTO will issue a final decision that includes an order for sanctions, if appropriate. The order will indicate what sanctions were deemed appropriate to address the improper conduct, and will identify the application(s) or registration(s) subject to the sanctions. For transparency of process, a copy of the decision will be included in the TSDR record of the relevant application(s) or registration(s).

For orders that include the sanction of termination and involve pending applications, the USPTO will terminate the involved applications and will update the USPTO's electronic records to include an appropriate entry in the application prosecution history in TSDR to indicate that the application was terminated upon the entry of sanctions. Generally, applicants may not revive a terminated application unless the applicant can demonstrate that the USPTO erred in including the application in the order for sanctions. The applicant should file a new application to seek registration of the mark that was the subject of a terminated application.

For orders that include the sanction of termination and involve registrations that issued before the administrative sanctions process was initiated, the USPTO does not intend to terminate the registrations, but will update the USPTO's electronic records to include an appropriate entry in the prosecution history indicating that the registration was subject to an order for sanctions. Affected registrants should note that findings made in the sanctions order may affect the underlying validity of the registration. In addition, the USPTO will consider a sanctions order that includes the sanction of termination to be a final decision adverse to the owner's right to keep a mark on the register under section 15 of the Trademark Act of 1946, 15 U.S.C. 1065. Therefore, owners of such registrations may wish to file a new application for the mark.

The USPTO may take additional actions to enforce orders for sanctions in cases where a sanctioned actor continues to violate the USPTO rules and/or the USPTO website's Terms of Use.

Andrew Hirshfeld,

Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2021–28536 Filed 1–4–22; 8:45 am]

BILLING CODE 3510–16–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: RP22–438–000.
Applicants: ETC Tiger Pipeline, LLC.
Description: § 4(d) Rate Filing: NRA Amendment No 2—Chesapeake to be effective 1/1/2022.
Filed Date: 12/28/21.
Accession Number: 20211228–5081.
Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: RP22–439–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 1–1–2022 to be effective 1/1/2022.
Filed Date: 12/29/21.
Accession Number: 20211229–5033.
Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: RP22–440–000.

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate—Northern Utilities 210363 Release eff 1–1–2022 to be effective 1/1/2022.

Filed Date: 12/29/21.

Accession Number: 20211229–5043.

Comment Date: 5 p.m. ET 1/10/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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: December 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–28551 Filed 1–4–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–13–000.

Applicants: Howard Wind LLC.

Description: Supplement to November 3, 2021 Application for Authorization Under Section 203 of the Federal Power Act of Howard Wind LLC.

Filed Date: 12/28/21.

Accession Number: 20211228–5244.

Comment Date: 5 p.m. ET 1/7/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2488–022.

Applicants: Oasis Power Partners, LLC.

Description: Notice of Non-Material Change in Status of Oasis Power Partners, LLC.

Filed Date: 12/28/21.

Accession Number: 20211228–5148.

Comment Date: 5 p.m. ET 1/18/22.

Docket Numbers: ER15–2013–013; ER19–2250–005.

Applicants: TrailStone Energy Marketing, LLC, Talen Energy Marketing, LLC.

Description: Triennial Market Power Analysis for Southwest Region of Talen Energy Marketing, LLC, et al.

Filed Date: 12/29/21.

Accession Number: 20211229–5173.

Comment Date: 5 p.m. ET 2/28/22.

Docket Numbers: ER17–1370–007; ER16–581–008; ER16–582–008; ER16–2271–007; ER19–828–003; ER20–539–003; ER20–1338–002; ER20–2505–001; ER21–1254–002; ER21–2204–001; ER21–2279–001.

Applicants: Iron Star Wind Project, LLC, ENGIE Power & Gas LLC, Genbright LLC, Triple H Wind Project, LLC, King Plains Wind Project, LLC, East Fork Wind Project, LLC, Solomon Forks Wind Project, LLC, ENGIE Resources LLC, ENGIE Retail, LLC, ENGIE Portfolio Management, LLC, ENGIE Energy Marketing NA, Inc.

Description: Triennial Compliance Filing—Southwest Power Pool Region of the ENGIE Southwest Power Pool MBR Sellers.

Filed Date: 12/28/21.

Accession Number: 20211228–5158.

Comment Date: 5 p.m. ET 2/28/22.

Docket Numbers: ER21–1369–001; ER21–1371–001; ER21–1373–002; ER21–1376–002.

Applicants: Sanborn Solar 1A, LLC, Edwards Solar 1A, LLC, Edwards Sanborn Storage II, LLC, Edwards Sanborn Storage I, LLC.

Description: Notice of Non-Material Change in Status of Edwards Sanborn Storage I, LLC, et al.

Filed Date: 12/28/21.

Accession Number: 20211228–5229.

Comment Date: 5 p.m. ET 1/18/22.

Docket Numbers: ER22–736–000.

Applicants: System Energy Resources, Inc.

Description: § 205(d) Rate Filing: SERI Depreciation Filing to be effective 3/1/2022.

Filed Date: 12/28/21.

Accession Number: 20211228–5140.

Comment Date: 5 p.m. ET 1/25/22.

Docket Numbers: ER22–737–000.

Applicants: American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: American Transmission Systems, Incorporated submits tariff filing per 35.13(a)(2)(iii: ATSI Submits Revised IA No. 3993 to be effective 2/28/2022.

Filed Date: 12/29/21.

Accession Number: 20211229–5006.

Comment Date: 5 p.m. ET 1/19/22.

Docket Numbers: ER22–738–000.

Applicants: Jersey Central Power & Light Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Jersey Central Power & Light Company submits tariff filing per 35.13(a)(2)(iii: JCPL Submits IA No. 5944 to be effective 2/28/2022.

Filed Date: 12/29/21.

Accession Number: 20211229–5007.

Comment Date: 5 p.m. ET 1/19/22.

Docket Numbers: ER22–739–000.

Applicants: Jersey Central Power & Light Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Jersey Central Power & Light Company submits tariff filing per 35.13(a)(2)(iii: JCPL Submits IA No. 5945 to be effective 2/28/2022.

Filed Date: 12/29/21.

Accession Number: 20211229–5009.

Comment Date: 5 p.m. ET 1/19/22.

Docket Numbers: ER22–741–000.

Applicants: Orange and Rockland Utilities, Inc., New York Independent System Operator, Inc.

Description: § 205(d) Rate Filing: Orange and Rockland Utilities, Inc. submits tariff filing per 35.13(a)(2)(iii: Joint Section 205 filing of TPIA among NYISO, O&R and Transco SA No. 2663 to be effective 12/15/2021.

Filed Date: 12/29/21.

Accession Number: 20211229–5063.

Comment Date: 5 p.m. ET 1/19/22.

Docket Numbers: ER22–742–000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Alligator Creek Solar LGIA Filing to be effective 12/14/2021.

Filed Date: 12/29/21.

Accession Number: 20211229–5089.

Comment Date: 5 p.m. ET 1/19/22.

Docket Numbers: ER22–743–000.

Applicants: Alabama Power Company.

Description: Tariff Amendment: Mitchell County Solar LGIA Termination Filing to be effective 12/29/2021.

Filed Date: 12/29/21.

Accession Number: 20211229–5090.

Comment Date: 5 p.m. ET 1/19/22.

Docket Numbers: ER22–744–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Service Agreement No. 902 to be effective 12/22/2020.

Filed Date: 12/29/21.

Accession Number: 20211229–5128.

Comment Date: 5 p.m. ET 1/19/22.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH22–4–000.

Applicants: Ullico Inc.

Description: Ullico Inc. submits FERC 65–A Exemption Notification.

Filed Date: 12/29/21.

Accession Number: 20211229–5172.

Comment Date: 5 p.m. ET 1/19/22.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–28550 Filed 1–4–22; 8:45 am]

BILLING CODE 6717–01–P

FARM CREDIT ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 9:00 a.m., Thursday, January 13, 2022.

PLACE: Because of the COVID–19 pandemic, the public may only virtually attend the open portions of this meeting. If you would like to virtually attend, at least 24 hours in advance, visit *FCA.gov,* select ''Newsroom,'' and then select ''Events.'' From there, access the linked ''Instructions for board meeting visitors.''

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Portions Open to the Public

- Approval of December 9, 2021 minutes
- Small Association Workgroup
- Bookletter-068 Tier 1/Tier 2 Capital Framework Guidance (Revised)
- OIG Year in Review and Report on FY 2021 Financial Statement Audit

Portions Closed to the Public

- Executive Session with Financial Statement Auditors [1]
- Report on FY 2021 FISMA Audit [2]

CONTACT PERSON FOR MORE INFORMATION: If you need more information, need assistance for accessibility reasons, or have questions, contact Ashley Waldron, Secretary to the Board. Telephone: 703–883–4009. TTY: 703–883–4056.

Ashley Waldron,

Secretary to the Board.

[FR Doc. 2022–00003 Filed 1–3–22; 4:15 pm]

BILLING CODE 6705–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Senior Executive Service; Performance Review Board

AGENCY: Federal Mine Safety and Health Review Commission.

ACTION: Notice.

SUMMARY: This notice announces the appointment of the members of the Performance Review Board (PRB) for the Federal Mine Safety and Health Review Commission. The PRB reviews the performance appraisals of career and non-career senior executives. The PRB makes recommendations regarding proposed performance appraisals, ratings, bonuses, pay adjustments, and other appropriate personnel actions.

DATES: Applicable on January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Lisa Boyd, Executive Director, Federal Mine Safety and Health Review Commission, (202) 434–9910.

SUPPLEMENTARY INFORMATION: This Notice announces the appointment of the following primary and alternate members to the Federal Mine Safety and Health Review Commission PRB:

Primary Members

Michael Cundiff, *Mike.Cundiff@fiscal.treasury.gov*, Office of Shared Services

Jason Hill, *Jason.Hill@fiscal.treasury.gov*, Office of Shared Services

Marisa Anthony, *Marisa.Anthony@fiscal.treasury.gov*, Fiscal Accounting Operations

Alternate Members

None.

[1] Session Closed-Exempt pursuant to 5 U.S.C. Section 552b(c)(2).

[2] Session Closed-Exempt pursuant to 5 U.S.C. Section 552b(c)(2).

Authority: 5 U.S.C. 4313(c)(4).

Lisa Boyd,

Executive Director, Federal Mine Safety and Health Review Commission.

[FR Doc. 2021–28535 Filed 1–4–22; 8:45 am]

BILLING CODE 6735–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the 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 January 20, 2022.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *The E&N–AMG National Trust Bank Irrevocable Trust fbo Michael S. Wright; the E&N–AMG National Trust Bank Irrevocable Trust fbo Jacob T. Wright; the E&N–AMG National Trust Bank Irrevocable Trust fbo James E. Wright; the NSW–AMG National Trust Bank Irrevocable Trust fbo Michael S. Wright; the NSW–AMG National Trust Bank Irrevocable Trust fbo David M. Wright; the NSW–AMG National Trust Bank Irrevocable Trust fbo Jacob T. Wright; the NSW–AMG National Trust Bank Irrevocable Trust fbo James E. Wright; all of Castle Pines, Colorado; Michael S. Wright, Castle Pines,*

Colorado, individually and as trustee of all of the trusts listed; the Bergmann 2011 Irrevocable Trust Under Agreement, Alma F. Bergmann, trustee, both of Bow Mar, Colorado; the Community Property Trusts under the Michael Dean Bergmann and Alma F. Bergmann Declaration of Trust, Alma F. Bergmann and Michael D. Bergmann, as co-trustees, all of Bow Mar, Colorado; Earl L. Wright, Castle Pines, Colorado; Nathan Bergmann and Kelley Bergmann, both of Denver, Colorado; to form the Wright/Bergmann group, a group acting in concert, to retain voting shares of AMG National Corp., Greenwood Village, Colorado, and thereby indirectly retain voting shares of AMG National Trust Bank, Boulder, Colorado.

B. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Scott A. Erickson and Matthew P. Bock, both of Sioux Falls, South Dakota:* To retain voting shares of Leackco Bank Holding Company, Inc., Huron, South Dakota, and thereby indirectly retain voting shares of American Bank & Trust, Wessington Springs, South Dakota.

Additionally, the 2021 Jeffory A. Erickson Irrevocable Trust No. 5 (Erickson Trust 5), the 2021 Jeffory A. Erickson Irrevocable Trust No. 6 (Erickson Trust 6), the 2021 Jeffory A. Erickson Irrevocable Trust No. 7 (Erickson Trust 7), and the 2021 Jeffory A. Erickson Irrevocable Trust No. 8 (Erickson Trust 8), and collectively, the ''New Erickson Trusts'', Matthew P. Bock, as trust protector of the New Erickson Trusts, Scott A. Erickson as investment trust advisor of the New Erickson Trusts and trustee of Erickson Trust 5, 6 and 8, and Jamie L. Brown as trustee of Erickson Trust 7, all of Sioux Falls, South Dakota; to join the Erickson family shareholder group, a group acting in concert, by retaining voting shares of Leackco Bank Holding Company, Inc., and thereby indirectly retaining voting shares of American Bank & Trust.

Finally, the 2021 Preston B. Steele Irrevocable Trust No. 1, the 2021 Preston B. Steele Irrevocable Trust No. 2, and the 2021 Preston B. Steele Irrevocable Trust No. 3, collectively, ''the New Steele Trusts'', Matthew P. Bock, as investment trust advisor and trustee of the New Steele Trusts, and Scott A. Erickson, as trust protector of the New Steele Trusts, all of Sioux Falls, South Dakota; to join the Steele family shareholder group, a group acting in concert, by retaining voting shares of Leackco Bank Holding Company, Inc., and thereby indirectly retaining voting shares of American Bank & Trust.

Board of Governors of the Federal Reserve System, December 30, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–28573 Filed 1–4–22; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

[File No. P222100]

HISA Racetrack Safety

AGENCY: Federal Trade Commission.

ACTION: Notice of Horseracing Integrity and Safety Authority (HISA) proposed rule; request for public comment.

SUMMARY: The Horseracing Integrity and Safety Act of 2020 recognizes a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority, which is charged with developing proposed rules on a variety of subjects. Those proposed rules and later proposed rule modifications take effect only if approved by the Federal Trade Commission. The proposed rules and rule modifications must be published in the **Federal Register** for public comment. Thereafter, the Commission has 60 days from the date of publication to approve or disapprove the proposed rule or rule modification. The Authority submitted to the Commission a proposed rule on Racetrack Safety on December 6, 2021. The Office of the Secretary of the Commission determined that the proposal complied with the Commission's rule governing such submissions. This document publicizes the Authority's proposed rule text and explanation, and it seeks public comment on whether the Commission should approve or disapprove the proposed rule.

DATES: If approved, the HISA proposed rule would have an effective date of July 1, 2022. Comments must be received on or before January 19, 2022.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Comment Submissions part of the **SUPPLEMENTARY INFORMATION** section below. Write ''HISA Racetrack Safety'' on your comment and file your comment online at *https://www.regulations.gov* under docket number FTC–2021–0076. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex B), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Austin King (202–326–3166), Associate General Counsel for Rulemaking, Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

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Background

The Horseracing Integrity and Safety Act of 2020 [1] recognizes a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority, which is charged with developing proposed rules on a variety of subjects. Those proposed rules and later proposed rule modifications take effect only if approved by the Federal Trade Commission.[2] The proposed rules and rule modifications must be published in the **Federal Register** for public comment.[3] Thereafter, the Commission has 60 days from the date of publication to approve or disapprove the proposed rule or rule modification.[4]

The Authority submitted to the Commission a proposed rule on Racetrack Safety on December 6, 2021. The Office of the Secretary of the Commission determined that the proposal complied with the Commission's rule governing such submissions.[5]

Pursuant to Section 3053(a) of the Horseracing Integrity and Safety Act of 2020 (the ''Act'') and Federal Trade Commission Rule 1.142, notice is hereby given that, on December 6, 2021, the Horseracing Integrity and Safety Authority (''HISA'' or the ''Authority'') filed with the Federal Trade Commission (the ''Commission'') the proposed Racetrack Safety rule and supporting documentation as described in Items I, II, III, IV, and X below, which Items have been prepared by HISA, as well as the Appendix. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization's Statement of the Background, Purpose of, and Statutory Basis for, the Proposed Rule

a. Background and Purpose

The Horseracing Integrity and Safety Act of 2020 (''Act'') recognizes that a national uniform set of standards for racetrack safety will apply to a broad range of racetracks with widely varying environments in terms of economic structure, race dates, physical attributes, prevailing weather conditions, and other factors. As such, the Act directs the Horseracing Integrity and Safety Authority (''HISA'' or the ''Authority'') to develop and implement ''training and racing safety standards and protocols taking into account regional differences and the character of differing racing facilities.'' The proposed Racetrack Safety rule utilizes a practical approach to this implementation, recognizing that some practices are already in place or can be put in place immediately, while others will require adequate time and resources to implement.

As directed in Section 3052(c)(2) of the Act, the Authority's Racetrack Safety Standing Committee (the ''Committee'') was constituted and undertook developing a comprehensive proposed rule setting forth a uniform set of training and racing safety standards and protocols. The Committee spent hundreds of hours in reviewing and analyzing existing standards and research, meeting and discussing key human and horse safety and welfare issues. The Racetrack Safety Standing Committee comprises four independent members and three industry members:

Susan Stover from California is an industry director on the HISA Board of Directors and chairs the Racetrack Safety Standing Committee of the Authority. Dr. Stover is a professor of surgical and radiological science at the University of California, Davis and an expert in clinical equine surgery and lameness. Her research investigates the prevalence, distribution and morphology of equine stress fractures, risk factors and injury prevention, as well as the impact of equine injuries on human welfare.

Lisa Fortier is an independent member from New York. Fortier is the James Law Professor of Surgery, Equine Park Faculty Director and associate chair for Graduate Education and Research at the Cornell University College of Veterinary Medicine. Her primary clinical and translational research interests are in equine orthopedic surgery, tendonitis, arthritis and regenerative medicine.

Peter Hester is an independent member from Kentucky. Hester is an orthopedic surgeon specializing in sports medicine and previously worked for equine veterinary surgeon William Reed at Belmont Park.

Paul Lunn is an independent member from North Carolina. Lunn is dean of the College of Veterinary Medicine at North Carolina State University. Previously, he was a professor and administrator at Colorado State University and the University of Wisconsin. Lunn's scholarly interests are in equine immunology and infectious disease.

Carl Mattacola is an independent member from North Carolina. Mattacola is dean of the University of North Carolina, Greensboro School of Health and Human Sciences. Prior to this, he was associate dean of academic and faculty affairs for the College of Health Sciences at the University of Kentucky. Mattacola's research has focused on neuromuscular, postural and functional considerations in the treatment and rehabilitation of lower extremity injury.

Glen Kozak is an industry member from New York. Kozak is senior vice president of operations and capital projects for the New York Racing Association's (NYRA) facility and track operations, which include Belmont Park, Saratoga Race Course, Aqueduct Racetrack and others. Prior to joining NYRA, Kozak worked for the Maryland Jockey Club as vice president of facilities and racing surfaces.

John Velazquez is an industry member from New York. Velazquez is one of the most accomplished and respected jockeys in the history of horse racing, having won almost 6,250 races. He is North America's all-time leading money-earning jockey and holds the record for most graded stakes wins. He is a board member of the Permanently Disabled Jockeys' Fund and co-chairman of the Jockeys' Guild. He was inducted into the National Museum of Racing and Hall of Fame in 2012.

Beginning in September 2021, HISA representatives shared various working drafts with several interested stakeholders for input as the rule proposals were being developed. Those interested stakeholders included: Racing Officials Accreditation Program; Racing Medication and Testing Consortium (Scientific Advisory Committee); Water Hay Oats Alliance; National Thoroughbred Racing Association; The Jockey Club; The Jockeys' Guild; Thoroughbred Racing Association; Arapahoe Park; Grants Pass Downs; Arizona Downs; Colonial Downs; Association of Racing Commissioners International (Model Rules Committee); California Horse Racing Board; Kentucky Racing Commission; Delaware Racing Commission; Maryland Racing Commission; National Horsemen's Benevolent and Protective Association; Thoroughbred Horsemen's Association Mid-Atlantic Safety Coalition; Thoroughbred Owner's and Breeders Association; Kentucky Thoroughbred Association; American Association of Equine Practitioners; American Veterinary Medical Association; North American Association of Racetrack Veterinarians; Thoroughbred Safety Coalition; New York Racing Association, Stronach Racing Group (5 Thoroughbred racetracks); Churchill Downs (6 Thoroughbred racetracks); Breeders' Cup; Keeneland; and Del Mar.

[1] 15 U.S.C. 3051 through 3060.

[2] 15 U.S.C. 3053(b)(2).

[3] 15 U.S.C. 3053(b)(1).

[4] 15 U.S.C. 3053(c)(1).

[5] 16 CFR 1.140–1.144; *see also* Fed. Trade Comm'n, Procedures for Submission of Rules Under the Horseracing Integrity and Safety Act, 86 FR 54819 (Oct. 5, 2021).

Additionally, videoconferences were conducted with all state racing commissions (except Arkansas), and a number of industry organizations.

Likewise, prior to finalization of the submissions by HISA to the Commission, working drafts of proposed regulations were made available to the public for review and comment on the HISA website at *https://www.hisausregs.org/.* The website received 1,864 unique visitors, 3,097 total visits, 162 registered users, 137 regulation downloads, and 360 comments. All submitted comments were catalogued by HISA.

With the review, input, and ultimate approval of the Authority's Board of Directors, the proposed Racetrack Safety rule would: (1) Put in place a mandatory national accreditation program for racetracks that utilizes the best practices developed to date for the safety and welfare of racehorses and human participants in horse racing and training; (2) set forth comprehensive record retention and data collection programs to aid HISA in further analysis, research and education on racetrack safety issues for purposes of continuous improvement based on the best empirical evidence available; and (3) establish specific restrictions, requirements and prohibited practices to address key health and safety issues in a uniform manner that can be implemented and enforced immediately in all racing jurisdictions and venues.

b. Statutory Basis

The Horseracing Integrity and Safety Act of 2020, 15 U.S.C. 3051 through 3060.

II. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule

a. Rule Series 2100—Racetrack Safety Accreditation Program

The proposed rule submitted by the Authority would establish a mandatory national accreditation program for all U.S. racetracks that conduct Covered Horseraces (as defined in the Act).

Existing Standards

In developing the mandatory national accreditation program, HISA considered and relied heavily on the substantive provisions of the National Thoroughbred Racing Association Safety and Integrity Alliance Code of Standards (''NTRA Code of Standards''), as directed by the Act. The NTRA Safety and Integrity Alliance (''Alliance''), comprising the largest tracks and horsemen's groups in the U.S. and Canada, was developed to function as a certification/accreditation body for the purpose of recognizing and incentivizing compliance by all stakeholders. Since its inception, the Alliance has helped spearhead reforms in the areas of improved medication and testing policies, guidelines for injury reporting and prevention, safety research, providing a safer racing environment, and post-racing care for retired racehorses. The Alliance reports that through its initiatives there has been a 29.5% drop in the rate across all surfaces since 2009. The NTRA Code of Standards has been maintained and updated based on in-the-field findings, consultation with regulators and industry participants, and collaboration with other industry organizations focused on safety and integrity. A broad-based Alliance Advisory Board as well as the NTRA Board of Directors approve updates to the Code of Standards. Twenty U.S. racetracks have been granted full Safety and Integrity accreditation under the NTRA program.

In developing the national accreditation program set forth in the proposed rule, HISA relied, in part, on the 2021 NTRA Code of Standards (Exhibit 1). The NTRA Code of Standards incorporates many of the specific standards and protocols set forth in the Association of Racing Commissioners International's Model Rules of Racing (''ARCI Rules'') (Exhibit 2). The ARCI ''Model Rules'' of racing and wagering are recognized worldwide as a standard for the independent and impartial regulation of horse racing as well as the conduct of pari-mutuel wagering. Relying on the collective expertise of regulatory personnel in member jurisdictions in consultation with regulated entities, industry stakeholders, fans and individuals, ARCI committees consider ways to improve and enhance the regulation of racing. In some racing jurisdictions, the Model Rules have the force of law as they have been adopted by reference statutorily or through a regulatory rule making. In others they form the basis on which rules are written ensuring substantial uniformity in the regulation of the sport. HISA prepared a comparison of the substantive terms of the proposed rule with various safety standards and provisions of the NTRA Code of Standards and the specific ARCI Rules (Exhibit 3). In addition to these existing standards, HISA also considered and relied on the International Federation of Horseracing Authority's International Agreement on Breeding, Racing, and Wagering (Exhibit 4) and the British Horseracing Authority's Equine Health and Welfare Program (Exhibits 5–7).

1. Rule 2110 *et seq.*—Accreditation Process

The Accreditation process allows the Authority to take into account the regional differences and the character of differing racetracks by providing various levels of accreditation and by allowing racetracks adequate time to comply with the accreditation requirements. At its core, the accreditation process creates a collaborative approach between the Authority and the Racetracks that recognizes all the requirements of accreditation cannot be fully implemented as of the Program Effective Date. A Racetrack that has already been accredited by the National Thoroughbred Racing Association is granted interim Racetrack Safety Accreditation. All other Racetracks are granted provisional Racetrack Safety Accreditation. The initial designations of interim and provisional Racetrack Safety Accreditation last at least until the Committee completes an accreditation assessment under the regulations. The accreditation assessment will evaluate whether a subject racetrack is in compliance with the accreditation requirements in the Rule 2100 Series. If the accreditation assessment concludes that the applicable Racetrack has not reached full compliance with the accreditation regulations, the Committee may grant provisional accreditation for one year and may extend such provisional accreditation if the subject racetrack is undertaking good faith efforts to comply with the accreditation requirements and achieve Accreditation.

2. Rule 2120 *et seq.*—Accreditation Requirements

i. Rule 2121—Racetrack Safety and Welfare Committee

Accreditation requires injury assessment and risk management protocols be in place to investigate equine and human injuries, to identify contributing factors, to educate participants, and to identify risk prevention and risk management measures to reduce the incidence/prevalence of injuries. These requirements are designed to enhance a culture of safety at the racetrack and thus improve safety for covered persons and covered horses. Injury incidence/prevalence will be reduced for the racetrack and racing commission. Racehorse attrition due to injury will be

reduced, maintaining racehorse inventory.[6]

ii. Rule 2130 *et seq.*—Required Safety Personnel: Safety Director

The proposed rule designates an individual that is responsible for overseeing risk assessment, risk management, and interacting with the Authority for Racetrack Safety Accreditation compliance. The proposed rule creates a position that establishes a reporting structure between the Authority and the State Racing Commissions who have entered into agreements with the Authority. This structure also enables coordination of risk assessment and risk management between the State Racing Commissions and the Authority, and thus standardizes risk assessment and risk management among the State Racing Commissions. Covered persons and covered horses will benefit from risk assessment, risk management, and development and implementation of strategies to mitigate future risk, thus creating a safer training and racing environment. Racetracks and racing commissions will benefit from fewer injuries, lower racehorse attrition, and enhanced social license to operate. The position of Safety Director is patterned after existing positions of ''Equine Medical Director'' in several racing jurisdictions including California, Kentucky, Maryland, New York, Virginia, and West Virginia. The position has expanded oversight (in addition to equine safety) of racetrack safety and safety of personnel working with horses.

Likewise, the proposed rule: (1) Designates that current stewards in jurisdictions having an agreement with the Authority will also enforce the Authority Regulations; (2) describes the duties and responsibilities of a Safety Officer who will oversee safety of the barn area, oversee safety protocols, and participate in the Safety and Welfare Committee; and (3) describes the duties and responsibilities of the Regulatory Veterinarian. The proposed rule is intended to ensure that specific individuals have designated responsibilities for creating a culture of safety by overseeing safety in the barn area, contributing to risk assessment and risk management, enforcing Authority regulations, and overseeing racehorse safety.[7]

iii. Rule 2140 *et seq.*—Racehorse Inspections and Monitoring

Rules 2141–2142—Racehorse Veterinary Inspections and Assessments

The rule requires that racehorses are screened and inspected by regulatory veterinarians at several times (opportunities) to detect horses that are unsound, injured or medically compromised. The purposes are to identify at-risk horses and prevent exacerbation of the condition by preventing racing while the horse is compromised, alert the trainer so an affected horse can be appropriately treated and rehabilitated, and detect abuse (*e.g.,* injuries from improper crop use). The rule promotes regulatory veterinarian collaboration with trainers in the appropriate management of racehorses. The proposed rule deters abusive practices such as excessive use of the crop on the racehorse. The rule enhances racehorse welfare by preventing career-ending and catastrophic injuries. The rule enhances jockey welfare because many jockey injuries are the result of racehorse falls from a catastrophic injury during a race. The rule enhances racetrack welfare by reducing racehorse attrition due to career-ending or catastrophic injuries. The rule enhances social perception of racing by preventing catastrophic injuries during racing.[8]

Rule 2143—Racehorse Monitoring

The rule requires that racehorses entering a racetrack be inspected by a veterinarian and determined to be in good health and to have been vaccinated for transmissible and life-threatening diseases. The purpose is to ensure racehorses entering the racetrack are in good health and to prevent transmission of disease by unhealthy racehorses to other racehorses in the racetrack environment. Further, the rule requires that for racehorses leaving the racetrack, information about their intended destination and transporter are provided so that in the case of a disease outbreak contact tracing can occur for disease investigation and containment. The stated ''purpose'' for exiting a racetrack is required for knowledge useful for investigation of medication and training-related factors for racehorse injury and attrition. The rule prevents disease entry and transmission to a dense population of racehorses in racetrack environments and allows for disease investigation and containment in the event of a disease outbreak. The rule also enhances investigations into causes of racehorse injury and attrition by collection of data useful for epidemiological studies. Racehorses travel among racetracks due to the scheduling of race meets at different racetracks throughout a calendar year. Disease prevention and containment are critical to maintaining a healthy racehorse population. The rule optimizes racehorse welfare and prevents closure of racing and racetracks due to a disease outbreak in the racehorse population.[9]

iv. Rule 2150 *et seq.*—Racetrack and Racing Surface Monitoring and Maintenance

The rule requires that racetracks are designed, configured, tested, maintained, and monitored to optimize the racing surface for safety of the racehorse and jockey. Racetracks must be constructed with components that optimize safety of racehorses and human participants. The rule stipulates design criteria for safest known products that are intended to prevent racehorse and jockey injury during training and racing events. The race surface and race surface material are known to influence risk for racehorse injury, and management of the race surface material is known to influence race surface properties. Because the safest design criteria for race surface materials and the effect of management procedures on surface material properties are largely unknown, there is a requirement for data collection to enable studies for association with racehorse injuries. The rule is intended to enhance racehorse welfare by preventing career-ending and catastrophic injuries due to poor race surfaces and preventing accidents due to poor racetrack design and racetrack component design (*e.g.,* starting gate padding). The rule similarly enhances jockey welfare because many jockey injuries are the result of racehorse falls from a catastrophic injury during a race and reducing the severity of jockey accidents by safer racetrack construction (*e.g.,* safety rails). The rule enhances racetrack welfare by reducing racehorse attrition due to career-ending or catastrophic injuries. The rule enhances the social perception of racing by the public by preventing catastrophic injuries during racing.[10]

[6] *See also* Exhibit 8; Exhibit 9 (pages 6–9); Exhibit 10.

[7] *See also* Exhibit 9 (pages 2–3); Exhibit 2 (ARCI–006–015 Stewards); Exhibit 8; Exhibit 2 (ARCI–006–070 Official Veterinarian); Exhibit 11.

[8] *See also* Exhibit 1; Exhibit 2.

[9] *See also* Exhibit 12; Exhibit 13; Exhibit 14; Exhibit 17.

[10] *See also* Exhibit 1; Exhibit 2 (ARCI–007–020, Facilities and Equipment); Exhibit 18 (Surfaces); Exhibit 19 (Racing Surfaces Testing Laboratory website); Exhibit 15.

v. Rule 2160 *et seq.*—Emergency Preparedness

The rule includes accreditation requirements that racetracks adequately undertake various emergency preparedness steps with respect to catastrophic injuries, fire safety, hazardous weather, infectious disease outbreaks and emergency drills. These provisions require racetracks to train emergency response personnel in the types of injuries and situations specific to racetracks. These requirements are intended to ensure racetracks and Covered Persons are adequately prepared to address emergencies in an effective manner if and when they arise. In particular, the rule also specifically provides for a dedicated ambulance to respond to human injuries that occur in the course of training and racing.[11]

vi. Rule 2170—Necropsies

The rule requires that a necropsy (autopsy) be performed on all horses that die or are euthanized at covered racetracks and training centers. The rule also outlines the types of necropsies acceptable to the Authority and unifies necropsy examination protocols and reporting of resultant examinations. Necropsies identify factors that caused or contributed to the horse's death and provide an opportunity to survey racehorses for other injuries. The resulting information will be used to identify abnormalities and implement protective measures to mitigate future injuries. The collected data will be used for research, to make improvements where needed and reduce equine injuries. This information is critical for making associations of causation between racetrack conditions, race and training data and injury. Some racing commissions do not require necropsies or limit them to certain circumstances. Thus, factors that cause racehorses' deaths are not always documented. The regulatory veterinarian will have the responsibilities of establishing the SOP and uploading the resultant necropsy data into the Equine Injury Database.[12]

vii. Rule 2180 *et seq.*—Safety Training and Continuing Education

The first part of the rule requires that participating State Racing Commissions use a uniform national trainer's test as part of the requirements for an individual to be a trainer. The purpose is to have a standardized test among all jurisdictions. The second part of the rule states that persons responsible for racehorse or racecourse management are required to have continuing education for the purpose of enhancing knowledge and conveying new knowledge to industry participants. Implementation of safety and welfare measures relies on the transfer of information known and generated through research to the industry participants that can implement change. Current continuing education opportunities are scarce, variable in quality, non-uniformly applied among jurisdictions, and address only some industry participants. The rule institutes uniform hourly requirements for existing offerings for a greater number of industry participants. Increasing the level of education of industry participants will help ensure that covered persons are familiar with best practices and regulatory requirements governing safety and integrity, promote a culture of safety at the racetrack, enhance safety and welfare of covered horses and covered persons, and increase welfare of the racehorse industry.[13]

viii. Rule 2190 *et seq.*—Jockey Health

The rule will require State Racing Commissions or Racetracks to conduct drug and alcohol testing for jockeys. The rule is intended to help ensure that jockeys are not impaired when riding in a race. Horse racing can be a dangerous sport and it is imperative that jockeys be mentally and physically fit while performing their duties. A jockey that is impaired is a danger to themselves, other jockeys, licensees, and horses.

The rule also requires Racing Commissions or Racetracks to develop protocols for concussion management. A concussion is a type of traumatic brain injury that interferes with normal function of the brain. Continuing to ride is dangerous for the jockey and may cause additional damage/injury. In addition, the impairment creates a dangerous situation for other jockeys and horses.

The rule provides an opportunity to assess a jockey for a possible concussion injury and if detected, reduce the chance of elevating the injury. It also protects other jockeys and horses that may be negatively affected by the injured jockey's impairment. Concussion assessment and requiring clearance for return to the sport from a medical provider are standard practices in most sports prone to concussion injuries. The rule will require that a jockey to be examined and ''cleared'' to return to ride by a qualified medical provider.[14]

b. Rule Series 2200—Specific Rules and Requirements

1. Rules 2220–2230—Attending Veterinarian and Treatment Restrictions

These rules require that only veterinarians licensed by the State Racing Commission can examine, diagnose, and treat racehorses and that the veterinarian is working with the trainer (agent of owner) to appropriately examine, diagnose abnormalities and treat racehorses. The rules are intended to ensure medications and treatments administered to racehorses are given by only veterinarians that have the specific knowledge and expertise to make diagnoses and treat racehorses. Further, the rules require that there is a valid veterinarian-owner/trainer relationship for treatment of racehorses. The rules optimize racehorse care by ensuring that racehorses are appropriately examined by veterinarians specifically knowledgeable about racehorse medicine and surgery, and racing regulations; and that veterinarians and trainers are working collaboratively for optimizing racehorse health.[15]

2. Rule 2240 *et seq.*—Veterinarians' List

The rule establishes a list of horses that have compromised health or unsoundness and prohibits these horses from racing. Further, the rule outlines the process by which the horses are determined to have recovered from their illness or unsoundness and may return to racing. Horses that participate in a race while medically or physically compromised are at risk for exacerbating the illness or physical injury, and in some cases having a career-ending or catastrophic injury, also risking severe injury to the jockey. The rule prevents affected horses from racing until the horses have recovered from their illness or injury. The rule is designed to protect horses from worsening an existing condition, and allow for recovery, rehabilitation, and return to racing in a healthy state. The rule is intended to protect jockeys from injuries associated with falls from horses due to the horse incurring a severe injury during a race and falling at high speed. Racetracks

[11] *See also* Exhibit 2 (ARCI–007–020, Facilities and Equipment); Exhibit 1 (pages 13–17, referring to ARCI standards above); Exhibit 16; Exhibit 15; Exhibit 17.

[12] *See also* Exhibit 10 (Veterinary Practices 1846.5, Postmortem Examination. (a)–(h)); Exhibit 1 (ARCI Model Rules ARCI–011–030 Physical Inspection of Horses, Assessment of Racing Condition, C. Postmortem Examinations(1)–(6)); Exhibit 20; Exhibit 8; Exhibit 9; Exhibit 21.

[13] *See also* Exhibit 1 (referencing ARCI Model Rules ARCI 008–020(A)(4); ARCI 006–015(A), ARCI 006–015(A)); Exhibit 22.

[14] *See also* Exhibit 23; Exhibit 24; Exhibit 25; Exhibit 26.

[15] *See also* Exhibit 1 (pages 42–43, referencing ARCI–011–10); Exhibit 2 (ARCI Model Rules of Racing—ARCI–011–010 Veterinary Practices).

will benefit from the prevention of horse fatalities during races. Racetracks and Racing Commissions will benefit because the Veterinarians' List will be shared among all Racing Jurisdictions so that horses put on the list at one jurisdiction will be identifiable when the horse moves to another jurisdiction.[16]

3. Rule 2250 *et seq.*—Racehorse Treatment History and Records

The rule requires attending veterinarians and trainers to report all medications, treatments, surgical procedures, and off-racetrack exercise history for all covered horses to the Authority's database. The purpose is to discover high risk practices so that injuries and illnesses can be prevented in the future. Knowledge of medication, treatments, surgical procedures, and off-track exercise history data is necessary to correlate medication, treatments, surgical procedures, and off-track exercise history with risk for injury and illness, so that high risk practices can be discovered, and injuries and illnesses can be prevented in the future. Collection and correlation of the information with data on injuries and illnesses will enhance equine welfare by allowing the development of strategies for injury and illness prevention. Jockey welfare and safety will be enhanced by a decrease in the incidence of horse falls due to injury and associated jockey injuries. Industry welfare will be enhanced by lower racehorse attrition. The Authority will develop technology (*e.g.,* tablet apps) to minimize the burden on covered persons.[17]

4. Rule 2260 *et seq.*—Claiming Races

Claiming races are races in which horses entered in the race may be purchased for the claiming price by a new trainer/owner. The horse becomes the property of the new trainer/owner as soon as the horse leaves the starting gate in the race. The rule provides the exceptions that, if the horse dies, is euthanized, is vanned off (due to the inability of the horse to exit the racecourse), becomes unsound or medically compromised, bleeds from the nostrils (and presumably the lungs) after the race, or has a positive drug test, transfer of the horse does not occur. The rule protects the purchaser of the horse from acquiring an injured, compromised, or dead horse. The rule provides disincentives to a trainer/owner to enter a horse compromised from latent injury or ailment in a race with the intent for another trainer/owner to take responsibility by claiming the horse in the race. The option for the claim not to be voided by the potential new trainer/owner is useful in circumstances in which a compromised horse may be rehabilitated after the race, or where the new trainer/owner desires to acquire a horse for breeding purposes as opposed to continuing to train and race. The Waiver Claim Option also allows a horse trainer/owner that rehabilitated a horse and wishes to start the horse in a race to start the horse in a claiming race without the possibility of the horse being claimed by another trainer/owner. This allows a horse trainer/owner to take time to rehabilitate a horse and allow them to then start the horse in a race without the possibility of losing the horse to another trainer/owner. The rule incentivizes trainers/owners to rehabilitate horses for long term health and an extended racing career.

In the case of a successful claim (horse purchase) the rule effects transfer of medical records to the new trainer/owner. Knowledge of medical history provides information to the new trainer/owner so the horse may be managed appropriately, given its history, and obtain the best training and medical care for the horse's optimal health.

The rule protects covered horses from being raced when they are not physically or medically fit to do so. The rule protects covered persons from purchasing a compromised horse. Racetracks, racing commissions, and the racing industry benefit because compromised horses in races are more likely to suffer a catastrophic injury; thus, some catastrophic or career-ending injuries are prevented.[18]

5. Rule 2270 *et seq.*—Prohibited and Restricted Practices

i. Rule 2271—Prohibited Practices

The rule regulates the use of practices that either: (1) Mask pain to allow horses to train and race with injuries or joint disease (*e.g.,* neurectomy, shock wave therapy, electrical medical devices); (2) induce inflammation and pain with the intent to speed healing of injured structures (*e.g.,* thermocautery); or (3) cause pain to stimulate a horse to run faster (*e.g.,* electrical shock). Certain specific practices (such as shock wave therapy) are also addressed in specific rules in this section. The rule is intended to prevent abuse of racehorses by preventing the masking of pain that allows horses to train and race while injured, and by preventing the stimulation of pain to coerce racehorses to perform beyond their athletic potential. Inhumane and dangerous practices on racehorses will be prevented.[19]

ii. Rule 2272—Shock Wave Therapy

The rule regulates the use and monitoring of a treatment (shock wave therapy) used on bone, tendon, and ligament injuries. Shock wave therapy can also provide pain relief that allows affected horses to continue to train and race on a mild injury. Continued training and racing on a mild injury could precipitate a career-ending or catastrophic injury. The rule addresses the problem by closely monitoring treatments and requiring treated horses to refrain from training at high speed or racing until an appropriate time for rehabilitation of the injury that was treated. The rule enhances safety of covered horses by reducing the incidence of career-ending and catastrophic injuries. Because jockey injuries are associated with horse falls due to catastrophic injuries during high-speed training and racing, the rule also enhances jockey safety and welfare.[20]

iii. Rules 2273–2275—Devices

The rules prohibit the use of any device meant to alter the speed or performance of a horse. The rules are in place in all U.S. racing jurisdictions. The penalty for noncompliance is not standard across jurisdictions and varies from a 10-year loss of racing license to suspensions and fines. The rules are intended to standardize the language nationally and standardize sanctions. Stewards will have national standardized language and sanctions when adjudicating cases and issuing sanctions. Covered Persons will know the industry considers use of performance-affecting devices a serious issue.[21]

iv. Rule 2276—Horseshoes

The rule limits the height of rims used as traction devices on forelimb and hindlimb horseshoes. The rule prohibits use of any other traction devices. Traction devices have been thought to

[16] *See also* Exhibit 2 (ARCI–011–030 Physical Inspection of Horses, B. Veterinarians' List; Exhibit 9 (pages 20–21); Exhibit 1 (Section E).

[17] *See also* Exhibit 1 (NTRA Safety & Integrity Alliance—Code of Standards 2021, Trainer Records and Reporting, page 21); Exhibit 2 (ARCI–008–020 Trainers); Exhibit 9 (''Layoff Report''); Exhibit 10 (Rule Nos. 1842, 1842.1, 1842.5).

[18] *See also* Exhibit 27; Exhibit 9 (pages 16–18).

[19] *See also* Exhibit 1 (Shock Wave Therapy, page 20); Exhibit 2 (ARCI Model Rules of Racing ARCI–011–015(4) (shock wave therapy), ARCI–006–020, ARCI–010–030, ARCI–024–025 (heel nerving), ARCI–011–015 (prohibited practices)).

[20] *See also* Exhibit 1 (page 20); Exhibit 2 (ARCI–011–015 Prohibited Practices).

[21] *See also* Exhibit 2 (ARCI–010–035 Running of the Race E(7)(c)—Use of Riding Crop); Exhibit 4.

increase a horse's ability to ''dig in'' to the track surface and prevent slipping. Traction devices reduce the horse's ability to plant its hoof properly and move correctly through the surface. That reduction of movement contributes to catastrophic breakdowns and skeletal and muscle-related injuries. The rule follows the scientific evidence that shows that traction devices increase equine injuries. The rule is intended to increase the safety of covered riders and covered horses by reducing the number of accidents resulting from injuries associated with the use of traction devices. Lower racehorse attrition will enhance racetrack welfare by having greater racehorse inventory to fill races, larger race fields, and consequently greater parimutuel betting. The rule will standardize traction device use nationwide.[22]

6. Rule 2280 *et seq.*—Use of Riding Crop

Allowing use of the crop is critical for the safety of horses and riders. The rule limits the number of times the crop can be used for encouragement. The rule unifies crop design and use of the crop across all jurisdictions. The rule unifies penalties for crop abuse or use of prohibited devices across jurisdictions. There has been heated debate about use of the riding crop, especially for encouragement. Some believe the new crops do not hurt the horse at all, while others remain concerned about the public perception of using a crop for encouragement. The rule allows riding crop use for safety of the horse and jockey. It also limits the number of times the crop can be used for encouragement during a race. This compromise of use of the crop for safety, and limited use for encouragement that will be unified across racing jurisdictions, is in the best interest of the horses, horsemen, the owners, the jockeys, the betting public, racing commissions, and the general public. The rule is intended to protect horses from excessive use of the crop. Jockeys will have a clear understanding of crop use rules and will be able to adapt their usage due to uniformity of the rules.[23]

7. Rule 2290 *et seq.*—Safety and Health of Jockeys

The rule requires that a jockey have a physical examination including baseline concussion testing in order to be eligible to ride in races. Further, the rule states that starting gate personnel and any person mounted on a horse must wear a protective helmet and vest. When mounted on a horse, jockeys must have medical information pertinent to emergency care on their vest. The rule ensures that jockeys are physically fit and capable of riding without endangering other participants during a race. The rule ensures that jockeys and starting gate personnel wear safety vests and helmets to minimize injury in case of an accident. In the case of a jockey injury, medical information pertinent to emergency care will be readily available to medical providers. In the case of a jockey injury, baseline concussion data is available for comparison to the injury-related concussion assessment. Stewards and the Clerk of Scales are responsible for monitoring and reporting non-compliance.[24]

III. Self-Regulatory Organization's Summary of Comments

As encouraged by the Commission's rule, beginning in September 2021, HISA representatives shared various working drafts with several interested stakeholders for input as the rule proposals were being developed. Those interested stakeholders included: Racing Officials Accreditation Program (''ROAP''); Racing Medication and Testing Consortium (Scientific Advisory Committee) (''RMTC''); Water Hay Oats Alliance (''WHOA''); National Thoroughbred Racing Association (''NTRA''); The Jockey Club; The Jockeys' Guild; Thoroughbred Racing Association (''TRA''); Arapahoe Park; Grants Pass Downs; Arizona Downs; Colonial Downs; Association of Racing Commissioners International (Model Committee) (''ARCI''); California Horse Racing Board; Kentucky Racing Commission; Delaware Racing Commission; Maryland Racing Commission; National Horsemen's Benevolent and Protective Association; Thoroughbred Horsemen's Association Mid-Atlantic Safety Coalition; Thoroughbred Owners and Breeders Association; Kentucky Thoroughbred Association; American Association of Equine Practitioners; American Veterinary Medical Association; North American Association of Racetrack Veterinarians; Thoroughbred Safety Coalition; New York Racing Association, Stronach Racing Group (5 Thoroughbred racetracks); Churchill Downs (6 Thoroughbred racetracks); Breeders' Cup; Keeneland; and Del Mar. Additionally, videoconferences were conducted with all State racing commissions (except Arkansas), and a number of industry organizations.

Likewise, prior to finalization of the submissions by HISA to the Commission, working drafts of proposed regulations were made available to the public for review and comment on the HISA website *https://www.hisausregs.org/.* The website received 1,864 unique visitors, 3,097 total visits, 162 registered users, 137 regulation downloads, and 360 comments. All submitted comments were catalogued by HISA and were submitted to the Commission herewith.

The primary areas of the Racetrack Safety Rule that received comments were with regard to Safety and

[22] *See also* Exhibit 28 (In a study of 201 Thoroughbred racehorses that died during racing or training at California racetracks, toe grabs were identified as possible risk factors for fatal musculoskeletal injury, fetlock suspensory apparatus failure, and fetlock condylar fracture. The odds of fatal musculoskeletal injury, fetlock suspensory apparatus failure, and fetlock condylar fracture were 1.8, 6.5, and 7.0, respectively, times greater for horses shod with low toe grabs than for horses shod without toe grabs on front shoes. Horses shod with regular toe grabs on front shoes had odds 3.5, 15.6, and 17.1 times greater ($P < 0.05$) for fatal musculoskeletal injury, fetlock suspensory apparatus failure, and fetlock condylar fracture, respectively, compared with horses shod without toe grabs. The odds of horses shod with rim shoes were a third ($P < 0.05$) of those shod without rim shoes for either fatal musculoskeletal injury or fetlock suspensory apparatus failure.); Exhibit 29; Exhibit 30 (The results supported the hypothesis that using studs will decrease foot slip distance in horses cantering on a grass surface.); Exhibit 31 (A marginal association ($p=0.08$) was detected between moderate ligamentous suspensory apparatus injury and height of toe grab. Toe grab height may remain a risk factor for suspensory apparatus failure and condylar fracture because moderate ligamentous suspensory apparatus injury is a risk factor for suspensory apparatus failure and condylar fracture.); Exhibit 32 (Horses that wore low, regular, or Quarter Horse height toe grabs the week of injury had higher odds of having a mild suspensory apparatus injury, compared with horses that did not wear toe grabs that week ($p=0.16$).); Exhibit 33 (Odds of injury in racehorses with toe grabs on front shoes were 1.5 times the odds of injury in horses without toe grabs, but this association was not statistically significant (95% confidence interval, 0.5–4.1).); Exhibit 34 (Although toe grab height was not a significant risk factor in the multivariable or univariable models in the present study, a prior related study, and a Florida study, found the direction of the relationship between toe grab height and injury in both studies was consistent with higher risk with higher toe grabs. Furthermore, toe grab height is associated with the development of mild suspensory apparatus injury, which is a risk factor for suspensory apparatus failure. The use of high toe grabs has decreased in recent years, and variability in toe grab height is associated with 10% to 16% of the variability in exercise variables, perhaps making it more difficult to detect a significant toe grab effect in univariable and multivariable analyses, respectively. It is possible that a toe grab effect is also confounded by other factors; but, in the absence of other known relationships, avoidance of use of high (≥4 mm) toe grabs is still recommended for injury prevention.); Exhibit 35; Exhibit 4 (Article 7, Racing (Shoeing of Racehorses)); Exhibit 2 (ARCI–010–030 (30)); Exhibit 10 (California Rule 1690.1).

[23] *See also* Exhibit 10 (Crop Rule); Exhibit 36; Exhibit 37; Exhibit 38; Exhibit 39; Exhibit 40; Exhibit 41; Exhibit 42; Exhibit 43; Exhibit 44; Exhibit 45; Exhibit 46; Exhibit 47; Exhibit 48; Exhibit 49; Exhibit 50; Exhibit 51; Exhibit 52; Exhibit 53; Exhibit 54; Exhibit 10; Exhibit 55; Exhibit 56; Exhibit 35; Exhibit 57; Exhibit 58.

[24] *See also* Exhibit 1 (pages 22–24); Exhibit 2 (ARCI–007–020 Facilities and Equipment); Exhibit 2 (ARCI–008–030 Jockeys).

Continuing Education (2182); Claiming Races (2260–2262); Veterinarians' List (2142, 2220–2242); Safety and Welfare Committee and Safety Director (2121–2131); Stewards and Safety Officer (2133–2136); Racehorse Treatment History (2250–2253); Prohibited Practices (2271); Medical Director (2132); Racetrack Surfaces, Monitoring and Maintenance (2150–2154); Necropsies (2170); Riding Crops (2280–2281); and Racehorse Treatment History and Records (2250–2253).

The Committee engaged in a continuous review and consideration process as comments were submitted, analyzed, and discussed both internally and with the various stakeholders. Many of the proposed rules received substantial and wide-ranging support, and thus there were few comments suggesting changes. In several instances, significant changes were made in the ongoing rule development and revision process in direct response to comments received. In some instances, the Committee considered comments but elected to maintain the original proposed provisions based on statutory requirements and limitations and/or substantive analysis based on the expertise of the Committee and the supporting documentation it reviewed and considered.

IV. Self-Regulatory Organization's Responses to Comments and Discussion of Alternatives

The following is a description of the primary subjects that received comments and the manner in which the Authority addressed those comments in developing the proposed rule submitted to the Commission, as well as the reasonable alternatives the Authority considered alongside the option ultimately proposed.

Safety and Continuing Education (Rule 2182)

Comments were received from RMTC, ROAP, WHOA, NTRA, and TRA among other individuals. Comments were highly supportive of requiring continuing education, and several comments asked for increased hourly requirements (*e.g.,* Assistant Trainers should have the same requirements as Trainers: 4 hours). Hourly requirements were increased, more categories of covered persons were added to the list of individuals required to have annual continuing education. Requirements were modified to facilitate compliance for existing resources (*e.g.,* Racing Officials have an 8-hour requirements every 2 years instead of annual requirements of 4 hours because the 8-hour requirements are achievable using the ROAP meeting as a resource). Other comments expressed the need to have a centralized resource with quality-controlled content. The Racing Safety Committee concurs, and after the initial Racing Safety rule rollout, plans to engage in development and implementation of a strategic plan that incorporates a centralized resource, funding and development of education resources, and compliance monitoring after the initial Racing Safety rule rollout. The plan will likely build on the ad hoc evolving HorsemenU industry website. Concerns were also raised about funding, which will also be considered next.

Claiming Races (Rule 2260)

The Transfer of Claimed Horse Records had support from several individual regulatory veterinarians whose perspective was to optimize the welfare of horse by providing historical treatments to the new owner of the horse. The Void Claim rule had few comments (and thus wide acceptance). This rule is generally perceived to incentivize trainers to rehabilitate poorly performing horses instead of racing those horses which are at high risk for catastrophic injury. The rule is thought to contribute to the dramatic drop of catastrophic injuries in those racing jurisdictions that implemented a similar rule. Specific comments were related to including a positive medication violation as an additional reason for voiding the claim. The positive medication violation was added to the items that would void a claim. The Waiver Claiming Option, drawn from the void claim rule in existing jurisdictions, is generally accepted and had few comments. This option allows an individual to retain a claimed horse that otherwise meets some of the requirements for a voided claim. The rule allows an individual to retain the horse, usually for non-racing (breeding) purposes. The RMTC, TRA, and individuals collectively commented and provided evidence that the purse to claim price ratio was unrealistic in consideration of the current structuring of purse monies for claiming races. The rule would penalize trainers/owners by dramatically lowering return for racing. The purse to claim price ratio text was removed from the regulations.

Assessment of Racing Condition and Veterinarians' List (Rules 2142, 2220–2242)

Assessment of Racing Condition by veterinary inspections/observations and placement of horses deemed ineligible to race due to unsoundness or medical conditions on the Veterinarians' List are common practices in many jurisdictions and had generally positive support. The numerous comments ranging from individuals to RMTC, CDI, WHOA, KHRC, NYRA, TRA, Mid-Atlantic Group, Oklahoma, and CNL related to specific items in the rules. In general, the first version of the rule was deemed too lax, and the second version of the rule was deemed too specific and not feasible for breeds other than Thoroughbreds (should the other breeds opt to participate under HISA). Further, there is general concern that there are not enough equine regulatory veterinarians for employment to support the rule. The submitted rule contained increased rigor by increasing the times of inspection by a veterinarian, with lesser regulation of the requirements for each inspection. The Authority intends to augment the requirements by distributing a ''Best Practices'' guidance document. Different jurisdictions had different standdown times for reasons to be put on the veterinarians' list—and commented accordingly. The rule, however, standardized standdown times and the requirements for removal from the veterinarians' list and incorporated a mandatory inspection of the horses by the attending veterinarian and trainer to ensure that a veterinarian attested to soundness and good health while facilitating consult and education of the trainer.

Safety Director and Safety and Welfare Committee (Rules 2121–2131)

The Safety Director and Safety and Welfare Committee are a new position and new structure for most racing jurisdictions. Some racing jurisdictions (*e.g.,* California, Mid-Atlantic Group, New York) have an Equine Medical Director which has similar responsibilities as, but fewer than, the Safety Director. The Safety Director and Safety and Welfare Committee are established specifically for Risk Assessment and Risk Management. Comments were received from broad constituencies including the Minnesota Racing Commission, RMTC, Maryland, WHOA, and Colonial Downs. Comments to the first version of the draft rules were largely related to the perception that jurisdictions would be required to hire additional individuals to fill these roles. Later versions of the rules clarified that existing individuals (*e.g.,* Equine Medical Director) could fill these roles and perform the responsibilities. Further, later revisions clarified that jurisdictions could share individuals to fill the roles and responsibilities. Comments also pointed out that some stakeholders did not have representation on the Safety and

Welfare Committee. Additional committee members were included on the Safety and Welfare Committee (*e.g.,* track superintendent) to include broad representation of all stakeholders.

Stewards and Safety Officer (Rules 2133, 2136)

The Stewards and Safety Officer sections went through considerable revisions in response to comments from ROAP, TRA, KHRC, Maryland, RMTC, CNL, NTRA, and CDI. The Racing Safety Committee recognized that the Stewards are largely employed by the racetracks and eliminated regulatory oversight except to only ensure that the Stewards were also responsible for enforcing the Racing Safety regulations (subject to the applicable State Racing Commission electing to enter into an agreement with the Authority). Similarly, the Stewards' List section was deleted largely due to comments from the RMTC, ROAP, and TRA. The Safety Officer, generally a steward, is currently a position at only some racetracks, but is deemed an important position by the Racing Safety Committee; with oversight of general safety procedures including in the barn stable area. The requirement for a Safety Officer was left in the regulations. There was profound disagreement that a Safety Officer only be required at racetracks that held Graded Stakes races. The intent of the Racing Safety Committee was to reduce the burden of having an additional individual on smaller racetracks, but the perception was that only expensive horses mattered. Therefore, the requirement for a Safety Officer was made standard for all racetracks.

Racehorse Treatment History (Rules 2250–2253)

Racehorse treatment history obtained from attending veterinarians and trainers (Responsible Persons) is deemed important by the Racing Safety Committee because of the scientific reports that indicate that intra-articular corticosteroids,[25] non-steroidal anti-inflammatory drugs,[26] exercise history,[27] and return from lay-up (*i.e.,* rest from racing and training)[28] increase the risk for career-ending or catastrophic musculoskeletal injury. This information will be stored in the Authority's database and used for research into associations with lay-up, and career-ending and catastrophic injuries. The Oklahoma Horse Racing Commission has numerous questions regarding the process and outcomes without suggestions. Comments from the Minnesota Racing Commission and ARCI indicated support for the centralization of data, suggested more rigorous reporting requirements (to those in the initial draft regulations), and the usefulness of the data for identifying horses needing additional scrutiny because of possible increased risk for injury. However, there was concern for the cumbersome process and burden on persons required to submit data. The Racing Safety Committee intends to work with the Authority's Technology section to facilitate ease of reporting and provide information back to data providers that will help them locally and incentivize data reporting.

Prohibited Practices (Rule 2271)

Several practices are prohibited because they may alleviate pain, mask signs of injury, or cause inflammation. These practices include shockwave therapy, neurectomy, thermocautery, and electrical medical therapeutic devices. RMTC, Minnesota Racing Commission, Maryland, KHRC, and Oklahoma Horse Racing Commission commented on the rule. Comments were largely related to two items: (1) Differences in regulating use of shockwave machines and stand down times for shockwave and (2) palmar digital neurectomy. The regulation of use of shockwave machines and stand down times were standardized in the rules. At least several racing jurisdictions currently (and historically) allow palmar digital neurectomy as permissible, stating that horses with palmar digital neurectomy can race safely without increased risk for injury. The Racing Safety Committee decided to disallow all neurectomies (including palmar digital neurectomy) on the principle that a procedure that alleviates pain without resolution of the underlying cause should not be permissible.

Medical Director (Rule 2132)

The Medical Director is included in the regulations to oversee the care and organization of medical needs for jockeys. The position was in the first draft of the regulations, removed because the Racing Safety Committee felt it needed more work, and then after further consideration and work, re-inserted the position of Medical Director to the last draft of the regulations. Consequently, while there are few written comments, the Racing Safety Committee has received verbal comments from stakeholders at the Global Symposium of Racing at the University of Arizona, conducted on December 6 and 7, 2020. Racing jurisdictions perceived that they would be required to hire a full-time physician, which is not the intent of the rule. Further, some racing jurisdictions thought they had adequate procedures in place and that the rule was not necessary. The Racing Safety Committee (with 3 members (athletic trainer, jockey, and physician) of a 7-member committee nominated by a separate Nominating Committee) thought it is important to ensure there is a standard minimum of care for jockey and exercise rider health and safety, and that national coordination of efforts would benefit the industry. Further, the Racing Safety Committee requires all racetracks to implement a concussion baseline assessment and evaluation protocol for determining fitness to ride, particularly after a fall or injury. A compromised jockey risks danger to not only him/herself but to other riders and horses in races.

Racetrack Surfaces (Rules 2150–2154)

The original draft of the Safety Regulations required that racetracks engaged in racetrack renovation consider the installation of a synthetic racing surface on the track. This requirement was based on data indicating that catastrophic injury rates for horses are reduced on synthetic surfaces. Several racetracks registered concerns about this provision, citing the cost of installing and maintaining synthetic surfaces, the training required for racetrack personnel in maintaining the surfaces, and the need for consideration of local climate conditions and product availability. The committee concluded that the proper course is to conduct further research and data on racetrack surfaces to guide the development of future regulations. Therefore, the rule as previously developed was removed from the final draft.

Necropsies (Rule 2170)

Necropsy is a critical tool in determining the cause of equine fatalities. The necropsy provisions in the rules are modeled on AAEP

[25] Whitton, et al. Musculoskeletal injury rates in Thoroughbred racehorses following local corticosteroid injection The Vet J 2014;200:71–76.

[26] Dirikolu, et al. Nonsteroidal anti-inflammatory agents and musculoskeletal injuries in Thoroughbred racehorses in Kentucky. J Vet Pharmacol. Therap. 2008;32:271–279.

[27] Anthenill, et al. Risk factors for proximal sesamoid bone fractures associated with exercise history and horseshoe characteristics in Thoroughbred racehorses. Am J Vet Res 2007;68:760–771.

[28] Carrier, et al. Association between long periods without high-speed workouts and risk of complete humeral or pelvic fracture in Thoroughbred racehorses: 54 cases (1991–1994). J Am Vet Med Assoc 1998;212:1582–1587.

guidelines, comments received that highlighted the practical issues faced by racing commissions and racetracks located in areas of the country that do not have laboratory facilities close by, or that are not open seven days per week. In the final draft, the regulations were revised to permit field necropsies when suitable facilities and resources are not available.

Racing Surface Monitoring and Maintenance (Rule 2154)

Racetrack surface monitoring via data collection is critical in identifying factors that contribute to equine injuries. The regulations regarding racetrack surface monitoring and maintenance were significantly influenced by constituent input. Regional differences, number of race days and available staffing differ greatly between racetracks. The Committee considered the input and fine-tuned the requirements to allow for those differences. Comments from racetracks indicated that the collection of data may be burdensome. The Committee therefore reduced the data collection requirements. For example, the original draft required collection of moisture content and cushion depth at four locations at every ⅛ pole; the revision reduced data collection to two locations at every ¼ pole. This section of the rules was also reworked to reduce the specific information to those items most impactful and common to racetracks. The Committee also plans to develop electronic applications that will speed and facilitate the process for the racetracks taking the measurements and increased the number of formats acceptable for submission of the required information. The Committee will produce ''Standard Protocol'' documents to provide guidance for complying with the rule.

Riding Crops (Rules 2280–2281)

The comments received concerning use of riding crops were numerous and ranged from urging that the use of crops be prohibited altogether except for safety and accident avoidance to urging full discretionary use of the crop by the jockey. Numerous regulations of differing character are presently in effect among racing jurisdictions across the country. After much consideration, the Committee settled on a rule that represents a reasonable accommodation of the various comments and concerns expressed. The rule allows unlimited use of the crop for safety of the jockeys and horses in the race, but limited use for encouragement to 6 uses of the crop on the horse. In addition, there were multiple concerns that the penalties for violation of the crop rule were not severe enough to deter violations. Further, comments were received urging the Committee to also incorporate owner and trainer accountability to relieve the jockey from pressure to make excessive use of the crop during a race. Therefore, loss of purse was incorporated in severe violations. Other comments referred to communication with the public when a jockey will ride without a crop in a race. The Committee adopted the recommendation that in addition to announcement at race time that the public would be notified further in advance by posting the information in the official racing program.

Hazardous Weather (Rule 2164)

The initial drafts contained very detailed requirements and protocols concerning fire safety, hazardous weather, and related provisions. Comments from the racetracks indicated many of these areas are already regulated in detail under local and state law. In response, the Committee removed some requirements in favor of requiring racetracks to document and report compliance with the applicable state and local requirements.

Horseshoes (Rule 2276)

Initial draft allowed some usage of toe grabs but, based on significant industry input and considered research and available industry information, ultimately concluded it was prudent and appropriate to totally preclude toe grabs on forelimbs and hind limbs.

Comments That Were Inapplicable

There were some comments that fell outside the jurisdiction of HISA, such as the following, so were not addressed in the proposed regulations. For example, one comment asked about the status of regulating two-year-old breeze up sales. The Act gives HISA authority over Covered Horses. Horses do not become Covered Horses until they have completed their first official work as defined by the Act, thus two-year-old horses offered in sales do not fall under the jurisdiction of HISA.

V. Legal Authority

This rule is proposed by the Authority for approval or disapproval by the Commission under 15 U.S.C. 3053(c)(1).

VI. Effective Date

If approved by the Commission, this proposed rule will take effect July 1, 2022.

VII. Request for Comments

Members of the public are invited to comment on the Authority's proposed rule. The Commission requests that factual data on which the comments are based be submitted with the comments. The exhibits referred to in the Authority's filing, as well as the written comments it received before submitting the proposed rule to the Commission, are available for public inspection at *www.regulations.gov* under docket number FTC–2021–0076.

The Commission seeks comments that address the decisional criteria provided by the Act. The Act gives the Commission two criteria against which to measure proposed rules and rule modifications: ''The Commission shall approve a proposed rule or modification if the Commission finds that the proposed rule or modification is consistent with—(A) this chapter; and (B) applicable rules approved by the Commission.'' [29] In other words, the Commission will evaluate the proposed racetrack safety rule for its consistency with the specific requirements, factors, standards, or considerations in the text of the Act as well as the Commission's procedural rule.

Although the Commission must approve the proposed rule if the Commission finds that the proposed rule is consistent with the Act and the Commission's procedural rule, the Commission may consider broader questions about the health and safety of horses or the integrity of horseraces and wagering on horseraces in another context: ''The Commission may adopt an interim final rule, to take effect immediately, . . . if the Commission finds that such a rule is necessary to protect—(1) the health and safety of covered horses; or (2) the integrity of covered horseraces and wagering on those horseraces.'' [30] The Commission may exercise its power to issue an interim final rule on its own initiative or in response to a petition from a member from the public. If members of the public wish to provide comments to the Commission that bear on protecting the health and safety of horses or the integrity of horseraces and wagering on horseraces but do not discuss whether HISA's proposed rule on racetrack safety is consistent with the Act or the applicable rules, they should not submit a comment here. Instead, they are encouraged to submit a petition requesting that the Commission issue an interim final rule addressing the subject of interest. The petition must meet all the criteria established in the Rules of

[29] 15 U.S.C. 3053(c)(2).

[30] 15 U.S.C. 3053(e).

Practice (Part 1, Subpart D) [31]; if it does, the petition will be published in the **Federal Register** for public comment. In particular, the petition for an interim final rule must ''identify the problem the requested action is intended to address and explain why the requested action is necessary to address the problem.'' [32] As relevant here, the petition should provide sufficient information for the public to comment on, and for the Commission to find, that the requested interim final rule is ''necessary to protect—(1) the health and safety of covered horses; or (2) the integrity of covered horseraces and wagering on those horseraces.'' [33]

VIII. Comment Submissions

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 19, 2022. Write ''HISA Racetrack Safety'' on your comment. Your comment—including your name and your State—will be placed on the public record of this proceeding, including, to the extent practicable, on the website *https://www.regulations.gov.*

Because of the public health emergency in response to the COVID–19 outbreak and the Commission's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website. To ensure that the Commission considers your online comment, please follow the instructions on the web-based form.

If you file your comment on paper, write ''HISA Racetrack Safety'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex B), Washington, DC 20024. If possible, please submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the public record, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not contain sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other State identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential''—as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov*—as legally required by FTC Rule 4.9(b), 16 CFR 4.9(b)—we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website to read this document and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments it receives on or before January 19, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/siteinformation/privacypolicy.*

IX. Communications by Outside Parties to the Commissioners or Their Advisors

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding, from any outside party to any Commissioner or Commissioner's advisor, will be placed on the public record. See 16 CFR 1.26(b)(5).

X. Self-Regulatory Organization's Proposed Rule Language

Rule 2000 Series—Racetrack Safety Program

2010 Definitions
2100 Racetrack Accreditation
2110 Accreditation Process
2120 Accreditation Requirements
2130 Required Safety
2140 Racehorse Inspections and Monitoring
2150 Racetrack and Racing Surface Monitoring and Maintenance
2160 Emergency Preparedness
2170 Necropsies
2180 Safety Training and Continuing Education
2190 Jockey Health
2200 Specific Rules and Requirements of Racetrack Safety Program
2210 Purpose and Scope
2220 Attending Veterinarian
2230 Treatment Restrictions
2240 Veterinarians' List
2250 Racehorse Treatment History and Records
2260 Claiming Races
2270 Prohibited Practices and Requirements for Safety and Health of Horses
2280 Use of Riding Crop
2290 Requirements for Safety and Health of Jockeys

2010. Definitions

When used in the Rule 2000 Series:

Act means the Horseracing Integrity and Safety Act of 2020.

Association Veterinarian means a Veterinarian employed by a Racetrack.

Attending Veterinarian means a Veterinarian hired by the Trainer or Owner.

Authority means the Horseracing Integrity and Safety Authority.

Bled means that blood from one or both nostrils of a Horse has been observed after exercise.

Claim means, in the context of a Claiming Race, the purchase of a Covered Horse for a designated amount.

Claiming Race means a Race in which a Horse after leaving the starting gate may be claimed in accordance with the rules and regulations of the applicable State Racing Commission.

Concussion means an injury to the brain that results in temporary loss of normal brain function.

[31] 16 CFR 1.31; *see* Fed. Trade Comm'n, Procedures for Responding to Petitions for Rulemaking, 86 FR 59851 (Oct. 29, 2021).

[32] 16 CFR 1.31(b)(3).

[33] 15 U.S.C. 3053(e).

Covered Horse means any Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State Racing Commission or the breed governing organization for such horse, beginning on the earlier of:

(1) The date of the Horse's first timed and reported workout at a Racetrack;

(2) the date of the Horse's first timed and reported workout at a Training Facility;

(3) the date of the Horse's entry in a Covered Horserace; or

(4) the date of the Horse's nomination for a Covered Horserace, and ending on the date on which the Authority receives written notice that the Horse has been retired in accordance with the Protocol.

Unless the context otherwise requires, Horse and Covered Horse shall have correlative meanings for purposes of this Rule 2000 Series.

Covered Horserace or *Race* means any horserace involving Covered Horses that has a substantial relation to interstate commerce, including any Thoroughbred horserace that is the subject of interstate off-track or advance deposit wagers.

Covered Persons means all Trainers, Owners, breeders, Jockeys, Racetracks, Veterinarians, and Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such persons and other Horse support personnel who are engaged in the care, training, or racing of Covered Horses.

Groom means a Covered Person who is not an Owner, Veterinarian, Trainer, or assistant Trainer but is involved in the care of a Covered Horse.

Jockey means a rider of a Covered Horse in a Covered Horserace.

Lead Veterinarian means any Veterinarian appointed pursuant to Rule 2134(b).

Medical Director means an individual designated as Medical Director in accordance with the provisions of Rule 2132.

Out-of-Competition means any period which is not during race day.

Owner means a Person or entity who holds an ownership or property interest in one or more Covered Horses.

Person means a natural person or an organization or other entity.

Program Effective Date means July 1, 2022.

Prohibited List means the Equine Prohibited List identifying the Prohibited Substances and

Prohibited Methods means those prohibited methods set forth in the Rule 4000 Series.

Prohibited Substance means any substance, or class of substances, so described on the Prohibited List.

Protocol means the Equine Anti-Doping and Medication Control Protocol set forth in the Rule 3000 Series.[34]

Race Meet means the entire period granted by the State Racing Commission to a Racetrack for the conduct of Covered Horseraces on the Racetrack's premises.

Racetrack means an organization licensed by a State Racing Commission to conduct Covered Horseraces.

Racetrack Safety Accreditation or *Accreditation* means the process for achieving, and the issuance of, safety Accreditation to a Racetrack in accordance with the Rules 2100 through 2193.

Racetrack Safety Committee means the committee established pursuant to 15 U.S.C. 3052(c)(2).

Racetrack Safety and Welfare Committee means the committee established pursuant to Rule 2121.

Regulatory Veterinarian means a Veterinarian employed, contracted, or appointed by a State Racing Commission, Racetrack, or the Authority, who, in addition to other duties, is responsible for monitoring the health and welfare of Covered Horses during Covered Horseraces.

Responsible Person means the individual designated in the registration with the Authority as the Responsible Person in accordance with the following:

(1) For a Covered Horse that has not yet performed its first Workout (or competed in a Race, whichever is earlier), the Responsible Person shall be the Owner of the Covered Horse unless the Horse is in training in another country.

(2) Once in training, the Responsible Person shall be the licensed Trainer for the Covered Horse. The licensed Trainer's designation as the Responsible Person shall be filed with the Authority. The Trainer designation must be kept current with the Authority. Designation transfers must be in writing and on record with the Authority prior to the effective date of the transfer, except for claiming Races in which transfers must be recorded the same day.

(3) If a Covered Horse ceases training for a period of time, the designation may be transferred to the Owner prior to the effective date.

(4) If the Owner is an entity, the managing Owner shall be named.

ROAP means the Racing Officials Accreditation Program.

Safety Director means an individual designated as, and having the responsibilities of, a Safety Director as set forth in Rule 2131.

Safety Officer means an individual designated as, and having the responsibilities of, a Safety Officer as set forth in Rule 2136.

Shock Wave Therapy means extracorporeal shock wave therapy or radial pulse wave therapy.

Starting Gate Person means any individual licensed as an assistant starter or any individual who handles Horses in the starting gate.

State Racing Commission means the regulatory body established or recognized by a State or the Federal government with authority to regulate, approve, or license Covered Persons and Covered Horses.

Trainer means a Person engaged in the training of Covered Horses.

Training Facility means a location that is not a Racetrack that operates primarily to house Covered Horses and conduct Workouts.

Veterinarian means a licensed veterinarian who provides veterinarian services to Covered Horses and who, as a prerequisite to providing veterinarian services to Covered Horses, has registered with the Authority.

Workout means an official timed running of a Covered Horse over a predetermined distance not associated with a Race.

2100. Racetrack Accreditation

2101. General

(a) The Racetrack Safety Committee and the Authority shall oversee Racetrack Safety Accreditation in accordance with the provisions of Rules 2100 through 2193. The Racetrack Safety Committee may also adopt best practices and guidance in accordance with the Act and the rules and regulations promulgated thereunder to provide further guidance to the Racetracks in the Accreditation Process.

(b) All Racetracks are required to seek and meet the requirements of Racetrack Safety Accreditation with the Racetrack Safety Committee in accordance with the provisions of Rules 2100 through 2193.

2110. Accreditation Process

2111. Interim and Provisional Accreditation

(a) Interim Accreditation.

(1) A Racetrack that is accredited by the National Thoroughbred Racing Association as of the Program Effective Date shall be granted interim Racetrack Safety Accreditation, which shall be effective until the later of:

[34] The Commission notes that the 3000 Series and 4000 Series rules have not yet been proposed by the Authority. This and other cross-references to forthcoming rule proposals will be effective if such rules are proposed by the Authority and approved by the Commission under the same process as this proposed rule.

(i) Such time as the Racetrack Safety Committee completes an Accreditation assessment under Rule 2112 with respect to such Racetrack; or

(ii) the time period established by the Authority under Rule 2114(a).

(b) Provisional Accreditation.

(1) A Racetrack that is not accredited by the National Thoroughbred Racing Association as of the Program Effective Date shall be granted provisional Racetrack Safety Accreditation, which shall be effective until the later of:

(i) Such time as the Racetrack Safety Committee completes an Accreditation assessment under Rule 2112 with respect to such Racetrack; or

(ii) the time period established by the Authority under Rule 2114(b).

(2) The Authority may at any time upon reasonable notice require a Racetrack with provisional Racetrack Safety Accreditation to report on its progress in achieving Accreditation. The Authority may request any additional information from the Racetrack necessary to make its determination and may conduct unannounced on-site inspections at any time.

2112. Accreditation Assessment

(a) Upon the initiation of an Accreditation assessment by the Racetrack Safety Committee, the subject Racetrack shall submit or provide access to any relevant information and documentation requested by the Racetrack Safety Committee. The Racetrack Safety Committee may request any additional information and documentation required for the assessment and may propound additional written questions or inquiries to the Racetrack. The Racetrack shall respond in writing to all additional questions and inquiries within 60 days of receipt of any additional questions and inquires.

(b) After review of all information submitted by the Racetrack under of Rule 2112(a), the Racetrack Safety Committee shall conduct an on-site inspection of the Racetrack. The Racetrack Safety Committee shall then prepare a post-inspection report identifying any aspects of the Racetrack's operations that are not in compliance with the requirements of Rules 2100 through 2193.

(c) Within 60 days of the Racetrack's receipt of the post-inspection report under Rule 2112(b), the Racetrack shall respond in writing to the Racetrack Safety Committee setting forth all actions to be taken by the Racetrack to remedy the areas of non-compliance identified in the post-inspection report, and the timeframes necessary for implementation of such remedial actions.

(d) The Racetrack Safety Committee shall assess the Racetrack's response and make a written recommendation to the Authority whether to issue or deny Accreditation or provisional Accreditation of the Racetrack.

2113. Issuance of Accreditation

(a) The Authority shall determine whether a Racetrack is entitled to Accreditation by evaluating compliance with the requirements set forth in Rules 2100 through 2193.

(b) In determining whether to grant, renew, or deny Accreditation to a Racetrack, the Authority shall review all information submitted by the Racetrack and the Racing Safety Committee's recommendation.

2114. Effective Periods of Accreditation

(a) Accreditation.

(1) Accreditation shall be effective for a period of 3 years.

(2) The Authority may modify the Accreditation period to a period of 1 to 7 years if the Authority determines that such modified period will be consistent with the requirements of Accreditation outlined in Rules 2100 through 2193.

(b) Provisional Accreditation.

(1) Provisional Accreditation shall be effective for an initial period of 1 year.

(2) Upon the expiration of the initial 1 year period referenced in paragraph (1) above, provisional Accreditation may be extended for additional 1 year periods if the Authority determines that the subject Racetrack is continuing to undertake good faith efforts to comply with the requirements of Rules 2100 through 2193 and achieve Accreditation.

2115. Annual Reporting

All Racetracks granted Accreditation under these Rules shall participate in ongoing reporting and review to the Racetrack Safety Committee. All accredited Racetracks shall, by December 31 of each calendar year, submit annual reports to the Racetrack Safety Committee demonstrating compliance with all Accreditation requirements.

2116. Suspension and Revocation of Accreditation

(a) An accredited Racetrack that is in material noncompliance with the Accreditation requirements, after having received notice of the noncompliance and been given a reasonable opportunity to remedy the noncompliance, may have its Accreditation suspended by the Authority.

(b) A provisionally accredited Racetrack that is in material noncompliance with the provisional Accreditation requirements, after having received notice of the noncompliance and been given a reasonable opportunity to remedy the noncompliance, may have its provisional Accreditation suspended by the Authority.

(c) A Racetrack under suspension shall not conduct any Covered Horserace.

(d) A suspended Racetrack that fails to remedy the noncompliance in a reasonable time may have its Accreditation or provisional Accreditation revoked by the Authority.

2120. Accreditation Requirements

2121. Racetrack Safety and Welfare Committee

(a) General. The Racetracks in each State shall form a Racetrack Safety and Welfare Committee to review the circumstances around fatalities, injuries, and racetrack safety issues with the goal of identifying possible contributing risk factors that can be mitigated. The Regulatory Veterinarian shall chair the Racetrack Safety and Welfare Committee.

(b) Composition. The composition of the Racetrack Safety and Welfare Committee may vary among jurisdictions, provided that each Racetrack Safety and Welfare Committee shall include, at a minimum, the following:

(1) Regulatory Veterinarian;

(2) Association Veterinarian;

(3) Medical Director;

(4) Safety Officer or steward, subject to the applicable State Racing Commission electing to enter into an agreement with the Authority if such individual is employed by the State Racing Commission;

(5) Horsemen's representative;

(6) Jockey;

(7) Trainer;

(8) racing secretary, and

(9) racetrack superintendent.

(i) The Regulatory Veterinarian shall chair the Racetrack Safety and Welfare Committee.

(ii) If the Safety Director is not a committee member, the Safety Director shall be an ex officio member of the Racetrack Safety and Welfare Committee.

(c) Responsibilities. The Racetrack Safety and Welfare Committee shall be responsible for:

(1) Review of all equine catastrophic injuries and the circumstances surrounding those injuries, including, at a minimum:

(i) Interviews with Trainers, Jockeys, exercise riders, and Attending Veterinarians, and when appropriate, a qualified human health provider;

(ii) examination of past performances, Workouts, pre-race inspection findings, necropsy examination findings, and Trainer and Veterinary treatment records;

(iii) review of Race or training video footage, if applicable;

(iv) review of racetrack surface conditions and weather information;

(v) convening a meeting with connections of the Covered Horse and other interested Persons, including, at a minimum, the Regulatory Veterinarian, Trainer, and Attending Veterinarian, and if applicable, the Jockey, exercise rider, and racetrack superintendent to:

(A) Convey the findings of the review;

(B) acquire additional information useful for developing strategies for injury prevention; and

(C) provide continuing education or continuing education recommendations related to cause of equine injury, if available, to persons related to the applicable Covered Horse;

(vi) evaluation of factors that may have contributed to injuries;

(vii) evaluation of the effectiveness of protocols and procedures for managing the equine injury scenario; and

(viii) developing strategies to mitigate identified factors that may have contributed to the injury.

(2) Review of all environmental factors related to racing and training that may have contributed to human injury occurrences including:

(i) Evaluation of external factors that may have contributed to injuries;

(ii) development of strategies to mitigate identified factors that may have contributed to the injury; and

(iii) evaluation of the effectiveness of protocols and procedures for managing human injury occurrences;

(3) Consideration of Racetrack safety issues brought to the Racetrack Safety and Welfare Committee's attention;

(4) Summary review of all injuries and considerations to review existing practices;

(5) Development of strategies to reduce or mitigate injury occurrences;

(6) Enhancement of the identification of Horses or conditions for which intervention is warranted;

(7) Enhancement of racetrack safety for equine and human participants; and

(8) Preparation and submission of a report that summarizes the findings of the Racetrack Safety and Welfare Committee under this paragraph (c) to the Authority within 60 days of the end of the applicable Race Meet, unless the Racetrack Safety Committee requires earlier submission.

2130. Required Safety Personnel

2131. Safety Director

(a) The Safety Director shall oversee equine safety, racetrack safety, and risk management and injury prevention at each Racetrack in accordance with the provisions of these rules. The Safety Director may at the same time serve in the applicable jurisdiction as a Regulatory Veterinarian or Safety Officer. Subject to the approval of the Racetrack Safety Committee, the Safety Director may be shared within and among jurisdictions.

(b) If the applicable State Racing Commission does not enter into an agreement with the Authority, then the Racetracks in such jurisdiction shall implement the requirements set forth in this Rule, subject to the Racetrack Safety Committee's approval of the individual named as Safety Director.

(c) The Safety Director shall be responsible for:

(1) Creating a culture of safety for Horses, riders, and Racetrack personnel;

(2) Overseeing all aspects of equine safety, racetrack safety, and safety of personnel working with Horses by ensuring that all activities and practices involving the training and racing of Horses at the track meet required safety standards;

(3) Implementing a risk management and injury prevention program under the oversight of the Racetrack Safety Committee;

(4) Providing guidance to Attending Veterinarians on safety issues;

(5) Maintaining and annually reviewing standard operating procedures and protocols;

(6) Coordinating and overseeing emergency drills that include equine injury and starting gate malfunction;

(7) Reporting all equine injuries and fatalities to the Authority within 72 hours of injury; and

(8) Interacting with the Authority concerning Racetrack Safety Accreditation compliance.

2132. Medical Director

(a) The Medical Director shall oversee the care and organization of the medical needs of Jockeys. The Medical Director shall be either a licensed physician or a board-certified athletic trainer. Subject to the approval of the Racetrack Safety Committee, the Medical Director may be shared within and among jurisdictions.

(b) In any jurisdiction where the applicable State Racing Commission does not elect to enter into an agreement with the Authority to establish a Medical Director consistent with this Rule, the Authority shall appoint and employ a Medical Director to serve as Medical Director in that jurisdiction. The Racetracks in the applicable jurisdiction shall reimburse the Authority for all costs associated with the employment of the Medical Director. Such reimbursement shall be shared by the Racetracks in such jurisdiction proportionally by total handle wagered in the applicable State in the prior calendar year.

(c) The Medical Director shall:

(1) Identify professional medical providers and referral networks that are licensed and certified to oversee racetrack emergency services, which may include, hospital affiliations, nursing staff, EMT service and paramedics, internists, surgeons, family practitioners, dentists, athletic trainers, or psychiatrists;

(2) Make medical provider contact information readily available for ease of communication and immediate coordination of care for any medical event;

(3) Report all human injuries to the Authority within 72 hours of injury;

(4) Coordinate and oversee a plan for on-site medical care, including provisions for emergency medical facilities and staffing;

(5) Implement an emergency drill for a rider injury;

(6) Coordinate and oversee a comprehensive plan for transportation of an injured rider to the nearest Trauma Level One or Two facility;

(7) Coordinate and oversee a plan for transportation of an injured rider to the Racetrack's first aid facility;

(8) Ensure compliance with mandatory annual rider physical examination requirements to indicate readiness to ride for Jockeys, and document compliance to the Authority;

(9) Exercise oversight of medical standards, including the minimum criteria for riding fitness;

(10) Certify a rider's fitness to resume riding after any on-track incident that may impair the rider's reflexes, decision-making or ability to maintain control of his or her Horse in a race;

(11) Implement the program for Concussion evaluation, rider exclusion and clearance, and return to ride protocol;

(12) Develop in writing, subject to annual review and revision as necessary, the Racetrack's Emergency Action Plan, which shall include readiness for medical needs of racing participants, workers, and spectators; and

(13) Work with local, State, and Federal regulators to standardize the approach and response to pandemic-related issues among riders, workers, and spectators.

2133. Stewards

(a) In States where the applicable State Racing Commission elects to enter into an agreement with the Authority, the stewards, in addition to their duties under State law, shall enforce the safety regulations set forth in Rules 2200 through 2293.

(b) To qualify for appointment as a steward, the appointee shall meet the experience, education, and examination requirements necessary to be accredited by the ROAP and be in good standing with all racing jurisdictions.

(c) The requirements of Rule 2133 for any steward employed by a State Racing Commission are subject to the applicable State Racing Commission electing to enter into an agreement with the Authority. If the applicable State Racing Commission does not enter into such an agreement, the Racetracks in the jurisdiction shall implement the requirements set forth in Rule 2133, subject to the Racetrack Safety Committee's approval of the individuals named as stewards by the Racetracks. The stewards named by the Racetracks shall enforce only the safety regulations set forth in Rules 2200 through 2293.

2134. Regulatory Veterinarian

(a) The Regulatory Veterinarian shall:

(1) Subject to the provisions of Rule 2134(b), be employed by the State Racing Commission or similar agency having jurisdictional authority;

(2) be licensed to practice in the applicable jurisdiction;

(3) refuse employment or payment, directly or indirectly, from any Owner or Trainer of a Horse racing or intending to race in the jurisdiction while employed as a Regulatory Veterinarian;

(4) refrain from directly treating or prescribing for any Horse within the applicable jurisdiction except in cases of emergency, accident, or injury; and

(5) be trained, and their proficiency verified, in identifying and stabilizing common musculoskeletal injuries.

(b) In any jurisdiction where the applicable State Racing Commission does not elect to enter into an agreement with the Authority to establish a Regulatory Veterinarian consistent with Rule 2134, the Authority shall employ a Veterinarian to serve as the Lead Veterinarian in such jurisdiction. The Lead Veterinarian shall perform all the duties, obligations, and responsibilities of the Regulatory Veterinarian in these regulations. The Racetracks in the applicable jurisdiction shall reimburse the Authority for all costs associated with the employment of the Lead Veterinarian. The reimbursement shall be shared by the Racetracks in the jurisdiction proportionally by total handle wagered in the applicable State in the prior calendar year.

2135. Responsibilities and Duties of Regulatory Veterinarian

(a) The Regulatory Veterinarian shall have the following responsibilities and duties:

(1) Notify the stewards of any Horse deemed unsafe to be raced, or a Horse that it would be inhumane to allow to race;

(2) conduct pre-race inspections on all potential starters on race day;

(3) inspect any Horse when there is a question as to the physical condition of such Horse independent of the Horse's entry status;

(4) be present in the paddock during saddling, on the racetrack during the post parade, and present at the starting gate until the Horses are dispatched from the starting gate for the Race;

(5) scratch any Horse that is, in the opinion of the Regulatory Veterinarian, injured, ill, or otherwise unable to compete due to a medical or health-related condition;

(6) inspect any Horse which appears to be in physical distress during the Race or at the finish of the Race;

(7) provide emergency medical care to Horses injured while racing and effect case transfer to the Attending Veterinarian;

(8) be authorized to euthanize, consistent with the current version of the AVMA Guidelines for the Euthanasia of Animals, any Horse deemed to be so seriously injured that it is in the best interests of the Horse to so act;

(9) report to the Safety Director the names of all Horses euthanized or which otherwise die at the meeting and the reasons therefor;

(10) maintain the Veterinarians' List of Horses ineligible to race and notify the stewards of the identities of all Horses placed on the Veterinarians' List; and

(11) collaborate with the Safety Director, Chief Veterinarian of the State Department of Agriculture, and other regulatory agencies to take measures to control communicable or reportable equine diseases.

(b) If the Regulatory Veterinarian and his or her staff are unable to fulfill any of the duties described in Rule 2135(a), such duties may, at the request of the Regulatory Veterinarian, be performed by an Association Veterinarian. In such case, the Association Veterinarian shall be responsible for adhering to and upholding the rules and regulations of the Authority and the State Racing Commission.

(c) The Regulatory Veterinarian, and any Association Veterinarian exercising duties of the Regulatory Veterinarian as provided in paragraph (b) above, are authorized to:

(1) Access any and all Horses housed on Racetrack grounds regardless of entry status;

(2) perform inspections of any Horse at any time;

(3) observe Horses during training activities and Workouts;

(4) perform pre-Race veterinary inspections and post-Race observations; and

(5) Place a Horse on the Veterinarians' List.

(d) The Regulatory Veterinarian shall have jurisdiction over the Attending Veterinarians within the grounds of the Racetrack and shall review and consult with the stewards, and State Racing Commission regarding the State Racing Commission license applications of Attending Veterinarians, veterinary technicians or assistants, vendors of medical supplies and equipment, and non-Veterinarian health care providers. The authority and responsibilities of the Regulatory Veterinarian under this paragraph (d) shall not be performed by an Association Veterinarian pursuant to Rule 2135(b).

2136. Racetrack Safety Officer

(a) Each Racetrack shall have a Safety Officer to ensure that all activities and practices involving the training and racing of Horses at the Racetrack meet required safety standards and regulatory guidelines. The Safety Officer may also be a steward.

(b) The Safety Officer shall:

(1) Monitor daily stable area activities and practices in the barn area and on the racetrack for compliance with the applicable State Racing Commission safety regulations and the Rules of the Authority;

(2) Conduct pre-Race Meet racetrack safety inspections;

(3) Monitor outrider compliance with Racetrack rules during morning workouts;

(4) Monitor starting gate procedures;

(5) Monitor ambulance and medical personnel protocols for Horses and riders;

(6) Assist Regulatory Veterinarians with follow-up on Horses barred from training or vanned off during training and racing;

(7) Review ship-in and ship-out lists and undertake appropriate investigations;

(8) Conduct random license checks in the stable area;

(9) Conduct random barn inspections to monitor safety and regulatory

compliance, including fire safety regulations;

(10) Conduct random inspections to verify acceptable management, equine husbandry, and veterinary practices;

(11) Advise stewards of all planned and random inspections;

(12) Enforce fire safety rules in the stable area;

(13) Serve as a member or ad hoc member of the Racetrack Safety and Welfare Committee; and

(14) Make recommendations to Racetrack management and racing officials to ensure the welfare of Horses and riders, the integrity of racing, and compliance with applicable horse racing laws and regulations.

2140. Racehorse Inspections and Monitoring

2141. Veterinary Inspections

(a) Veterinary inspections shall be performed by the Regulatory Veterinarians on all Horses entered in a Race. Such inspections shall include the items listed in Rule 2142.

(b) If, prior to starting a Race, a Horse is determined to be unfit for competition, or if the Regulatory Veterinarian is unable to make a determination of racing soundness, the Regulatory Veterinarian shall notify the stewards that the Horse is scratched. Regulatory Veterinarians shall have the unconditional authority to scratch a Covered Horse from a Race.

2142. Assessment of Racing Soundness

(a) Post-entry screening. The Regulatory Veterinarian shall perform post-entry screenings of previous pre-Race inspection findings of entered Horses to identify Horses that may be at increased risk for injury. The Regulatory Veterinarian shall review past performances, lay-ups (more than 60 days without a timed Workout or Race), last 30 days medical history, previous injury and lameness diagnostics, intra-articular corticosteroid injections, previous surgery, and individual Horse risk factors.

(b) Pre-race veterinary inspection. Every Horse entered to participate in a Covered Horserace shall be subjected to inspection by a Regulatory Veterinarian prior to starting in the Race for which it is entered on race day not later than 1 hour prior to scratch time for the Race in which the Horse is to compete.

(1) The Trainer of each Horse or a representative of the Trainer who is knowledgeable about the Horse and able to communicate with the Regulatory Veterinarian must present the Horse for inspection. Horses presented for inspection must have bandages removed, and the legs must be clean and dry. Prior to inspection, Horses may not be placed in ice and no device or substance shall be applied to the Horse that impedes veterinary clinical assessment.

(2) The Regulatory Veterinarian's inspection of each Horse prior to participating in a Race shall include, at a minimum, the following:

(i) Identification of the Horse;

(ii) Ascertainment of the sex of the Horse;

(iii) Performance of an overall inspection of the entire Horse, assessing general appearance, behavior, disposition, posture, and body condition;

(iv) Observation of the Horse jogging in hand, moving toward and away from the Veterinarian so that both hind-end and front-end motion can be evaluated;

(v) Performance of a digital palpation on both distal forelimbs;

(vi) Placement of the Horse on the Veterinarians' List if the Horse does not jog sound or warm up to the Regulatory Veterinarian's satisfaction;

(vii) Visual observation in the paddock and saddling area, during the parade to post, and at the starting gate; and

(viii) Any other inspection deemed necessary by the Regulatory Veterinarian, including Jockey consultation for the Jockey's mount.

(3) A report summarizing the results of a pre-Race inspection under paragraph (a) shall be submitted to the Authority on the day of the inspection.

(c) Post-race assessment. Post-Race visual observations shall be performed by a Regulatory Veterinarian on all Horses leaving the racetrack at the conclusion of every Race.

(1) If a Horse is determined to have Bled or to be physically distressed, medically compromised, injured, or unsound at any time before exiting the racetrack or leaving the test barn, the Horse shall be placed on the Veterinarians' List and the Regulatory Veterinarian shall document post-race inspection findings to the Authority.

(2) If a Horse is determined to have skin lacerations, swellings, or welts that resulted from crop use, the stewards and Attending Veterinarian shall be notified, and the information documented to the Authority.

(d) Training. Regulatory Veterinarians may observe Horses during training activities. Horses deemed physically distressed, medically compromised, injured, or unsound may be placed on the Veterinarians' List and reported to the Authority.

2143. Racehorse Monitoring

(a) All Horses, including stable ponies, entering the Racetrack grounds must have proof of health certificate and required vaccinations, which shall include:

(1) Certificate of veterinary inspection within the prior 5 days or fewer days if high risk situations dictate;

(2) Verification of EEE/WEE/WNV (encephalitides), rabies, and tetanus vaccinations within the prior 12 months;

(3) Verification of Influenza and Rhinopneumonitis vaccinations within the prior 180 days or fewer days if high risk situations dictate; and

(4) Verification of Negative Equine Infectious Anemia (Coggins) Test within the calendar year or in a shorter period of time if high risk situations dictate.

(b) Each Racetrack shall submit the following information to the Authority with respect to each Horse on its grounds:

(1) Horse identification;

(2) Origin of Horse;

(3) Date of entry;

(4) Verification of certificate of veterinary inspection; and

(5) Verification of vaccinations.

(c) Each Racetrack shall submit the following information to the Authority with respect to each Horse leaving its grounds:

(1) Horse identification;

(2) Intended destination;

(3) Reason for departure;

(4) Date of exit;

(5) Vehicle license plate; and

(6) Transporter.

(d) Horses moving interstate must meet the entry requirements of the destination State, the State Racing Commission in the destination State, and the individual Racetracks or Training Facilities to which the horse is being shipped in the destination State.

2150. Racetrack and Racing Surface Monitoring and Maintenance

2151. Data Collection, Recordkeeping and Submission

(a) Racetracks shall have data collection protocols in place to assist in the proper and consistent maintenance of all racing and training surfaces. Racing and training surface testing and maintenance should be performed based on the Racetrack's written standard operating procedures which are reviewed annually and updated as needed. The Racetrack Safety Committee, or its designees, shall develop and annually update a Racetrack Surface Standard Practices Document.

(b) All Racetrack design records, racing and training surface maintenance

records, surface material tests, and daily tests data shall be recorded in a format acceptable to the Authority and shall be submitted to the Authority. Any test results shall be submitted to the Authority within 1 week of the test results.

2152. Testing Methods

Surface test methods and surface material test methods must be documented and consistent with testing standards from internationally recognized standards organizations including ASTM International, American Society of Agricultural and Biological Engineers, or other relevant international standards, and when possible for unpublished standards, methods consistent with those documented by the Racing Surfaces Testing Laboratory.

2153. Racetrack Facilities

The Racetrack facilities must be designed, constructed, and maintained as provided in Rule 2153 to provide for the safety of Covered Persons and Covered Horses.

(a) Rails.

(1) Racetracks shall have inside, outside, and gap rails designed, constructed, and maintained to provide for the safety of Jockeys and Horses.

(2) Objects within 10 feet of the inside rail shall be flexible enough to collapse upon impact of a Horse or rider, or sufficiently padded as to prevent injury.

(3) Rails shall be inspected prior to each Race Meet and daily during training and racing events.

(b) Gaps.

(1) All gaps must be clearly marked, must have protective padding covering any sharp edges or unique angles, and have proper mechanisms to allow for secure closure when needed.

(2) Main gaps and on-gaps should include signage with safety rules, Racetrack hours, and other applicable rules.

(3) For Races breaking from a chute there should be sufficient temporary rail extension to prevent Horses from ducking in or out.

(c) Starting gate.

(1) All gates, and the vehicle that moves the gates, must be inspected pre-Race Meet and documented to be in proper working condition.

(2) All gates must have protective padding to ensure the safety of the Horse, Jockey, and gate personnel. Protective padding shall protect the riders and gate personnel from contact with sharp edges and help to distribute impact loads. All padding shall be designed to ensure durability for outdoor use and shall be capable of maintaining safety and physical integrity during all weather conditions.

(3) Gates and the vehicle that moves the gates shall be inspected and tested each race day before the Races and each morning before schooling to ensure proper functioning.

(4) No personnel, other than those required for steering the gate, shall ride on the gate while the gate is in motion or being transported.

(5) Racetracks shall have in place annually reviewed and documented standard operating procedures for the removal of the starting gate after the start of each Race as needed in a safe and timely manner. This plan shall also include procedures for gate removal if the primary removal mechanism fails.

(6) Every Starting Gate Person shall wear protective gear when working on or around the starting gate, including approved helmets and safety vests.

(7) If the starting gate becomes inoperable during racing hours, racing may not continue until the starting gate is brought back to safe operating standards or the inoperable gate is replaced with a properly functioning alternate gate.

(8) During racing hours, a Racetrack should ensure that sufficient assistant starters are available to safely handle each Horse entered in a Race.

(9) A Racetrack shall make at least one starting gate and one Starting Gate Person available for racehorse schooling during designated gate training hours.

(d) Emergency warning system.

(1) Each Racetrack shall have an operational emergency warning system on all racing and training tracks. The emergency warning system shall be approved by the State Racing Commission, subject to the applicable State Racing Commission electing to enter into an agreement with the Authority. If such agreement does not exist, the emergency warning system shall be approved by the Authority.

(2) The emergency warning system shall be tested bi-weekly before training or racing.

(3) During training, when the emergency warning system is activated, all persons on horseback shall slow to a walk and no one on horseback shall enter the racetrack.

(4) The Racetrack announcer shall be trained to utilize the public address system to:

(i) Warn riders of potentially dangerous situations and provide direction; and

(ii) Warn patrons of potentially dangerous situations and provide direction.

2154. Racetrack Surface Monitoring

(a) Racetracks shall provide equipment and personnel necessary to maintain the racetrack surface in a safe and consistent condition.

(b) Pre-meet inspection shall be performed on all surfaces prior to the start of each Race Meet with sufficient time allotted to facilitate corrections of any issues prior to racing. For Race Meets spanning periods with significant weather variation, inspections shall be performed seasonally prior to anticipated weather changes.

(1) Inspections for dirt and synthetic surfaces shall include the following elements:

(i) Determine and document race and training track configurations and geometries, including:

(A) Geometry and slopes of straights and turns and slopes at each distance marker pole;

(B) The accuracy of distances from the finish line to the marker poles; and

(C) Cushion and base geometries;

(ii) Base inspection, including windrowing and base survey, surface survey, ground penetrating radar, or other method;

(iii) Mechanical properties of racing and training tracks using a biomechanical surface tester shall be determined and documented;

(iv) Surface material samples of racing and training tracks shall be analyzed for material composition pursuant to the Racetrack Surface Standard Practices Document; and

(v) Corrective measures to address issues under paragraphs (i) through (iv) above.

(2) Inspections for turf surfaces shall include the following elements:

(i) Determine and document racetrack configuration and geometry, including:

(A) Geometry and slopes of straights and turns and slopes at each distance marker pole;

(B) irrigation systems;

(C) turf profile; and

(D) ensure distances from the finish line to the marker poles are correct;

(ii) Document turf species;

(iii) Mechanical properties of racing and training tracks using a surface tester should be determined and documented;

(iv) Surface material samples of racing and training tracks shall be analyzed for material composition pursuant to the Racetrack Surface Standard Practices Document;

(v) The irrigation system must be tested to evaluate function of all components and water coverage including gaps and overlap; and

(vi) Corrective measures to address issues under paragraphs (i) through (v) above.

(c) Daily measurements shall be taken at the beginning of all daily training and racing sessions for racing and training tracks, and taken at each ¼ mile marker pole at locations 5 and 15 feet outside the inside rail.

(1) For dirt and synthetic surfaces, such daily measurements shall include:

(i) Moisture content;

(ii) Cushion depth; and

(iii) Weather conditions and precipitation at 15-minute intervals from a national or local weather service.

(2) For turf surfaces, such daily measurements shall include:

(i) Moisture content; and

(ii) Penetration and shear properties.

(d) Surface equipment inventory, surface maintenance logs, and surface material addition or renovation logs shall be maintained and submitted to the Authority.

(1) Daily surface maintenance logs should include equipment used, direction of travel, and water administration.

(2) Documentation of the source, timing, quantity, and method of all additions to the surfaces shall be submitted to the Authority.

2160. Emergency Preparedness

2161. Emergency Drills

Emergency protocols shall be reviewed, and drills shall be conducted, prior to the beginning of each Race Meet for purposes of demonstrating the Racetrack's proficiency in managing the following emergencies:

(a) Starting gate malfunction;

(b) Paddock emergencies;

(c) Equine injury;

(d) Jockey injury;

(e) Loose Horse;

(f) Fire;

(g) Hazardous weather condition; and

(h) Multiple injury scenarios for both Horses and Jockeys.

2162. Catastrophic Injury

Racetracks and Training Facilities under the jurisdiction of a State Racing Commission shall have protocols in place for instances of catastrophic injury to Horses during racing and training. Protocols should include, but not be limited to, requiring collection of biological samples in sufficient volume, to permit comprehensive drug testing. Planning shall include appropriate means of communication to the public.

2163. Fire Safety

Racetracks and Training Facilities under the jurisdiction of a State Racing Commission shall plan for and have protocols in place for instances of fire within their enclosures. Fire and life safety inspections shall be performed in accordance with the local authority and appropriate National Fire Protection Association standards and shall be conducted at the required frequency. Racetracks shall document adherence to the applicable local fire protection authority.

2164. Hazardous Weather

Each Racetrack shall develop, implement, and annually review a hazardous weather protocol which shall include:

(a) Designation of the personnel responsible for monitoring weather conditions, immediately investigating any known impending threat of dangerous weather conditions and determining if conditions exist which warrant delay or cancellation of training or racing and the notification to the public of such dangerous weather conditions;

(b) Use of a designated weather watcher and a reliable source for monitoring the weather, including lightning strike distance/radius notifications;

(c) Implementation of a dangerous weather protocol, which includes for extreme heat and chill factors and air quality;

(d) Designation by the Racetrack of an official responsible for monitoring weather conditions during training and racing hours;

(e) Consideration by the Racetrack of lightning safety guidelines such as the National Athletic Trainers' Association Position Statement, or more recent evidence-based recommendations;

(f) Requirements that the stewards shall contact Racetrack management when weather conditions may become hazardous, and that the stewards shall commence a racing and training delay when weather conditions pose risks to human and equine welfare; and

(g) Designation by the Racetrack of an official responsible for enforcing any weather associated training delay.

2165. Infectious Disease Management

(a) Plans and protocols shall be put in place by each Racetrack to manage an infectious disease outbreak. Such protocols shall be based on guidelines recommended by the AAEP General Biosecurity Guidelines and AAEP Healthy Horse Protocols: Biosecurity Guidelines for Racetrack Entry and Stabling or more recent versions or developed in consultation with the appropriate State agency or official.

(b) The Regulatory Veterinarian shall maintain written biosecurity guidelines and standard operating procedures and train Racetrack safety personnel in basic biosecurity protocols. All Covered Persons must report any symptoms that may be attributed to an infectious disease to the Regulatory Veterinarian and Safety Director.

(c) During an infectious disease outbreak, the above requirements may be revised as dictated by the circumstances, and all Covered Persons shall adhere to disease control measures implemented by State Racing Commissions or applicable State veterinary authorities.

(d) The Safety Director, or Regulatory Veterinarian if the Safety Director is not a licensed veterinarian, must notify the Chief Veterinarian of the relevant State Department of Agriculture (or comparable State government official) to enable timely and accurate reporting of disease outbreaks at the racetrack to the Equine Disease Communication Center.

2166. Human Ambulance Support

(a) A Racetrack shall provide a properly staffed and equipped Advanced Life Support ambulance during training and racing hours. If the ambulance is being used to transport an individual, the Racetrack may not conduct a race, or allow Horses with riders on the racetrack, until the ambulance is replaced or available for service.

(b) Racetracks shall ensure the Advanced Life Support ambulance staff has been trained in Concussion management. Any Jockey who falls or is thrown from a Horse during a race must be examined by the Advanced Life Support staff. Advanced Life Support staff shall report their findings to the stewards who will determine if the Jockey may continue riding.

(c) Unless otherwise approved by the State Racing Commission or the stewards, an ambulance shall follow the field at a safe distance during the running of races.

(d) The ambulance must be parked at an entrance to the racing strip except when the ambulance is being used to transport an individual or when it is following the field during the running of a race.

2167. Accident Reporting System

(a) Racetracks shall develop standard operating procedures for the collection of data associated with all incidents resulting in Jockey or exercise rider injuries sustained at the racetrack and submit such information to the Authority within 10 days of the injury occurrence. Covered Persons involved in, or witnesses to, the circumstances surrounding the injury shall make themselves available to and cooperate with those individuals collecting data for the database.

(b) Data collected shall include:
(1) Name of person injured;
(2) nature of the injury;
(3) date and time of day of injury;
(4) occupation of person;
(5) cause of the incident;
(6) weather;
(7) location of the incident; and
(8) witness statements.

2168. Equine Ambulance

A dedicated Horse ambulance with personnel trained to operate the ambulance shall at all times be available for rapid deployment during racing and training periods. It is recommended that a second ambulance be available in the case of multiple equine injuries or failure of the primary Horse ambulance.

2169. Paddock Safety

Racetracks shall have protocols in place to manage the safety of their saddling paddocks and walking rings. Such protocols should include crowd management policies as well as emergency response procedures for human and equine injuries. An emergency medical technician or paramedic shall be present during saddling.

2170. Necropsies

(a) All Horses that die or are euthanized on Racetrack grounds shall have an autopsy (necropsy) examination performed.

(b) Necropsies should be performed at facilities and by personnel with capabilities and expertise to perform necropsy examination of racehorses. Relationships and contact information shall be included in the necropsy standard operating procedure. The Veterinarian performing the necropsy shall not be an Attending Veterinarian of the affected Horse.

(c) Field necropsy is strongly discouraged. When a field necropsy is the only practical option available, necropsy examinations shall be performed under direct or indirect supervision of a board-certified pathologist including phone call guidance or video conferencing. Necropsies shall be performed in a secure area on all Horses that die or are euthanized on Racetrack premises, isolated from the general public. Whenever possible, the Veterinarian performing the necropsy shall not be an Attending Veterinarian of the affected Horse.

(d) Transportation options for necropsy cases and invoicing for the transportation and necropsy shall be identified prior to need and included in a standard operating procedure. Secure storage, pending transport, and transportation of the body should be managed in such a way that tissue degradation and the development of post-mortem artifacts are minimized. Care shall also be taken to implement sound infection control practices with respect to equine infectious or zoonotic disease.

(e) Gross necropsy examination findings must be submitted by the Regulatory Veterinarian to the Authority within 72 hours of receiving the necropsy report, and updates submitted to the Authority within 72 hours as the results of ancillary tests and the final report are received. This workflow shall be included in the necropsy standard operating procedures.

2180. Safety Training and Continuing Education

2181. Uniform National Trainers Test

Subject to the applicable State Racing Commission electing to enter into an agreement with the Authority, the State Racing Commission shall require the use of a uniform National Trainers Test in addition to any State licensing requirements. This test shall have a written component and include practical interviews that demonstrate knowledge and proficiency in basic horsemanship skills, knowledge of racing office protocols, State specific information, and basic equine health care.

2182. Continuing Education

(a) Subject to the applicable State Racing Commission electing to enter into an agreement with the Authority, the State Racing Commission shall identify existing, or provide locally, training opportunities for all Racetrack employees having roles in Racetrack safety or direct contact with Covered Horses.

(b) Required annual continuing education shall include:

(1) Regulatory Veterinarians must complete, on an annual basis, at least 8 hours continuing education specific to racetrack regulatory medicine;

(2) Attending Veterinarians must complete, on an annual basis, at least 8 hours continuing education specifically applicable to racetrack practice;

(3) Medical Directors must complete, on an annual basis, at least 8 hours continuing education;

(4) stewards shall be either accredited or actively participating in gaining accreditation through the ROAP and Certification Programs (maintenance of the ROAP Accreditation requires at least 16 hours of continuing education every 2 calendar years);

(5) Trainers must complete, on an annual basis, at least 4 hours annual continuing education;

(6) assistant trainers must complete, on an annual basis, at least 4 hours annual continuing education;

(7) Owners must complete, on an annual basis, at least 2 hours annually;

(8) Racetrack surface managers must complete at least 8 hours of continuing education every 2 years;

(9) Grooms must complete, on an annual basis, at least 2 hours annual continuing education offered in English and Spanish;

(10) outriders must complete, on an annual basis, at least 2 hours safety and outrider protocol training delivered locally prior to the beginning of a Race Meet;

(11) Jockeys and exercise riders must complete at least 2 hours safety and rider protocols delivered locally in English and Spanish prior to the beginning of a Race Meet;

(12) starters and assistant starters must complete, on an annual basis, at least 2 hours safety training either delivered locally prior to the beginning of a Race Meet or through the ROAP certification; and

(13) Equipment operators must complete, on an annual basis, at least 2 hours safety training either delivered locally prior to the beginning of a Race Meet or through a continuing education program.

2190. Jockey Health

2191. Jockey Drug and Alcohol Testing

Subject to the applicable State Racing Commission electing to enter into an agreement with the Authority, the State Racing Commission shall develop and implement a testing program for drugs and alcohol for Jockeys. The program shall include provisions for medications prescribed by licensed medical doctors that do not affect mental and physical abilities. If a State Racing Commission does not elect to enter into an agreement with the Authority, the Racetracks in such States shall develop and implement a testing program for drugs and alcohol for Jockeys, subject to the approval of the Authority.

2192. Concussion Management

State Racing Commissions, or Racetracks if the applicable State Racing Commission does not enter into an agreement with the Authority, shall implement a Concussion management program for Jockeys containing the following elements:

(a) Each Jockey shall acknowledge in writing that they have been made aware of the Concussion protocols in place for the facility at which they are riding;

(b) A minimum assessment shall include a current Concussion assessment tool examination;

(c) A return-to-ride guideline shall be established in order to clear a Jockey who has been concussed, or is believed to have been concussed, once the Jockey is declared fit-to-ride; and

(d) The stewards shall be notified when a Jockey is not permitted to ride and when the Jockey has been authorized to return to riding.

2193. Insurance

In States where workers compensation benefits are not afforded to Jockeys by State statute or regulation, Racetracks shall maintain a minimum standard of One Million Dollars ($1,000,000) per incident worth of accident medical expense coverage for all Jockeys.

2200. Specific Rules and Requirements of Racetrack Safety Program

2210. Purpose and Scope

(a) The purpose of Rules 2200 through 2293 is to establish specific safety rules and requirements designed to enhance equine and Jockey safety in Horse racing.

(b) Violation of, or failure to comply with, the requirements of Rules 2200 through 2293 shall result in disciplinary action by racing officials and the Authority.

(c) Safety rules arising under State laws or regulations not preempted by 15 U.S.C. 3054(b) shall be governed by applicable State laws and regulations.

2220. Attending Veterinarian

(a) Only Veterinarians licensed by the State Racing Commission may attend to Covered Horses at any location under the jurisdiction of a State Racing Commission.

(b) Veterinarians attending at any location under the jurisdiction of a State Racing Commission are under the authority of the Regulatory Veterinarian and the stewards.

2221. Treatments by Attending Veterinarian

The following limitations apply to drug treatments by Attending Veterinarians of Covered Horses that are engaged in activities related to racing, including training:

(a) No drug shall be prescribed, dispensed, or administered except in the context of a valid Veterinarian-client patient relationship between a Veterinarian, the Owner (who may be represented by the Trainer) and the Covered Horse. The Owner is not required to follow the Veterinarian's instructions, but no drug may be administered without a Veterinarian having examined the Horse and provided the treatment recommendation. Such relationship requires the following:

(1) The Veterinarian, with the consent of the Trainer (on behalf of the Owner), has accepted responsibility for making medical judgments about the health of the Horse;

(2) the Veterinarian has sufficient knowledge of the Horse to make a preliminary diagnosis of its medical condition;

(3) the Veterinarian has performed an examination of the Horse and is acquainted with the keeping and care of the Horse;

(4) the Veterinarian is available to evaluate and oversee treatment outcomes, or has made appropriate arrangements for continuing care and treatment;

(5) the relationship is maintained by veterinary visits as needed; and

(6) the medical judgments of the Veterinarian are independent and are not dictated by the Trainer or Owner of the Horse.

(b) The Trainer and Veterinarian are both responsible for ensuring compliance with this Rule, except that the medical judgment to recommend a drug treatment or to prescribe a drug is the responsibility of the Veterinarian, and the decision to proceed with a drug treatment that has been so recommended is the responsibility of the Owner (who may be represented by the Trainer or other agent).

2230. Treatment Restrictions

(a) Only Trainers or their designees shall be permitted to authorize veterinary medical treatment of Covered Horses under their care, custody, and control at locations under the jurisdiction of the State Racing Commission.

(b) No person other than a Veterinarian licensed to practice veterinary medicine in the State and licensed by the State Racing Commission may prescribe medication with instructions for administration by a Responsible Person for a Covered Horse.

(c) Attending Veterinarians shall not have contact with an entered Horse within 24 hours before the scheduled post time of the race in which the Horse is scheduled to compete unless approved by the Regulatory Veterinarian, or in an emergency. Any unauthorized contact may result in the Horse being scratched from the race in which it was scheduled to compete and may result in further disciplinary action by the stewards.

(d) The Regulatory Veterinarian may administer emergency treatment to Horses on Racetrack grounds when the Attending Veterinarian is not present.

(e) Except as set forth in paragraph (f) below, no person shall possess a hypodermic needle, syringe capable of accepting a needle or injectable of any kind on racetrack grounds or any facility under the jurisdiction of the Regulatory Authority, unless otherwise approved in writing by the State Racing Commission.

(f) At any location under the jurisdiction of the State Racing Commission, Veterinarians may use only one-time disposable syringes, needles, or IV infusion sets; and shall dispose of items in a manner approved by the State Racing Commission and applicable State and governmental regulations.

(g) If a person has a medical condition which makes it necessary to have a syringe at any location under the jurisdiction of the State Racing Commission, that person may request permission of the stewards or the State Racing Commissioning in writing, shall furnish a letter from a licensed physician explaining why it is necessary for the person to possess a syringe, and shall comply with any conditions and restrictions set by the stewards and the State Racing Commission.

2240. Veterinarians' List

(a) A Veterinarians' List shall be maintained by the Authority of all Horses that are determined to be ineligible to compete in a Covered Horserace in any jurisdiction until released by a Regulatory Veterinarian.

(b) The following Horses shall be placed on the Veterinarians' List until removed in accordance with Rules 2241 and 2242:

(1) Horses affected by illness, physical distress, medical compromise, unsoundness, injury, infirmity, heat exhaustion, positive test or overage, administration of a medication invoking a mandatory stand down time, administration of Shock Wave Therapy, positive Out-of-Competition test or any other assessment or determination by Regulatory Veterinarians that such Horse is unfit to race;

(2) Horses which have not started in more than 365 days; and

(3) Horses which have not made a start prior to January 1 of their 4-year-old year.

(c) Trainers and Owners shall be notified in writing within 24 hours that their Horse has been placed on the Veterinarians' List.

(d) Diagnostic testing may be required for any Horse placed on the Veterinarians' List, at the discretion of

the Safety Director, Regulatory Veterinarian, or Association Veterinarian.

2241. Duration of Stay on the Veterinarians' List

Horses placed on the Veterinarians' List in accordance with Rule 2240 shall remain on the Veterinarians' List as follows:

(a) Horses placed on the Veterinarians' List for unsoundness or Epistaxis shall remain on the list for 14 days;

(b) Horses placed on the Veterinarians' List multiple times for unsoundness within the previous 365 days shall remain on the Veterinarians' List for 45 days for the second time, 75 days for the third time, and shall be barred from further racing after the fourth time;

(c) Horses placed on the Veterinarians' List multiple times for Epistaxis within the previous 365 days shall remain on the Veterinarians' List for 30 days for the second time, 180 days for the third time, and shall be barred from further racing after the fourth time;

(d) Horses placed on the Veterinarians' List for illness shall remain on the list for 7 days;

(e) Horses treated with Shock Wave Therapy shall be placed on the Veterinarians' List for 30 days; and

(f) If before, during, or after the workout for removal from the Veterinarians' List, the Horse is deemed to be unsound or to have Bled, the stay on the Veterinarians' List shall be extended an additional 14 days, and further diagnostic testing may be required as determined by the Regulatory Veterinarian.

2242. Removal of Horses From the Veterinarians' List

Regulatory Veterinarians may remove Horses from the Veterinarians' List in accordance with Rule 2242 and shall document such removal to the Authority.

(a) A Horse placed on the Veterinarians' List as unsound or suffering from Epistaxis may be removed from the Veterinarians' List upon satisfaction of paragraphs (1) through (3) below.

(1) A trainer must apply to the Regulatory Veterinarian for permission to work the Horse for removal from Veterinarians' List. Upon receiving such approval, the Trainer and Attending Veterinarian must observe the Horse jog and submit to the Regulatory Veterinarian a co-signed statement that the Horse is fit to perform a Workout.

(2) The Horse must perform a Workout under the supervision of the Regulatory Veterinarian and demonstrate to the satisfaction of the Regulatory Veterinarian that the Horse is sound to race.

(3) The Regulatory Veterinarian determines there is no evidence or signs of Epistaxis, physical distress, medical compromise, unsoundness, or lameness within1 hour after the Workout conducted pursuant to paragraph (a)(2) above.

(b) A Horse placed on the Veterinarians' List as physically distressed or medically compromised may be removed from the Veterinarians' List provided sound health has been declared by the Attending Veterinarian or demonstrated to the Regulatory Veterinarian and documented to the Authority.

(c) In addition to the requirements set forth herein and any requirements of the Protocol, if a Horse is placed on the Veterinarians' List for a positive test or overage of a primary substance invoking a mandatory stand down time, a positive Out-of-Competition test, or any other veterinary administrative withdrawal, the Horse shall be prohibited from entering a Race and may be released from the Veterinarians' List only after also undergoing a post-Workout inspection by the Regulatory Veterinarian.

2250. Racehorse Treatment History and Records

2251. Veterinary Reports

(a) All Veterinarians shall provide treatment records pursuant to Rule Series 3000. In addition to the uses set forth therein, these records may be used by Regulatory Veterinarians in the performance of their duties at the racetrack, for transfer of 60 day medical records to the new trainer of a claimed Horse, and for purposes of research to enhance the safety and welfare of racehorses.

(b) In addition to the information required to be submitted by Veterinarians pursuant to Rule Series 3000, every Veterinarian who examines or treats a Covered Horse shall, within 24 hours of such examination or treatment, submit the following information in an electronic format designated by the Authority:

(1) The identity of the Horse treated;

(2) the name of the Trainer of the Horse;

(3) the name of the Veterinarian;

(4) contact information for the Veterinarian (phone, email address);

(5) any information concerning the presence of unsoundness and responses to diagnostic tests;

(6) diagnosis;

(7) condition treated;

(8) any medication, drug, substance, or procedure administered or prescribed, including date and time of administration, dose, route of administration (including structure treated if local administration), frequency, and duration (where applicable) of treatment;

(9) any non-surgical procedure performed (including but not limited to diagnostic tests, imaging, and shockwave treatment) including the structures examined/treated and the date and time of the procedure;

(10) any surgical procedure performed including the date and time of the procedure; and

(11) any other information necessary to maintain and improve the health and welfare of the Horse.

2252. Responsible Persons' Records

(a) In addition to the information required to be submitted by Responsible Persons under Rule Series 3000, a Responsible Person is responsible for maintaining a record of medical, therapeutic, and surgical treatments and procedures for every Covered Horse in his or her control.

(b) For purposes of this Rule, the term treatment:

(1) Means the administration of any medication or substance containing a medication to a Horse by a Responsible Person or his or her designee;

(2) includes the administration of medications that are prescribed by a Veterinarian but administered by the Responsible Person or his or her designee, or medications prescribed or administered by a Veterinarian not licensed by the State Racing Commission; and

(3) specifically excludes medications or procedures directly administered by a Veterinarian licensed by the State Racing Commission or that Veterinarian's employees.

(c) Records must include the information outlined in paragraphs (1) and (2) below.

(1) For medical treatments:

(i) Name of the Horse (or, if unnamed, the registered name of the dam and year of foaling);

(ii) name of Trainer;

(iii) generic name of the drug, or brand name if a non-generic drug is used;

(iv) name of the prescribing Veterinarian;

(v) date of the treatment;

(vi) route of administration;

(vii) dosage administered;

(viii) approximate time (to the nearest hour) of each treatment; and

(ix) full name and contact information of the individual who administered the treatment.

(2) For medical procedures, including, but not limited to, physiotherapy, acupuncture, chiropractic, and surgeries:

(i) Name of the Horse, or, if unnamed, the registered name of the dam and year of foaling;

(ii) name of Trainer;

(iii) diagnosis and condition being treated;

(iv) name of procedure or surgery;

(v) date of the procedure;

(vi) first and last name of the individual who administered or performed the procedure; and

(vii) any other information necessary to maintain and improve the health and welfare of the Horse.

(d) In addition to the uses of records set forth in the Rules Series 3000, records may be used by Regulatory Veterinarians in the performance of their duties at the Racetrack, for transfer of 60 day medical records to the new Owner of a claimed Horse, and for purposes of research to enhance the safety and welfare of racehorses. Records may also be accessed by the State Racing Commission or the stewards.

2253. Records for Horses Shipping to the Racetrack

(a) If a Horse is not stabled at a facility under the Authority's jurisdiction for the full 30 days prior to a Race or Workout for purposes of removal from the Veterinarians' List, the Responsible Person shall obtain and maintain the following information for the previous 30 days:

(1) Name of the Horse or, if unnamed, the registered name of the dam and year of foaling;

(2) generic name of the drug, or brand name of the drug if a non-generic drug is used;

(3) date and duration of the treatment;

(4) route of administration;

(5) dosage administered;

(6) surgical procedures;

(7) non-surgical therapies and procedures; and

(8) any other information necessary to maintain and improve the health and welfare of the Horse.

(b) If a Horse is not stabled at a facility under the Authority's jurisdiction for 60 days prior to a Race or Workout for purposes of removal from the Veterinarians' List, the Responsible Person shall obtain and maintain the following information:

(1) The last 30 days of exercise activity at the facility;

(2) the last 30 days of treatments and procedures at the facility; and

(3) any other information necessary to maintain and improve the health and welfare of the Horse.

2260. Claiming Races

2261. Transfer of Claimed Horse Records

(a) Entry of Horses subject to being claimed in a Claiming Race implies Owner (Trainer as the agent of the Owner) consent for transfer of all Trainer and veterinary examination and treatment records for the last 60 days to the new Trainer of the claimed Horse.

(b) If a Horse is successfully claimed by a new Trainer, the previous Trainer must transfer Trainer records and authorize transfer of veterinary records to the new Trainer within 3 days of transfer of the Horse to the new Trainer.

2262. Void Claim

(a) Title to a Horse which is claimed shall be vested in the successful claimant from the time the field has been dispatched from the starting gate and the Horse becomes a starter.

(b) All claimed Horses shall go to the test barn for observation by the Regulatory Veterinarian.

(c) The claim shall be voided, and ownership of the Horse retained by the original Owner if:

(1) The Horse dies on the racing track;

(2) the Horse is euthanized before leaving the racing track;

(3) the Horse is vanned off of the racing track by discretion of the Regulatory Veterinarian;

(4) the Regulatory Veterinarian determines within 1 hour of the race that the Horse will be placed on the Veterinarians' List as Bled, physically distressed, medically compromised, unsound, or lame before the Horse is released to the successful claimant; or

(5) the Horse has a positive test for a Prohibited Substance.

(d) The claim shall not be voided if, prior to the Race in which the Horse is claimed, the claimant elects to claim the Horse regardless of whether the Regulatory Veterinarian determines the Horse will be placed on the Veterinarians' List as Bled or unsound or the Horse tests positive for a Prohibited Substance.

2262. Waiver Claiming Option

At time of entry into a Claiming Race an Owner or Trainer may opt to declare a Horse ineligible to be claimed provided:

(a) The Horse has not started in 120 days;

(b) the Horse's last start must have been for a claiming price; and

(c) the Horse is entered for a claiming price equal or greater than the price it last started for.

2270. Prohibited Practices and Requirements for Safety and Health of Horses

2271. Prohibited Practices

The following are prohibited practices:

(a) Use of physical or veterinary procedures to mask the effects or signs of injury so as to allow training or racing to the detriment of the Horse's health and welfare.

(b) Use of extracorporeal shock wave therapy in a manner that may desensitize any limb structures during racing or training.

(c) Surgical or chemical neurectomy to cause desensitization of musculoskeletal structures associated with the limbs.

(d) Thermocautery including but not limited to pin firing and freeze firing, or application of any substance to cause vesiculation or blistering of the skin, or a counter-irritant effect.

(e) Use of a device to deliver an electrical shock to the Horse including but not limited to cattle prods and batteries.

(f) Use of electrical medical therapeutic devices including magnetic wave therapy, laser, electro-magnetic blankets, boots, electro-shock, or any other electrical devices that may produce an analgesic effect within 48 hours of a training activity or of the start of the published post time for which a Horse is scheduled to race.

2272. Shock Wave Therapy

(a) The use of Shock Wave Therapy shall be disclosed to the Regulatory Veterinarian no less than 48 hours prior to use and shall not be permitted unless the following conditions are met:

(1) Any Shock Wave Therapy may only be performed with machines that are:

(i) Registered and approved for use by the State Racing Commission; and

(ii) used at a previously disclosed location that is approved by the State Racing Commission.

(2) The use of Shock Wave Therapy shall be limited to licensed Veterinarians and must be reported to the Regulatory Veterinarian within 48 hours of treatment to the Authority.

(3) Any treated Horse shall be placed on the Veterinarians' List and shall not be permitted to Race or breeze for 30 days following treatment.

(b) The Veterinarian and Trainer shall be suspended from the Racetrack for a period of 5 days if Shock Wave Therapy

has not been reported within 48 hours of any treatment or procedure administered to a Covered Horse. For each subsequent omission of reporting, an additional 5 days suspension shall be added. If there are 3 violations in a calendar year, the Veterinarian and Trainer shall be suspended for 6 months in the subsequent calendar year.

2273. Other Devices

No electrical or mechanical device or other expedient designed to increase or retard the speed of Covered Horse, other than the riding crop permitted under these regulations, shall be possessed by anyone, or applied by anyone, to a Covered Horse at any time on Racetrack grounds or during a Workout.

2274. Other Device Penalties

Penalties for violations of Rule 2273 shall be as follows:

(a) The penalty for a first offense shall be loss of eligibility to obtain a racing license in all racing jurisdictions for 10 years.

(b) For any subsequent violation, the penalty shall be loss of eligibility to obtain a racing license in all racing jurisdictions for the life of the Covered Person.

2275. Communication Devices

The use of a hand-held communication device by a rider is prohibited while the rider is on the racing track.

2276. Horseshoes

(a) Except for full rims 2 millimeters or less from the ground surface of the Horseshoe, traction devices are prohibited on forelimb and hindlimb Horseshoes during racing and training on dirt or synthetic racing tracks.

(b) Traction devices are prohibited on forelimb and hindlimb Horseshoes during training and racing on the turf.

(c) Traction devices include but are not limited to rims, toe grabs, bends, jar calks and stickers.

2280. Use of Riding Crop

(a) A Jockey or exercise rider who uses a crop during a Race or Workout shall do so only in a professional manner consistent with maintaining focus and concentration of the Horse for safety of Horses and riders, or for encouragement to achieve optimal performance.

(b) A rider may:

(1) Use the crop on the hindquarters to activate and focus the Horse a maximum of 6 times during a race. The 6 permitted uses shall be in increments of 2 or fewer strikes. The rider must allow at least 2 strides for the Horse to respond before using the crop again.

(2) Tap the Horse on the shoulder with the crop while both hands are holding on to the reins and both hands are touching the neck of the Horse.

(3) Show or wave the crop to the Horse without physically contacting the Horse.

(4) Use the crop to preserve the safety of Horses and riders.

(c) A rider may not:

(1) Raise the crop with the rider's wrist above the rider's helmet when using the crop;

(2) Injure the Horse with the crop or leave any physical marks, such as welts, bruises, or lacerations;

(3) Use the crop on any part of the Horse's body other than the shoulders or hindquarters;

(4) Use the crop during the post parade or after the finish of the race other than to avoid a dangerous situation or preserve the safety of Horses and riders;

(5) Use the crop if the Horse has obtained its maximum placing;

(6) Use the crop persistently even though the Horse is showing no response;

(7) Use a crop on a 2-year-old Horse in races before April 1 of each year other than to avoid a dangerous situation or preserve the safety of Horses and riders; or

(8) Strike another Horse or person with the crop.

(d) In any Race in which a Jockey will ride without a crop, that fact shall be declared at entry, included in the official program, and an announcement of that fact shall be made over the public address system.

2281. Riding Crop Specifications

(a) Riding crops are subject to inspection by the Safety Officer, stewards, and the clerk of the scales.

(b) All riding crops must be soft-padded.

(c) Riding crops shall have a shaft and a smooth foam cylinder and must conform to the following dimensions and construction:

(1) The maximum allowable weight shall be 8 ounces;

(2) The maximum allowable length, including the smooth foam cylinder attachment, shall be 30 inches;

(3) The minimum diameter of the shaft shall be three-eighths of one inch; and

(4) The shaft, beyond the grip, must be smooth, with no protrusions or raised surface, and covered by shock absorbing material that gives a compression factor of at least one millimeter throughout its circumference.

(5) There shall be no binding within 7 inches of the end of the shaft.

(6) The smooth foam cylinder is the only allowable attachment to the shaft and must meet the following specifications:

(i) Shall have no reinforcements;

(ii) Shall have a maximum length beyond the shaft of one inch;

(iii) Shall have a minimum diameter of 0.8 inches and a maximum width of 1.6 inches;

(iv) There shall be no other reinforcements or additions beyond the end of the shaft;

(v) Shall be made of shock absorbing material with a compression factor of at least 5 millimeters throughout its circumference;

(vi) Shall be made of a waterproof, ultraviolet, and chemical resistant foam material that is durable and preserves its shock absorption in use under all conditions; and

(vii) Shall be replaced after reasonable wear and tear is visibly evident.

(7) Riding crops shall not be altered and shall have an appropriate label or marking designating that the riding crop meets the required standards as established by the Authority.

2282. Riding Crop Violations and Penalties

(a) Violations of Rule 2280 shall be categorized as follows, with the exception that use of the crop for the safety of Horse and rider shall not count toward the total crop uses:

(1) Class 3 Violation—1 to 3 strikes over the limit.

(2) Class 2 Violation—4 to 9 strikes over the limit.

(3) Class 1 Violation—10 or more strikes over the limit.

(b) Unless the stewards determine the merits of an individual case warrant consideration of an aggravating or mitigating factor, the penalties for violations are as follows:

(1) Class 3 Violation—

(i) $250 or 10% of Jockey's portion of the purse, whichever is greater;

(ii) Minimum 1-day suspension for the Jockey; and

(iii) 3 points;

(2) Class 2 Violation—

(i) $500 or 20% of Jockey's portion of the purse, whichever is greater;

(ii) Horse disqualified from purse earnings,

(iii) Minimum 3-day suspension for the Jockey; and

(iv) 5 points;

(3) Class 1 Violation—

(i) $750 fine or 30% of Jockey's portion of the purse, whichever is greater,

(ii) Horse disqualified from purse earnings,

(iii) Minimum 5-day suspension for the Jockey;

(iv) 10 points.

2283. Multiple Violations

(a) Stewards shall submit violations of Rule 2282 to the Authority to identify when multiple violations warrant additional suspensions consistent with the following schedule:

(1) 11–15 points: 7 days.

(2) 16–20 points: 15 days.

(3) 21 or more points: 30 days.

(b) Points assigned under Rule 2282 shall expire according to the following schedule:

(1) Class 3 Violation: 6 months.

(2) Class 2 Violation: 9 months.

(3) Class 1 Violation: 1 year.

(c) For purposes of paragraph (b), points are expunged from the date of final adjudication of the violation and not from the date of the violation. Mandatory suspensions are based on points accumulated for multiple violations and do not apply to single violations.

2290. Requirements for Safety and Health of Jockeys

2291. Jockey Eligibility

(a) A Jockey shall pass a physical examination given within the previous 12 months by a licensed physician affirming the Jockey's fitness to participate as a Jockey, as well as a baseline Concussion test using a current Concussion testing protocol. The results of the physical examination and the baseline Concussion test shall be submitted to the State Racing Commission and the Authority.

(b) The stewards may require that any Jockey be reexamined and may refuse to allow any Jockey to ride in a race or Workout pending completion of such examination.

2292. Jockey and Exercise Rider Medical History Information

(a) At all times while mounted on a Horse at a Racetrack, a Jockey or exercise rider shall securely attach to his or her safety vest one or more medical information cards describing his or her medical history and any conditions pertinent to emergent care, including a listing of any previous injuries, drug allergies and current medications.

(b) The stewards shall confirm compliance during their safety vest inspections at the beginning of the season and with random inspections throughout the Race Meet.

(c) The stewards may, in their discretion, take disciplinary action against, suspend, make ineligible to race, or fine any Jockey or exercise rider found in violation of Rule 2292.

2293. Equipment

(a) Helmets.

(1) Any person mounted on a Horse or stable pony anywhere on racetrack grounds shall always wear a properly secured safety helmet.

(2) All starting gate personnel shall always wear a properly secured safety helmet while performing their duties or handling a Horse.

(3) The safety helmet may not be altered in any manner and the product marking shall not be removed or defaced.

(4) The stewards, or their designees, shall inspect safety helmets at the beginning of a Race Meet and randomly throughout the Race Meet.

(5) The Clerk of Scales shall report to the stewards any variances of safety helmets seen during the course of their work.

(6) The helmet must comply with one of the following minimum safety standards or later revisions:

(i) American Society for Testing and Materials (ASTM 1163);

(ii) European Standards (EN–1384 or PAS–015 or VG1);

(iii) Australian/New Zealand Standards (AS/NZ 3838 or ARB HS 2012); or

(iv) Snell Equestrian Standard 2001.

(b) Vests.

(1) Any person mounted on a Horse or stable pony on the racetrack grounds must wear a properly secured safety vest at all times.

(2) All starting gate personnel must wear a properly secured safety vest at all times while performing their duties or handling a Horse.

(3) The safety vest may not be altered in any manner and the product marking shall not be removed or defaced.

(4) The stewards shall inspect safety vests at the beginning of a Race Meet and randomly throughout the Race Meet.

(5) The clerk of scales shall report to the stewards any variances of safety vests seen during their course of work.

(6) The safety vest must comply with one of the following minimum standards, as the same may be from time to time amended or revised:

(i) British Equestrian Trade Association (BETA):2000 Level 1;

(ii) iEuro Norm (EN) 13158:2000 Level 1;

(iii) American Society for Testing and Materials (ASTM) F1781–08 or F1937;

(iv) Shoe and Allied Trade Research Association (SATRA) Jockey Vest Document M6–3; or

(v) Australian Racing Board (ARB) Standard 1.1998.

Appendix—Supporting Documentation Submitted by HISA

The Authority submitted a variety of materials to reflect existing standards, scientific data, studies, and analysis utilized in the development of the proposed rules, which are available for public inspection at *https://www.regulations.gov* under docket number FTC–2021–0076. These materials are referred to in the Authority's filing as exhibits, a complete list of which appears below:

Exhibit 1—National Thoroughbred Racing Association Safety & Integrity Alliance Code of Standards (2021).

Exhibit 2—Association of Racing Commissioners International, Model Rules of Racing, Version 10.1 (2021), *https://www.arci.com/wp-content/uploads/2021/12/MODELRULESMASTERVERSION10.11129.pdf.*

Exhibit 3—A comparison of the substantive terms of the proposed rule with safety standards and provisions of the NTRA Code of Standards and the specific ARCI Rules.

Exhibit 4—International Federation of Horseracing Authority, International Agreement on Breeding, Racing and Wagering.

Exhibit 8—Mid-Atlantic Strategic Plan to Reduce Equine Fatalities Goal l: Develop regional safety best practices.

Exhibit 9—Mid-Atlantic Strategic Plan to Reduce Equine Fatalities—Best Practices Mortality Review Board.

Exhibit 10—California Code of Regulations Article 15; Veterinary Practices 1846.5; Postmortem Examination (a)–(h).

Exhibit 11—Jockeys' Guild, Inc. and the NTRA Safety & Integrity Alliance Medical Director Committee, Medical Care Recommendations.

Exhibit 12—AAEP Healthy Horse Protocol: Biosecurity Guidelines for Racetrack Entry and Stabling (2020).

Exhibit 13—AAEP General Biosecurity Guidelines.

Exhibit 14—AAEP Clinical Guidelines for Veterinarians Practicing in a Pari-Mutuel Environment—Infectious Disease Control.

Exhibit 15—Walsh KM, Cooper MA, Holle R, Rakov VA, Roeder WP, Ryan M. ''Lightning Safety for Athletics and Recreation.'' Journal of Athletic Training (2013): 258–70.

Exhibit 16—American Association of Equine Practitioners, Thoroughbred Race Day Injury Management Guidelines.

Exhibit 17—Equine Disease Communication Center website.

Exhibit 18—National Thoroughbred Racing Association Safety & Integrity Alliance Code of Standards: Surfaces 2020.

Exhibit 19—Racing Surfaces Testing Laboratory website.

Exhibit 20—AAEP Guidelines, Necropsies of Racehorses, General Guidelines, Revised by AAEP Racing Committee 2020.

Exhibit 21—NYCRR Title 9, Executive Subtitle T New York State Gaming Commission Chapter 1 Division of Horse Racing and Pari-mutuel Wagering, Subchapter A Thoroughbred Racing, Article 1 Rules of Racing, Part 4007 Horses.

Exhibit 22—Thoroughbred Horseman's Association, Continuing Education for Trainers and Assistant Trainers.

Exhibit 23—Centers for Disease Control, Heads Up—Brain Injury Basics—Returning to Sports and Activities.

Exhibit 24—National Athletic Trainers' Association Position Statement: Management of Sports Concussion.

Exhibit 25—MedStar Sports Medicine Concussion Protocol for Jockeys and Horsemen.

Exhibit 26—MedStar Sports Medicine—Concussion Protocol video.

Exhibit 27—The Jockey Club Thoroughbred Safety Committee Recommendation, August 12, 2012 (revised August 5, 2021).

Exhibit 28—Kane AJ, Stover SM, Gardner IA, et al. Horseshoe characteristics as possible risk factor for fatal musculoskeletal injury of Thoroughbred racehorses. American Journal of Veterinary Research, 1996, Vol. 57, No. 8, Pages 1147–52.

Exhibit 29—Casner B. 2010 Jockey Club Welfare & Safety Committee Presentation—Welfare and Safety of the Racehorse Summit.

Exhibit 30—Harvey AM, Williams SB, Singer ER. The effect of lateral heel studs on the kinematics of the equine digit while cantering on grass. Veterinary Journal 2012 May;192(2):217–21. doi: 10.1016/j.tvjl.2011.06.003. Epub 2011 Jul 12. PMID: 21752677.

Exhibit 31—Hill AE, Gardner IA, Carpenter TE, Stover SM. Effects of injury to the suspensory apparatus, exercise, and horseshoe characteristics on the risk of lateral condylar fracture and suspensory apparatus failure in forelimbs of Thoroughbred racehorses. American Journal Veterinary Research, 2004, 65 (11), 1508–17.

Exhibit 32—Hill AE, Stover SM, Gardner IA, et al. Risk factors for and outcomes of noncatastrophic suspensory injury in Thoroughbred racehorses. Journal American Veterinary Medical Association. 2001, Vol. 218, 1136–44.

Exhibit 33—Hernandez JA, Scollay MC, Hawkins DL, et al. Evaluation of horseshoe characteristics and high-speed exercise history as possible risk factors for catastrophic musculoskeletal injury in Thoroughbred racehorses. American Journal Veterinary Research 2005; 66:1314–1320.

Exhibit 34—Anthenill LA, Stover SM, Garner IA, Hill AE. Risk Factors for proximal sesamoid bone fractures associated with exercise history and horseshoe characteristics in Thoroughbred racehorses. American Journal Veterinary Research, 2007, 68 (7), 760–71.

Exhibit 35—Kentucky Horse Racing Commission Administrative Regulations—810 KAR 4:010. Horses—Section 11 Equipment.

Exhibit 36—IFHA Use of the Whip, ''IFHA Principles of Good Practice for the use of the Whip in Horseracing.''

Exhibit 37—Schambourg nociceptive thresholds in endurance horses, Vet Rec 2019.

Exhibit 38—The Use of Whips in Thoroughbred Racing in Australia, RSPCA Information Paper—November 2020.

Exhibit 39—Thompson—Is Whip Use Important to Thoroughbred Racing Integrity? What Stewards' Reports Reveal about Fairness to Punters, Jockeys and Horses—Animals, 1985.

Exhibit 40—Toma—Assessing Forces Exerted on Horses Using Varying Riding Crop—Journal of Equine Veterinary Science, 2021.

Exhibit 41—Tong—A Comparative Neuro-Histological Assessment of Gluteal Skin.

Exhibit 42—Ueda Y, Yoshia K, Oikawa M. Analysis of race accident conditions through use of patrol video. J Equine Vet Sci 1993;13:707–710.

Exhibit 43—Deuel—Effects of Urging by the Rider on Gallop Stride Characteristics of Quarter Horses—Equine Nutrition and Physiology Society—1988 Issue.

Exhibit 44—McGreevy—Whip Use by Jockeys in a Sample of Australian Thoroughbred Races—An Observational Study—PLOS ONE 2012.

Exhibit 45—Pinchbeck—Whip use and race progress are associated with horse falls in hurdle and steeplechase racing in the UK—Equine Veterinary Journal, 2004.

Exhibit 46—Mills and Higgins—Investigation of the Potential of Whips to Injure Horses—1996.

Exhibit 47—Jones—A Critical Analysis of the British Horseracing Authority's Review of the Use of the Whip in Horseracing—Animals 2015.

Exhibit 48—Luna—Validation of mechanical, electrical and thermal nociceptive stimulation methods in horses—Equine Veterinary Journal 2015.

Exhibit 49—McGreevy—A note on the force of whip impacts delivered by jockeys using forehand and backhand strikes—Journal of Veterinary Behavior 2013.

Exhibit 50—Evans—An Investigation of Racing Performance and Whip Use by Jockeys in Thoroughbred Races—PLOS ONE 2011.

Exhibit 51—Graham—Changing Human-Animal Relationships in Sport: An Analysis of the UK and Australian Horse Racing Whips Debates, Animals, 2016.

Exhibit 52—Haussler—Mechanical nociceptive thresholds in the axial skeleton of horses, Equine Veterinary Journal, 2006.

Exhibit 53—ARCI Crop Rule Penalties—ARCI–010–035 Running of the Race—(Proposed Rule Text).

Exhibit 54—The Jockey Club Thoroughbred Safety Committee Recommendation, August 14, 2016 (modified 8/11/19).

Exhibit 55—California Proposed Crop Equipment Rule—1685. Equipment Requirement.

Exhibit 56—New Jersey Rule 13:70–11.12.

Exhibit 57—Gulfstream Park Crop Rule.

Exhibit 58—British Horseracing Authority Rules of Racing 1 October 2021 Version 2021.4.1, 4–Whip Rule (F)45.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2021–28513 Filed 1–4–22; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PAR 18–812, NIOSH Member Conflict Review.

Date: February 23, 2022.

Time: 1:00 p.m.–4:00 p.m., EST.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26506, Telephone: (304) 285–5951, Email: *MGoldcamp@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–28521 Filed 1–4–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE–22–002, Grants to Support New Investigators in Conducting Research Related to Preventing Interpersonal Violence Impacting Children and Youth.

Dates: March 8–9, 2022.

Times: 8:30 a.m.–5:30 p.m., EST.

Place: Web Conference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Aisha L. Wilkes, M.P.H., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341–3717, Telephone: (404) 639–6473, Email: *AWilkes@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–28522 Filed 1–4–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE–22–001, Grants to Support New Investigators in Conducting Research Related to Understanding Polydrug Use Risk and Protective Factors.

Dates: March 15–16, 2022.

Times: 8:30 a.m.–5:30 p.m., EDT.

Place: Web Conference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Aisha L. Wilkes, M.P.H., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341–3717, Telephone: (404) 639–6473, Email: *AWilkes@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–28523 Filed 1–4–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—Funding Opportunity Announcement (FOA), PAR 20–280, Cooperative Research Agreements Related to the World Trade Center Health Program (U01); and RFA OH–22–004, World Trade Center Health Research related to WTC Survivors (U01—No Applications with Responders Accepted).

Dates: March 22–23, 2022.

Times: 11:00 a.m.–5:00 p.m., EDT.

Place: Virtual.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Laurel Garrison, M.P.H., Scientific Review Officer, National Institute for Occupational Safety and Health, CDC, 5555 Ridge Avenue, Cincinnati, Ohio 45213, Telephone: (513) 533–8324, Email: *LGarrison@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–28524 Filed 1–4–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10410, CMS–10554, CMS–10791 and CMS–10377]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by March 7, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10410 Medicaid Program; Eligibility Changes under the Affordable Care Act of 2010
CMS–10554 Children's Health Insurance Program Managed Care and Supporting Regulations
CMS–10791 Requirements Related to Surprise Billing; Part II
CMS–10377 Student Health Insurance Coverage

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Program; Eligibility Changes under the Affordable Care Act of 2010; *Use:* The State Medicaid and CHIP agencies will collect all information needed to determine and redetermine eligibility for Medicaid and will transmit information, as appropriate, to other insurance affordability programs. The information collection requirements will assist the public to understand information about health insurance affordability programs and will assist CMS in ensuring the seamless, coordinated, and simplified system of Medicaid and CHIP application, eligibility determination, verification, enrollment, and renewal. *Form Number:* CMS–10410 (OMB control number: 0938–1147); *Frequency:* Occasionally; *Affected Public:* Individuals or Households, and State, Local, and Tribal Governments; *Number of Respondents:* 25,500,096; *Total Annual Responses:* 76,500,218; *Total Annual Hours:* 21,276,302. (For policy questions regarding this collection contact Stephanie Bell at 410–786–0617.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Children's Health Insurance Program Managed Care and Supporting Regulations; *Use:* CHIP enrollees use the information collected and reported as a result of this regulation to make informed choices regarding health care, including how to access health care services and the grievance and appeal system. States use the information collected and reported as part of contracting processes with managed care entities, as well as its compliance oversight role. CMS uses the information collected and reported in an oversight role of State CHIP managed care programs and CHIP state agencies. *Form Number:* CMS–10554 (OMB control number: 0938–1282); *Frequency:* Yearly; *Affected Public:* State, Local, and Tribal Governments, and the Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 62; *Total Annual Responses:* 2,735,906; *Total Annual Hours:* 410,989. (For policy questions regarding this collection contact Meg Barry at 410–786–1536.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Requirements Related to Surprise Billing; Part II; *Use:* The information requirements have two components: Good faith estimates and patient-provider dispute resolution for uninsured (or self-pay) individuals. Good Faith Estimates. Providers and facilities must furnish a good faith estimate of expected items and services beginning on or after January 1, 2022, which 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 items and services. Additionally, uninsured (or self-pay) individuals will need a good faith estimate to initiate the patient-provider dispute resolution process. Patient-Provider Dispute Resolution Process. HHS will request information from uninsured (or self-pay) individuals in order to initiate 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 SDR entities to inform the SDR entity's payment determinations. *Form Number:* CMS–10791 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 238,942; *Total Annual Responses:* 398,680; *Total Annual Hours:* 6,564,413. For policy questions regarding this collection contact Janny Frimpong at 301–492–4174.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Student Health Insurance Coverage; *Use:* Under the Student Health Insurance Coverage Final Rule published March 21, 2012 (77 FR 16453), student health insurance coverage is a type of individual health insurance coverage provided pursuant to a written agreement between an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students who are enrolled in that institution and their dependents. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule provided that, for policy years beginning on or after July 1, 2016, student health insurance coverage is exempt from the actuarial value (AV) requirements under section 1302(d) of the Affordable Care Act, but must provide coverage with an AV of at least 60 percent. This provision also requires issuers of student health insurance coverage to specify in any plan materials summarizing the terms of the coverage the AV of the coverage and the metal level (or the next lowest metal level) the coverage would otherwise satisfy under § 156.140. This disclosure will provide students with information that allows them to compare the student health coverage with other available coverage options. *Form Number:* CMS–10377 (OMB control number 0938–1157); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 48; *Total Annual Responses:* 953,541; *Total Annual Hours:* 48. For policy questions regarding this collection contact Russell Tipps at 301–492–4371.

Dated: December 29, 2021.

William N. Parham, III

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–28527 Filed 1–4–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before February 4, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: For HHS/OHRP Consultation Process, Institutional Review Board Records.

Type of Collection: New OMB No. 0990–XXXX.

Abstract: The Assistant Secretary for Health, Office for Human Research Protections is requesting a new approval from the Office of Management and Budget of the Office for Human Research Protections (OHRP) requirement that Institutional Review Board records be submitted when an IRB or its institution request an HHS consultation process, for proposed research involving, respectively: (1) Pregnant women, human fetuses and neonates; (2) prisoners; or, (3) children, as subjects that are not otherwise approval by an IRB. The Office of the Assistant Secretary for Health, on behalf of the Secretary of HHS, may determine that such research can be conducted or supported by HHS after consulting with experts and allowing for public review of, and comment on, the proposed research.

Likely Respondents: IRBs.

TABLE—ANNUALIZED BURDEN HOUR

45 CFR part 46—HHS consultation process provision	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Subpart B, § 46. 207	3	1	1	3
Subpart C, § 46.306 (iii) and (iv)	3	1	1	3
Subpart D, § 46.407	4	1	1	4

TABLE—ANNUALIZED BURDEN HOUR—Continued

45 CFR part 46—HHS consultation process provision	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Total				10

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021–28566 Filed 1–4–22; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Physician-Focused Payment Model Technical Advisory Committee; Meetings

ACTION: Notice of meetings.

SUMMARY: This notice announces the 2022 meetings of the Physician-Focused Payment Model Technical Advisory Committee (PTAC). These meetings include deliberation and voting on proposals for physician-focused payment models (PFPMs) submitted by individuals and stakeholder entities and may include discussions on topics related to current or previously submitted PFPMs. All meetings are open to the public.

DATES: The 2022 PTAC meetings will occur on the following dates:

- Monday–Tuesday, March 7–8, 2022, from 10:00 a.m. to 3:00 p.m. ET
- Tuesday–Wednesday, June 7–8, 2022, from 9:00 a.m. to 5:00 p.m. ET
- Monday–Tuesday, September 19–20, 2022, from 9:00 a.m. to 5:00 p.m. ET
- Thursday–Friday, December 8–9, 2022, from 9:00 a.m. to 5:00 p.m. ET

Please note that times are subject to change. If the times change, the ASPE PTAC website will be updated (*https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee*) and registrants will be notified directly via email.

ADDRESSES: All PTAC meetings will be held virtually or in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Lisa Shats, Designated Federal Officer at *Lisa.Shats@hhs.gov* (202) 875–0938.

SUPPLEMENTARY INFORMATION:

Agenda and Comments. PTAC will hear presentations on proposed PFPMs that have been submitted by individuals and stakeholder entities and/or discussion on topics related to current or previously submitted PFPMs. Regarding proposed PFPMs, following each presentation, PTAC will deliberate on the proposed PFPM. If PTAC completes its deliberation, PTAC will vote on the extent to which the proposed PFPM meets criteria established by the Secretary of Health and Human Services and on an overall recommendation to the Secretary. Time will be allocated for public comments. The agenda and other documents will be posted on the PTAC section of the ASPE website, *https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee,* prior to the meeting. The agenda is subject to change. If the agenda does change, registrants will be notified directly via email, the website will be updated, and notification will be sent out through the PTAC email listserv (*https://list.nih.gov/cgi-bin/wa.exe?A0=PTAC* to subscribe).

Meeting Attendance. These meetings are open to the public and may be hosted in-person or virtually. We intend that in-person meetings will be held in the Great Hall of the Hubert H. Humphrey Building. The public may attend in person, when feasible, via conference call, or view the meeting via livestream at *www.hhs.gov/live.* The conference call dial-in information will be sent to registrants prior to the meeting. Space may be limited, and registration is preferred. For meetings that are held virtually, the public may attend via WebEx link (including a dial-in only option) or view the meeting via livestream at *www.hhs.gov/live.* Registration may be completed online at *http://www.cvent.com/d/gbq2tg.* Name, organization name, and email address are submitted when registering. Registrants will receive a confirmation email shortly after completing the registration process.

Special Accommodations. If sign language interpretation or other reasonable accommodation for a disability is needed, please contact ASPE PTAC staff, no later than two weeks prior to the scheduled meeting. Please submit your requests by email to *PTAC@hhs.gov.*

Authority. 42 U.S.C 1395(ee); Section 101(e)(1) of the Medicare Access and CHIP Reauthorization Act of 2015; Section 51003(b) of the Bipartisan Budget Act of 2018.

PTAC is governed by provisions of the Federal Advisory Committee Act, as amended (5 U.S.C app.), which sets forth standards for the formation and use of federal advisory committees.

Dated: December 30, 2021.

Rebecca Haffajee,

Acting Assistant Secretary for Planning and Evaluation, Principal Deputy.

[FR Doc. 2021–28578 Filed 1–4–22; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Small Business Innovation Research (SBIR) Phase II Program Contract Solicitation (PHS 2020–1) NIAID Research Topic No. 85 Phase II Adaptable RNA-based antibody platform for protection against contemporary/emerging human enteroviruses.

Date: January 26, 2022.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E70, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Mohammed S. Aiyegbo, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural

Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E70, Rockville, MD 20852, (301) 761–7106, *mohammed.aiyegbo@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28530 Filed 1–4–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; SBIR PHS 2022–1: Digital Tools Against Misinformation About Infectious Disease Treatments and Vaccines (Topic 112).

Date: January 26–28, 2022.

Time: 9:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Patricia A. Gonzales Hurtado, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71A, Rockville, MD 20852, 240–627–3556, *Patricia.Gonzales@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; PHS–2022–1: Digital Tools Against Misinformation About Infectious Disease Treatments and Vaccines (Topic 112)—Phase II.

Date: January 28, 2022.

Time: 12:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Patricia A. Gonzales Hurtado, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71A, Rockville, MD 20852, 240–627–3556, *Patricia.Gonzales@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28532 Filed 1–4–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2022–1 Phase I: Point of Care (POC) Diagnostics for Antimicrobial Resistant (AMR) Enteric Bacterial and Parasitic Pathogens (Topic 110).

Date: January 28, 2022.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals..

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E61, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Ann Marie M. Brighenti, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E61, Rockville, MD 20852, 301–761–3100, *AnnMarie.Cruz@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2022–1 Phase II: Point of Care (POC) Diagnostics for Antimicrobial Resistant (AMR) Enteric Bacterial and Parasitic Pathogens (Topic 110).

Date: January 28, 2022.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E61, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Ann Marie M. Brighenti, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E61, Rockville, MD 20852, 301–761–3100, *AnnMarie.Cruz@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28531 Filed 1–4–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Cellular, Molecular, and Immunobiology Study Section.

Date: February 1–2, 2022.

Time: 10:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: George M. Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301–435–0696, *barnasg@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.
Date: February 2–3, 2022.
Time: 10:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Biobehavioral Medicine and Health Outcomes Study Section.
Date: February 7–8, 2022.
Time: 9:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Mark A. Vosvick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, Bethesda, MD 20892, (301) 402–4128, *mark.vosvick@nih.gov*.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Modeling and Analysis of Biological Systems Study Section.
Date: February 8–9, 2022.
Time: 10:00 a.m. to 7:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Noffisat Oki, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 240–627–3648, *noffisat.oki@nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroscience of Basic Visual Processes Study Section.
Date: February 9–10, 2022.
Time: 10:00 a.m. to 7:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, *kgt@mail.nih.gov*.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry A Study Section.
Date: February 9–10, 2022.
Time: 10:00 a.m. to 6:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Anita Szajek, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4187, Bethesda, MD 20892, 301–827–6276, *anita.szajek@nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurogenesis and Cell Fate Study Section.
Date: February 9–10, 2022.
Time: 11:00 a.m. to 9:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Christine Jean DiDonato, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1014J, Bethesda, MD 20892, (301) 435–1042, *didonatocj@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28529 Filed 1–4–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grant (R34); NIAID Clinical Trial Implementation Cooperative Agreement (U01); NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44); Investigator Initiated Extended Clinical Trial (R01).
Date: February 3–4, 2022.
Time: 10:00 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Rockville, MD 20892 (Virtual Meeting).
Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Rockville, MD 20852, 240–669–5026, *haririmf@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28533 Filed 1–4–22; 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 (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Project: Substance Abuse Prevention and Treatment Block Grant Synar Report Format, FFY 2022–2024—(OMB No. 0930–0222)—Extension

Section 1926 of the Public Health Service Act [42 U.S.C. 300x–26] stipulates that Substance Abuse Prevention and Treatment Block Grant (SABG) funding agreements for alcohol

and drug abuse programs for fiscal year 1994 and subsequent fiscal years require states to have in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 21. This section further requires that states conduct annual, random, unannounced inspections to ensure compliance with the law; that the state submit annually a report describing the results of the inspections, the activities carried out by the state to enforce the required law, the success the state has achieved in reducing the availability of tobacco products to individuals under the age of 21, and the strategies to be utilized by the state for enforcing such law during the fiscal year for which the grant is sought.

Before making an award to a state under the SABG, the Secretary must make a determination that the state has maintained compliance with these requirements. If a determination is made that the state is not in compliance, penalties shall be applied. According to Public Law 116–94 (''Tobacco 21''), signed on December 20, 2019, penalties are capped at 10 percent. Respondents include the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, Palau, Micronesia, and the Marshall Islands. Red Lake Indian Tribe is not subject to tobacco requirements.

Regulations that implement this legislation are at 45 CFR 96.130, are approved by OMB under control number 0930–0163, and require that each state submit an annual Synar report to the Secretary describing their progress in complying with section 1926 of the PHS Act. The Synar report, due December 31 following the fiscal year for which the state is reporting, describes the results of the inspections and the activities carried out by the state to enforce the required law; the success the state has achieved in reducing the availability of tobacco products to individuals under the age of 21; and the strategies to be utilized by the state for enforcing such law during the fiscal year for which the grant is sought. SAMHSA's Center for Substance Abuse Prevention will request an extension of OMB approval of the current report format associated with section 1926 (42 U.S.C. 300x–26) to 2024. Extending OMB approval of the current report format will continue to facilitate consistent, credible, and efficient monitoring of Synar compliance across the states.

ANNUAL REPORTING BURDEN

45 CFR citation	Number of respondents [1]	Responses per respondents	Total number of responses	Hours per response	Total hour burden
Annual Report (Section 1—States and Territories) 96.130(e)(1–3)	59	1	59	15	885
State Plan (Section II—States and Territories) 6.130(e)(4,5)96.130(g)	59	1	59	3	177
Total	59		118		1,062

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. 2021–28564 Filed 1–4–22; 8:45 am]

BILLING CODE 4162–20–P

[1] Red Lake Indian Tribe is not subject to tobacco requirements.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, SAMHSA will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including leveraging automated data collection techniques or other forms of information technology.

Proposed Project: Community Mental Health Services Block Grant and Substance Abuse Prevention and Treatment Block Grant FY 2022–2023 Plan and Report Guidance and Instructions (OMB No. 0930–0168)—Extension

SAMHSA is requesting approval from the Office of Management and Budget (OMB) for an extension of the 2020–21 Community Mental Health Services Block Grant (MHBG) and Substance Abuse Prevention and Treatment Block Grant (SABG) Application Plan and Report Guidance and Instructions.

Currently, the SABG and the MHBG differ on a number of their practices (*e.g.,* data collection at individual or aggregate levels) and statutory authorities (*e.g.,* method of calculating MOE, stakeholder input requirements for planning, set asides for specific populations or programs, etc.). Historically, the Centers within SAMHSA that administer these block grants have had different approaches to application requirements and reporting. To compound this variation, states have different structures for accepting, planning, and accounting for the block grants and the prevention set aside within the SABG. As a result, how these dollars are spent and what is known about the services and clients that receive these funds varies by block grant and by state.

SAMHSA has conveyed that block grant funds must be directed toward four purposes: (1) To fund priority treatment and support services for individuals without insurance or who cycle in and out of health insurance coverage; (2) to fund those priority treatment and support services not covered by Medicaid, Medicare, or private insurance offered through the exchanges and that demonstrate success in improving outcomes and/or supporting recovery; (3) to fund universal, selective and targeted prevention activities and services; and (4) to collect performance and outcome data to determine the ongoing effectiveness of behavioral health prevention, treatment and recovery support services and to plan the implementation of new services on a nationwide basis.

States will need help to meet future challenges associated with, the implementation and management of an integrated physical health, mental health, and addiction service system. SAMHSA has established standards and expectations that will lead to an improved system of care for individuals with or at risk of mental and substance use disorders. Therefore, this application package continues to fully exercise SAMHSA's existing authority regarding states', territories' and the Red Lake Band of the Chippewa Tribe's (subsequently referred to as ''states'') use of block grant funds as they fully integrate behavioral health services into the broader health care continuum.

Consistent with previous applications, the FY 2022–2023 application has required sections and other sections where additional information is requested. The FY 2022–2023 application requires states to submit a face sheet, a table of contents, a behavioral health assessment and plan, reports of expenditures and persons served, an executive summary, and funding agreements and certifications. In addition, SAMHSA is requesting information on key areas that are critical to the states' success in addressing health care equity. Therefore, as part of this block grant planning process, states should identify promising or effective strategies as well as technical assistance needed to implement the strategies identified in their plans for FYs 2022 and 2023.

Pursuant to the supplemental funding appropriations for the MHBG and the SABG found in the Consolidated Appropriations Act, 2021 [Pub. L. 116–260] and the American Rescue Plan Act, 2021 [Pub. L. 117–2], SAMHSA has made changes to the Block Grant Plan and Report requirements for FFY 2022 and 2023. These changes are necessary to ensure that funds are spent in an appropriate and timely manner. Adjustments were made to pre-existing tables in the plan and report. Additionally, six new tables were added to the report to capture necessary changes based on the priorities of the supplemental funding. For simplification, one table was removed from both the plan and the report.

On the Application Planning document the narrative has been updated to reflect new funding streams (COVID–19 and ARP funding). Additionally, SABG and MHBG have split their funding tables (table 2 and table 6) in both the plan and the report to allow for more accurate reporting of both standard and supplemental funding. Table 5b has been absorbed into Table 5a and Table 5c is now relabeled Table 5b. Tables 5a and 5b are also now required. On the report there are more changes with the addition of six new tables to expenditures section (Table 2b on the SABG and Table 2c on the MHBG) and tables recording client service levels under the population and services reports section (Tables 10b, 11b and 11c on the SABG and Table 19b on the MHBG). These additional tables should not require excessive effort as all data should already be being collected by the states for the additional funding efforts. Table 5b has also been absorbed into Table 5a for ease of response on both the application and reporting process and Table 5c has now been relabeled Table 5b and made a required table.

While the statutory deadlines and block grant award periods remain unchanged, SAMHSA encourages states to turn in their application as early as possible to allow for a full discussion and review by SAMHSA. Applications for the MHBG-only are due no later than September 1, 2021. The application for SABG-only is due no later than October 1, 2021. A single application for MHBG and SABG combined is due no later than September 1, 2021.

Estimates of Annualized Hour Burden

The estimated annualized burden for the uniform application will increase to 33,493 hours to account for recording of the additional supplemental funding efforts (approximately 2 hours per state agency). Burden estimates are broken out in the following tables showing burden separately for Year 1 and Year 2. Year 1 includes the estimates of burden for the uniform application and annual reporting. Year 2 includes the estimates of burden for the recordkeeping and annual reporting. The reporting burden remains constant for both years.

TABLE 1—ESTIMATES OF APPLICATION AND REPORTING BURDEN FOR YEAR 1

Substance abuse prevention and treatment and community mental health services block grants						
Authorizing legislation SABG	Authorizing legislation MHBG	Implementing regulation	Number of respondent	Number of responses per year	Number of hours per response	Total hours
Reporting:						
Standard Form and Content						
42 U.S.C. § 300x–32(a)						
SABG:						
Annual Report						11,190
42 U.S.C. 300x–52(a)		45 CFR 96.122(f)	60	1		
42 U.S.C. 300x–30–b			5	1		
42 U.S.C. 300x–30(d)(2)		45 CFR 96.134(d)	60	1		
MHBG:						
Annual Report						11,003

TABLE 1—ESTIMATES OF APPLICATION AND REPORTING BURDEN FOR YEAR 1—Continued

Substance abuse prevention and treatment and community mental health services block grants						
Authorizing legislation SABG	Authorizing legislation MHBG	Implementing regulation	Number of respondent	Number of responses per year	Number of hours per response	Total hours
	42 USC § 300x–6(a).		59	1		
	42 U.S.C. 300x–52(a).					
	42 U.S.C. 300x–4(b)(3)B.		59	1		
State Plan (Covers 2 years)						
SABG elements:						
42 U.S.C. 300x–22(b)		45 CFR 96.124(c)()1)	60	1		
42 U.S.C. 300x–23		45 CFR 96.126(f)	60	1		
42 U.S.C. 300x–27		45 CFR 96.131(f)	60	1		
42 U.S.C. 300x–32(b)		45 CFR 96.122(g)	60	1	120	7,230
MHBG elements:	42 U.S.C. 300x–1(b).		59	1	120	7,109
	42 U.S.C. 300x–1(b)(2).		59	1		
	42 U.S.C. 300x–2(a).		59	1		
Waivers						3,240
42 U.S.C. 300x–24(b)(5)(B)			20	1		
42 U.S.C. 300x–28(d)		45 CFR 96.132(d)	5	1		
42 U.S.C. 300x–30(c)		45 CFR 96.134(b)	10	1		
42 U.S.C. 300x–31(c)			1	1		
42 U.S.C. 300x–32(c)			7	1		
42 U.S.C. 300x–32(e)			10			
	42 U.S.C. 300x–2(a)(2).		10			
	42 U.S.C 300x–4(b)(3).		10			
	42 U.S.C 300x–6(b).		7			
Recordkeeping:						
42 U.S.C. 300x–23	42 U.S.C. 300x–3	45 CFR 96.126(c)	60/59	1	20	1,200
42 U.S.C. 300x–25		45 CFR 96.129(a)(13)	10	1	20	200
42 U.S.C 300x–65		42 CFR Part 54	60	1	20	1,200
Combined Burden						42,373

Report:
300x–52(a)—Requirement of Reports and Audits by States—Report.
300x–30(b)—Maintenance of Effort (MOE) Regarding State Expenditures—Exclusion of Certain Funds (SABG).
300x–30(d)(2)—MOE—Noncompliance—Submission of Information to Secretary (SABG).
State Plan—SABG.
300x–22(b)—Allocations for Women.
300x–23—Intravenous Substance Abuse.
300x–27—Priority in Admissions to Treatment.
300x–29—Statewide Assessment of Need.
300x–32(b)—State Plan.
State Plan—MHBG.
42 U.S.C. 300x–1(b)—Criteria for Plan.
42 U.S.C. 300x–1(b)(2)—State Plan for Comprehensive Community Mental Health Services for Certain Individuals—Criteria for Plan—Mental Health System Data and Epidemiology.
42 U.S.C. 300x–2(a)—Certain Agreements—Allocations for Systems Integrated Services for Children.
Waivers—SABG.
300x–24(b)(5)(B)—Human Immunodeficiency Virus—Requirement regarding Rural Areas.
300x–28(d)—Additional Agreements.
300x–30(c)—MOE.
300x–31(c)—Restrictions on Expenditure of Grant—Waiver Regarding Construction of Facilities.
300x–32(c)—Certain Territories.
300x–32(e)—Waiver amendment for 1922, 1923, 1924 and 1927.
Waivers—MHBG.
300x–2(a)(2)—Allocations for Systems Integrated Services for Children.
300x–6(b)—Waiver for Certain Territories.
Recordkeeping.
300x–23—Waiting list.
300x–25—Group Homes for Persons in Recovery from Substance Use Disorders.
300x–65—Charitable Choice.

TABLE 2—ESTIMATES OF APPLICATION AND REPORTING BURDEN FOR YEAR 2

	Number of respondent	Number of responses per year	Number of hours per response	Total hours
Reporting:				
SABG	60	1	187	11,220
MHBG	59	1	187	11,033
Recordkeeping	60/59	1	40	2,360
Combined Burden				24,613

The total annualized burden for the application and reporting is 33,493 hours (42,373 + 24,613 = 66,986/2 years = 33,493).

Link for the application: *https://www.samhsa.gov/grants/block-grants.*

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 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. 2021–28563 Filed 1–4–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[FR–6301–N–01]

Regulatory and Administrative Requirement Waivers and Flexibilities Available to HUD Public Housing and Section 8 During CY 2022 and CY 2023 to Public Housing Agencies To Assist With Recovery and Relief Efforts on Behalf of Families Affected by Presidentially Declared Disasters

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

ACTION: Notice.

SUMMARY: This notification advises the public of HUD's expedited process for waivers and flexibilities from HUD regulatory and administrative requirements (''HUD requirements'') during Presidentially Declared Disasters (PDDs). To respond to PDDs, this notice establishes an expedited process for the review of waiver requests and flexibilities for calendar years (CY) 2022 and 2023, for Public Housing Agencies (PHAs) located within PDDs (PDD PHAs). PDD PHAs may make such requests utilizing the expedited process set forth in this notification.

DATES: Waivers and flexibilities set forth in this document are effective from January 1, 2022 until December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Tesia Irinyenikan, Office of Field Operations, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Room 3180, Washington, DC 20410–5000, phone 202–402–7026 (this is not a toll-free number) or email *PIH_Disaster_Relief@hud.gov.* Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. How This Notice Is Organized

This notice is organized as follows:

- Section I provides an outline for this notice.
- Section II describes the operating subsidy flexibility allowed under 24 CFR 990.145(b) (Public housing dwelling units with approved vacancies).
- Section III describes specific HUD requirements that may, per request and HUD approval, be waived or granted a flexibility to facilitate a PDD PHA's ability to participate in disaster relief and recovery efforts. A PDD PHA may request a waiver or flexibility of a HUD requirement not listed in Section III and receive an expedited review of the request if the PDD PHA demonstrates that the waiver or flexibility is needed to assist its disaster relief and recovery efforts. A PDD PHA may not adopt any requested waiver prior to receiving HUD approval.
- Section IV describes exceptions.
- Section V provides instructions for PDD PHAs on how to submit waiver, flexibility, and exception requests.

II. HUD Operating Subsidy Flexibility in Approved Vacancies

HUD, exercising discretionary authority from Section 106 of the Department of Housing and Urban Development Reform Act of 1989 (42 U.S.C. 3535(q)), which is consistent with 24 CFR 5.110 (Waivers), is providing this flexibility regarding operating subisdy. Upon review of a PDD PHA's request via application, HUD may approve, as noted below, waivers and flexibilities for disaster relief and recovery to PDD PHAs. If a PHA needs the waivers and flexibilities for an extended period, it must submit documentation of good cause, and HUD may consider extension, subject to statutory limitations and pursuant to 24 CFR 5.110, to facilitate a PDD PHA's ability to participate in disaster relief and recovery efforts. Unless otherwise stated, the deadline for requesting waivers and flexibilities is 120 days after the initial PDD.

24 CFR 990.145(b) (Public Housing Dwelling Units With Approved Vacancies)

Under Section 990.145(b)(2), a PHA is eligible to receive operating subsidy for vacant public housing units that are vacant due to a federally declared, state declared or other declared disaster, subject to prior HUD approval, on a project-by-project basis. If a PDD PHA has one or more units that have been vacated due to a PDD, then the PDD PHA, with HUD approval, may treat the unit as an ''approved vacancy.'' Upon the request of a PDD PHA and HUD approval, on a case-by-case basis, such units may be considered approved vacancies for a period not to exceed 12 months from the date of HUD approval.

III. HUD Requirements That May Be Waived or Granted a Flexibility on an Expedited Basis

For a PDD PHA, HUD will review requests for waivers of HUD requirements on an expedited basis. This section lists procedural and substantive requirements for regulatory waivers in event of an PDD. A PDD PHA may also request a waiver of a HUD requirement not listed in this section and receive expedited review of the request if the PDD PHA documents that the waiver is needed for major disaster relief and/or recovery. If a PHA needs the regulatory relief for more time, the PDD PHA must submit documentation of good cause, and HUD may consider extending the waiver, subject to statutory limitations and pursuant to 24 CFR 5.110, to facilitate the PDD PHA's ability to participate in disaster relief and recovery efforts. PHAs should note that waivers of essential program requirements such as property inspection or income verification will not be granted in their entirety, although modifications may be considered. Also, HUD's ability to grant waivers or approval of alternative requirements imposed by statute is limited to expressed statutory authority. If sources of household income are difficult to find, PHAs should go through the hierarchy of verifying income as found in Notice PIH 2018–24. Similarly, while the requirement for Housing Quality Standards (HQS) inspections cannot be waived, HUD can consider variations to the acceptability criteria to HQS in case of disaster (under the authority of 982.401(a)(4)).

A PDD PHA seeking a waiver or flexibility of a HUD requirement listed below or of any other HUD requirement needed to assist the PDD PHA in its disaster relief and recovery efforts must submit a waiver request pursuant to the process that will be provided in Section V of this notification. The request must be submitted to HUD not later than 120 days following the date of the relevant disaster declaration. HUD will not approve a PDD PHA's or other recipient's request to waive or be

granted a flexibility for a fair housing, civil rights, labor standards, or environmental protection requirement.

A. 24 CFR 5.801(c) and 5.801(d)(1) (Uniform Financial Reporting Standards; Filing of Financial Reports; Reporting Compliance Dates)

Section 5.801 establishes uniform financial reporting standards (UFRS) for PHAs (and other entities). Section 5.801(c) requires that PHAs submit financial information in accordance with 24 CFR 5.801(b) annually, not later than 60 days after the end of the fiscal year of the reporting period. Section 5.801(d)(1) requires that PHAs submit their unaudited financial statements not later than 60 calendar days after the end of their fiscal year and that PHAs submit their audited financial statements not later than 9 months after the end of their fiscal year. HUD may consider requests to extend these reporting deadlines.

For PDD PHAs with a deadline to submit only audited financial information in accordance with 24 CFR 5.801(b) and (d) within 6 months after the date of the disaster related to the PDD, HUD may consider a request to waive the due date. For PDD PHAs with a deadline to submit unaudited financial information in accordance with 24 CFR 5.801(b) and (d) within 120 days before and up to 6 months after the date of the disaster related to the PDD, HUD may consider a request to waiver the due date. For these PHAs, HUD also may consider a request to waive the due date of the audited financial information.

For situations beyond a PHA's control, HUD may consider requests from the PDD PHAs with financial submission due dates that fall outside these dates. The deadline for submission of financial information in accordance with 24 CFR 5.801(b) and the deadline for submission of unaudited financial statement may be extended to 180 calendar days, and the deadline for submission of audited financial statements may be extended to 13 months.

B. 24 CFR 902 (Public Housing Assessment System)

Part 902 sets out the indicators by which HUD measures the performance of a PHA. The indicators measure a PHA's physical condition, financial condition, management operations, and Capital Fund obligation and occupancy.

For PDD PHAs with fiscal year end (FYE) dates within 4 months before and up to 10 months after the effective date of the PDD, HUD may consider a request to waive the physical inspection and scoring of public housing projects, as required under 24 CFR part 902. For situations beyond the PHA's control, HUD may consider requests from PDD PHAs with a FYE date that falls outside these dates.

C. 24 CFR 905.322(b) (Fiscal Closeout)

Section 905.322(b) establishes deadlines for the submission of an Actual Development Cost Certificate (ADCC) and an Actual Modernization Cost Certificate (AMCC). Specifically, the ADCC must be submitted 12 months from the date of completion/termination of a modernization activity, and the AMCC must be submitted not later than 12 months from the activity's expenditure deadline. However, 2 CFR 200.344 requires submission of all financial, performance and other reports no later than 120 calendar days after the end date of the period of performance. In accordance with 2 CFR 200.344(b), HUD may authorize an extension; however, if the PHA does not submit all reports within one year, HUD must report the failure under the OMB designate integrity and performance system. To exceed 12 months, HUD may consider a case-by-case exception under 2 CFR 200.102(a).

D. 24 CFR 905.314(b)–(c) (Cost and Other Limitations; Maximum Project Cost; TDC Limit)

42 U.S.C. 1437d(b) requires HUD to calculate total development costs, which may not be exceeded ''unless the Secretary provides otherwise, and in any case may not exceed 110 per centum of such amount unless the Secretary for good cause determines otherwise.'' Section 905.314(b)–(c) establishes the calculation of maximum project cost and the calculation of total development cost.

To facilitate the use of Capital Funds for repairs and construction for needed housing in the disaster areas, HUD may consider waiving the total development cost (TDC) and housing cost cap limits for all work funded by the Capital Grant (with unexpended Capital Grant funds and HOPE VI funds) until the next issuance of TDC levels. PDD PHAs that request to waive this provision and receive approval to do so must strive to keep housing costs reasonable given local market conditions, based upon the provisions outlined in 2 CFR part 200.

E. 24 CFR 905.314(j) (Cost and Other Limitations; Types of Labor)

This section establishes that for high performer PHAs, they may use force account labor for modernization and development activities without including it in a Board-approved Capital Fund Program 5-Year Action Plan. HUD may waive this requirement to allow for the use of force account labor for modernization only activities for non-high performers even if this activity has not been included in the non-high performer PDD PHA's 5-Year Action Plan. Should HUD waive this requirement, the waiver will be in effect for a period not to exceed 12 months from the date of HUD approval.

F. 24 CFR 905.400(i)(5) (Capital Fund Formula; Replacement Housing Factor To Reflect Formula Need for Projects With Demolition or Disposition Occurring on or After October 1, 1998, and Prior to September 30, 2013)

Section 905.400 describes the Capital Fund formula. Section 905.400(i)(5) limits the use of replacement housing funds to the development of new public housing. To help address housing needs because of the displacement caused by the PDD, HUD may consider waiving section 905.400(i)(5) to allow all unexpended Capital Fund Replacement Housing Factor Grants to be used for public housing modernization. Should HUD waive this requirement, the waiver will be in effect for funds obligated within a period not to exceed 12 months from the date of HUD approval.

G. 24 CFR 960.202(c)(1) (Tenant Selection Policies) and 982.54(a) (Administrative Plan)

Section 960.202(c)(1) provides that public housing tenant selection policies must be duly adopted and implemented. Section 982.54(a) provides that a PHA's Section 8 administrative plan must be formally adopted by the PHA Board of Commissioners or other authorized PHA officials. For temporary revisions to an PDD PHA's public housing tenant selection policies or Section 8 administrative plan that an PDD PHA wishes to put into place to address circumstances unique to relief and recovery efforts, HUD may consider requests to waive the requirements under 960.202(c)(1) and 982.54(a) noted above. Any waiver request must include documentation that an PDD PHA's Board of Commissioners or an authorized PDD PHA official supports the waiver request and must identify the temporary revisions, which shall be effective for a period not to exceed 12 months from the date of HUD's approval. Additionally, any waiver request would be limited to revisions that do not constitute a significant amendment or modification to the PHA or MTW plan; pursuant to Section 5A(g) of the 1937 Act, HUD cannot waive the approval by the board or other authorized PHA officials if the proposed revision would constitute a significant

amendment or modification to the PHA or MTW plan. Finally, HUD cannot waive any terms within a PHA's own plan or state law requiring the approval of the board or authorized PHA officials.

H. 24 CFR 982.206(a)(2) (Waiting List; Opening and Closing; Public Notice)

This section describes where a PHA must provide public notice when it opens its waiting list for tenant-based assistance. HUD may consider a request from a PDD PHA that wishes, in lieu of the requirement to provide notice in a local newspaper of general circulation, to provide public notice via its website, at any of its offices, and/or in a voice-mail message, for any opening of the waiting list for tenant-based assistance that occurs within a period not to exceed 12 months from the date of HUD approval.

PDD PHAs that request a waiver of this requirement and receive HUD approval, must comply with applicable fair housing and other civil rights requirements when they provide public notice. For example, an PDD PHA that chooses to provide public notice at its offices must consider the impact on persons with disabilities, who may have difficulty visiting the office in-person. Similarly, an PDD PHA that chooses to provide public notice via voice-mail message must consider how it will reach persons with hearing impairments and persons with limited English proficiency. HUD maintains the requirement that an PDD PHA must also provide the public notice in minority media. Any notice must comply with HUD fair housing requirements.

I. 24 CFR 982.503(c) (HUD Approval of Exception Payment Standard Amount)

24 CFR 982.503(c) authorizes HUD to approve an exception payment standard amount that is higher than 110 percent of the published fair market rent (FMR). Typically, a PHA must provide data about the local market to substantiate the need for an exception payment standard. In a natural disaster situation, however, the typical data sources fail to capture conditions on the ground. In these cases, HUD considers the most recently available data on the rental market, prior to the disaster, then estimates the number of households seeking housing units in the wake of the disaster to arrive at an emergency exception payment standard amount. In the event of a disaster, HUD will consider, based on this data, whether exception payment standard amounts up to 150 percent of the FMR have a good cause justification even in the absence of supporting data. If so, an PDD PHA may request this payment standard.

Upon approval by HUD, an exception payment standard adopted pursuant to this notification may be adopted for any Housing Assistance Payments (HAP) contract entered as of the effective date of this notification. HUD intends for these exception payment standards to remain in effect until HUD implements changes to the FMRs in the affected areas. PDD PHAs are reminded that increased per-family costs resulting from the use of exception payment standards may result in a reduction in the number of families assisted or may require other cost-saving measures for an PDD PHA to stay within its funding limitations.

J. 24 CFR 982.401(d) (Housing Quality Standards; Space and Security)

This section establishes a standard for adequate space for an HCV-assisted family. Specifically, it requires that each dwelling unit have at least 1 bedroom or living/sleeping room for each 2 persons. HUD may consider a request from an PDD PHA that wishes to waive this requirement to house families displaced due to natural disasters. Should the waiver be granted, it will be in effect only for HAPs entered into during the up to 12-month period following the date of HUD approval, and then only with the written consent of the family. HUD will not waive reasonable accommodation requirements. For any family occupying a unit pursuant to this waiver, the waiver will be in effect for the initial lease term.

K. 24 CFR 982.633(a) (Occupancy of Home)

This section establishes the requirement that PHAs may make HAP for homeownership assistance only while a family resides in their home and must stop HAP no later than the month after a family moves out. HUD may consider a request from a PDD PHA wishing to waive this requirement to allow families displaced from their homes located in areas affected by PDD(s) to comply with mortgage terms or make necessary repairs. A PHA requesting a waiver of this type must show good cause by demonstrating that the family is not already receiving assistance from another source. Note: An PDD PHA that wishes in addition to request a waiver of the requirement at 982.312 that a family be terminated from the program if they have been absent from their home for 180 consecutive calendar days must do so separately.

L. 24 CFR 984.303(d) (Contract of Participation; Contract Extension)

Part 984 establishes the requirements for the Section 8 and Public Housing Family Self-Sufficiency (FSS) Program. Section 984.303(d) authorizes a PHA to extend a family's contract of participation for a period not to exceed 2 years, upon a finding of good cause, for any family that requests such an extension in writing. HUD may consider a request from an PDD PHA that wishes to extend family contracts for up to 3 years, if such extensions are merited based on circumstances deriving from PDDs. Any waiver granted pursuant to this request will be in effect for requests made to the PDD PHA during a period not to exceed 12 months from the date of HUD approval.

M. 24 CFR Part 985 (Section 8 Management Assessment Program (SEMAP))

Part 985 sets out the requirements by which Section 8 tenant-based assistance programs are assessed. For a PDD PHA that has a SEMAP score due during CY 2022 or CY 2023, HUD may consider a written request to carry forward the last SEMAP score received by the PHA.

N. Notice PIH 2018–24, Section 8(c) Verification of the Social Security Notice (SSN))

PHAs are required to transmit form HUD–50058 not later than 30 calendar days following receipt of an applicant's or participant's SSN documentation. HUD may consider a request to extend this requirement to 90 calendar days, for a period not to exceed 12 months from the date of HUD approval.

O. 24 CFR 970.15(b)(1)(ii) (Specific Criteria for HUD Approval of Demolition Requests)

For Section 18 demolition applications (and disposition applications) justified by location obsolescence for PDD PHAs, HUD will accept an environmental review performed under 24 CFR part 50 or 24 CFR part 58 if HUD determines the environmental review indicates the environmental conditions jeopardize the suitability of the site or a portion of the site and its housing structures for residential use.

P. 24 CFR 970.15(b)(2) (Specific Criteria for HUD Approval of Demolition Requests)

For Section 18 demolition applications justified by obsolescence, HUD requires that PHAs support the cost estimate by a list of specific and detailed work items that require rehabilitation or repair, as identified on

form HUD–52860–B and other criteria outlined in PIH Notice 2018–04, Section A. HUD may consider requests to waive these requirements if a PDD PHA submits other evidence (*e.g.,* insurance adjuster reports, condemnation orders from local municipalities, and photographs) that support the PDD PHA's certification that a program of modifications is not cost-effective.

IV. Exceptions

A PDD PHA may request an exception of a HUD requirement not listed in Section II or III of this notice. HUD will only consider such exception requests subject to statutory limitations and pursuant to 24 CFR 5.110.

V. Instructions for Notification and Expedited Approval Process for PDD PHAs During CY 2022 and CY 2023

A PDD PHA seeking a waiver or flexibility of a HUD requirement listed within this notice or of any other HUD requirement needed to assist the PDD PHA in its disaster relief and recovery efforts must submit a request pursuant to the process that will be provided in this section. HUD will not approve a PDD PHA's or other recipient's request to waive or be granted a flexibility for a fair housing, civil rights, labor standards, or HUD's environmental review requirements.

Waiver requests approved by HUD pursuant to this notification will be published in the **Federal Register** and will identify the PDD PHAs receiving such approvals. The process that HUD will use in assessing applications for waivers and flexibilities is covered below.

HUD has developed a checklist (Attachment A to this notice) that a PDD PHA must complete and submit to take advantage of the waivers identified in this notice and the expedited review of waiver requests. Each provision on the checklist indicates the documentation that must accompany the PDD PHA's submission. Each request for a waiver (Section 3 of the checklist) must include a good-cause justification stating why the waiver is needed for the PHA's disaster relief and recovery efforts.

To complete the checklist, take the following steps:

1. Copy and paste the checklist found in Attachment A into a new document on your computer, saving the document with the following filename format: FR–6301–N–01–XX123. This format includes the **Federal Register** docket number (FR–6301–N–01), a hyphen, then your Agency's HA Code. For example: FR–6301–N–01–AL123.

2. Complete the section titled ''Information about Requesting Agency'' in its entirety. This section must be complete. An official of the PDD PHA must sign where indicated. If the information about the requesting agency is incomplete or the checklist has not been signed, then the checklist will be returned without review.

3. Complete Sections 1, 2, and/or 3 of the checklists, as applicable, noting the documentation (if any) that accompanies each provision.

4. Address an email to both *PIH_Disaster_Relief@hud.gov* and your HUD Field Office Public Housing Director. In the subject line, type ''PHA Name—PHA Code—PDD Disaster Relief—Month and Year.'' For example, Allenway Housing Authority—AL123–PDD Disaster Relief–October 2022.

5. Attach the completed checklist, letter of justification, and all supporting documentation as applicable to your email. HUD will consider other methods of submission as needed.

Checklists and any supporting documentation or information must be submitted not later than 120 days following the PDD. Requests submitted after that time will not be considered except in special cases outside of the agency's control.

VI. Finding of No Significant Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

The FONSI is available for public inspection between 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, an advance appointment to review the docket file must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Hearing or speech-impaired individuals may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

VII. Paperwork Reduction Act

The information collections referenced in this Notice have been approved by OMB pursuant to the Paperwork Reduction Act under, OMB Control Number 2577–0292.

Dominique G. Blom,

General Deputy Assistant Secretary for Public and Indian Housing.

Attachment A—Checklist

Relief From HUD Public Housing and Section 8 Requirements Available During CY 2022 and CY 2023 to Public Housing Agencies To Assist With Recovery and Relief Efforts on Behalf of Families Affected by Presidentially Declared Disasters

Information About Requesting Agency

NAME OF PHA: _____
PHA CODE: _____
Address: _____
City or Locality: (Must be covered under PDD) _____
Parish: _____
Date of Submission: _____
Signature of PHA Official: _____
Name/Title of PHA Official: _____
Phone number of PHA Official: _____
Email address of PHA Official: _____

Section 1. List the Presidentially Declared Disaster (PDD) Your Agency Is Under

_____

Section 2. Insert an ''X'' Next to the Applicable Flexibilities

A PDD PHA may adopt the flexibility listed below.

____*A. 24 CFR 990.145(b) (Public housing dwelling units with approved vacancies).* (Public Housing Financial Management Division)

My agency requests HUD approval to treat certain vacant public housing units in our inventory as approved vacancies for the continued receipt of Operating Subsidy. I have attached a project-by-project listing of the units for which this approval is requested. I understand that any units that remain vacant shall be considered approved vacancies only for a period not to exceed 12 months from the date of HUD approval.

Section 3. Insert an ''X'' Next to the Applicable Waiver Requests

A PDD PHA may request a waiver of a HUD requirement listed below or of any other HUD requirement and receive expedited review of the request, if the PDD PHA demonstrates that the waiver is needed for disaster relief and recovery purposes. Each request must include a good-cause justification for the waiver, documenting why the waiver is needed for such purposes. No requested waiver may be implemented unless and until written approval from HUD has been obtained.

____*A. 24 CFR 5.801(c) and 5.801(d)(1) (Uniform financial reporting standards; Filing of financial reports; Reporting compliance dates).*

____*B. 24 CFR 902 (Public Housing Assessment System).*

____*C. 24 CFR 905.322(b) (Fiscal closeout); 2 CFR 200.344(b) (Closeout).*

____*D.24 CFR 905.314(b)–(c) (Cost and other limitations; Maximum project cost; TDC limit).*

____E. 24 CFR 905.314(j) (Cost and other limitations; Types of labor).

____F. 24 CFR 905.400(i)(5) (Capital Fund Formula; Replacement Housing Factor to reflect formula need for projects with demolition or disposition occurring on or after October 1, 1998, and prior to September 30, 2013).

____G. 24 CFR 960.202(c)(1) (Tenant selection policies) and 982.54(a) (Administrative plan).

____H. 24 CFR 982.206(a)(2) (Waiting List; Opening and closing; Public notice).

____I. 24 CFR 982.503(c) (HUD approval of exception payment standard amount).

____J. 24 CFR 982.401(d) (Housing quality standards; Space and security).

____K. 24 CFR 982.633(a) (Occupancy of home).

____L. 24 CFR 984.303(d) (Contract of participation; contract extension).

____M. 24 CFR part 985 (Section 8 Management Assessment Program (SEMAP)).

____N. Notice PIH 2018–24, Section 8(c) (Verification of the Social Security Number).

____O. 24 CFR 970.15(b)(1)(ii) (Specific criteria for HUD approval of demolition requests).

____P. 24 CFR 970.15(b)(2) (Specific criteria for HUD approval of demolition requests).

____Q. Waivers not identified in this PIH Notice. My agency seeks waivers of the HUD requirements listed below. None of the requests are to waive a fair housing, civil rights, labor standards, or environmental review requirement. I have included documentation justifying the need for the waivers.

[FR Doc. 2021–28561 Filed 1–4–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7038–N–23]

60-Day Notice of Proposed Information Collection: Annual Adjustment Factors (AAF) Rent Increase Requirement, OMB Control Number: 2502–0507

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* March 7, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Stephan A. Martin, Director, Assisted Housing Oversight Division, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; 202–708–3000; email: *Stephen.A.Martin@hud.gov.* This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Annual Adjustment Factors (AAF) Rent Increase Requirement.

OMB Approval Number: 2502–0507.

Type of Request: Reinstatement, with change, of previously approved collection for which approval has expired.

Form Number: HUD–92273–S8.

Description of the need for the information and proposed use: Owners of project-based section 8 contracts that utilize the AAF as the method of rent adjustment provide this information which is necessary to determine whether or not the subject properties' rents are to be adjusted and, if so, the amount of the adjustment.

Respondents: Business, not for profit institutions.

Estimated Number of Respondents: 1,080.

Estimated Number of Responses: 8.

Frequency of Response: On occasion.

Average Hours per Response: 1.5 hours.

Total Estimated Burden: 12.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Janet M. Golrick,

Acting, Chief of Staff for the Office of Housing—Federal Housing Administration.

[FR Doc. 2021–28562 Filed 1–4–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[FR–6301–N–02]

Regulatory and Administrative Requirement Flexibilities Available to Native American Programs During CY 2022 and CY 2023 to Tribal Grantees To Assist With Recovery and Relief Efforts on Behalf of Families Affected by Presidentially Declared Disasters

AGENCY: Office of Assistant Secretary for Public and Indian Housing, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: This notification advises the public of waivers and flexibilities from HUD requirements for its Indian Housing Block Grant (IHBG), Indian Community Development Block Grant (ICDBG), and Native Hawaiian Housing Block Grant (NHHBG) grantees located in areas that are covered by Presidentially Declared Disasters (PDDs). A PDD is a major disaster or emergency declared under the Robert T. Stafford Disaster Relief and Emergency Assistance Act that activates an array of federal programs to assist in the

response and recovery efforts. When they occur, disasters and their aftermath impose significant barriers and challenges for housing programs to overcome or operate. To provide relief during such challenging times for its IHBG, ICDBG, and NHHBG grantees, HUD is publishing this standing Notice of regulatory and administrative requirement flexibilities to assist affected grantees. Instructions are provided below on how to apply for flexibilities. A grantee may request a waiver or flexibility of a HUD requirement not listed in this standing Notice and receive an expedited review of the request if the grantee demonstrates that the waiver or flexibility is needed to assist its disaster relief and recovery efforts. Please note that the waivers and flexibilities in this Notice do not apply to the various COVID-relief related programs administered by the Office of Native American Programs (IHBG–CARES, IHBG–ARP, ICDBG–CARES, ICDBG–ARP, and NHHBG–ARP) because HUD has issued separate waivers and alternative requirements that apply to those programs, as further outlined in the Implementation and Waiver Notices governing those programs.

DATES: This document announces the waivers and flexibilities set out in this document as of January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Hilary Atkin, Office of Native American Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Room 4108, Washington, DC 20410–5000, or email *Hilary.C.Atkin@hud.gov.* Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

I. Flexibilities That Are Available to PDD Tribes, Tribally Designated Housing Entities, and the Department of Hawaiian Homelands During CY 2022 and CY 2023

The following is a list of HUD requirement waivers and flexibilities available for IHBG, ICDBG, and NHHBG grantees located within PDD areas. Grantees may use any of the waivers and flexibilities below to assist their communities in addressing challenges and issues that result from a disaster covered by a PDD.

A. 24 CFR Part 1000 (IHBG)

1. Total Development Costs (24 CFR 1000.156, 1000.158, 1000.160, and 1000.162)

The IHBG regulations at 24 CFR part 1000 require that affordable housing under the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA) be of moderate design with a size and with amenities consistent with unassisted housing offered for sale in the Indian tribe's general geographic area to buyers who are at or below the area median income (AMI). To achieve this requirement the recipient must either: Adopt written standards for its affordable housing programs that reflect the requirement specified, or use total development cost (TDC) limits published periodically by HUD that establish the maximum amount of funds (from all sources) that the recipient may use to develop or acquire/rehabilitate affordable housing. The limits provided by the TDC may not, without prior HUD approval, exceed by more than 10 percent the TDC maximum cost for the project. Non-dwelling structures used to support an affordable housing activity must be of a design, size and with features or amenities that are reasonable and necessary to accomplish the purpose intended by the structures.

Disasters may result in disruptions to supply chains, lead to labor and contractor shortages, and result in overall increases in construction costs. Given this possibility of increased costs of resources and the urgency to rehabilitate homes following a disaster, HUD is waiving the TDC regulatory requirements in 24 CFR 1000.156, 1000.158, 1000.160, and 1000.162 relating to limitations on cost or design standards and TDC with respect to dwelling and non-dwelling units developed, acquired, or assisted with IHBG funding. Under this waiver, an IHBG recipient may exceed the current TDC maximum by 20 percent without HUD review or approval (other than notification by the grantee pursuant to the procedures outlined in Section II of this Notice). The recipient, however, must maintain documentation that indicates the dwelling units and non-dwelling structures developed, acquired, or assisted with this funding will, after the PDD, be for IHBG eligible families and the design, size, and amenities are moderate and comparable to housing in the area. The TDC limits can be exceeded by more than 20 percent if the recipient receives written approval from HUD Headquarters. This waiver applies to both single-family and multi-family housing, as well as non-dwelling structures.

2. Income Verification (24 CFR 1000.128)

24 CFR 1000.128 requires IHBG recipients to verify that a family is income eligible. Families are required to provide documentation to verify this determination, and a recipient is required to maintain that documentation. Families may be required by the IHBG recipient to periodically verify income after initial occupancy, and the recipient is required to maintain documentation.

As families may be displaced during a disaster and may not have access to their income documentation, HUD is waiving section 1000.128, and allowing the following:

(a) IHBG recipients may deviate from their current written admissions and occupancy policies, and may allow less frequent income recertifications; and

(b) IHBG recipients may carry out intake and other tasks necessary to verify income through alternative means if the IHBG recipient chooses to do so, including allowing income self-certification over the phone (with a written record by the IHBG recipient's staff), or through an email with a self-certification form signed by a family.

3. Assistance to Middle-Income Families Impacted by a Disaster (24 CFR 1000.104, 1000.106, 1000.108, and 1000.110)

Generally, Section 201 of NAHASDA and the IHBG regulations at 24 CFR 1000.104, 1000.106, 1000.108, and 1000.110 require that IHBG recipients limit assistance to low-income Native American families, with some exceptions for non-low-income families at 80–100 percent AMI, families over 100 percent of AMI, and essential families under section 201(b)(3) of NAHASDA. Section 201(b)(2) and 24 CFR 1000.110 provide that an IHBG recipient may aid a non-low-income family upon a documented determination by the recipient that there is a need for housing for such family that cannot reasonably be met without such assistance. 24 CFR 1000.110(c) provides that a recipient may use up to 10 percent of the amount planned for the tribal program year for families whose income falls within 80 to 100 percent of AMI without HUD approval. HUD approval is required if a recipient plans to use more than 10 percent of the amount planned for the tribal program year for such assistance or to provide housing for families with income over 100 percent of AMI. Finally, 24 CFR 1000.110(d) provides that non-low-

income families cannot receive the same benefits provided low-income Indian families. The amount of rental assistance, homeownership assistance, and other assistance that non-low-income families may receive will be determined in accordance with the formula provided in that regulation.

Disasters may devastate and displace Native American families in a community of all incomes, make housing uninhabitable, damage community infrastructure, and result in a loss of life and property. IHBG recipients may find it in the public interest to aid non-low-income families that are displaced due to a disaster, including by using IHBG funds to provide such assistance as temporary rental assistance to otherwise ineligible families in IHBG-assisted housing owned or operated by the recipient, housing such families in hotels/motels, and similar facilities, providing such families with necessary relocation assistance, and more. To help alleviate the impact of disasters on Tribal communities, HUD is waiving 24 CFR 1000.104, 1000.106, 1000.108, and 1000.110 to the extent necessary to allow for the following flexibilities:

(a) IHBG recipients in PDDs may exceed the 10 percent cap on serving Native American families whose income falls within 80 to 100 percent of AMI without HUD approval, provided the recipient decides that the families are impacted by the disaster and that there is a need for housing for such family that cannot reasonably be met without such assistance.

(b) IHBG recipients in PDDs may provide IHBG assistance to middle-income Native American families whose income is at or below 120 percent of AMI without HUD approval, provided the recipient decides that the families are impacted by the disaster and that there is a need for housing for such family that cannot reasonably be met without such assistance.

In all cases, assistance to these non-low-income families must still comply with limits on assistance specified in 24 CFR 1000.110(d). Additionally, all assistance must be temporary in nature. For instance, such families may receive temporary rental assistance that is time-limited pursuant to the recipient's policies but may not receive permanent tenant-based rental assistance with no specified end date. IHBG recipients must ensure that IHBG assistance provided does not result in a duplication of benefits. For example, IHBG recipients should not pay for costs that are already covered by private insurance or other Federal, State, or Tribal funds or programs. Finally, when providing this assistance, IHBG recipients must also maintain records documenting that all these criteria were met at the time that such assistance was provided.

B. 24 CFR Part 1003 (ICDBG)

1. Purchasing Equipment (24 CFR 1003.207(b)(1)(i))

The purchase of equipment with ICDBG funds is generally ineligible under 24 CFR 1003.207(b)(1)(i), with some exceptions. Given the immediate need for certain equipment to carry out ICDBG eligible activities related to disaster recovery, such as construction equipment, necessary for clearance, construction, rehabilitation, and other recovery efforts in the aftermath of a disaster, HUD is waiving 24 CFR 1003.207(b)(1)(i) and authorizing the use of ICDBG funds for the purchase of equipment necessary to carry out ICDBG eligible activities that assist with clearance, rehabilitation, construction, and other uses related to housing, public facilities, improvements, and works, and other disaster-recovery related purposes. Equipment must be used for authorized program purposes, and any proceeds from the disposition of equipment will be considered ICDBG program income. HUD may issue further guidance in the future on the disposition of program income after grant closeout.

2. Emergency Payments for Up to Six Months (24 CFR 1003.207(b)(4))

Under 24 CFR 1003.207(b)(4), the general rule is that ICDBG funds may not be used for income payments. For purposes of the ICDBG program, income payments mean a series of subsistence-type grant payments made to an individual or family for items such as food, clothing, housing (rent or mortgage), or utilities. However, ICDBG may be used to make emergency payments over a period of up to three months to the provider of such items or services on behalf of an individual or family.

Low- and moderate-income families impacted by disasters may have an immediate need for short term rental assistance, mortgage assistance, utility assistance, food, clothing, and similar services.

To provide additional relief to families impacted by disasters, HUD is waiving 24 CFR 1003.207(b)(4) to the extent necessary to allow ICDBG grant funds to be used to provide emergency payments for low- and moderate-income individuals or families impacted by a disaster. These grant funds may be used for items such as food, medicine, clothing, and other necessities, as well as rental, mortgage, and utility assistance, without regard for the 3-month limitation in 24 CFR 1003.207(b)(4), but for a period not to exceed six months, unless further approved in writing by HUD on a case-by-case basis.

ICDBG grantees may establish lines of credit with third party providers (*e.g.,* grocery stores) on behalf of specific beneficiary families, provided all expenses can be properly documented and all ICDBG funds used for this purpose are expended on eligible activities. In all cases, ICDBG grantees must ensure that proper documentation is maintained to ensure that all costs incurred are eligible. ICDBG grantees using this waiver flexibility must document, in their policies and procedures, how they will determine the necessary and reasonable amount of assistance to be provided.

C. 24 CFR Part 1006 (NHHBG)

1. Assistance to Middle-Income Families Impacted by Disaster (24 CFR 1006.301(a))

24 CFR 1006.301(a) describes families eligible for NHHBG assistance as low-income Native Hawaiian families who are eligible to reside on the Hawaiian homelands. Section 809(a)(2) of NAHASDA limits assistance for families who are not low-income to homeownership activities, as approved by HUD, to address a housing need that cannot be reasonably met without that assistance. Section 1006.301(d) requires DHHL to have written policies governing eligibility, admission, and occupancy of families for NHHBG-assisted housing.

Disasters may devastate and displace Native Hawaiian families in a community of all incomes, make housing uninhabitable, damage community infrastructure, and result in loss of life and property. DHHL may find it in the public interest to aid non-low-income families that are displaced due to a disaster by using NHHBG funds to provide such assistance as temporary mortgage assistance, temporary rental assistance on or off the Hawaiian homelands, housing such families in hotels, motels, or similar facilities, providing such families with necessary relocation assistance, and more. To help alleviate the impact of disasters on Native Hawaiian communities, HUD is waiving 24 CFR 1006.301(a) to allow DHHL more flexibility to provide NHHBG assistance to families that are middle income (defined as 120 percent of AMI), provided the assistance is for homeownership activities (which may

include short-term rental assistance to displaced homeowners), is temporary in nature, and DHHL determines that the families are impacted by the disaster and that there is a need for housing for such family that cannot reasonably be met without such assistance.

Under this waiver, Native Hawaiian families impacted by PDD can automatically be served provided their household income does not exceed 120 percent of AMI, there is no duplication of benefits, and all eligible criteria in this waiver are met. All assistance must be temporary in nature. For instance, such families may receive temporary rental assistance that is time-limited pursuant to DHHL's policies but may not receive permanent tenant-based rental assistance with no specified end date. DHHL must ensure that NHHBG assistance provided does not result in a duplication of benefits. For example, DHHL should not pay for costs that are already covered by private insurance or other Federal or State funds or programs. Further, when providing this assistance, DHHL must maintain records documenting that all these criteria were met at the time that such assistance was provided. HUD encourages DHHL to update its written policies to allow middle-income Native Hawaiian families who are impacted by disasters covered by a PDD to be considered eligible for NHHBG homeownership assistance and include a definition for 'temporary' assistance.

2. Income Verification (24 CFR 1006.320)

24 CFR 1006.320 requires DHHL to have written policies regarding tenant and homebuyer selection and criteria related to eligibility for NHHBG assistance. Many families whose homes were damaged or destroyed by the disaster may not have any documentation of income. DHHL may modify its policy and procedures to streamline any income verification and documentation requirements for families impacted by PDDs. This may include allowing income self-certification over the phone (with a written record by the DHHL's staff), or through an email with a self-certification form signed by a family. This waiver applies only to families impacted by PDDs whose income documentation was destroyed or made difficult to access by the disaster.

II. Instructions

To use the waivers or flexibilities, grantees must provide notification in writing, preferably by email, to the Administrator in the ONAP Area Office serving their area before the grantee anticipates using the waiver or flexibility. The written notification should include the following details:

- Requestor's Tribe/TDHE/DHH, name, title, and contact information.
- Presidentially declared major disaster area(s) where the waivers will be used.
- Date on which the grantee anticipates the first use of the waiver or flexibility, and its expected duration (which must include a specific end date),and
- A list of the waivers and flexibilities the grantee will use.

III. Exceptions

An IHBG, ICDBG, or NHHBG grantee within in a PDD may request an exception of a HUD requirement not listed in Section I of this notice. HUD will only consider such exception requests subject to statutory limitations and pursuant to 24 CFR 5.110.

IV. Period of Use for Waivers and Flexibilities

Waivers and flexibilities provided in this Notice will remain available to grantees provided a grantee is using the waivers or flexibilities in response to the PDD or as part of the recovery process effort. HUD recommends that grantees clearly document the need for each waiver and flexibility in their records and ensure that a specific time period for which the grantee will use the waivers and flexibilities that the grantee specifies in its written notification to HUD, described in Section II of this Notice, is reasonably set and ties back to the response and recovery effort. If a grantee finds a need to extend the period for which it will use a waiver or flexibility beyond the end date initially set by the grantee in its initial written notification to aid in its ongoing recovery effort, the grantee should send HUD written notification of its intent to extend the end date. The request must also demonstrate to HUD's satisfaction that the new time period is reasonably set and ties back to the response and recovery effort.

V. Finding of No Significant Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

The FONSI is available for public inspection between 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, an advance appointment to review the docket file must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Hearing or speech-impaired individuals may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

VI. Paperwork Reduction Act

The information collections referenced in this Notice have been approved by OMB pursuant to the Paperwork Reduction Act under, OMB Control Number 2577–0292.

Dominique G. Blom,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 2021–28565 Filed 1–4–22; 8:45 am]

BILLING CODE 4210–67–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–1273]

Certain Residential Premises Security Monitoring and Automation Control Panels, and Components Thereof; Correction Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Correction of notice.

Correction is made to notice 82 FR 42879, which was published on August 5, 2021. The notice erroneously does not state that the Office of Unfair Import Investigations is a party to the investigation. The notice should read:

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served: . . . (c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and . . .

Issued: December 30, 2021.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2021–28549 Filed 1–4–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Integrated Circuit Products and Devices Containing the Same, DN 3589;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Future Link Systems, LLC on December 28, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain integrated circuit products and devices containing the same. The complainant names as respondents: Advanced Micro Devices, Inc. of Santa Clara, CA; Apple, Inc. of Cupertino, CA; Broadcom Inc. of San Jose, CA; Broadcom Corporation of San Jose, CA; Qualcomm Inc. of San Diego, CA; Qualcomm Technologies Inc. of San Diego, CA; Amlogic Holdings Ltd. of Cayman Islands; Amlogic (CA) Co., Inc. of Santa Clara, CA; Realtek Semiconductor Corp. of Taiwan; Dell Technologies Inc. of Round Rock, TX; HP Inc. of Palo Alto, CA; Acer Inc. of Taiwan; Acer America Corp. of San Jose CA; Lenovo Group Ltd. of Hong Kong; Lenovo (United States) Inc. of Morrisville, NC; Motorola Mobility LLC of Chicago, IL; and Google LLC of Mountain View, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3589'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

Issued: December 30, 2021.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2021–28545 Filed 1–4–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1575–1577 (Preliminary)]

Emulsion Styrene-Butadiene Rubber From Czechia, Italy, and Russia

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of emulsion styrene-butadiene rubber from Czechia, Italy, and Russia, provided for in subheading 4002.19.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'').[2] [3]

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under § 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under § 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

Effective November 15, 2021, Lion Elastomers LLC, Port Neches, Texas filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV imports of emulsion styrene-butadiene rubber from Czechia, Italy, and Russia. Accordingly, effective November 15, 2021, the Commission instituted antidumping duty investigation Nos. 731–TA–1575–1577 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of November 22, 2021 (86 FR 66335). In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission conducted its conference through written testimony and video conference. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to § 733(a) of the Act (19 U.S.C. 1673b(a)). It completed and filed its determinations in these investigations on December 30, 2021. The views of the Commission are contained in USITC Publication 5274 (January 2022), entitled *Emulsion Styrene-Butadiene Rubber from Czechia, Italy, and Russia: Investigation Nos. 731 TA 1575–1577 (Preliminary).*

Issued: December 30, 2021.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2021–28568 Filed 1–4–22; 8:45 am]

BILLING CODE 7020–02–P

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 86 FR 70447 (December 10, 2021).

[3] Vice Chair Randolph J. Stayin not participating.

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Clarence L. Werner; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Clarence L. Werner,* Civil Action 1:21–cv–03332. On December 22, 2021, the United States filed a Complaint alleging that Clarence L. Werner violated the premerger notification and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. 18a, in connection with the acquisition of voting securities of Werner Enterprises Inc. The proposed Final Judgment, filed at the same time as the Complaint, requires Clarence L. Werner to pay a civil penalty of $486,900.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments in English should be directed to Maribeth Petrizzi, Special Attorney, United States, c/o Federal Trade Commission, 600 Pennsylvania Avenue NW, CC–8416, Washington, DC 20580 or by email to *bccompliance@ftc.gov.*

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

United States District Court for the District of Columbia

United States of America, c/o Department of Justice, Washington, DC 20530, Plaintiff, v. *Clarence L. Werner, c/o Werner Enterprises, Inc., 14507 Frontier Road, Omaha, NE 68138,* Defendant.

Civil Action No. 1:21–cv–03332

Judge: James E. Boasberg

Complaint for Civil Penalties for Failure To Comply With the Premerger Reporting and Waiting Requirements of the Hart-Scott Rodino Act

The United States of America, acting under the direction of the Attorney General of the United States and at the request of the United States Federal Trade Commission, brings this civil antitrust action to obtain monetary relief in the form of civil penalties against Defendant Clarence L. Werner (''Werner''). The United States alleges as follows:

I. Nature of the Action

1. Werner violated the notice and waiting period requirements of Section 7A of the Clayton Act, (15 U.S.C. 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ''HSR Act'' or ''Act''), with respect to the acquisition of voting securities of Werner Enterprises, Inc. (''Werner Inc.'') from May 2007 through February 2020.

II. Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter of this action pursuant to Section 7A(g) of the Clayton Act, 15 U.S.C. 18a(g), and 28 U.S.C. 1331, 1337(a), 1345, and 1355, and over Defendant by virtue of Defendant's consent, in the Stipulation relating hereto, to the maintenance of this action and entry of the Final Judgment in this District.

3. Venue is proper in this District by virtue of Defendant's consent, in the Stipulation relating hereto, to the maintenance of this action and entry of the Final Judgment in this District.

III. The Defendant

4. Defendant Werner is a natural person with his principal office and place of business at 14507 Frontier Road, Omaha, NE 68138. Werner is the founder of Werner Inc. and during the relevant period alternatively served as the Chairman, Chairman Emeritus, and Executive Chairman of its Board of Directors. Werner is engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. 18a(a)(1). At all times relevant to this complaint, Werner had sales or assets that met the operative threshold.

IV. Other Entity

5. Werner Inc. is a corporation organized under the laws of Nebraska with its principal place of business at 14507 Frontier Road, Omaha, NE 63138. Werner Inc. is engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. 18a(a)(1). At all times relevant to this complaint, Werner Inc. had sales or assets that met the operative threshold.

V. The Hart-Scott-Rodino Act and Rules

6. The HSR Act requires certain acquiring persons and certain persons whose voting securities or assets are acquired to file notifications with the Department of Justice and the Federal Trade Commission (collectively, the ''federal antitrust agencies'') and to observe a waiting period before consummating certain acquisitions of voting securities or assets. 15 U.S.C. 18a(a) and (b). These notification and waiting period requirements apply to acquisitions that meet the HSR Act's size of transaction and size of person thresholds, which have been adjusted annually since 2004. The size of transaction threshold is met for transactions valued over $50 million, as adjusted ($94 million in 2020). In addition, there is a separate filing requirement for transactions in which the acquirer will hold voting securities in excess of $100 million, as adjusted ($188 million in 2020), and for transactions in which the acquirer will hold voting securities in excess of $500 million, as adjusted ($940.1 million in 2020). With respect to the size of person thresholds, the HSR Act requires one person involved in the transaction to have sales or assets in excess of $10 million, as adjusted ($18.8 million in 2020), and the other person to have sales or assets in excess of $100 million, as adjusted ($188 million in 2020).

7. The HSR Act's notification and waiting period requirements are intended to give the federal antitrust agencies prior notice of, and information about, proposed transactions. The waiting period is also intended to provide the federal antitrust agencies with the opportunity to investigate a proposed transaction and to determine whether to seek an injunction to prevent the consummation of a transaction that may violate the antitrust laws.

8. Pursuant to Section (d)(2) of the HSR Act, 15 U.S.C. 18a(d)(2), rules were promulgated to carry out the purposes of the HSR Act. 16 CFR 801–03 (''HSR Rules''). The HSR Rules, among other things, define terms contained in the HSR Act.

9. Pursuant to Section 801.13(a)(1) of the HSR Rules, 16 CFR 801.13(a)(1), ''all voting securities of [an] issuer which will be held by the acquiring person after the consummation of an acquisition''—including any held before the acquisition—are deemed held ''as a result of'' the acquisition at issue.

10. Pursuant to Sections 801.13(a)(2) and 801.10(c)(1) of the HSR Rules, 16 CFR 801.13(a)(2) and § 801.10(c)(1), the value of voting securities already held is the market price, defined to be the lowest closing price within 45 days prior to the subsequent acquisition.

11. Section 802.21 of the HSR Rules, 16 CFR 802.21, provides that, once a person has filed under the HSR Act and the waiting period has expired, that person can acquire additional voting securities of the same issuer without filing a new notification for five years from the expiration of the waiting period, so long as the value of the person's holdings do not exceed a threshold higher than was indicated in the filing (''802.21 exemption'').

12. Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1), provides that any person, or any officer, director, or partner thereof, who fails to comply with any provision of the HSR Act is liable to the United States for a civil penalty for each day during which such person is in violation. Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), the dollar amounts of civil penalties listed in Federal Trade Commission Rule 1.98, 16 CFR 1.98, are adjusted annually for inflation; the maximum amount of civil penalty in effect at the time of Werner's corrective filing was $43,280 per day. 85 FR 2014 (January 14, 2020).

VI. Defendant's Violation of the HSR Act

13. On May 14, 2007, Werner exercised options to acquire 475,000 Werner Inc. voting securities, which resulted in his aggregated holdings of Werner Inc. voting securities exceeding the $100 million threshold, as adjusted, which in May 2007, was $119.6 million. Although required to do so, Werner did not file under the HSR Act or observe the HSR Act's waiting period prior to completing the May 14, 2007, transaction.

14. Werner continued to acquire Werner Inc. voting securities through open market purchases, the exercise of options, and otherwise.

15. Werner acquired 320,100 voting securities on November 18, 2009, 8,500 voting securities on November 24, 2009, 59,406 voting securities on November 27, 2009, and 32,094 voting securities on November 30, 2009. All of these acquisitions were made on the open market. Open market acquisitions require an acquirer to affirmatively and

actively decide to acquire voting securities; in particular for very large open market acquisitions, it is not excusable negligence to be unaware of HSR Act legal requirements.

16. On November 20, 2012, Werner exercised options to acquire 100,000 Werner Inc. voting securities, which resulted in his aggregated holdings of Werner Inc. voting securities again exceeding the $100 million threshold, as adjusted, which in November 2012, was $136.4 million. Although required to do so, Werner did not file under the HSR Act or observe the HSR Act's waiting period prior to completing the November 20, 2012 transaction. Thereafter, Werner continued to acquire Werner Inc. voting securities.

17. On February 7, 2019, Werner received 3,738 Werner Inc. voting securities with the vesting of a tranche of restricted stock, which resulted in his aggregated holdings of Werner Inc. voting securities again exceeding the $100 million threshold, as adjusted, which in February 2019, was $168.8 million. Although required to do so, Werner did not file under the HSR Act or observe the HSR Act's waiting period prior to completing the February 7, 2019 transaction.

18. On January 17, 2020, Werner's counsel contacted the Premerger Notification Office (''PNO'') of the Federal Trade Commission to inform PNO staff that counsel was analyzing a situation that counsel anticipated would likely entail multiple post-consummation filings. As of that date, Werner, through his counsel, was aware that he had violated the HSR Act.

19. Thereafter, Werner made additional acquisitions of Werner Inc. voting securities on February 7 and 11, 2020, through the vesting of restricted stock awards. Werner did not file an HSR notification prior to either of these acquisitions.

20. On March 4, 2020, Werner made corrective filings under the HSR Act for the acquisitions he made on May 14, 2007, November 20, 2012, and February 7, 2019. Each of these transactions resulted in Werner's aggregated holdings of Werner Inc. voting securities exceeding the $100 million threshold, as adjusted. Had Werner filed under the HSR Act for these three acquisitions on a timely basis, all his other acquisitions of Werner Inc. voting securities during the relevant period would have been exempt pursuant to the 802.21 exemption.

21. Werner was in continuous violation of the HSR Act from May 14, 2007, when he acquired the Werner Inc. voting securities valued in excess of the HSR Act's $100 million filing threshold, as adjusted, through April 3, 2020, when the waiting period expired on his corrective filings.

VIII. Requested Relief

Wherefore, the United States requests:

a. That the Court adjudge and decree that Defendant's acquisitions of Werner Inc. voting securities from May 14, 2007, through February 11, 2020, were violations of the HSR Act, 15 U.S.C. 18a; and that Defendant was in violation of the HSR Act each day from May 14, 2007, through April 3, 2020;

b. that the Court order Defendant to pay to the United States an appropriate civil penalty as provided by the Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1), the Debt Collection Improvement Act of 1996, Public Law 104 134 § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461), and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), and Federal Trade Commission Rule 1.98, 16 CFR 1.98, 85 FR 2014 (January 14, 2020);

c. that the Court order such other and further relief as the Court may deem just and proper; and

d. that the Court award the United States its costs of this suit.

Dated:

FOR THE PLAINTIFF UNITED STATES OF AMERICA:

Jonathan S. Kanter,

Assistant Attorney General, Department of Justice, Antitrust Division, Washington, DC 20530.

Maribeth Petrizzi,

D.C. Bar No. 435204, Special Attorney.

Kenneth A. Libby,

Special Attorney.

Kelly Horne,

Special Attorney, Federal Trade Commission, Washington, DC 20580, (202) 326–2694.

United States District Court for the District of Columbia

United States of America, Plaintiff, v. *Clarence L. Werner,* Defendant.

Civil Action No. 1:21–cv–03332

Judge: James E. Boasberg

[Proposed] Final Judgment

Whereas, the United States of America filed its Complaint on December 22, 2021, alleging that Defendant Clarence L. Werner violated Section 7A of the Clayton Act (15 U.S.C. 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the ''HSR Act''));

and whereas the United States and Defendant, have consented to the entry of this Final Judgment without the taking of testimony, without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact or law;

Now, therefore, it is ordered, adjudged, and decreed:

I. Jurisdiction

The Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief can be granted against Defendant under Section 7A of the Clayton Act, 15 U.S.C. 18a.

II. Civil Penalty

Judgment is hereby entered in this matter in favor of the United States and against Defendant, and, pursuant to Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1), the Debt Collection Improvement Act of 1996, Public Law 104–134 § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461), the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74 § 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), and Federal Trade Commission Rule 1.98, 16 CFR 1.98, 86 FR 2541 (January 13, 2021), Defendant is hereby ordered to pay a civil penalty in the amount of four hundred eighty-six thousand nine hundred dollars ($486,900). Payment of the civil penalty ordered hereby must be made by wire transfer of funds or cashier's check. If the payment is to be made by wire transfer, prior to making the transfer, Defendant will contact the Budget and Fiscal Section of the Antitrust Division's Executive Office at *ATR.EXO-Fiscal-Inquiries@usdoj.gov* for instructions. If the payment is made by cashier's check, the check must be made payable to the United States Department of Justice and delivered to: Chief, Budget & Fiscal Section, Executive Office, Antitrust Division, United States Department of Justice, Liberty Square Building, 450 5th Street NW, Room 3016, Washington, DC 20530.

Defendant must pay the full amount of the civil penalty within thirty (30) days of entry of this Final Judgment. In the event of a default or delay in payment, interest at the rate of eighteen percent (18%) per annum will accrue

thereon from the date of the default or delay to the date of payment.

III. Costs

Each party will bear its own costs of this action, except as otherwise provided in Paragraph IV.C.

IV. Enforcement of Final Judgment

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendant agrees that in a civil contempt action, a motion to show cause, or a similar action brought by the United States regarding an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of a remedy therefor by a preponderance of the evidence, and Defendant waives any argument that a different standard of proof should apply.

B. Defendant agrees that he may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. The terms of this Final Judgment should not be construed against either party as the drafter.

C. In connection with a successful effort by the United States to enforce this Final Judgment against Defendant, whether litigated or resolved before litigation, Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as all other costs including experts' fees, incurred in connection with that enforcement effort, including in the investigation of the potential violation.

V. Expiration of Final Judgment

This Final Judgment will expire upon payment in full by the Defendant of the civil penalty required by Section II of this Final Judgment.

VI. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Dated: _____

[Court approval subject to the procedures of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16]

_____

United States District Judge

United States District Court for the District of Columbia

United States of America, Plaintiff, v. *Clarence L. Werner,* Defendant.

Civil Action No. 1:21–cv–03332

Judge: James E. Boasberg

Competitive Impact Statement

The United States of America (''United States''), under Section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h) (''APPA'' or ''Tunney Act''), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On December 22, 2022, the United States filed a Complaint against Defendant Clarence L. Werner (''Werner'' or ''Defendant''), relating to Werner's acquisitions of voting securities of Werner Enterprises, Inc. (''Werner Inc.'') from May 2007 through February 2020. The Complaint alleges that Werner violated Section 7A of the Clayton Act, 15 U.S.C. 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the ''HSR Act''). The HSR Act requires certain acquiring persons and certain persons whose voting securities or assets are acquired to file notifications with the Department of Justice and the Federal Trade Commission (collectively, the ''federal antitrust agencies'') and to observe a waiting period before consummating certain acquisitions of voting securities or assets. 15 U.S.C. 18a (a) and (b).

These notification and waiting period requirements apply to acquisitions that meet the HSR Act's size of transaction and size of person thresholds, which have been adjusted annually since 2004. The size of transaction threshold is met for transactions valued over $50 million, as adjusted ($94 million in 2020). In addition, there is a separate filing requirement for transactions in which the acquirer will hold voting securities in excess of $100 million, as adjusted ($188 million in 2020), and for transactions in which the acquirer will hold voting securities in excess of $500 million, as adjusted ($940.1 million in 2020).

With respect to the size of person thresholds, the HSR Act requires one person involved in the transaction to have sales or assets in excess of $10 million, as adjusted ($18.8 million in 2020), and the other person to have sales or assets in excess of $100 million, as adjusted ($188 million in 2020). A key purpose of the notification and waiting period requirements is to protect consumers and competition from potentially anticompetitive transactions by providing the federal antitrust agencies an opportunity to conduct an antitrust review of proposed transactions before they are consummated.

An exemption from HSR Act filings may apply under certain circumstances. Section 802.21 of the HSR Rules, 16 CFR 802.21, provides that, once a person has filed under the HSR Act and the waiting period has expired, that person can acquire additional voting securities of the same issuer without filing a new notification for five years from the expiration of the waiting period, so long as the value of the person's holdings do not exceed a threshold higher than was indicated in the filing (''802.21 exemption'').

The Complaint alleges that Werner acquired voting securities of Werner Inc. without filing the required pre-acquisition HSR Act notifications with the federal antitrust agencies and without observing the waiting period. Werner's acquisitions of Werner Inc. voting securities exceeded the $100-million statutory threshold, as adjusted, and Werner and Werner Inc. met the then-applicable adjusted statutory size of person thresholds. Moreover, none of Werner's acquisitions were exempt from HSR Act notification and waiting period requirements under the 802.21 exemption because he had not previously filed the requisite pre-acquisition HSR Act notifications.

At the same time the Complaint was filed in the present action, the United States also filed a Stipulation and Order and proposed Final Judgment that resolve the allegations made in the Complaint. The proposed Final Judgment is designed to address the violation alleged in the Complaint and penalize Werner's HSR Act violations. Under the proposed Final Judgment, Werner must pay a civil penalty to the United States in the amount of $486,900.

The United States and Werner have stipulated that the proposed Final Judgment may be entered after compliance with the APPA, unless the United States first withdraws its consent. Entry of the proposed Final Judgment will terminate this action, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and punish violations thereof.

II. Description of the Events Giving Rise to the Alleged Violation

The crux of Werner's violation is that he failed to submit HSR Act notifications even though his acquisitions of Werner Inc. voting securities satisfied the HSR Act filing requirements and he was not eligible to take advantage of the 802.21 exemption. At all times relevant to the Complaint, Werner had sales or assets in excess of $10 million, as adjusted. At all times relevant to the Complaint, Werner Inc. had sales or assets in excess of $100 million, as adjusted.

Werner is the founder of Werner Inc. and during the relevant period alternatively served as the Chairman, Chairman Emeritus, and Executive Chairman of its Board of Directors. On May 14, 2007, Werner exercised options to acquire 475,000 shares of Werner Inc. voting securities, which resulted in his aggregated holdings of Werner Inc. voting securities exceeding the $100 million threshold, as adjusted, which in May 2007 was $119.6 million. Although required to do so, Werner did not file under the HSR Act or observe the HSR Act's waiting period prior to completing the May 14, 2007, transaction.

Werner continued to acquire Werner Inc. voting securities, through open market purchases, the exercise of options, and otherwise. Werner acquired 320,100 voting securities on November 18, 2009, 8,500 voting securities on November 24, 2009, 59,406 voting securities on November 27, 2009, and 32,094 voting securities on November 30, 2009. All of these acquisitions were made on the open market. Open market acquisitions require an acquirer to affirmatively and actively decide to acquire voting securities; in particular for very large open market acquisitions, it is not excusable negligence to be unaware of HSR Act legal requirements.

On November 20, 2012, Werner exercised options to acquire 100,000 Werner Inc. voting securities, which resulted in his aggregated holdings of Werner Inc. voting securities again exceeding the $100 million threshold, as adjusted, which in November 2012 was $136.4 million. Although required to do so, Werner did not file under the HSR Act or observe the HSR Act's waiting period prior to completing the November 20, 2012 transaction. Thereafter, Werner continued to acquire Werner Inc. voting securities.

On February 7, 2019, Werner received 3,738 Werner Inc. voting securities with the vesting of a tranche of restricted stock, which resulted in his aggregated holdings of Werner Inc. voting securities again exceeding the $100 million threshold, as adjusted, which in February 2019 was $168.8 million. Although required to do so, Werner did not file under the HSR Act or observe the HSR Act's waiting period prior to completing the February 7, 2019 transaction.

On January 17, 2020, Werner's counsel contacted the Premerger Notification Office (''PNO'') of the Federal Trade Commission to inform PNO staff that counsel was analyzing a situation that counsel anticipated would likely entail multiple post-consummation filings. As of that date, Werner, through his counsel, was aware that he had violated the HSR Act. Thereafter, Werner made additional acquisitions of Werner Inc. voting securities on February 7 and 11, 2020, through the vesting of restricted stock awards. Werner did not file an HSR notification prior to either of these acquisitions.

On March 4, 2020, Werner made corrective filings under the HSR Act for the acquisitions he made on May 14, 2007, November 20, 2012, and February 7, 2019. Each of these transactions resulted in Werner's aggregated holdings of Werner Inc. stock exceeding the $100 million threshold, as adjusted. Had Werner filed under the HSR Act for these three acquisitions on a timely basis, all his other acquisitions of Werner Inc. voting securities during the relevant period would have been exempt pursuant to the 802.21 exemption.

Werner was in continuous violation of the HSR Act from May 14, 2007, when he acquired the Werner Inc. voting securities valued in excess of the HSR Act's $100 million filing threshold, as adjusted, through April 3, 2020, when the waiting period expired on his corrective filings.

III. Explanation of the Proposed Final Judgment

The proposed Final Judgment imposes a $486,900 civil penalty designed to address the violation alleged in the Complaint, penalize the Defendant, and deter others from violating the HSR Act. The United States adjusted the penalty downward from the maximum permitted under the HSR Act because the violation was inadvertent and the Defendant is willing to resolve the matter by proposed final judgment and thereby avoid prolonged investigation and litigation. However, the penalty amount reflects that Defendant was serving in a director capacity throughout the period he was in violation of the HSR Act. In addition, many of these acquisitions were open market acquisitions, such that he should have been aware of his obligations under the HSR Act. Open market acquisitions require an acquirer to affirmatively and actively decide to acquire voting securities; in particular for very large open market acquisitions, it is not excusable negligence to be unaware of HSR Act legal requirements. Further, Defendant made reportable acquisitions even after Defendant, through his counsel, was aware that he had violated the HSR Act. The penalty will not have any adverse effect on competition; instead, the relief should have a beneficial effect on competition because it will deter the Defendant and others from failing to properly notify the federal antitrust agencies of future acquisitions, in accordance with the law.

IV. Remedies Available to Potential Private Litigants

There is no private antitrust action for HSR Act violations; therefore, entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust action.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and the Defendant have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 days of the date of publication of this Competitive Impact Statement in the **Federal Register** or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States, which remains free to withdraw its consent to the proposed Final Judgment at any time before the Court's entry of the Final Judgment. The comments and the response of the United States will be filed with the Court. In addition, the comments and the United States' responses will be published in the **Federal Register** unless the Court agrees that the United States instead may publish them on the U.S. Department of

Justice, Antitrust Division's internet website. Written comments should be submitted in English to: Maribeth Petrizzi, Special Attorney, United States, c/o Federal Trade Commission, 600 Pennsylvania Avenue NW, CC–8416, Washington, DC 20580, *Email: bccompliance@ftc.gov.*

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits against the Defendant. The United States is satisfied, however, that the proposed relief is an appropriate remedy in this matter. Given the facts of this case, including the Defendant's self-reporting of the violations and willingness to promptly settle this matter, the United States is satisfied that the proposed civil penalty is sufficient to address the violations alleged in the Complaint and to deter violations by similarly situated entities in the future, without the time, expense, and uncertainty of a full trial on the merits.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

Under the Clayton Act and APPA, proposed Final Judgments or ''consent decrees'' in antitrust cases brought by the United States are subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

(A) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States* v. *U.S. Airways Grp., Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that a court's review of a proposed Final Judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable'').

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the proposed Final Judgment, a court may not ''make de novo determination of facts and issues.'' *United States* v. *W. Elec. Co.,* 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead, ''[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General.'' *W. Elec. Co.,* 993 F.2d at 1577 (quotation marks omitted). ''The court should bear in mind the *flexibility* of the public interest inquiry: The court's function is not to determine whether the resulting array of rights and liabilities is one that will *best* serve society, but only to confirm that the resulting settlement is within the *reaches* of the public interest.'' *Microsoft,* 56 F.3d at 1460 (quotation marks omitted); *see also United States* v. *Deutsche Telekom AG,* No. 19–2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would ''have enormous practical consequences for the government's ability to negotiate future settlements,'' contrary to congressional intent. *Microsoft,* 56 F.3d at 1456. ''The Tunney Act was not intended to create a disincentive to the use of the consent decree.'' *Id.*

The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft,* 56 F.3d at 1461 (recognizing courts should give ''due respect to the Justice Department's . . . view of the nature of its case''); *United States* v. *Iron Mountain, Inc.,* 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) (''In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' (internal citations omitted)); *United States* v. *Republic Servs., Inc.,* 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting ''the deferential review to which the government's proposed remedy is accorded''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (''A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case.''). The ultimate question is whether ''the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.' '' *Microsoft,* 56 F.3d at 1461 (*quoting W. Elec. Co.,* 900 F.2d at 309).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''[T]he 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged.''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it

follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60.

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using judgments proposed by the United States in antitrust enforcement, Public Law 108–237 § 221, and added the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). ''A court can make its public interest determination based on the competitive impact statement and response to public comments alone.'' *U.S. Airways,* 38 F. Supp. 3d at 76 (citing *Enova Corp.,* 107 F. Supp. 2d at 17).

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Date: December 22, 2021.

Respectfully submitted,

Kenneth A. Libby,

Special Attorney, U.S. Department of Justice, Antitrust Division, c/o Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, Phone: (202) 326–2694, Email: klibby@ftc.gov.

[FR Doc. 2021–28538 Filed 1–4–22; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Biglari Holdings Inc.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Biglari Holdings Inc.,* Civil Action 1:21–cv–03331. On December 22, 2021, the United States filed a Complaint alleging that Biglari Holdings Inc. violated the premerger notification and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. 18a, in connection with the acquisition of voting securities of Cracker Barrel Old Country Store Inc. The proposed Final Judgment, filed at the same time as the Complaint, requires Biglari Holdings Inc. to pay a civil penalty of $1,374,190.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments in English should be directed to Maribeth Petrizzi, Special Attorney, United States, c/o Federal Trade Commission, 600 Pennsylvania Avenue NW, CC–8416, Washington, DC 20580 or by email to *bccompliance@ftc.gov.*

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

United States District Court for the District of Columbia

United States of America, c/o Department of Justice, Washington, DC 20530, Plaintiff, v. *Biglari Holdings Inc., 17802 IH 10 West, Suite 400, San Antonio, TX 78257,* Defendant.

Civil Action No. 1:21–cv–03331

Judge: Tanya S. Chutkan

Complaint for Civil Penalties for Failure To Comply With the Premerger Reporting and Waiting Requirements of the Hart-Scott Rodino Act

The United States of America, acting under the direction of the Attorney General of the United States and at the request of the Federal Trade Commission, brings this civil antitrust action to obtain monetary relief in the form of civil penalties against Defendant Biglari Holdings Inc. (''Biglari''). The United States alleges as follows:

Nature of the Action

1. Biglari violated the notice and waiting period requirements of Section 7A of the Clayton Act, (15 U.S.C. 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ''HSR Act'' or ''Act''), with respect to the acquisition of voting securities of Cracker Barrel Old Country Store, Inc. (''Cracker Barrel'') in 2020.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter of this action pursuant to Section 7A(g) of the Clayton Act, 15 U.S.C. 18a(g), and 28 U.S.C. 1331, 1337(a), 1345, and 1355 and over Defendant by virtue of Defendant's consent, in the Stipulation relating hereto, to the maintenance of this action and entry of the Final Judgment in this District.

3. Venue is proper in this District by virtue of Defendant's consent, in the Stipulation relating hereto, to the maintenance of this action and entry of the Final Judgment in this District.

The Defendant

4. Biglari is a corporation organized under the laws of Indiana with its principal office and place of business at 17802 IH 10 West, Suite 400, San Antonio, TX 78257. Biglari is engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. 18a(a)(1). At all times relevant to this complaint, Biglari had sales or assets in excess of $18.8 million.

Other Entity

5. Cracker Barrel is a corporation organized under the laws of Tennessee with its principal place of business at 305 Hartmann Drive, Lebanon, TN 37087. Cracker Barrel is engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. 18a(a)(1). At all times relevant to this complaint, Cracker

Barrel had sales or assets in excess of $188 million.

The Hart-Scott-Rodino Act and Rules

6. The HSR Act requires certain acquiring persons and certain persons whose voting securities or assets are acquired to file notifications with the Department of Justice and the Federal Trade Commission (collectively, the ''federal antitrust agencies'') and to observe a waiting period before consummating certain acquisitions of voting securities or assets. 15 U.S.C. 18a(a) and (b). The notification and waiting period requirements apply to acquisitions that meet the HSR Act's size of transaction and size of person thresholds, which have been adjusted annually since 2004. The size of transaction threshold is met for transactions valued over $50 million, as adjusted ($94 million in 2020). In addition, there is a separate filing requirement for transactions in which the acquirer will hold voting securities in excess of $100 million, as adjusted ($188 million in 2020), and for transactions in which the acquirer will hold voting securities in excess of $500 million, as adjusted ($940.1 million in 2020). With respect to the size of person thresholds, the HSR Act applies if one person involved in the transaction has sales or assets in excess of $10 million, as adjusted ($18.8 million in 2020), and the other person has sales or assets in excess of $100 million, as adjusted ($188 million in 2020).

7. The HSR Act's notification and waiting period requirements are intended to give the federal antitrust agencies prior notice of, and information about, proposed transactions. The waiting period is also intended to provide the federal antitrust agencies with the opportunity to investigate a proposed transaction and to determine whether to seek an injunction to prevent the consummation of a transaction that may violate the antitrust laws.

8. Pursuant to Section (d)(2) of the HSR Act, 15 U.S.C. 18a(d)(2), rules were promulgated to carry out the purposes of the HSR Act. 16 CFR 801–03 (''HSR Rules''). The HSR Rules, among other things, define terms contained in the HSR Act.

9. Pursuant to Section 801.13(a)(1) of the HSR Rules, 16 CFR 801.13(a)(1), ''all voting securities of [an] issuer which will be held by the acquiring person after the consummation of an acquisition''—including any held before the acquisition—are deemed held ''as a result of'' the acquisition at issue.

10. Pursuant to Sections 801.13(a)(2) and 801.10(c)(1) of the HSR Rules, 16 CFR 801.13(a)(2) and § 801.10(c)(1), the value of voting securities already held is the market price, defined to be the lowest closing price within 45 days prior to the subsequent acquisition.

11. Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1), provides that any person, or any officer, director, or partner thereof, who fails to comply with any provision of the HSR Act is liable to the United States for a civil penalty for each day during which such person is in violation. Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, § 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), the dollar amounts of civil penalties listed in Federal Trade Commission Rule 1.98, 16 CFR 1.98, are adjusted annually for inflation; the maximum amount of civil penalty in effect at the time of Biglari's corrective filing was $43,280 per day. 85 FR 2014 (January 14, 2020).

Defendant's Prior Violation of the HSR Act

12. The violation alleged in this complaint is not Biglari's first violation of the HSR Act. On June 8, 2011, Biglari acquired Cracker Barrel voting securities that resulted in its holdings exceeding the adjusted $50 million threshold then in effect under the HSR Act. Biglari continued to acquire Cracker Barrel voting securities through June 13, 2011. Although required to do so, Biglari did not file under the HSR Act or observe the HSR Act's waiting period prior to acquiring Cracker Barrel voting securities on June 8, 2011.

13. Biglari claimed that its acquisitions of Cracker Barrel voting securities beginning June 8, 2011, were exempt from the reporting and waiting period requirements of the HSR Act under the exemption for certain acquisitions made solely for the purpose of investment. 15 U.S.C. 18a(c)(9) and 16 CFR 802.9. On August 26, 2011, Biglari filed under the HSR Act to increase its holdings of Cracker Barrel voting securities beyond the 10% limit of the exemption for acquisitions made solely for the purpose of investment. The waiting period on this filing expired on September 22, 2011.

14. On March 2, 2012, Biglari sought to re-characterize its August 2011 filing as a corrective filing for its June 2011 acquisitions of Cracker Barrel voting securities. In the explanatory letter submitted at that time, Biglari committed to seeking advice from HSR counsel prior to making future acquisitions of any issuer's voting securities that could result in its aggregated holdings crossing the $50 million (as adjusted) threshold.

15. On September 25, 2012, the Department of Justice, acting at the request of the Federal Trade Commission, filed a complaint for civil penalties alleging that Biglari's acquisitions of voting securities of Cracker Barrel in June 2011 violated the HSR Act. *United States.* v. *Biglari Holdings, Inc.,* Civil Action No. 1:12–cv–01586 (D.D.C. 2012). The complaint alleged that Biglari did not qualify for the exemption for acquisitions made solely for the purpose of investment, 15 U.S.C. 18a(c)(9) and 16 CFR 802.9, because Biglari's intent was inconsistent with this exemption. This inconsistent intent was evidenced by, among other things, a request by Biglari's CEO for two seats on Cracker Barrel's board of directors within days after making the June 2011 acquisitions.

16. At the same time as the complaint was filed, the Department of Justice filed a stipulation signed by Biglari and a proposed final judgment settling the case. The final judgment required Biglari to pay a civil penalty of $850,000 for the violations alleged in the complaint. On May 30, 2013, the court entered the final judgment.

Defendant's Current Violation of the HSR Act

17. Prior to March 16, 2020, Biglari indirectly held 2,000,000 Cracker Barrel voting securities, valued at approximately $155.1 million. On March 16, 2020, two entities controlled by Biglari acquired an additional 55,141 Cracker Barrel voting securities. When aggregated with the voting securities already held by Biglari, these acquisitions resulted in Biglari holding 2,055,141 Cracker Barrel voting securities, valued at approximately $159.4 million. Biglari's holdings of Cracker Barrel voting securities therefore exceeded the $50 million threshold, which in March 2020 was $94 million. Additionally, Biglari and Cracker Barrel exceeded the size of person thresholds, which in March 2020 were $18.8 million and $188 million.

18. The HSR Act required Biglari to file a notification with the federal antitrust agencies and to observe a waiting period before consummating the March 16, 2020, acquisitions of Cracker Barrel voting securities. Biglari and Cracker Barrel each met the HSR Act's size of person test; the acquisitions met the HSR Act's size of transaction test; and no exemption applied.

19. Although required to do so, Biglari did not file under the HSR Act or observe the HSR Act's waiting period

prior to completing the March 16, 2020, acquisitions.

20. Biglari's HSR Act violation was not discovered by Biglari itself. Rather, on June 9, 2020, the Premerger Notification Office of the Federal Trade Commission emailed counsel for Biglari to ask why no filing had been made under the HSR Act prior to Biglari's March 16, 2020 acquisitions of Cracker Barrel voting securities.

21. On June 19, 2020, Biglari made a corrective filing under the HSR Act. In the explanatory letter that accompanied Biglari's corrective filing, Biglari acknowledged the violation that began on March 16, 2020. Biglari also admitted in the explanatory letter that Biglari had not sought advice from HSR counsel prior to the March 16, 2020 acquisitions, contrary to the commitment it made in connection with its 2011 HSR Act violation.

22. The HSR waiting period on the corrective filing expired on July 20, 2020. Biglari was in continuous violation of the HSR Act from March 16, 2020, when it acquired the Cracker Barrel voting securities valued in excess of the HSR Act's then applicable $94 million filing threshold through July 20, 2020, when the waiting period expired on its corrective filing.

Requested Relief

Wherefore, the United States requests:

a. That the Court adjudge and decree that Defendant's acquisitions of Cracker Barrel voting securities on March 16, 2020 were violations of the HSR Act, 15 U.S.C. 18a; and that Defendant was in violation of the HSR Act each day from March 16, 2020 through July 20, 2020;

b. that the Court order Defendant to pay to the United States an appropriate civil penalty as provided by Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1), the Debt Collection Improvement Act of 1996, Public Law 104–134 § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461), and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), and Federal Trade Commission Rule 1.98, 16 CFR 1.98, 85 FR 2014 (January 14, 2020);

c. that the Court order such other and further relief as the Court may deem just and proper; and

d. that the Court award the United States its costs of this suit.

Dated: _____

FOR THE PLAINTIFF UNITED STATES OF AMERICA:

Jonathan S. Kanter,

Assistant Attorney General, Department of Justice, Antitrust Division, Washington, DC 20530.

Maribeth Petrizzi,

D.C. Bar No. 435204, Special Attorney.

Kenneth A. Libby,

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Special Attorney, Federal Trade Commission, Washington, DC 20580, (202) 326–2564.

United States District Court for the District of Columbia

United States of America, Plaintiff, v. *Biglari Holding Inc.*, Defendant.

Civil Action No. 1:21–cv–03331

[Proposed] Judge: Tanya S. Chutkan

Final Judgment

Whereas, the United States of America filed its Complaint on December 22, 2021, alleging that Defendant Biglari Holding Inc. violated Section 7A of the Clayton Act (15 U.S.C. 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the ''HSR Act'')):

And whereas, the United States and Defendant have consented to the entry of this Final Judgment without the taking of testimony, without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact or law;

Now, therefore, it is

Ordered, adjudged, and decreed:

I. Jurisdiction

The Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Defendant under Section 7A of the Clayton Act, 15 U.S.C. 18a.

II. Civil Penalty

Judgment is hereby entered in this matter in favor of the United States and against Defendant, and, pursuant to Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1), the Debt Collection Improvement Act of 1996, Public Law 104–134 § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461), the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74 § 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), and Federal Trade Commission Rule 1.98, 16 CFR 1.98, 86 FR 2541 (January 13, 2021), Defendant is hereby ordered to pay a civil penalty in the amount of one million, three hundred seventy four thousand, one hundred ninety dollars ($1,374,190). Payment of the civil penalty ordered hereby must be made by wire transfer of funds or cashier's check. If the payment is to be made by wire transfer, prior to making the transfer, Defendant will contact the Budget and Fiscal Section of the Antitrust Division's Executive Office at *ATR.EXO-Fiscal-Inquiries@usdoj.gov* for instructions. If the payment is made by cashier's check, the check must be made payable to the United States Department of Justice and delivered to: Chief, Budget & Fiscal Section, Executive Office, Antitrust Division, United States Department of Justice, Liberty Square Building, 450 5th Street NW, Room 3016, Washington, DC 20530.

Defendant must pay the full amount of the civil penalty within thirty (30) days of entry of this Final Judgment. In the event of a default or delay in payment, interest at the rate of eighteen percent (18%) per annum will accrue thereon from the date of the default or delay to the date of payment.

III. Costs

Each party will bear its own costs of this action, except as otherwise provided in Paragraph IV.C.

IV. Enforcement of Final Judgment

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendant agrees that in a civil contempt action, a motion to show cause, or a similar action brought by the United States regarding an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of a remedy therefor by a preponderance of the evidence, and Defendant waives any argument that a different standard of proof should apply.

B. Defendant agrees that it may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. The terms of this Final Judgment should not be construed against either party as the drafter.

C. In connection with a successful effort by the United States to enforce this Final Judgment against Defendant, whether litigated or resolved before litigation, Defendant agrees to reimburse the United States for the fees and

expenses of its attorneys, as well as all other costs including experts' fees, incurred in connection with that enforcement effort, including in the investigation of the potential violation.

V. Expiration of Final Judgment

This Final Judgment will expire upon payment in full by the Defendant of the civil penalty required by Section II of this Final Judgment.

VI. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Dated: _____

[Court approval subject to the procedures of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16]

_____

United States District Judge

United States District Court for the District of Columbia

United States of America, Plaintiff, v. *Biglari Holdings Inc.*, Defendant.

Civil Action No. 1:21–cv–03331

Judge: Tanya S. Chutkan

Competitive Impact Statement

The United States of America (''United States''), under Section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h) (''APPA'' or ''Tunney Act''), files this Competitive Impact Statement related to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On December 22, 2021, the United States filed a Complaint against Defendant Biglari Holdings Inc. (''Biglari'' or ''Defendant''), related to Biglari's acquisitions of voting securities of Cracker Barrel Old Country Store, Inc. (''Cracker Barrel'') in March 2020. The Complaint alleges that Biglari violated Section 7A of the Clayton Act, 15 U.S.C. 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the ''HSR Act''). The HSR Act requires certain acquiring persons and certain persons whose voting securities or assets are acquired to file notifications with the Department of Justice and the Federal Trade Commission (collectively, the ''federal antitrust agencies'') and to observe a waiting period before consummating certain acquisitions of voting securities or assets. 15 U.S.C. 18a (a) and (b). These notification and waiting period requirements apply to acquisitions that meet the HSR Act's size of transaction and size of person thresholds, which have been adjusted annually since 2004. The size of transaction threshold is met for transactions valued over $50 million, as adjusted ($94 million in 2020). In addition, there is a separate filing requirement for transactions in which the acquirer will hold voting securities in excess of $100 million, as adjusted ($188 million in 2020), and for transactions in which the acquirer will hold voting securities in excess of $500 million, as adjusted ($940.1 million in 2020).

With respect to the size of person thresholds, the HSR Act applies if one person involved has sales or assets in excess of $10 million, as adjusted ($18.8 million in 2020), and the other person has sales or assets in excess of $100 million, as adjusted ($188 million in 2020). A key purpose of the notification and waiting period requirements is to protect consumers and competition from potentially anticompetitive transactions by providing the federal antitrust agencies the opportunity to conduct an antitrust review of proposed transactions before they are consummated.

The Complaint alleges that Biglari acquired voting securities of Cracker Barrel without filing the required pre-acquisition HSR Act notifications with the federal antitrust agencies and without observing the waiting period. Biglari's acquisition of Cracker Barrel voting securities exceeded the $50-million statutory threshold, as adjusted, ($94 million at the time of the acquisition) and Biglari and Cracker Barrel met the then-applicable statutory size of person thresholds (which were $18.8 and $188 million, respectively).

At the same time the Complaint was filed in the present action, the United States also filed a Stipulation and Order and proposed Final Judgment that resolve the allegations made in the Complaint. The proposed Final Judgment is designed to address the violation alleged in the Complaint and to penalize Biglari's HSR Act violations. Under the proposed Final Judgment, Biglari must pay a civil penalty to the United States in the amount of $1,374,190.

The United States and Biglari have stipulated that the proposed Final Judgment may be entered after compliance with the APPA, unless the United States first withdraws its consent. Entry of the proposed Final Judgment will terminate this action, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and punish violations thereof.

II. Description of the Events Giving Rise to the Alleged Violation

The crux of Biglari's violation is that it failed to submit an HSR Act notification even though its acquisition of Cracker Barrel voting securities satisfied the HSR Act filing requirements. At all times relevant to the Complaint, Biglari had sales or assets in excess of $18.8 million. At all times relevant to the Complaint, Cracker Barrel had sales or assets in excess of $188 million.

On March 16, 2020, two entities controlled by Biglari acquired 55,141 Cracker Barrel voting securities. When aggregated with the voting securities already held by Biglari, these acquisitions resulted in Biglari holding 2,055,141 Cracker Barrel voting securities, valued at approximately $159.4 million. Although required to do so, Biglari did not file under the HSR Act and observe the HSR Act's waiting period prior to completing the March 16, 2020 acquisitions.

Biglari made a corrective HSR Act filing on June 19, 2020, but Biglari's HSR Act violation was not discovered by Biglari itself. Rather, prior to Biglari's corrective filing, the Premerger Notification Office of the Federal Trade Commission emailed counsel for Biglari and asked why Biglari had not made an HSR filing before the March 16, 2020, acquisitions of Cracker Barrel voting securities. The waiting period for that corrective filing expired on July 20, 2020.

In addition to alleging that Biglari failed to file a required HSR notification, the Complaint further alleges that this was not the first time Biglari had failed to observe the HSR Act's notification and waiting period requirements. In June 2011, Biglari acquired voting securities of Cracker Barrel that resulted in its holdings exceeding the then-applicable HSR Act notification thresholds. In the explanatory letter that accompanied Biglari's corrective filing, Biglari committed to seeking advice from HSR counsel prior to making future acquisitions of any issuer's voting securities that could result in its aggregated holdings crossing the $50 million (as adjusted) threshold.

On September 25, 2012, the Department of Justice, acting at the

request of the Federal Trade Commission, filed a complaint for civil penalties alleging that Biglari's acquisitions of voting securities of Cracker Barrel in June 2011 violated the HSR Act. At the same time as the complaint was filed, the Department of Justice filed a stipulation signed by Biglari and a proposed final judgment settling the case. The final judgment required Biglari to pay a civil penalty of $850,000 for the violations alleged in the complaint. On May 30, 2013, the court entered the final judgment. *See United States.* v. *Biglari Holdings, Inc.,* Civil Action No. 1:12–cv–01586 (D.D.C. 2012).

III. Explanation of the Proposed Final Judgment

The proposed Final Judgment imposes a $1,374,190 civil penalty designed to address the violation alleged in the Complaint, penalize the Defendant, and deter others from violating the HSR Act. The United States adjusted the penalty downward from the maximum permitted under the HSR Act because the violation was inadvertent, and the Defendant is willing to resolve the matter by proposed final judgment and thereby avoid prolonged investigation and litigation. However, the penalty amount reflects that this is Defendant's second violation of the HSR Act in connection with the same issuer (*i.e.,* Cracker Barrel), that Defendant did not make a corrective filing until the FTC's Premerger Notification Office notified Biglari of its failure to file, and that Defendant did not consult HSR counsel prior to its acquisitions as it had committed to do in connection with its 2011 HSR Act violation. The penalty will not have any adverse effect on competition; instead, the relief should have a beneficial effect on competition because it will deter the Defendant and others from failing to properly notify the federal antitrust agencies of future acquisitions, in accordance with the law.

IV. Remedies Available to Potential Private Litigants

There is no private antitrust action for HSR Act violations; therefore, entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust action.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and the Defendant have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States, which remains free to withdraw its consent to the proposed Final Judgment at any time before the Court's entry of the Final Judgment. The comments and the response of the United States will be filed with the Court. In addition, the comments and the United States' responses will be published in the **Federal Register** unless the Court agrees that the United States instead may publish them on the U.S. Department of Justice, Antitrust Division's internet website. Written comments should be submitted in English to: Maribeth Petrizzi, Special Attorney, United States, c/o Federal Trade Commission, 600 Pennsylvania Avenue NW, CC–8416, Washington, DC 20580, *bccompliance@ftc.gov*.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits against the Defendant. The United States is satisfied, however, that the proposed relief is an appropriate remedy in this matter. Given the facts of this case, including the Defendant's acknowledgment of the violations and willingness to promptly settle this matter, the United States is satisfied that the proposed civil penalty is sufficient to address the violation alleged in the Complaint and to deter violations by similarly situated entities in the future, without the time, expense, and uncertainty of a full trial on the merits.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

Under the Clayton Act and APPA, proposed Final Judgments or ''consent decrees'' in antitrust cases brought by the United States are subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States* v. *U.S. Airways Grp., Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that a court's review of a proposed Final Judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable'').

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the

adequacy of the relief secured by the proposed Final Judgment, a court may not ''make de novo determination of facts and issues.'' *United States* v. *W. Elec. Co.,* 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead, ''[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General.'' *W. Elec. Co.,* 993 F.2d at 1577 (quotation marks omitted). ''The court should bear in mind the *flexibility* of the public interest inquiry: the court's function is not to determine whether the resulting array of rights and liabilities is one that will *best* serve society, but only to confirm that the resulting settlement is within the *reaches* of the public interest.'' *Microsoft,* 56 F.3d at 1460 (quotation marks omitted); *see also United States* v. *Deutsche Telekom AG,* No. 19–2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would ''have enormous practical consequences for the government's ability to negotiate future settlements,'' contrary to congressional intent. *Microsoft,* 56 F.3d at 1456. ''The Tunney Act was not intended to create a disincentive to the use of the consent decree.'' *Id.*

The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft,* 56 F.3d at 1461 (recognizing courts should give ''due respect to the Justice Department's . . . view of the nature of its case''); *United States* v. *Iron Mountain, Inc.,* 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) (''In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' (internal citations omitted)); *United States* v. *Republic Servs., Inc.,* 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting ''the deferential review to which the government's proposed remedy is accorded''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (''A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case.''). The ultimate question is whether ''the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.' '' *Microsoft,* 56 F.3d at 1461 (*quoting W. Elec. Co.,* 900 F.2d at 309).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''[T]he 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged.''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60.

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using judgments proposed by the United States in antitrust enforcement, Public Law 108–237, 221, and added the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). ''A court can make its public interest determination based on the competitive impact statement and response to public comments alone.'' *U.S. Airways,* 38 F. Supp. 3d at 76 (citing *Enova Corp.,* 107 F. Supp. 2d at 17).

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Date: December 22, 2021.

Respectfully submitted,

/s/ Kenneth A. Libby,

Kenneth A. Libby,

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[FR Doc. 2021–28539 Filed 1–4–22; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed First Amendment To Consent Decree Under the Clean Water Act

On December 29, 2021, the Department of Justice lodged a proposed First Amendment to Consent Decree with the United States District Court for the Southern District of Ohio in the lawsuit entitled *United States and the State of Ohio* v. *City of Middletown, Ohio,* Civil Action No. 18–cv–90.

The Complaint in the United States' lawsuit sought civil penalties and injunctive relief for alleged violations of the Clean Water Act (''CWA'') relating to the City of Middletown's sewer system in Middletown, Ohio. The Complaint alleged that: (1) Various discharges from Middletown's wastewater treatment plant violated the CWA by exceeding the effluent limitations in Middletown's permits; (2) Middletown's combined sewer overflow discharges violated the CWA by impairing downstream uses in the Great Miami River; (3) Middletown illegally discharged untreated sewage from its combined sewer overflow outfalls during dry weather; and (4) Middletown violated the CWA by failing to monitor and/or report the monitoring results for its outfalls as required.

A Consent Decree resolving the claims in the Complaint was entered by the Court on April 12, 2018. The Consent Decree requires that Middletown, among other things, implement a Long Term Control Plan to reduce the discharges of combined stormwater and sanitary sewage from the portion of Middletown's sewer system known as

the combined sewer system. The current LTCP, which was included with the Consent Decree as Appendix A, includes a number of combined sewer overflow control measures. During the detailed design phase of one of these measures following entry of the Consent Decree, Middletown discovered technical difficulties in carrying out the project as originally planned. The proposed First Amendment to Consent Decree substitutes an alternative project to convert a portion of Middletown's combined sewer system into a stormwater-only system.

The publication of this notice opens a period for public comment on the First Amendment to Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the State of Ohio* v. *City of Middletown, Ohio,* D.J. Ref. No. 90–5–1–1–08978. 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	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the First Amendment to Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the First Amendment to 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 $2.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Patricia McKenna,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–28574 Filed 1–4–22; 8:45 am]

BILLING CODE P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 21–CRB–0013–BER (2024–2028)]

Determination of Royalty Rates and Terms for Making Ephemeral Copies of Sound Recordings for Transmission to Business Establishments (Business Establishments IV)

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Notice announcing commencement of proceeding with request for Petitions to Participate.

SUMMARY: The Copyright Royalty Judges (Judges) announce commencement of a proceeding to determine reasonable royalty rates and terms for the recording of ephemeral copies of sound recordings to facilitate digital audio transmissions of those sound recordings to business establishments pursuant to the limitation on exclusive rights specified by the Copyright Act. The royalty rates and terms the Judges determine in this proceeding will apply during the period beginning January 1, 2024, and ending December 31, 2028. The Judges also announce the date by which a party wishing to participate in the rate determination proceeding must file its Petition to Participate and pay the accompanying $150 filing fee.

DATES: Petitions to Participate and the filing fee are due no later than February 4, 2022.

ADDRESSES: The petition to participate form is available online in eCRB, the Copyright Royalty Board's online electronic filing application, at *https://app.crb.gov/.*

Instructions: The petition to participate process has been simplified. Interested parties file a petition to participate by completing and filing the petition to participate form in eCRB and paying the fee in eCRB. Do not upload a petition to participate document.

Docket: For access to the docket to read submitted documents, go to eCRB, the Copyright Royalty Board's electronic filing and case management system at *https://app.crb.gov/* and search for docket number 21–CRB–0013–BER (2024–2028).

FOR FURTHER INFORMATION CONTACT: Anita Blaine, CRB Program Specialist, (202) 707–7658, *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: The Copyright Act provides that the Copyright Royalty Judges (Judges) commence a proceeding every fifth year [1] to determine royalty rates and terms for the recording of ephemeral copies of sound recordings pursuant to the statutory license in 17 U.S.C. 112(e)(1) to facilitate digital audio transmissions of those sound recordings to business establishments pursuant to the limitation on exclusive rights specified by 17 U.S.C. 114(d)(1)(C)(iv). *See* 17 U.S.C. 804(b)(2). This notice commences the rate determination proceeding for the license period 2024–2028, inclusive. Section 803(b)(1)(A)(i)(II) directs the Judges to publish in the **Federal Register** a notice commencing this proceeding by no later than January 5, 2022.

Petitions To Participate

Parties with a significant interest in the outcome of the ''business establishments'' royalty rate proceeding must provide the information required by § 351.1(b) of the Judges' regulations by completing and filing the Petition to Participate form in eCRB. Parties must pay the $150 filing fee when filing each Petition to Participate form. 37 CFR 351.1(b). Parties must use the form in eCRB instead of uploading a document.

Only attorneys who are admitted to the bar in one or more states or the District of Columbia and are members in good standing will be allowed to represent parties before the Judges. Only an individual may represent herself or himself and appear without legal counsel. 37 CFR 303.2.

Dated: December 16, 2021.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2021–27669 Filed 1–4–22; 8:45 am]

BILLING CODE 1410–72–P

[1] The Judges commenced a proceeding to determine the 2019–2023 rates and terms in 2017. *See* 82 FR 143 (Jan. 3, 2017).

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Subject 60-Day Notice for the "Program and Event Feedback Surveys for the Creative Forces®: NEA Military Healing Arts Network Community Arts Engagement Subgranting Program" Proposed Collection; Comment Request

AGENCY: National Endowment for the Arts.

ACTION: Notice.

SUMMARY: The National Endowment for the Arts (NEA), 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. This program helps to ensure that requested data is 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 is properly assessed. Currently, the National Endowment for the Arts is soliciting comments concerning the proposed information collection through two surveys: The Program Feedback Survey and the Event Feedback Survey for individuals who participate in community arts programs and events, respectively funded by the Creative Forces®: NEA Military Healing Arts Network Community Arts Engagement Subgranting Program. A copy of the information collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the address section below within 60 days from the date of this publication in the **Federal Register**.

ADDRESSES: Send comments to Sunil Iyengar, National Endowment for the Arts, via email to *research@arts.gov.*

SUPPLEMENTARY INFORMATION: The NEA 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 submission of responses.

Dated: December 29, 2021.

Meghan Jugder,

Support Services Specialist, Office of Administrative Services & Contracts, National Endowment for the Arts.

[FR Doc. 2021–28515 Filed 1–4–22; 8:45 am]

BILLING CODE 7537–01–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 28, 2021, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 213 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–34, CP2022–41.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–28584 Filed 1–4–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 17, 2021, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express & Priority Mail Contract 128 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–33, CP2022–40.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–28583 Filed 1–4–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, & First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 28, 2021, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, & First-Class Package Service Contract 78 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–35, CP2022–42.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–28585 Filed 1–4–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 17, 2021, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 734 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–32, CP2022–39.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–28582 Filed 1–4–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 5, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 28, 2021, it filed with the Postal Regulatory Commission a *USPS Request to Add First-Class Package Service Contract 119 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–36, CP2022–43.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–28586 Filed 1–4–22; 8:45 am]

BILLING CODE 7710–12–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information (RFI) on Strengthening Community Health Through Technology

AGENCY: White House Office of Science and Technology Policy (OSTP).

ACTION: Notice of RFI.

SUMMARY: The White House Office of Science and Technology Policy (OSTP) requests input from community health stakeholders, technology developers, and other interested parties about how digital health technologies are used, or could be used in the future, to transform community health, individual wellness, and health equity. This request is part of an initiative led by OSTP dedicated to Community Connected Health—an effort that will explore and act upon how innovation in science and technology can lower the barriers for all Americans to accessing quality healthcare and lead healthier lives by meeting people where they are in their communities. We are particularly interested in information from community-based health settings and about populations traditionally underserved by healthcare. To support this effort, OSTP seeks information about: Successful models of strengthening community health through digital health technologies within the United States and abroad, barriers to uptake, trends from the COVID–19 pandemic, how user experience is measured, need for tools and training, ideas for potential government action, and effects on health equity.

DATES: Interested persons and organizations are invited to submit comments on or before 5:00 p.m. ET on February 28, 2022.

ADDRESSES: Interested individuals and organizations should submit comments electronically to *connectedhealth@ostp.eop.gov* and include ''Connected Health RFI'' in the subject line of the email. While email is preferred, brief voicemail messages may be left at 202–456–3030. Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline cannot be ensured to be incorporated or taken into consideration.

Instructions

Response to this RFI is voluntary. Each responding entity (individual or organization) is requested to submit only one response. OSTP welcomes responses to inform and guide policies and actions related to strengthening community health through digital health technologies. Please feel free to respond to one or as many prompts as you choose. Please be concise with your submissions, which must not exceed 3 pages in 12-point or larger font, with a page number provided on each page. Responses should include the name of the person(s) or organization(s) filing the comment. OSTP invites input from all stakeholders including members of the public, representing all backgrounds and perspectives. In particular, OSTP is interested in input from community health workers (CHWs) and CHW organizations of all kinds; social workers; maternal health workers; telehealth navigators; peer recovery specialists; healthcare providers (please further specify); faith and community-based organizations; community health centers; State, local, tribal, and territorial governments; academic researchers; technology developers; global partners; health insurance providers; and individuals who have used, or are interested in using, digital health technologies or telehealth services. Please indicate which of these stakeholder type best fits you as a respondent. If a comment is submitted on behalf of an organization, the individual respondent's role in the organization may also be provided on a voluntary basis. Comments containing references, studies, research, and other empirical data that are not widely published should include copies or electronic links of the referenced materials. No business proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI. Please be aware that comments submitted in response to this RFI may be posted on OSTP's website or otherwise released publicly.

In accordance with Federal Acquisition Regulation (FAR) 15.202(3), responses to this notice are not offers and cannot be accepted by the Federal Government to form a binding contract. Additionally, those submitting responses are solely responsible for all expenses associated with response preparation.

FOR FURTHER INFORMATION CONTACT: For additional information, please direct questions to Jacqueline Ward at *connectedhealth@ostp.eop.gov* or leave by voicemail at 202–456–3030.

SUPPLEMENTARY INFORMATION:

Background: Despite decades of investment in the digital health ecosystem, the COVID–19 pandemic illuminated continuing, substantial limitations in the U.S. healthcare systems, including profound disparities in healthcare and associated poorer health outcomes within certain communities. Yet the pandemic has also provided an opportunity for innovation in healthcare delivery across the U.S. and internationally, particularly in community-based settings. As part of OSTP's mission to maximize the benefits of science and technology to advance health and our charge to drive innovation in healthcare and improve health for *all* Americans, we are seeking

information and comments about how digital health technologies are used, or could be used in the future, to improve community health, individual wellness, and health equity. Community health, defined as the collective influence of socioeconomic factors, physical environment, health behaviors, and availability of quality clinical care services, serves as one of the most important drivers of health and wellness for all Americans. This request is part of an initiative dedicated to Community Connected Health—an effort that will explore and act upon how innovation in science and technology can lower the barriers to access quality healthcare and lead healthier lives by meeting people where they are in their communities.

Scope and terminology: OSTP invites input from all interested parties as outlined in the instructions. The term 'digital health technologies' should be interpreted broadly as any tool or set of tools that improve health or enable better healthcare delivery by connecting people with other people, with data, or with health information. Examples of this include but are not limited to: Telehealth, remote patient monitoring devices, health trackers, mobile devices (*e.g.,* smart phones, tablets), mobile health apps, and technologies for managing health information including electronic health records.

Information Requested: Respondents may provide information for one or as many topics below as they choose.

1. Successful models within the U.S.: Descriptions of innovative examples or models of how community health providers within the United States successfully use digital health technology to deliver healthcare, enable healthier lifestyles, or reduce health disparities. This can include: The key features of the organizations and/or the digital health technologies that have been most successful, what is needed to support the scale up beyond individual organizations, examples of best practices, examples of important user protections to institute (*e.g.,* privacy best practices), examples of positive user experiences, metrics or measurement strategies of how community health providers measure outcomes or success, and creative ideas or models that may be in nascent stages.

2. Barriers: Specific descriptions of the current barriers faced by individuals or organizations to the use of digital health technologies in community-based settings. It would be very helpful for respondents to indicate how these barriers may align to the following broad categories: Technical (including broadband access), training, costs, reimbursement/policies, buy-in across organization or community, user education/comfort, or other. In the case of barriers that include user comfort/willingness to use the technology, it would be useful for respondents to detail any concerns users might have such as privacy, security, discrimination, the effectiveness of the technology, or other such concerns.

3. Trends from the pandemic: Impressions or data reflecting how the use of digital health technologies (including the use of telemedicine) has changed over the course of the pandemic by individuals, community-based organizations, and in community-based health settings. This includes impressions of what is likely to continue, or not, after the end of the public health emergency or COVID–19 pandemic.

4. User experience: Descriptions of how technology developers, community-based healthcare providers, or other community-based stakeholders consider and/or assess the patient and client experience in the use of health technologies. This includes direct experiences from individuals and patients who have used digital health technologies. We welcome descriptions of how digital health technologies could be better designed with the user experience (*e.g.,* community health workers, healthcare providers, or patients) in mind, as well as aspects of the user experience that could be changed to help remove barriers due to willingness to use (*e.g.,* privacy protections).

5. Tool and training needs: Information about the current technological tools, equipment, and infrastructure needs of community health workers and other community-based health providers. Descriptions about what is needed to train and/or certify community health organizations and workers on the use of digital health technologies for their work are also welcome.

6. Proposed government actions: Opportunities for the Federal Government to support the transformation of community health settings through the uptake of innovative digital health technologies and telemedicine at the community level. Please specify whether these opportunities could take place in the immediate future (*i.e.,* 0–2 years), in the next 5 years, in the next 10 years or beyond.

7. Health Equity: Information about how digital health technologies have been used, or could be used, in community-based settings to drive towards a reduction in health disparities or achieving health equity. This could include any concerns about the health equity impacts of digital health technologies

8. International models: Examples from outside of the United States, particularly from low or middle-income countries, that exemplify innovation at the intersection of healthcare delivery and technology. This can include: The key features of the organizations and/or the digital health technologies that have been most successful, what is needed to support the scale up beyond individual organizations, examples of best practices, examples of important user protections to institute (*e.g.,* privacy best practices), examples of positive user experiences, metrics of how community health providers measure outcomes or success, and creative ideas or models that may be in nascent stages. We encourage responses that extrapolate to how these international models could be applied within the United States healthcare system.

Stacy Murphy,

Operations Manager.

[FR Doc. 2021–28193 Filed 1–4–22; 8:45 am]

BILLING CODE 3270–F2–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34457; File No. 812–15223]

Flat Rock Global, LLC, et al.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

Summary of Application: Applicants request an order to permit certain business development companies and closed-end management investment companies to co-invest in portfolio companies with each other and with affiliated investment funds and accounts.

Applicants: Flat Rock Global, LLC (''Flat Rock'') on behalf of itself and its successors,[1] Flat Rock Opportunity Fund, Flat Rock Core Income Fund (together, the ''Existing Registered

[1] The term ''successor,'' as applied to each Adviser (defined below), means an entity which results from a reorganization into another jurisdiction or change in the type of business organization.

Funds''), and Flat Rock Credit Partners LLC (the ''Existing Affiliated Fund'').

Filing Dates: The application was filed on April 28, 2021, and amended on August 12, 2021, November 18, 2021, and December 27, 2021.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on January 24, 2022, and should be accompanied by proof of service on the Applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: c/o Robert K. Grunewald, Chief Executive Officer, by email to *robert@flatrockglobal.com.*

FOR FURTHER INFORMATION CONTACT: Laura J. Riegel, Senior Counsel, at 202–551–3038, or Trace W. Rakestraw, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Introduction

1. Applicants request an Order of the Commission under sections 17(d) and 57(i) under the Act and rule 17d–1 under the Act to permit, subject to the terms and conditions set forth in the application (the ''Conditions''), one or more Regulated Funds [2] and/or one or more Affiliated Funds [3] to enter into Co-Investment Transactions with each other. ''Co-Investment Transaction'' means any transaction in which one or more Regulated Funds (or its Wholly-Owned Investment Sub (defined below)) participated together with one or more Affiliated Funds and/or one or more other Regulated Funds in reliance on the Order. ''Potential Co-Investment Transaction'' means any investment opportunity in which a Regulated Fund (or its Wholly-Owned Investment Sub) could not participate together with one or more Affiliated Funds and/or one or more other Regulated Funds without obtaining and relying on the Order.[4]

Applicants

2. Each Existing Registered Fund is a Delaware statutory trust that is a non-diversified, closed-end management investment company that is registered under the Act. The Existing Registered Funds operate as ''interval funds'' pursuant to rule 23c–3 under the Act. Flat Rock Opportunity Fund is managed by a Board [5] comprised of three persons, two of whom are Independent Directors. [6] Flat Rock Core Income Fund is managed by a Board comprised of four persons, three of whom are Independent Directors.

3. Flat Rock, a Delaware limited liability company that is registered under the Advisers Act, serves as the investment adviser to the Existing Regulated Funds and the investment adviser to the Existing Affiliated Fund.

4. Applicants represent that the Existing Affiliated Fund would be an investment company but for section 3(c)(1) of the Act.

5. Applicants state that a Regulated Fund may, from time to time, form one or more Wholly-Owned Investment Subs.[7] Such a subsidiary may be prohibited from investing in a Co-Investment Transaction with a Regulated Fund (other than its parent) or any Affiliated Fund because it would be a company controlled by its parent Regulated Fund for purposes of section 57(a)(4) and rule 17d–1. Applicants request that each Wholly-Owned Investment Sub be permitted to participate in Co-Investment Transactions in lieu of the Regulated Fund that owns it and that the Wholly-Owned Investment Sub's participation in any such transaction be treated, for purposes of the Order, as though the parent Regulated Fund were participating directly.

Applicants' Representations

A Allocation Process

1. Applicants represent that Flat Rock has established processes for allocating initial investment opportunities, opportunities for subsequent investments in an issuer and dispositions of securities holdings reasonably designed to treat all clients fairly and equitably. Further, applicants represent that these processes will be extended and modified in a manner reasonably designed to ensure that the additional transactions permitted under the Order will both (i) be fair and equitable to the Regulated Funds and the Affiliated Funds and (ii) comply with the Conditions.

[2] ''Regulated Funds'' means the Existing Registered Funds and the Future Regulated Funds. ''Future Regulated Fund'' means a closed-end management investment company (a) that is registered under the Act or has elected to be regulated as a business development company under the Act (''BDC''), (b) whose investment adviser is an Adviser, and (c) that intends to participate in the proposed co-investment program (the ''Co-Investment Program''). Section 2(a)(48) of the Act defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in section 55(a)(1) through 55(a)(3) and makes available significant managerial assistance with respect to the issuers of such securities.

''Adviser'' means Flat Rock together with any future investment adviser that (i) controls, is controlled by or is under common control with Flat Rock, (ii) is registered as an investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act'') and (iii) is not a Regulated Fund or a subsidiary of a Regulated Fund.

[3] ''Affiliated Fund'' means any Existing Affiliated Fund, any Future Affiliated Fund or any Flat Rock Proprietary Account. ''Future Affiliated Fund'' means any entity (a) whose investment adviser is an Adviser, (b) that either (A) would be an investment company but for section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act or (B) relies on rule 3a–7 exemption from investment company status, and (c) that intends to participate in the Co-Investment Program.. ''Flat Rock Proprietary Account'' means any direct or indirect, wholly- or majority-owned subsidiary of Flat Rock that is formed in the future that, from time to time, may hold various financial assets in a principal capacity.

[4] All existing entities that currently intend to rely on the Order have been named as applicants and any existing or future entities that may rely on the Order in the future will comply with the terms and Conditions set forth in the application.

[5] ''Board'' means, with respect to a Regulated Fund, the board of directors (or equivalent) of the Regulated Fund.

[6] ''Independent Director'' means a member of the Board of any relevant entity who is not an ''interested person'' as defined in section 2(a)(19) of the Act. No Independent Director of a Regulated Fund will have a financial interest in any Co-Investment Transaction, other than indirectly through share ownership in one of the Regulated Funds.

[7] ''Wholly-Owned Investment Sub'' means an entity (i) that is a wholly-owned subsidiary of a Regulated Fund (with such Regulated Fund at all times holding, beneficially and of record, 95% or more of the voting and economic interests); (ii) whose sole business purpose is to hold one or more investments on behalf of such Regulated Fund; (iii) with respect to which such Regulated Fund's Board has the sole authority to make all determinations with respect to the entity's participation under the Conditions to the application; and (iv) (A) that would be an investment company but for section 3(c)(1), 3(c)(5)(C), or 3(c)(7) of the Act, or (B) that qualifies as a real estate investment trust within the meaning of section 856 of the Internal Revenue Code of 1986, as amended (''Code'') because substantially all of its assets would consist of real properties.

2. If the requested Order is granted, the Adviser will establish, maintain and implement policies and procedures reasonably designed to ensure that when such opportunities arise, the Adviser to the relevant Regulated Funds is promptly notified and receives the same information about the opportunity as any other Adviser considering the opportunity for its clients. In particular, consistent with Condition 1, if a Potential Co-Investment Transaction falls within the then-current Objectives and Strategies [8] and any Board-Established Criteria [9] of a Regulated Fund, the policies and procedures will require that the Adviser to such Regulated Fund receive sufficient information to allow such Adviser's investment committee to make its independent determination and recommendations under the Conditions.

3. The Adviser to each applicable Regulated Fund will then make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances. If the Adviser to a Regulated Fund deems the Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate, then it will formulate a recommendation regarding the proposed order amount for the Regulated Fund.

4. Applicants state that, for each Regulated Fund and Affiliated Fund whose Adviser recommends participating in a Potential Co-Investment Transaction, such Adviser's investment committee will approve an investment amount to be allocated to each Regulated Fund and/or Affiliated Fund participating in the Potential Co-Investment Transaction. Applicants state further that, each proposed order amount may be reviewed and adjusted, in accordance with the Adviser's written allocation policies and procedures, by the Adviser's investment committee.[10] The order of a Regulated Fund or Affiliated Fund resulting from this process is referred to as its ''Internal Order.'' The Internal Order will be submitted for approval by the Required Majority of any participating Regulated Funds in accordance with the Conditions.[11]

5. If the aggregate Internal Orders for a Potential Co-Investment Transaction do not exceed the size of the investment opportunity immediately prior to the submission of the orders to the underwriter, broker, dealer or issuer, as applicable (the ''External Submission''), then each Internal Order will be fulfilled as placed. If, on the other hand, the aggregate Internal Orders for a Potential Co-Investment Transaction exceed the size of the investment opportunity immediately prior to the External Submission, then the allocation of the opportunity will be made pro rata on the basis of the size of the Internal Orders.[12] If, subsequent to such External Submission, the size of the opportunity is increased or decreased, or if the terms of such opportunity, or the facts and circumstances applicable to the Regulated Funds' or the Affiliated Funds' consideration of the opportunity, change, the participants will be permitted to submit revised Internal Orders in accordance with written allocation policies and procedures that the Advisers will establish, implement and maintain.[13]

B. Follow-On Investments

6. Applicants state that from time to time the Regulated Funds and Affiliated Funds may have opportunities to make Follow-On Investments [14] in an issuer in which a Regulated Fund and one or more other Regulated Funds and/or Affiliated Funds previously have invested.

7. Applicants propose that Follow-On Investments would be divided into two categories depending on whether the prior investment was a Co-Investment Transaction or a Pre-Boarding Investment.[15] If the Regulated Funds and Affiliated Funds have previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Follow-On Investment would be subject to the Standard Review Follow-Ons described in Condition 8. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Follow-On Investment would be subject to the Enhanced-Review Follow-Ons described in Condition 9. All Enhanced Review Follow-Ons require the approval of the Required Majority. For a given issuer, the participating Regulated Funds and Affiliated Funds need to comply with the requirements of Enhanced-Review Follow-Ons only for the first Co-Investment Transaction. Subsequent Co-Investment Transactions with respect to the issuer would be governed by the requirements of Standard Review Follow-Ons.

8. A Regulated Fund would be permitted to invest in Standard Review Follow-Ons either with the approval of the Required Majority under Condition 8(c) or without Board approval under

[8] ''Objectives and Strategies'' means with respect to any Regulated Fund its investment objectives and strategies, as described in its most current registration statement, other current filings with the Commission under the Securities Act of 1933 (the ''Securities Act'') or under the Securities Exchange Act of 1934, as amended, and its most current report to stockholders.

[9] ''Board-Established Criteria'' means criteria that the Board of a Regulated Fund may establish from time to time to describe the characteristics of Potential Co-Investment Transactions regarding which the Adviser to such Regulated Fund should be notified under Condition 1. The Board-Established Criteria will be consistent with the Regulated Fund's Objectives and Strategies. If no Board-Established Criteria are in effect, then the Regulated Fund's Adviser will be notified of all Potential Co-Investment Transactions that fall within the Regulated Fund's then-current Objectives and Strategies. Board-Established Criteria will be objective and testable, meaning that they will be based on observable information, such as industry/sector of the issuer, minimum EBITDA of the issuer, asset class of the investment opportunity or required commitment size, and not on characteristics that involve a discretionary assessment. The Adviser to the Regulated Fund may from time to time recommend criteria for the Board's consideration, but Board-Established Criteria will only become effective if approved by a majority of the Independent Directors. The Independent Directors of a Regulated Fund may at any time rescind, suspend or qualify its approval of any Board-Established Criteria, though Applicants anticipate that, under normal circumstances, the Board would not modify these criteria more often than quarterly.

[10] The reason for any such adjustment to a proposed order amount will be documented in writing and preserved in the records of each Adviser.

[11] ''Required Majority'' means a required majority, as defined in section 57(o) of the Act. In the case of a Regulated Fund that is a registered closed-end fund, the Board members that make up the Required Majority will be determined as if the Regulated Fund were a BDC subject to section 57(o).

[12] The Advisers will maintain records of all proposed order amounts, Internal Orders and External Submissions in conjunction with Potential Co-Investment Transactions. Each applicable Adviser will provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with the Conditions. ''Eligible Directors'' means, with respect to a Regulated Fund and a Potential Co-Investment Transaction, the members of the Regulated Fund's Board eligible to vote on that Potential Co-Investment Transaction under section 57(o) of the Act (treating any registered investment company or series thereof as a BDC for this purpose).

[13] The Board of the Regulated Fund will then either approve or disapprove of the investment opportunity in accordance with Condition 2, 6, 7, 8 or 9, as applicable.

[14] ''Follow-On Investment'' means an additional investment in the same issuer, including, but not limited to, through the exercise of warrants, conversion privileges or other rights to purchase securities of the issuer.

[15] ''Pre-Boarding Investments'' are investments in an issuer held by a Regulated Fund as well as one or more Affiliated Funds and/or one or more other Regulated Funds that were acquired prior to participating in any Co-Investment Transaction: (i) In transactions in which the only term negotiated by or on behalf of such funds was price in reliance on one of the JT No-Action Letters (defined below); or (ii) in transactions occurring at least 90 days apart and without coordination between the Regulated Fund and any Affiliated Fund or other Regulated Fund.

Condition 8(b) if it is (i) a Pro Rata Follow-On Investment [16] or (ii) a Non-Negotiated Follow-On Investment.[17] Applicants believe that these Pro Rata and Non-Negotiated Follow-On Investments do not present a significant opportunity for overreaching on the part of any Adviser and thus do not warrant the time or the attention of the Board. Pro Rata Follow-On Investments and Non-Negotiated Follow-On Investments remain subject to the Board's periodic review in accordance with Condition 10.

C. Dispositions

9. Applicants propose that Dispositions [18] would be divided into two categories. If the Regulated Funds and Affiliated Funds holding investments in the issuer have previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Disposition would be subject to the Standard Review Dispositions described in Condition 6. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Disposition would be subject to the Enhanced Review Dispositions described in Condition 7. Subsequent Dispositions with respect to the same issuer would be governed by Condition 6 under the Standard Review Dispositions.[19]

10. A Regulated Fund may participate in a Standard Review Disposition either with the approval of the Required Majority under Condition 6(d) or without Board approval under Condition 6(c) if (i) the Disposition is a Pro Rata Disposition [20] or (ii) the securities are Tradable Securities [21] and the Disposition meets the other requirements of Condition 6(c)(ii). Pro Rata Dispositions and Dispositions of a Tradable Security remain subject to the Board's periodic review in accordance with Condition 10.

D. Delayed Settlement

11. Applicants represent that under the terms and Conditions of the application, all Regulated Funds and Affiliated Funds participating in a Co-Investment Transaction will invest at the same time, for the same price and with the same terms, conditions, class, registration rights and any other rights, so that none of them receives terms more favorable than any other. However, the settlement date for an Affiliated Fund in a Co-Investment Transaction may occur up to ten business days after the settlement date for the Regulated Fund, and vice versa. Nevertheless, in all cases, (i) the date on which the commitment of the Affiliated Funds and Regulated Funds is made will be the same even where the settlement date is not and (ii) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other.

E. Holders

12. Under Condition 15, if an Adviser, its principals, or any person controlling, controlled by, or under common control with the Adviser or its principals, and the Affiliated Funds (collectively, the ''Holders'') own in the aggregate more than 25 percent of the outstanding voting shares of a Regulated Fund (the ''Shares''), then the Holders will vote such Shares as required under Condition 15.

Applicants' Legal Analysis

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit participation by a registered investment company and an affiliated person in any ''joint enterprise or other joint arrangement or profit-sharing plan,'' as defined in the rule, without prior approval by the Commission by order upon application. Section 17(d) of the Act and rule 17d–1 under the Act are applicable to Regulated Funds that are registered closed-end investment companies.

2. Similarly, with regard to BDCs, section 57(a)(4) of the Act generally prohibits certain persons specified in section 57(b) from participating in joint transactions with the BDC or a company controlled by the BDC in contravention of rules as prescribed by the Commission. Section 57(i) of the Act provides that, until the Commission prescribes rules under section 57(a)(4), the Commission's rules under section 17(d) of the Act applicable to registered closed-end investment companies will be deemed to apply to transactions subject to section 57(a)(4). Because the Commission has not adopted any rules under section 57(a)(4), rule 17d–1 also applies to joint transactions with Regulated Funds that are BDCs.

3. Co-Investment Transactions are prohibited by either or both of rule 17d–1 and section 57(a)(4) without a prior exemptive order of the Commission to the extent that the Affiliated Funds and the Regulated Funds participating in such transactions fall within the category of persons described by rule 17d–1 and/or section 57(b), as modified by rule 57b–1 thereunder, as applicable,

[16] A ''Pro Rata Follow-On Investment'' is a Follow-On Investment (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investments in the issuer or security, as appropriate, immediately preceding the Follow-On Investment, and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in the pro rata Follow-On Investments as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Follow-On Investments, in which case all subsequent Follow-On Investments will be submitted to the Regulated Fund's Eligible Directors in accordance with Condition 8(c).

[17] A ''Non-Negotiated Follow-On Investment'' is a Follow-On Investment in which a Regulated Fund participates together with one or more Affiliated Funds and/or one or more other Regulated Funds (i) in which the only term negotiated by or on behalf of the funds is price and (ii) with respect to which, if the transaction were considered on its own, the funds would be entitled to rely on one of the JT No-Action Letters. ''JT No-Action Letters'' means SMC Capital, Inc., SEC No-Action Letter (pub. avail. Sept. 5, 1995) and Massachusetts Mutual Life Insurance Company, SEC No-Action Letter (pub. avail. June 7, 2000).

[18] ''Disposition'' means the sale, exchange or other disposition of an interest in a security of an issuer.

[19] However, with respect to an issuer, if a Regulated Fund's first Co-Investment Transaction is an Enhanced Review Disposition, and the Regulated Fund does not dispose of its entire position in the Enhanced Review Disposition, then before such Regulated Fund may complete its first Standard Review Follow-On in such issuer, the Eligible Directors must review the proposed Follow-On Investment not only on a stand-alone basis but also in relation to the total economic exposure in such issuer (*i.e.,* in combination with the portion of the Pre-Boarding Investment not disposed of in the Enhanced Review Disposition), and the other terms of the investments. This additional review is required because such findings were not required in connection with the prior Enhanced Review Disposition, but they would have been required had the first Co-Investment Transaction been an Enhanced Review Follow-On.

[20] A ''Pro Rata Disposition'' is a Disposition (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investment in the security subject to Disposition immediately preceding the Disposition; and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in pro rata Dispositions as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Dispositions, in which case all subsequent Dispositions will be submitted to the Regulated Fund's Eligible Directors.

[21] ''Tradable Security'' means a security that meets the following criteria at the time of Disposition: (i) It trades on a national securities exchange or designated offshore securities market as defined in rule 902(b) under the Securities Act; (ii) it is not subject to restrictive agreements with the issuer or other security holders; and (iii) it trades with sufficient volume and liquidity (findings as to which are documented by the Advisers to any Regulated Funds holding investments in the issuer and retained for the life of the Regulated Fund) to allow each Regulated Fund to dispose of its entire position remaining after the proposed Disposition within a short period of time not exceeding 30 days at approximately the value (as defined by section 2(a)(41) of the Act) at which the Regulated Fund has valued the investment.

vis-à-vis each participating Regulated Fund. Each of the participating Regulated Funds and Affiliated Funds may be deemed to be affiliated persons vis-à-vis a Regulated Fund within the meaning of section 2(a)(3) by reason of common control because (i) Flat Rock manages and may be deemed to control the Existing Affiliated Fund and an Adviser will manage and may be deemed to control any Future Affiliated Fund; (ii) Flat Rock manages and may be deemed to control the Existing Registered Funds, and an Adviser will manage and may be deemed to control any Future Regulated Fund; and (iii) the Advisers will control, be controlled by, or under common control with, Flat Rock. Thus, each of the Affiliated Funds could be deemed to be a person related to the Regulated Funds in a manner described by section 57(b) and related to Future Regulated Funds in a manner described by rule 17d–1; and therefore the prohibitions of rule 17d–1 and section 57(a)(4) would apply respectively to prohibit the Affiliated Funds from participating in Co-Investment Transactions with the Regulated Funds. Each Regulated Fund would also be related to each other Regulated Fund in a manner described by section 57(b) or rule 17d–1, as applicable, and thus prohibited from participating in Co-Investment Transactions with each other. In addition, because Flat Rock Proprietary Accounts will be controlled by Flat Rock and, therefore, may be under common control with the Existing Registered Funds, any future Advisers, and any Future Regulated Funds, the Flat Rock Proprietary Accounts could be deemed to be persons related to the Regulated Funds (or a company controlled by the Regulated Funds) in a manner described by section 57(b) and also prohibited from participating in the Co-Investment Program.

4. In passing upon applications under rule 17d–1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

5. Applicants state that in the absence of the requested relief, in many circumstances the Regulated Funds would be limited in their ability to participate in attractive and appropriate investment opportunities. Applicants state that, as required by rule 17d–1(b), the Conditions ensure that the terms on which Co-Investment Transactions may be made will be consistent with the participation of the Regulated Funds being on a basis that it is neither different from nor less advantageous than other participants, thus protecting the equity holders of any participant from being disadvantaged. Applicants further state that the Conditions ensure that all Co-Investment Transactions are reasonable and fair to the Regulated Funds and their shareholders and do not involve overreaching by any person concerned, including the Advisers. Applicants state that the Regulated Funds' participation in the Co-Investment Transactions in accordance with the Conditions will be consistent with the provisions, policies, and purposes of the Act and would be done in a manner that is not different from, or less advantageous than, that of other participants.

Applicants' Conditions

Applicants agree that the Order will be subject to the following Conditions:

1. Identification and Referral of Potential Co-Investment Transactions

(a). The Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that each Adviser is promptly notified of all Potential Co-Investment Transactions that fall within the then-current Objectives and Strategies and Board-Established Criteria of any Regulated Fund the Adviser manages.

(b). When an Adviser to a Regulated Fund is notified of a Potential Co-Investment Transaction under Condition 1(a), the Adviser will make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances.

2. Board Approvals of Co-Investment Transactions

(a). If the Adviser deems a Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Fund, it will then determine an appropriate level of investment for the Regulated Fund.

(b). If the aggregate amount recommended by the Advisers to be invested in the Potential Co-Investment Transaction by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, the investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application. Each Adviser to a participating Regulated Fund will promptly notify and provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with these Conditions.

(c). After making the determinations required in Condition 1(b) above, each Adviser to a participating Regulated Fund will distribute written information concerning the Potential Co-Investment Transaction (including the amount proposed to be invested by each participating Regulated Fund and each participating Affiliated Fund) to the Eligible Directors of its participating Regulated Fund(s) for their consideration. A Regulated Fund will enter into a Co-Investment Transaction with one or more other Regulated Funds or Affiliated Funds only if, prior to the Regulated Fund's participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i). The terms of the transaction, including the consideration to be paid, are reasonable and fair to the Regulated Fund and its equity holders and do not involve overreaching in respect of the Regulated Fund or its equity holders on the part of any person concerned;

(ii). the transaction is consistent with:

(A). The interests of the Regulated Fund's equity holders; and

(B). the Regulated Fund's then-current Objectives and Strategies;

(iii). the investment by any other Regulated Fund(s) or Affiliated Fund(s) would not disadvantage the Regulated Fund, and participation by the Regulated Fund would not be on a basis different from, or less advantageous than, that of any other Regulated Fund(s) or Affiliated Fund(s) participating in the transaction; provided that the Required Majority shall not be prohibited from reaching the conclusions required by this Condition 2(c)(iii) if:

(A). The settlement date for another Regulated Fund or an Affiliated Fund in a Co-Investment Transaction is later than the settlement date for the Regulated Fund by no more than ten business days or earlier than the settlement date for the Regulated Fund by no more than ten business days, in either case, so long as: (x) The date on which the commitment of the Affiliated Funds and Regulated Funds is made is the same; and (y) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other; or

(B). any other Regulated Fund or Affiliated Fund, but not the Regulated Fund itself, gains the right to nominate

a director for election to a portfolio company's board of directors, the right to have a board observer or any similar right to participate in the governance or management of the portfolio company so long as: (x) The Eligible Directors will have the right to ratify the selection of such director or board observer, if any; (y) the Adviser agrees to, and does, provide periodic reports to the Regulated Fund's Board with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and (z) any fees or other compensation that any other Regulated Fund or Affiliated Fund or any affiliated person of any other Regulated Fund or Affiliated Fund receives in connection with the right of one or more Regulated Funds or Affiliated Funds to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among any participating Affiliated Funds (who may, in turn, share their portion with their affiliated persons) and any participating Regulated Fund(s) in accordance with the amount of each such party's investment; and

(iv). the proposed investment by the Regulated Fund will not involve compensation, remuneration or a direct or indirect [22] financial benefit to the Advisers, any other Regulated Fund, the Affiliated Funds or any affiliated person of any of them (other than the parties to the Co-Investment Transaction), except (A) to the extent permitted by Condition 14, (B) to the extent permitted by section 17(e) or 57(k), as applicable, (C) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction, or (D) in the case of fees or other compensation described in Condition 2(c)(iii)(B)(z).

3. Right to Decline

Each Regulated Fund has the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. General Limitation

Except for Follow-On Investments made in accordance with Conditions 8 and 9 below,[23] a Regulated Fund will not invest in reliance on the Order in any issuer in which a Related Party has an investment.[24]

5. Same Terms and Conditions

A Regulated Fund will not participate in any Potential Co-Investment Transaction unless (i) the terms, conditions, price, class of securities to be purchased, date on which the commitment is entered into and registration rights (if any) will be the same for each participating Regulated Fund and Affiliated Fund and (ii) the earliest settlement date and the latest settlement date of any participating Regulated Fund or Affiliated Fund will occur as close in time as practicable and in no event more than ten business days apart. The grant to one or more Regulated Funds or Affiliated Funds, but not the respective Regulated Fund, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this Condition 5, if Condition 2(c)(iii)(B) is met.

6. Standard Review Dispositions

(a). *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of an interest in a security and one or more Regulated Funds and Affiliated Funds have previously participated in a Co-Investment Transaction with respect to the issuer, then:

(i). The Adviser to such Regulated Fund or Affiliated Fund [25] will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time; and

(ii). the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition.

(b). *Same Terms and Conditions.* Each Regulated Fund will have the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Funds and any other Regulated Fund.

(c). *No Board Approval Required.* A Regulated Fund may participate in such a Disposition without obtaining prior approval of the Required Majority if:

(i). (A) the participation of each Regulated Fund and Affiliated Fund in such Disposition is proportionate to its then-current holding of the security (or securities) of the issuer that is (or are) the subject of the Disposition; [26] (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in such Dispositions on a pro rata basis (as described in greater detail in the application); and (C) the Board of the Regulated Fund is provided on a quarterly basis with a list of all Dispositions made in accordance with this Condition; or

(ii). each security is a Tradable Security and (A) the Disposition is not to the issuer or any affiliated person of the issuer; and (B) the security is sold for cash in a transaction in which the only term negotiated by or on behalf of the participating Regulated Funds and Affiliated Funds is price.

(d). *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests.

7. Enhanced Review Dispositions

(a). *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of a Pre-Boarding Investment in a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i). The Adviser to such Regulated Fund or Affiliated Fund will notify each

[22] For example, procuring the Regulated Fund's investment in a Potential Co-Investment Transaction to permit an affiliate to complete or obtain better terms in a separate transaction would constitute an indirect financial benefit.

[23] This exception applies only to Follow-On Investments by a Regulated Fund in issuers in which that Regulated Fund already holds investments.

[24] ''Related Party'' means (i) any Close Affiliate and (ii) in respect of matters as to which any Adviser has knowledge, any Remote Affiliate.

''Close Affiliate'' means the Advisers, the Regulated Funds, the Affiliated Funds and any other person described in section 57(b) (after giving effect to rule 57b–1) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) except for limited partners included solely by reason of the reference in section 57(b) to section 2(a)(3)(D).

''Remote Affiliate'' means any person described in section 57(e) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) and any limited partner holding 5% or more of the relevant limited partner interests that would be a Close Affiliate but for the exclusion in that definition.

[25] Any Flat Rock Proprietary Account that is not advised by an Adviser is itself deemed to be an Adviser for purposes of Conditions 6(a)(i), 7(a)(i), 8(a)(i) and 9(a)(i).

[26] In the case of any Disposition, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Disposition.

Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time;

(ii). the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition; and

(iii). the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b). *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that:

(i). The Disposition complies with Condition 2(c)(i), (ii), (iii)(A), and (iv); and

(ii). the making and holding of the Pre-Boarding Investments were not prohibited by section 57 or rule 17d–1, as applicable, and records the basis for the finding in the Board minutes.

(c). *Additional Requirements:* The Disposition may only be completed in reliance on the Order if:

(i). *Same Terms and Conditions.* Each Regulated Fund has the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and Conditions as those applicable to the Affiliated Funds and any other Regulated Fund;

(ii). *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(iii). *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable;

(iv). *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial [27] in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(v). *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

8. Standard Review Follow-Ons

(a). *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer and the Regulated Funds and Affiliated Funds holding investments in the issuer previously participated in a Co-Investment Transaction with respect to the issuer:

(i). The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time; and

(ii). the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund.

(b). *No Board Approval Required.* A Regulated Fund may participate in the Follow-On Investment without obtaining prior approval of the Required Majority if:

(i). (A) The proposed participation of each Regulated Fund and each Affiliated Fund in such investment is proportionate to its outstanding investments in the issuer or the security at issue, as appropriate,[28] immediately preceding the Follow-On Investment; and (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in Follow-On Investments on a pro rata basis (as described in greater detail in the application); or

(ii). it is a Non-Negotiated Follow-On Investment.

(c). *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority makes the determinations set forth in Condition 2(c). If the only previous Co-Investment Transaction with respect to the issuer was an Enhanced Review Disposition the Eligible Directors must complete this review of the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms of the investment.

(d). *Allocation.* If, with respect to any such Follow-On Investment:

(i). The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii). the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e). *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

[27] In determining whether a holding is ''immaterial'' for purposes of the Order, the Required Majority will consider whether the nature and extent of the interest in the transaction or arrangement is sufficiently small that a reasonable person would not believe that the interest affected the determination of whether to enter into the transaction or arrangement or the terms of the transaction or arrangement.

[28] To the extent that a Follow-On Investment opportunity is in a security or arises in respect of a security held by the participating Regulated Funds and Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Follow-On Investment using the most recent available valuation thereof. To the extent that a Follow-On Investment opportunity relates to an opportunity to invest in a security that is not in respect of any security held by any of the participating Regulated Funds or Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the issuer immediately preceding the Follow-On Investment using the most recent available valuation thereof.

9. Enhanced Review Follow-Ons

(a). *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer that is a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds holding investments in the issuer have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i). The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time;

(ii). the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund; and

(iii). the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b). *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority reviews the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms and makes the determinations set forth in Condition 2(c). In addition, the Follow-On Investment may only be completed in reliance on the Order if the Required Majority of each participating Regulated Fund determines that the making and holding of the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable. The basis for the Board's findings will be recorded in its minutes.

(c). *Additional Requirements.* The Follow-On Investment may only be completed in reliance on the Order if:

(i). *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(ii). *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable;

(iii). *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(iv). *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

(d). *Allocation.* If, with respect to any such Follow-On Investment:

(i). The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii). the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e). *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

10. Board Reporting, Compliance and Annual Re-Approval

(a). Each Adviser to a Regulated Fund will present to the Board of each Regulated Fund, on a quarterly basis, and at such other times as the Board may request, (i) a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Funds or any of the Affiliated Funds during the preceding quarter that fell within the Regulated Fund's then-current Objectives and Strategies and Board-Established Criteria that were not made available to the Regulated Fund, and an explanation of why such investment opportunities were not made available to the Regulated Fund; (ii) a record of all Follow-On Investments in and Dispositions of investments in any issuer in which the Regulated Fund holds any investments by any Affiliated Fund or other Regulated Fund during the prior quarter; and (iii) all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Funds or Affiliated Funds that the Regulated Fund considered but declined to participate in, so that the Independent Directors, may determine whether all Potential Co-Investment Transactions and Co-Investment Transactions during the preceding quarter, including those investments that the Regulated Fund considered but declined to participate in, comply with the Conditions.

(b). All information presented to the Regulated Fund's Board pursuant to this Condition will be kept for the life of the Regulated Fund and at least two years thereafter, and will be subject to examination by the Commission and its staff.

(c). Each Regulated Fund's chief compliance officer, as defined in rule 38a–1(a)(4), will prepare an annual report for its Board each year that evaluates (and documents the basis of that evaluation) the Regulated Fund's compliance with the terms and Conditions of the application and the procedures established to achieve such compliance.

(d). The Independent Directors will consider at least annually whether continued participation in new and existing Co-Investment Transactions is in the Regulated Fund's best interests.

11. Record Keeping

Each Regulated Fund will maintain the records required by section 57(f)(3) of the Act as if each of the Regulated Funds were a BDC and each of the investments permitted under these

Conditions were approved by the Required Majority under section 57(f).

12. Director Independence

No Independent Director of a Regulated Fund will also be a director, general partner, managing member or principal, or otherwise be an ''affiliated person'' (as defined in the Act) of any Affiliated Fund.

13. Expenses

The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the Securities Act) will, to the extent not payable by the Advisers under their respective advisory agreements with the Regulated Funds and the Affiliated Funds, be shared by the Regulated Funds and the participating Affiliated Funds in proportion to the relative amounts of the securities held or being acquired or disposed of, as the case may be.

14. Transaction Fees [29]

Any transaction fee (including break-up, structuring, monitoring or commitment fees but excluding brokerage or underwriting compensation permitted by section 17(e) or 57(k)) received in connection with any Co-Investment Transaction will be distributed to the participants on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Adviser pending consummation of the transaction, the fee will be deposited into an account maintained by an Adviser at a bank or banks having the qualifications prescribed in section 26(a)(1), and the account will earn a competitive rate of interest that will also be divided pro rata among the participants. None of the Adviser, the Affiliated Funds, the other Regulated Funds or any affiliated person of the Affiliated Funds or the Regulated Funds will receive any additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction other than (i) in the case of the Regulated Funds and the Affiliated Funds, the pro rata transaction fees described above and fees or other compensation described in Condition 2(c)(iii)(B)(z), (ii) brokerage or underwriting compensation permitted by section 17(e) or 57(k) or (iii) in the case of the Adviser, investment advisory compensation paid in accordance with investment advisory agreements between the applicable Regulated Fund(s) or Affiliated Fund(s) and its Adviser.

15. Independence

If the Holders own in the aggregate more than 25 percent of the Shares of a Regulated Fund, then the Holders will vote such Shares in the same percentages as the Regulated Fund's other shareholders (not including the Holders) when voting on (1) the election of directors; (2) the removal of one or more directors; or (3) any other matter under either the Act or applicable State law affecting the Board's composition, size or manner of election.

For the Commission, by the Division of Investment Management, under delegated authority.

Dated: December 29, 2021.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2021–28512 Filed 1–4–22; 8:45 am]

BILLING CODE 8011–01–P

[29] Applicants are not requesting and the Commission is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93876; File No. SR–NASDAQ–2021–101]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change To Amend Rule 4754 Related to Certain Order Handling in the LULD Closing Cross

December 29, 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 December 22, 2021, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to a proposal to amend its rule related to certain order handling in the Limit-Up Limit-Down (''LULD'') closing cross.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Equity 4, Rule 4754 [3] related to certain order handling in the LULD closing cross (''LULD Closing Cross'').[4] On May 28, 2021, the Commission approved the Exchange's proposal to make certain changes to the Exchange's LULD Closing Cross, including the timing of the LULD Closing Cross, the process for determining the LULD Closing Cross price, establishing price protections for the LULD Closing Cross, the handling of on-close orders, and the imbalance information disseminated for the LULD Closing Cross.[5] The Exchange has not yet implemented the proposed LULD Closing Cross changes in SR–NASDAQ–2021–009, and recently filed to delay implementation in order to allow the Exchange additional time to test and implement these functionalities.[6]

During the testing conducted to date, Nasdaq has identified some changes that it wishes to make to the approved rule governing the LULD Closing Cross in Rule 4754(b)(6). Accordingly, the Exchange is submitting this proposal to

[3] All Rule 4000 series referenced in this filing are within Equity 4.

[4] The LULD Closing Cross is the Exchange's auction process for executing closing trades in Nasdaq-listed securities when a Trading Pause pursuant to Rule 4120(a)(12) exists at or after 3:50 p.m. and before 4:00 p.m. ET. *See* Rule 4754(b)(6).

[5] *See* Securities Exchange Act Release No. 92068 (May 28, 2021), 86 FR 29864 (June 3, 2021) (SR–NASDAQ–2021–009) (''Approval Order'').

[6] *See* Securities Exchange Act Release No. 93250 (October 4, 2021), 86 FR 56307 (October 8, 2021) (SR–NASDAQ–2021–077).

amend the rule text prior to implementation. Specifically, the Exchange is proposing to provide that in the context of the LULD Closing Cross, Limit on Close (''LOC'') orders [7] entered between 3:55 p.m. ET and immediately prior to 3:58 p.m. ET (''late LOC orders'') will use the same reference prices for re-pricing as the reference prices used during the standard Nasdaq Closing Cross.[8]

Today, Rule 4702(b)(12) describes the treatment of late LOC orders during the standard Closing Cross. The Rule provides that late LOC orders may be entered between 3:55 p.m. ET and immediately prior to 3:58 p.m. ET provided that there is a First Reference Price [9] (*i.e.,* the Current Reference Price [10] disseminated at 3:50 p.m. ET) or a Second Reference Price [11] (*i.e.,* the Current Reference Price disseminated at 3:55 p.m. ET). Between 3:55 p.m. ET and immediately prior to 3:58 p.m. ET, LOC Orders can only be cancelled and/or modified if the Participant requests that Nasdaq correct a legitimate error in the Order (*e.g.,* Side, Size, Symbol, or Price, or duplication of an Order). LOC Orders cannot be cancelled or modified at or after 3:58 p.m.

A late LOC order will be accepted at its limit price, unless its limit price is higher (lower) than the higher (lower) of the First Reference Price and the Second Reference Price for a late LOC order to buy (sell), in which case the late LOC order will be handled consistent with the Participant's instruction that the late LOC order is to be: (1) Rejected; or (2) re-priced to the higher (lower) of the First Reference Price and the Second Reference Price.[12]

As stated in SR–NASDAQ–2021–009, the intent of the proposed rule change was to align the LULD Closing Cross process as closely as possible to the standard Closing Cross process, including the handling of various closing cross order types like LOC orders (and their subset, late LOC orders). As such, the Exchange amended Rule 4754(b)(6)(F)(ii) to provide that MOC, LOC, and IO orders may be entered, modified, and cancelled pursuant to Rules 4702(b)(11), 4702(b)(12), and 4702(b)(13) to allow these order types to participate in the LULD Closing Cross in the same way as a standard Closing Cross. This includes accepting late LOC orders during the LULD Closing Cross and re-pricing (in certain cases) these orders to the more aggressive of First Reference Price or Second Reference Price in the same way as a standard Closing Cross.

In the context of the standard Closing Cross, the First Reference Price and the Second Reference Price, at the time of their dissemination at 3:50 p.m. ET and 3:55 p.m. ET, respectively, each represent the current price, bounded by the continuous market (*i.e.,* the Nasdaq best bid and offer), at which paired on-close shares are maximized (with certain tie-breakers if multiple prices meet this criterion).[13] SR–NASDAQ–2021–009, however, defined the 3:50 p.m. ET reference price and 3:55 p.m. ET reference price in the context of the LULD Closing Cross as the price at which the LULD Closing Cross would execute should the cross conclude at that time, and further indicated that the reference price would be bounded by the benchmark prices.[14] As described in SR–NASDAQ–2021–009, the benchmark prices represent the price range within which the LULD Closing Cross price must fall and are calculated off the last disseminated LULD Auction Collar or the LULD Band that triggered the Trading Pause, as further described in Rule 4754(b)(6)(E). As a result of the foregoing, in cases where a Trading Pause exists at or prior to 3:50 p.m. ET, the 3:50 and 3:55 p.m. ET reference prices in the LULD Closing Cross would not be bounded by continuous market (*i.e.,* the Nasdaq best bid and offer) like the 3:50 and 3:55 p.m. ET reference prices in the standard Closing Cross as there was no continuous market in the halted security during those times, and those reference prices in the LULD Closing Cross would instead be bounded by the benchmark prices described above. Similarly, if a Trading Pause is triggered after 3:50 p.m. ET but before 3:55 p.m. ET, the 3:50 reference price would reflect and be bounded by the Nasdaq best bid and offer at the time of dissemination like the 3:50 reference price used in a standard Closing Cross whereas the 3:55 reference price would not. Lastly, if a Trading Pause is triggered after 3:55 p.m. ET, both the 3:50 and 3:55 reference prices would reflect and be bounded by the Nasdaq best bid and offer at the time of dissemination like the reference prices used in a standard Closing Cross. The consequence of using the LULD Closing Cross-derived reference price and not the standard Closing Cross-derived reference price may result in late LOC orders being accepted and potentially repriced to 3:50 or 3:55 p.m. ET reference prices that are not reflective of the continuous market at the time of their dissemination (*i.e.,* reference prices disseminated at a time when trading has been paused and that are not bounded by the Nasdaq best bid and offer), and which are bounded by benchmark prices that are calculated off the last disseminated LULD Auction Collar or the LULD Band that triggered the Trading Pause. The Exchange believes that this is inconsistent with market participant expectations of how late LOC orders would be normally repriced during a closing cross process (*i.e.,* repriced to reference prices disseminated at a time when trading has been paused and that are not bounded by the Nasdaq best bid and offer), and therefore proposes to amend late LOC order handling so that its LULD Closing Cross and standard Closing Cross processes are more consistent.

Accordingly, the Exchange proposes to state in its rules that it will only accept and if needed, re-price a late LOC order in the LULD Closing Cross if a standard Closing Cross-derived reference price (*i.e.,* First Reference Price or Second Reference Price) is available. In particular, the Exchange proposes to add the following language at the end of Rule 4754(b)(6)(F)(ii):

[7] A ''Limit On Close Order'' or ''LOC Order'' is an Order Type entered with a price that may be executed only in the Nasdaq Closing Cross, and only if the price determined by the Nasdaq Closing Cross is equal to or better than the price at which the LOC Order was entered. *See* Rule 4702(b)(12).

[8] ''Nasdaq Closing Cross'' shall mean the process for determining the price at which orders shall be executed at the close and for executing those orders. *See* Rule 4754(a)(6).

[9] ''First Reference Price'' shall mean the Current Reference Price in the Early Order Imbalance Indicator (''EOII'') disseminated at 3:50 p.m. ET, or 10 minutes prior to the early closing time on a day when Nasdaq closes early. *See* Rule 4754(a)(9).

[10] ''Current Reference Price'' means the following: (i) The single price that is at or within the current Nasdaq Market Center best bid and offer at which the maximum number of shares of MOC, LOC, and IO orders can be paired; (ii) if more than one price exists under subparagraph (i), the Current Reference Price shall mean the price that minimizes any Imbalance; (iii) it more than one price exists under subparagraph (ii), the Current Reference Price shall mean the entered price at which shares will remain unexecuted in the cross; or (iv) if more than one price exists under subparagraph (iii), the Current Reference Price shall mean the price that minimizes the distance from the bid-ask midpoint of the inside quotation prevailing at the time of the order imbalance indicator dissemination. *See* Rule 4754(a)(7)(A).

[11] ''Second Reference Price'' shall mean the Current Reference Price in the Order Imbalance Indicator (''NOII'') disseminated at 3:55 p.m. ET, or five minutes prior to the early closing time on a day when Nasdaq closes early. *See* Rule 4754(a)(11).

[12] Furthermore, if either the First Reference Price or the Second Reference Price is not at a permissible minimum increment, the First Reference Price or the Second Reference Price, as applicable, will be rounded (i) to the nearest permitted minimum increment (with midpoint prices being rounded up) if there is no imbalance, (ii) up if there is a buy imbalance, or (iii) down if there is a sell imbalance. The default configuration for Participants that do not specify otherwise will be to have such late LOC orders re-priced rather than rejected. *See* Rule 4702(b)(12).

[13] *See* definition of Current Reference Price in Rule 4754(a)(7)(A).

[14] *See* Approval Order at 29866.

With respect to LOC orders entered between 3:55 p.m. ET and immediately prior to 3:58 p.m. ET (hereinafter, ''late LOC orders''), the System will handle such orders in the LULD Closing Cross as follows:

(a) If the security entered a Trading Pause prior and up to 3:50 p.m., the System will not accept late LOC orders.[15]

(b) If the security entered a Trading Pause after 3:50 p.m. and up to 3:55 p.m., the System will accept late LOC orders, provided that there is a First Reference Price. Such orders may then be subject to re-pricing in accordance with Rule 4702(b)(12) or rejected, in either case consistent with the Participant's instructions.[16]

(c) If the security entered a Trading Pause after 3:55 p.m., the System will accept late LOC orders, provided that there is a First Reference Price or a Second Reference Price. Such orders may then be subject to re-pricing in accordance with Rule 4702(b)(12) or rejected, in either case consistent with the Participant's instructions.[17]

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 because it would amend the LULD Closing Cross process with respect to certain LOC order handling as approved in SR–NASDAQ–2021–009 in order to further align the LULD Closing Cross with the standard Nasdaq Closing Cross. Specifically, the Exchange is proposing to provide in Rule 4754(b)(6)(F)(ii) that it will only accept and if needed, re-price a late LOC order in the LULD Closing Cross if a First Reference Price or Second Reference Price for the standard Closing Cross is available, identical to the handling of late LOC orders for the standard Closing Cross. As discussed above, in the context of the standard Closing Cross, the First Reference Price and the Second Reference Price, at the time of their dissemination at 3:50 p.m. ET and 3:55 p.m. ET, respectively, each represent the current price, bounded by the continuous market (*i.e.,* the Nasdaq best and offer), at which paired on-close shares are maximized. SR–NASDAQ–2021–009, however, defined the 3:50 p.m. ET reference price and 3:55 p.m. ET reference price in the context of the LULD Closing Cross as the price, bounded by the benchmark prices, at which the LULD Closing Cross would execute should the cross conclude at that time. Because the benchmark prices are based on the LULD Auction Collar or LULD Band instead of the continuous market, the consequence of using the LULD Closing Cross-derived reference price and not the standard Closing Cross-derived reference price may result in late LOC orders being accepted and potentially repriced to 3:50 or 3:55 reference prices that are not reflective of the continuous market at the time of their dissemination (*i.e.,* reference prices disseminated at a time when trading has been paused and that are not bounded by the Nasdaq best bid and offer), and which are bounded by benchmark prices that are calculated off the last disseminated LULD Auction Collar or the LULD Band that triggered the Trading Pause. The Exchange believes that this is an undesirable outcome and contrary to market participant expectations of how a late LOC order would normally be repriced by the Exchange. The Exchange believes that the proposed changes will align the LULD Closing Cross with the standard Closing Cross more closely, thereby promoting a more consistent experience for market participants, and reducing any potential confusion regarding Nasdaq's closing processes.

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. Rather, the proposed changes would allow the Exchange to make certain changes to the Exchange's rules and functionality related to certain LOC order handling in the LULD Closing Cross in a manner consistent with the current standard Closing Cross. Ultimately, the Exchange believes that the proposed changes will render the LULD Closing Cross more attractive to market participants by providing a more consistent experience for Nasdaq's closing processes.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2021–101 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2021–101. 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

[15] The System will not accept late LOC orders in this scenario because if a security entered a Trading Pause prior and up to 3:50 p.m. ET, there would not be a First Reference Price or a Second Reference Price for the standard Closing Cross.

[16] The System will accept late LOC orders provided there is a First Reference Price because in this scenario, the security entered a Trading Pause after 3:50 p.m. ET (but before 3:55 p.m. ET) so the First Reference Price would be disseminated at 3:50 p.m. ET for the standard Closing Cross but the Second Reference Price for the standard Closing Cross would not be disseminated at 3:55 p.m. ET. The option to have the Participant's aggressively priced late LOC order rejected instead of re-priced is consistent with the standard Closing Cross. *See* Rule 4702(b)(12).

[17] The System will accept late LOC orders provided there is a First Reference Price or Second Reference Price because in this scenario, the security entered a Trading Pause after 3:55 p.m. ET so both the First Reference Price and the Second Reference Price would be disseminated for the standard Closing Cross.

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2021–101 and should be submitted on or before January 26, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2021–28519 Filed 1–4–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93887; File No. SR–C2–2021–019]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change Relating to Certain Fine Amounts in Rule 13.15, Which Governs the Exchange's Minor Rule Violation Plan, and Non-Substantive Clarifying Changes

December 30, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 16, 2021, Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') 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 Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 13.15, which governs the Exchange's Minor Rule Violation Plan (''MRVP''), in connection with applicable fines, as well as a clarifying, nonsubstantive change. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*https://markets.cboe.com/us/options/regulation/rule_filings/ctwo/*), at the Exchange's Office of the Secretary, 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 III below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its MRVP in Rule 13.15(g)(14) in connection with the fine schedule applicable for minor rule violations of a Market-Maker's quoting obligations and proposes to update language in Chapter 13 to reflect recent changes to Cboe Exchange, Inc. (''Cboe Options'') MRVP. Chapter 13 of the C2 Rulebook incorporates Cboe Options Chapter 13, in most part, by reference. Rule 13.15 provides for disposition of specific violations through assessment of fines in lieu of conducting a formal disciplinary proceeding. Rule 13.15(g) sets forth the list of specific Exchange Rules under which a Trading Permit Holder (''TPH'') or person associated with or employed by a TPH may be subject to a fine for violations of such Rules and the applicable fines that may be imposed by the Exchange.

The proposed rule change amends the fine schedule applicable to Maker-Makers for failure to meet Exchange continuous quoting obligations. The Exchange notes that because Cboe Options Rule 13.15(g)(9)[3] applies to violations of Cboe Options' Market-Maker quoting obligations, this subparagraph is inapplicable to Market-Makers on C2. Instead, the Exchange maintains its own Rule 13.15(g)(14),[4] which governs minor rule violations of C2 Market-Makers' continuous quoting obligations. Specifically, Rule 13.15(g)(14) (13.15(g)(9), as amended)[5] provides that a fine will be imposed upon a Market-Maker in accordance with the fine schedule set forth below for failure to meet its continuous quoting obligations (Rule 5.52(d)):

For the first offense during any rolling 24-month period, the fine schedule imposed by Rule 13.15(g)(14) currently permits the Exchange to apply a fine ranging between $2,000 and $4,000. For subsequent offenses during the same period, the fine schedule currently permits the Exchange to apply a fine ranging between $4,000 and $5,000. The proposed rule change updates the fine schedule to provide that, during any rolling 24-month period, the Exchange may give a Letter of Caution for a first offense, may apply a fine of $1,500 for a second offense, may apply a fine of $3,000 for a third offense,[6] and may proceed with formal disciplinary action for subsequent offenses. As is the case for all rule violations covered under Rule 13.15(g), the Exchange may determine that a violation of Market-Maker quoting obligations is intentional, egregious, or otherwise not minor in nature and choose to proceed under the Exchange's formal disciplinary rules rather than its MRVP.[7] The Exchange may continue to aggregate individual

[20] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Previously Cboe Options Rule 13.15(g)(14). The paragraphs in Cboe Options Rule 13.15(g) were recently renumbered. *See* Securities Exchange Release No. 92702 (August 18, 2021), 86 FR 47346 (August 24, 2021) (SR–CBOE–2021–045). As a result, the proposed rule change updates Rules 13.15(g)(6), (g)(14), and (g)(19) to Rules (g)(4), (g)(9), and (g)(14), respectively, as well as references where applicable, to be consistent with the recently renumbered paragraphs in Cboe Options Rule 13.15(g).

[4] *See id.*

[5] *See id.*

[6] The Exchange notes that Rule 13.15(a) authorizes the Exchange to impose a fine, not to exceed $5,000, for minor rule violations in lieu of commencing a disciplinary proceeding. Additionally, any fine imposed pursuant to Rule 13.15 that (1) does not exceed $2,500 and (2) is not contested, shall be reported by the Exchange to the Commission on a periodic, rather than a current, basis, except as may otherwise be required by Exchange Act Rule 19d–1 and by any other regulatory authority.

[7] *See* Rule 13.15(f).

violations of particular rules and treat such violations as a single offense.[8]

The Exchange believes it is appropriate to remove the range of fines imposed for first and subsequent offenses and, instead, apply a letter of caution for a first offense, a specified fine amount for a second and a third offense, and formal disciplinary proceedings for subsequent offenses. Particularly, the Exchange believes that applying a lesser penalty (Letter of Caution) for a first offense and then providing a higher, itemized fine per second and third offenses and, ultimately, formal disciplinary proceedings for any subsequent offenses during a rolling 24-month period, will allow the Exchange to levy progressively larger fines and greater penalties against repeat-offenders (as opposed to a fine range for any offenses that may come after a first offense). The Exchange believes this fine structure may serve to more effectively deter repeat-offenders while providing reasonable warning for a first offense during a rolling 24-month period. The Exchange notes that the proposed fine schedule for violations of a Market Maker's continuous quoting obligation is identical to the fine schedule under Cboe Options' MRVP for market maker violations of continuous quoting obligations on Cboe Options. The Exchange further notes that the proposed change is intended to provide for consistency across the Exchange's MRVP and the MRVPs of its affiliated options exchanges, Cboe Options, Cboe BZX Exchange, Inc. (''BZX Options'') and Cboe EDGX Exchange, Inc. (''EDGX''), as BZX Options and EDGX Options also intend to file proposals to update their minor rule violation fines for market maker violations of continuous quoting requirements on their exchanges in an identical manner.

The proposed rule change also makes a nonsubstantive, clarifying change to Chapter 13 by removing the provision which currently provides that Cboe Options Rules 13.15(g)(4), 13.15(g)(5) and 13.15(g)(7) do not apply to C2.[9] Cboe Options recently eliminated these provisions from its MRVP; therefore, this provision is no longer applicable.[10]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change to remove the range of fines imposed for first and subsequent Market-Maker quoting offenses and, instead, apply a letter of caution for a first offense, a specified fine amount for a second and a third offense, and formal disciplinary proceedings for subsequent offenses will assist the Exchange in preventing fraudulent and manipulative acts and practices and promoting just and equitable principles of trade, and will serve to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest. Particularly, the Exchange believes that applying a lesser penalty (Letter of Caution) for a first offense and then providing an itemized fine per second and third offenses and, ultimately, formal disciplinary proceedings for any subsequent offenses during a rolling 24-month period, will allow the Exchange to levy greater penalties (*i.e.,* formal disciplinary proceedings) against repeat-offenders (as opposed to a fine range for any offenses that may come after a first offense) which may serve to more effectively deter repeat-offenders while providing reasonable warning for a first offense during a rolling 24-month period. The Exchange believes that more effectively deterring repeat-offenders and making first instance offenders aware of their quoting obligation violations and the subsequent consequences for continued failure, will, in turn, further motivate Market-Makers to continue to uphold their quoting obligations, providing liquid markets to the benefit of all investors. The Exchange again notes that the proposed fine schedule is consistent with the fine schedule under Cboe Options' MRVP applicable to marker maker violations of continuous quoting requirements on Cboe Options. As described above, BZX Options and EDGX Options intend to file proposals to update their minor rule violation fines applicable to violations of market maker continuous quoting obligations in the same manner as Cboe Options and as proposed herein. As such, the proposed rule change is also designed to benefit investors by providing from consistent penalties across the MRVPs of the Exchange and its affiliated options exchanges.

Additionally, the proposed clarification in Chapter 13 will benefit investors by providing for Rules that accurately reflect current Cboe Options Rule 13.15, which Chapter 13 incorporates, in most part, by reference.

The Exchange further believes that the proposed rule changes to Rule 13.15(g) are consistent with Section 6(b)(6) of the Act,[14] which provides that members and persons associated with members shall be appropriately disciplined for violation of the provisions of the rules of the exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction. As noted, the proposed rule change amends the fine schedule applicable to Market-Maker failures to meet their quoting obligations in a manner that appropriately sanctions such failures.

The Exchange also believes that the proposed change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[15] Rule 13.15, currently and as amended, does not preclude a TPH or person associated with or employed by a TPH from contesting an alleged violation and receiving a hearing on the matter with the same procedural rights through a litigated disciplinary proceeding.

[8] *See* Rule 13.15(a).

[9] As a result of removing this provision, the proposed rule change also makes a nonsubstantive change to the subsequent provision by updating the reference to multiple above paragraphs to instead reference a single above paragraph.

[10] *See* Securities Exchange Release No. 92702 (August 18, 2021), 86 FR 47346 (August 24, 2021) (SR–CBOE–2021–045).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78f(b)(6).

[15] 15 U.S.C. 78f(b)(7) and 78f(d).

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 proposed rule change is not intended to address competitive issues but rather is concerned solely with amending its MRVP in connection with the fine schedule for Market-Maker failures to meet quoting obligations. The Exchange believes the proposed rule change will strengthen the Exchange's ability to carry out its oversight and enforcement functions and deter potential violative conduct.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. 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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2021–019 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–C2–2021–019. 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 (*https://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–C2–2021–019 and should be submitted on or before January 26, 2022.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

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.[16] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[17] which requires that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also believes that the proposal is consistent with Sections 6(b)(1) and 6(b)(6) of the Act[18] which require that the rules of an exchange enforce compliance with, and provide appropriate discipline for, violations of Commission and Exchange rules. Finally, the Commission finds that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act, as required by Rule 19d–1(c)(2) under the Act,[19] which governs minor rule violation plans.

As stated above, generally the Exchange proposes to: (1) Amend the fine amounts applicable to a Maker-Maker's failure to meet the Exchange's continuous quoting obligations, and (2) make non-substantive and clarifying changes to Chapter 13. Specifically, the Exchange proposes to amend the fine amounts in proposed Rule 13.15(g)(9) to provide that, during any rolling 24-month period, the Exchange may give a Letter of Caution for a first offense, may apply a fine of $1,500 for a second offense, may apply a fine of $3,000 for a third offense, and may proceed with formal disciplinary action for subsequent offenses.

The Commission believes that Rule 13.15, as incorporated by reference, is an effective way to discipline a member for a minor violation of a rule. The Commission finds that the Exchange's proposal to amend the fine amounts related to a Market-Maker's failure to meet the Exchange's quoting obligations as required by Rule 5.52(d), as set forth in proposed Rule 13.15(g)(9), is consistent with the Act because it may help the Exchange's ability to better carry out its oversight and enforcement responsibilities. The Commission also believes that the Exchange's proposal to make non-substantive changes that reflect updated rule numbers is consistent with the Act because such changes will add clarity and accuracy to the Exchange's rules.

In approving the propose rule change, the Commission in no way minimizes the importance of compliance with the Exchange's rules and all other rules subject to fines under Rule 13.15. The Commission believes that a violation of any self-regulatory organization's rules, as well as Commission rules, is a serious matter. However, Rule 13.15 provides a reasonable means of addressing rule violations that may not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. The Commission expects that the Exchange will continue to conduct surveillance with due diligence and make a determination based on its findings, on a case-by-case basis, whether a fine of more or less than the recommended amount is appropriate for a violation under Rule 13.15 or whether a violation requires formal disciplinary action.

For the same reasons discussed above, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[20] for approving the proposed rule change prior to the thirtieth day after the date of publication of the notice of the filing thereof in the **Federal Register**. The proposal will assist the Exchange in preventing fraudulent and manipulative practices by allowing the Exchange to adequately enforce compliance with, and provide

[16] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78f(b)(1) and 78f(b)(6).

[19] 17 CFR 240.19d–1(c)(2).

[20] 15 U.S.C. 78s(b)(2).

appropriate discipline for, violations of Exchange rules. Accordingly, the Commission believes that a full notice-and-comment period is not necessary before approving the proposal.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act [21] and Rule 19d–1(c)(2) thereunder,[22] that the proposed rule change (SR–C2–2021–019) be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Eduardo A. Aleman,

Assistant Secretary.

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[21] 15 U.S.C. 78s(b)(2).

[22] 17 CFR 240.19d–1(c)(2).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93886; File No. SR–NASDAQ–2021–105]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delay Implementation of SR–NASDAQ–2021–009

December 30, 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 December 23, 2021, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delay implementation of SR–NASDAQ–2021–009.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On February 11, 2021, the Exchange filed a proposed rule change to make certain changes to the Exchange's Limit Up-Limit Down (''LULD'') closing cross, including the timing of the LULD closing cross, the process for determining the LULD closing cross price, establishing price protections for the LULD closing cross, the handling of on-close orders, and the imbalance information disseminated for the LULD closing cross.[3] The Exchange originally intended to implement the new functionalities in Q3 2021,[4] and subsequently extended the implementation to Q4 2021 to allow the Exchange additional time to test and implement these functionalities.[5] During the testing conducted to date, the Exchange has identified some changes that it wishes to make to the approved rule, which relate to the handling of certain Limit on Close orders during the LULD closing cross (''Proposed Amendments'').[6] Accordingly, the Exchange proposes to delay implementation of SR–NASDAQ–2021–009 until April 2022 so as to allow additional time for the Commission to consider the Proposed Amendments. If the Proposed Amendments are approved by the Commission, the Exchange will issue an Equity Trader Alert notifying market participants prior to implementing these functionalities.

[3] *See* Securities Exchange Act Release No. 92068 (May 28, 2021), 86 FR 29864 (June 3, 2021) (SR–NASDAQ–2021–009).

[4] *Id.*

[5] *See* Securities Exchange Act Release No. 93250 (October 4, 2021), 86 FR 56307 (October 8, 2021) (SR–NASDAQ–2021–077).

[6] The Exchange will submit a separate rule filing to address these changes. *See* SR–NASDAQ–2021–101 (not yet published).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by allowing the Exchange additional time to test and implement the LULD closing cross changes, pending any Commission action on the Proposed Amendments.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange's proposal to delay the implementation of SR–NASDAQ–2021–009 does not impose an undue burden on competition. Delaying the implementation will simply allow the Exchange additional time to properly implement SR–NASDAQ–2021–009, pending any Commission action on the Proposed Amendments.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10]

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

A proposed rule change filed under Rule 19b–4(f)(6) [11] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[12] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. Waiver of the operative delay would allow the Exchange to immediately delay the implementation of SR–NASDAQ–2021–009 and provide the Exchange additional time to test and implement new LULD closing cross functionalities. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2021–105 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2021–105. 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 (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2021–105 and should be submitted on or before January 26, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Eduardo A. Aleman,

Deputy Secretary.

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[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93873; File No. SR–NSCC–2021–017]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Add Fees for NSCC's MF Info Xchange Service, Modify Fees for NSCC's Alternative Investment Product Service and Make Certain Other Clarification Changes to Addendum A of the NSCC Rules

December 29, 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 December 27, 2021, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared primarily by the clearing agency. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A) [3] of the Act and subparagraphs (f)(2) and (f)(4) [4] of Rule 19b–4 thereunder. 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

(a) The proposed rule change of National Securities Clearing Corporation (''NSCC'') is annexed hereto as Exhibit 5 and consists of modifications to Addendum A (Fee Structure) (''Addendum A'') of NSCC's Rules & Procedures (''Rules'') in order to (i) add fees for NSCC's MF Info Xchange service, (ii) make certain adjustments in the fees for NSCC's Alternative Investment Product service (''AIP'') and (iii) make certain other clarification changes to Addendum A, as described below.[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2) and (f)(4).

[5] Capitalized terms used herein and not otherwise defined shall have the meaning assigned to such terms in the Rules, *available at http://dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to (i) add fees for MF Info Xchange, (ii) make certain adjustments in the fees for AIP and (iii) make certain clarifications to Addendum A, as described below. The fee changes are being made to better align fees with the costs of services provided by NSCC by adjusting the fees so that the revenue received by NSCC would be closer to the costs of building and providing the services consistent with NSCC's cost-based plus markup fee model.[6] In general, fee levels for NSCC are set by NSCC after periodic reviews of a number of factors, including revenues, operating costs and potential service enhancements. NSCC also continuously engages in discussions with NSCC Members regarding proposed fee changes and potential impacts.

(i) MF Info Xchange Fees

MF Info Xchange facilitates and centralizes the delivery and receipt of time-critical notifications, including corporate actions, service disruptions, large trade notifications and other critical alerts. The service was launched on November 30, 2018 with 3 event types.[7] Given the limited number of event types available for event notifications upon the launch of MF Info Xchange, NSCC did not charge fees initially for the use of the service.[8] NSCC indicated that it would file with the Commission an appropriate rule change proposal to implement any fees for MF Info Xchange if NSCC added fees for the service.[9] Fund Members are typically funds or asset managers of funds and use MF Info Xchange to send notifications regarding the funds to their distribution partners. NSCC Members that are not Fund Members are typically broker/dealers or other distributors that use MF Info Xchange to receive and track such notifications sent by the Fund Members as well as send notifications to Fund Members about their funds.

Since the launch, MF Info Xchange has been enhanced with an additional 25 event types and additional user interface capabilities. NSCC believes that it is appropriate to begin charging fees for the service given the added capabilities and in order to offset the costs of building and maintaining the service.

NSCC is proposing to implement a two-tiered billing structure for MF Info Xchange based on the anticipated amount of use of the service by NSCC Members.[10] Based on a review of the usage by NSCC Members, NSCC believes that NSCC Members that are not Fund Members and larger Fund Members use the service more than smaller Fund Members. NSCC believes that the number of Security Issue IDs that a Fund Member maintains on Fund/SERV® is a good indication of the size of the Fund Member and the level of usage of MF Info Xchange by such Fund Member. Most notifications in MF Info Xchange relate to a specific security issuance and each Security Issue ID represents a security issuance. Therefore, Fund Members that maintain more Security Issue IDs, will have a greater number of security issuances for which notifications will need to be sent. NSCC Members that are not Fund Members typically receive notifications from multiple Fund Members and often benefit from receiving notifications for a large number of security issuances.

Fund/SERV is an NSCC service providing for the processing and settling of Fund/SERV Eligible Funds.[11] Each Fund/SERV Eligible Fund that is processed through Fund/SERV is required to be assigned a Security Issue ID, such as a CUSIP.[12] NSCC is proposing to charge NSCC Members that are not Fund Members that use MF Info Xchange and Fund Members that maintain more than 25 Security Issue IDs on Fund/SERV that use MF Info Xchange, $1,500 per month (''Tier 1''). NSCC is proposing to charge Fund Members that maintain 25 or fewer Security Issue IDs on Fund/SERV that use MF Info Xchange $250 per month (''Tier 2'').

NSCC believes that the tiered structure will align the fees with the costs of services provided by NSCC by setting the fees so that the revenue received by NSCC would be sufficient to recover the costs of building and maintaining the service. The tiered billing structure is similar to NSCC's billing structure for its Mutual Fund Profile Service (''MFPS''). Users of MFPS that use Phases I & II[13] that have greater than 25 Security Issue IDs in MFPS pay $1,250.00 per month whereas users that have 25 or fewer Security Issue IDs registered in MFPS that use Phases I & II pay $250.00 per month.[14] Based on its experience with MFPS[15] and discussions with Fund Members, NSCC believes that the threshold of greater than 25 Security Issue IDs has been a good estimation of the size of the Fund Member and the amount of use of the service by each Fund Member. Also based on pricing levels and usage in MFPS and discussions with NSCC Members, NSCC believes that the $1,500 and $250 pricing levels are sufficient to recover the costs of building and maintaining the service without being so excessive as to materially disincentivize use of MF Info Xchange.

[6] NSCC has in place procedures to control costs and to regularly review pricing levels against costs of operation. NSCC's fees are cost-based plus a markup as approved by its Board of Directors. This markup is applied to recover development costs and operating expenses, and to accumulate capital sufficient to meet regulatory and economic requirements. *See* NSCC Disclosure Framework for Covered Clearing Agencies and Financial Market Infrastructures, available at *https://www.dtcc.com/-/media/Files/Downloads/legal/policy-and-compliance/NSCC_Disclosure_Framework.pdf,* at 120.

[7] *See* Securities Exchange Act Release No. 84611 (November 16, 2018), 83 FR 59427 (November 23, 2018) (SR–NSCC–2018–010). The initial 3 event types were Fund Merger, Fund Closure—Hard Close and Fund Closure—Soft Close.

[8] *Id.*

[9] *Id.*

[10] For purposes of this filing, NSCC Members refers to Members and Limited Members.

[11] Fund/SERV Eligible Fund means a fund or other pooled investment entity which are subject of orders processed through Mutual Fund Services. *See* definition of ''Fund/SERV Eligible Fund, Rule 1, *supra* note 5 and Section 1(c) of Rule 3, *supra* note 5.

[12] *See* Section 1(c) of Rule 3, *supra* note 5, which requires that unless otherwise required by NSCC, each Fund/SERV Eligible Fund be assigned a CUSIP number. CUSIP is a registered trademark of the American Bankers Association.

[13] Phases I & II are also known as MFPS I (Daily Price and Rate File) and MFPS II (Security Issue Database and Distribution Database). The terms Phase I and Phase II are used in the Rules because MFPS I and MFPS II were implemented in phases with MFPS I implemented first in 1996 and MFPS II implemented in 1999. *See* Securities Exchange Act Release No. 37171 (May 8, 1996), 61 FR 24344 (May 14, 1996) (SR–NSCC–96–04) (order approving MFPS I implementation) and Securities Exchange Act Release No. 40614 (October 28, 1998), 63 FR 59615 (November 4, 1998) (SR–NSCC–98–09) (notice of filing of rule change implementing MFPS II).

[14] Section IV.J.b. of Addendum A and accompanying footnote 5 in Addendum A, *supra* note 5. *See also* Securities Exchange Act Release No. 61413 (January 25, 2010), 75 FR 4894 (January 29, 2010) (SR–NSCC–2009–12) (NSCC introduced the credit for MFPS for smaller fund families that had 25 or fewer funds in their fund family) and Securities Exchange Act Release No. 84771 (December 10, 2018), 83 FR 64393 (December 14, 2018) (SR–NSCC–2018–012) (NSCC reduced the fees in MFPS to current levels) (''2018 Filing'').

[15] After NSCC lowered its fees in 2019 for funds with 25 or fewer Security IDs on MFPS from $850 to $250, the number of such funds using MFPS has doubled. *See* 2018 Filing, *Id.*

(ii) AIP Fee Changes

AIP is a standardized, trading and reporting platform that links the alternative investments industry to securely and efficiently exchange data and money relating to alternative investment products, including hedge funds, funds of funds, private equity, non-traded real estate investment trusts, managed futures and limited partnerships. NSCC has undertaken a strategic review of its pricing structure for AIP, and developed a revenue and pricing strategy with the goal of aligning the pricing of AIP with costs of providing the service. As a result of the review, NSCC has determined that certain fees in AIP have, over time, become misaligned with the costs of service as a result of increased technology run costs relating to the service. NSCC would also like to lower certain fees relating to capital calls and lower volume transfers [16] to incentivize greater use of those products. In connection with the realignment, NSCC is proposing to eliminate a cap of $250,000 currently in place for AIP Distributors. Currently, there are certain products for which a $250,000 fee cap applies for AIP Distributors.[17] Once an AIP Distributor has been charged $250,000 for transactions relating to such products in a calendar year, it will not pay with respect to transactions in those products for the remainder of the calendar year.[18] The fee cap was put in place to incentivize greater use of AIP with respect to certain products for AIP Distributors.[19]

NSCC believes that the fee cap has been successful in incentivizing AIP Distributors to use AIP and to require more of their fund counterparties (*i.e.,* AIP Manufacturers) to use AIP.[20] Given the growth of AIP and to readjust the overall revenues, NSCC no longer believes that the fee cap is necessary as an incentive or appropriate given AIP's operating margin.

NSCC is also proposing to increase lower volume record transaction fees for AIP Manufacturers from $1 to $2 (AIP Distributors will continue to pay $1) in order to better align revenues of AIP with the costs of providing the services.

NSCC is proposing to lower fees relating to capital calls to incentivize use of AIP with respect to capital calls. Capital calls are considered ''Trades'' in the Rules and higher volume Trades are currently priced at a range from $5 per trade to $4 per trade depending on the number of trades in each calendar year [21] and lower volume Trades are $10 per trade.[22] In addition to capital calls, Trades include initial purchases, subsequent purchases, partial redemption requests, full redemption requests and commitments. NSCC has received feedback from AIP Members indicating that capital calls are performed more frequently than other types of Trades and as a result, AIP Members have not been using AIP for capital calls because the AIP Members believe the price is currently too high for both higher volume products and lower volume products with respect to capital calls. As a result, NSCC is proposing to reduce the price for all capital calls to $2 to incentivize use of AIP for capital calls. This reduction would apply to capital calls with respect to higher volume products and lower volume products.

NSCC is also proposing to lower fees relating to lower volume transfers to incentivize use of AIP with respect to lower volume transfers. NSCC has received feedback from AIP Members that lower volume transfers are also priced too high and as a result AIP Members have not been using AIP for lower volume transfers. NSCC is proposing to reduce lower volume transfers from $5 to $2 in order to incentivize use of AIP for lower volume transfers.

(iii) Clarification Changes

NSCC is also proposing to add a heading for Mutual Fund Services in Addendum A and renumber the headings in Addendum A to reflect that a number of services listed in Addendum A fall within Mutual Fund Services. NSCC would also renumber other sections of Addendum A to reflect the renumbering for Mutual Fund Services.

(iv) Proposed Rule Changes

A. MF Info Xchange Fees

NSCC is proposing to add the fees to MF Info Xchange in new proposed section IV.G.5 of Addendum A.

B. AIP Fee Changes

NSCC is proposing to state that all capital calls are $2 per trade in new proposed Section IV.L.1.c (for higher volume capital calls) and new proposed Section IV.L.2.c (for lower volume capital calls) of Addendum A. NSCC would add ''(other than capital calls)'' in proposed sections IV.L.1.b. and IV.L.2.b. of Addendum A to reflect that capital calls would be separately covered in other sections. NSCC is proposing to increase the lower volume record transactions fees for AIP Manufacturers in new proposed section IV.L.2.a. of Addendum A from $1 dollar per trade to $2 dollar per trade. NSCC is also proposing to reduce lower volume transfers from $5 to $2 in new proposed Section IV.L.2.d. of Addendum A. NSCC is proposing to remove the $250,000 fee cap for AIP Distributors in new proposed Section IV.L.3. and to remove the accompanying footnote 12 of Addendum A.

Based on feedback from NSCC Members and a review of other pricing levels, NSCC believes that:

- Reducing fees to $2 for all capital calls and reducing lower volume transfers to $2 would incentivize NSCC Members to begin using AIP with respect to capital calls and with respect to lower volume transfers
- increasing the lower volume record transaction fees from $1 to $2 and removing the fee cap for AIP Distributors would raise revenue to an appropriate level to help ensure that AIP operates with a positive operating margin without being so excessive as to materially disincentivize the use of AIP for lower volume record transactions or the use of AIP by AIP Distributors

C. Clarification Changes

NSCC is proposing to add a heading ''Mutual Fund Services'' in Section IV.G. of Addendum A and proposing to renumber Mutual Fund Services under that heading to reflect the services that fall within Mutual Fund Services. NSCC is also proposing to renumber sections following Section IV.G. to reflect the renumbering within Section IV.G. of Addendum A.

(iii) Expected Member/NSCC Impact

A. MF Info Xchange Fees

The fee changes for MF Info Xchange would impact all users of the service.

[16] AIP has a tiered billing system based on whether services are being used for higher volume products or lower volume products. *See* Section L.O.3 of Addendum A, *supra* note 5, which indicates which products are considered higher volume and which are considered lower volume. Fees are lower with respect to higher volume products.

[17] *See* Section IV.O.3. of Addendum A and accompanying footnote 12 of Addendum A, *supra* note 5.

[18] *Id.*

[19] *See* Securities Exchange Act Release No. 63634 (January 3, 2011), 76 FR 1475 (January 10, 2011) (SR–NSCC–2010–19) (stating that the fee cap was implemented to ''encourage broker-dealers to use the service and expand coverage of these products and increase the value of the overall market'').

[20] For instance, since the fee cap was put in place in 2010, the number of Eligible AIP Products on the AIP platform has grown from under 500 to over 7000.

[21] Section IV.O.1.ii of Addendum A, *supra* note 5.

[22] Section IV.O.2.ii of Addendum A, *supra* note 5.

Based on a review of users in the first quarter of 2021, it is anticipated that initially approximately 67% of the users will fall within Tier 1 and be charged $1,500 per month and approximately 33% of the users will fall within Tier 2 and be charged $250 per month. Of the users in Tier 1, approximately 67% are expected to be Fund Members that maintain more than 25 Security Issue IDs and approximately 33% are expected to be NSCC Members that are not Fund Members.

The fees are intended to cover the costs of developing and maintaining MF Info Xchange in accordance with NSCC's cost-based plus markup fee model.[23] Following the implementation of fees, assuming revenues and expenses remain constant,[24] NSCC anticipates recouping the costs of building MF Info Xchange within approximately three years of implementing the fees and expects to have a positive operating margin thereafter.

B. AIP Fee Changes

In general, NSCC anticipates that, as result of the proposed changes to remove the $250,000 fee cap, four AIP Distributors will see a fee increase for use of the affected products. Based on a review of client invoices in June 2021, which NSCC believes is representative of typical AIP usage, NSCC anticipates that as a result of all of the fee changes approximately 59% of AIP users comprised of mainly AIP Manufacturers engaging in lower volume activity will see a fee increase, approximately 40% of AIP users comprised of mainly AIP users engaging in higher volume activity will see no fee impact and less than 1% of AIP users will see a fee decrease.

The fee changes are intended to realign AIPs revenue with its costs. AIP had a negative operating margin in 2020 and it is anticipated to have a negative operating margin in 2021. Following the fee changes, AIP anticipates that it will have a positive operating margin in 2022 and going forward, consistent with NSCC's cost-based plus markup fee model.[25]

(iv) Implementation Timeline

NSCC expects to implement the proposed rule changes on January 1, 2022. As proposed, a legend would be added to Addendum A stating there are changes that became effective upon filing with the Commission but have not yet been implemented. The proposed legend also would include January 1, 2022, as the date on which such changes would be implemented and the file number of this proposal, and state that, once this proposal is implemented, the legend would automatically be removed from Addendum A.

2. Statutory Basis

NSCC believes this proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. Specifically, NSCC believes this proposal is consistent with Sections 17A(b)(3)(D)[26] and 17A(b)(3)(F)[27] of the Act and Rule 17Ad–22(e)(23)(ii),[28] as promulgated under the Act, for the reasons described below.

Section 17A(b)(3)(D) of the Act[29] requires, in part, that the Rules provide for the equitable allocation of reasonable dues, fees, and other charges among its participants. The proposed fee changes set forth above are consistent with 17A(b)(3)(D) of the Act[30] because the proposed fees would be allocated equitably among the NSCC Members that subscribe for those services based on each NSCC Member's use of such services. In addition, NSCC believes that the proposed fee changes are reasonable because they would enable NSCC to better align its revenue with the costs and expenses required for NSCC to provide the services to NSCC Members consistent with NSCC's cost-based plus markup fee model.[31] Specifically, NSCC has determined that assuming revenue and expenses remain constant,[32] adding the fee for MF Info Xchange would allow NSCC to recoup the investments it has made in building the service within approximately three years and allow it to operate with a positive operating margin going forward. Based on the current usage and projected revenue for AIP, the realignment of fees would result in overall revenue that would be closer to the costs of providing the service and at the same time provide incentives for users to use AIP for capital calls and lower volume transfers. Therefore, by establishing fees that align with the costs of delivery of these products and services and allocating those fees equitably among the subscribing NSCC Members, the proposed fee changes are consistent with the requirements of Section 17A(b)(3)(D) of the Act.[33]

Section 17A(b)(3)(F) of the Act[34] requires, in part, that the Rules promote the prompt and accurate clearance and settlement of securities transactions. NSCC believes that the proposed clarifications adding the Mutual Fund Services heading in Addendum A and renumbering Addendum A as forth above would enhance NSCC Members' ability to understand the fees associated with Mutual Fund Services. Specifically, the proposed clarifications would clarify which services fall within Mutual Fund Services, similar to the structure for Insurance & Retirement Services and AIP in Addendum A. As such, the proposed clarifications would allow NSCC Members to have a better understanding of the Rules in relation to their activities and thereby assist in promoting the requirements of Section 17A(b)(3)(F) of the Act.[35]

Rule 17Ad–22(e)(23)(ii) under the Act[36] requires NSCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency. The proposed clarifications adding the Mutual Fund Services heading in Addendum A and renumbering Addendum A as set forth above would help ensure that the fees set forth in Addendum A are clear and transparent to NSCC Members. Having a clear and transparent Addendum A would help NSCC Members to better understand NSCC's fees and help provide NSCC Members with increased predictability and certainty regarding the fees they incur in participating in NSCC. As such, by improving the clarity and transparency of the Rules, NSCC believes the proposed clarifications are consistent with Rule 17Ad–22(e)(23)(ii) under the Act.[37]

(B) Clearing Agency's Statement on Burden on Competition

NSCC believes the proposed rule changes to add fees for MF Info Xchange

[23] *See* note 6, *supra.*

[24] It is not certain that revenues and expenses will remain constant. Costs of providing the service may change, for instance, if NSCC Members request service enhancements or NSCC's technology costs change. In addition, revenues may change depending on the number of users of the service. NSCC regularly reviews pricing levels against costs of operation. As with its other services, if NSCC determines that its operating margin is too high or too low, NSCC would change pricing levels accordingly. *See* 2018 Filing, *supra* note 14.

[25] *Id.*

[26] 15 U.S.C. 78q–1(b)(3)(D).

[27] 15 U.S.C. 78q–1(b)(3)(F).

[28] 17 CFR 240.17Ad–22(e)(23)(ii).

[29] 15 U.S.C. 78q–1(b)(3)(D).

[30] *Id.*

[31] *See* note 6, *supra.*

[32] *See* note 24, *supra.*

[33] 15 U.S.C. 78q–1(b)(3)(D).

[34] 15 U.S.C. 78q–1(b)(3)(F).

[35] *Id.*

[36] 17 CFR 240.17Ad–22(e)(23)(ii).

[37] *Id.*

and increase certain fees for AIP, may have an impact on competition. NSCC believes these proposed rule changes could burden competition by negatively affecting such NSCC Members' operating costs. While these NSCC Members may experience increases in their fees when compared to their fees under the current fee structure, NSCC does not believe such change in fees would in and of itself mean that the burden on competition is significant. This is because even though the amount of the fee increase may seem significant in some instances to certain NSCC Members (*e.g.,* charging $1,500/mo for MF Info Xchange when it is free now and removing the AIP $250,000 fee cap), NSCC believes the increase in fees would similarly affect all NSCC Members that utilize the services, and therefore the burden on competition would not be significant.

Regardless of whether the burden on competition is deemed significant, NSCC believes any burden on competition that is created by these proposed rule changes would be necessary and appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.[38]

The proposed rule changes to add fees for MF Info Xchange and increase certain fees for AIP would be necessary in furtherance of the purposes of the Act because the Rules must provide for the equitable allocation of reasonable dues, fees, and other charges among its participants.[39] As described above, NSCC believes that the proposed rule changes would result in fees that are equitably allocated (by applying uniformly to all NSCC Members that use the applicable services) and would result in reasonable fees (by allowing NSCC to recoup its expenses in building MF Info Xchange and allow both MF Info Xchange and AIP to operate with a positive operating margin). As such, NSCC believes these proposed rule changes would be necessary in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.[40]

NSCC also believes that the fees are appropriate in furtherance of the purposes of the Act because the fees are set so that the revenue received by NSCC would be closer to the costs of building and providing the services consistent with NSCC's cost-based plus markup fee model and are being equitably allocated among NSCC Members.[41] Moreover, NSCC believes that the fees will enable NSCC to pay for building and continue to operate MF Info Xchange. NSCC believes MF Info Xchange has a positive effect on competition among users because the service allows data providers to more effectively communicate event notifications relating to funds and other pooled investment entities (''Funds''). The service provides data providers with a more efficient method of distributing event notifications to parties that need to see such information in order to facilitate the trading and processing of Fund securities. NSCC believes this enhances competition among Funds and Fund participants by allowing parties to distribute such information more quickly and in a more streamlined manner. Based on experiences with the similar billing structure used in MFPS and discussions with NSCC Members, NSCC does not believe that that the addition of the proposed fees for MF Info Xchange would materially disincentivize use of MF Info Xchange. As such, NSCC believes these proposed rule changes would be appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.[42]

NSCC does not believe that any proposed fee reductions would have a burden on competition and may promote competition because the proposed fee reductions would allow NSCC Members to engage in a greater number of transactions with lower costs than the prices they would incur today for the same transactions.

NSCC does not believe that the proposed clarifications to add the Mutual Fund Services heading to Addendum A and to renumber Addendum A would have any impact on competition because such changes are clarifications of the Rules that would not affect the rights or obligations of NSCC Members.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has conducted ongoing outreach to NSCC Members in order to provide them with notice of the proposed changes to the affected fees.

NSCC has not received or solicited any written comments relating to this proposal. If any written comments are received by NSCC, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, available at *https://www.sec.gov/regulatory-actions/how-to-submit-comments.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

NSCC reserves the right not to respond to any comments received.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)[43] of the Act and paragraph (f)[44] of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NSCC–2021–017 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[38] 15 U.S.C. 78q–1(b)(3)(I).

[39] 15 U.S.C. 78q–1(b)(3)(D).

[40] 15 U.S.C. 78q–1(b)(3)(I).

[41] See note 6, *supra.*

[42] 15 U.S.C. 78q–1(b)(3)(I).

[43] 15 U.S.C 78s(b)(3)(A).

[44] 17 CFR 240.19b–4(f).

Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–NSCC–2021–017. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of NSCC and on DTCC's website (*https://dtcc.com/legal/sec-rule-filings.aspx*). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSCC–2021–017 and should be submitted on or before January 26, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[45]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–28518 Filed 1–4–22; 8:45 am]

BILLING CODE 8011–01–P

[45] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93880; File No. SR–ICEEU–2021–015]

Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Adoption of the Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures

December 30, 2021.

I. Introduction

On November 15, 2021, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4,[2] a proposed rule change to adopt a new Counterparty Credit Risk Policy (the ''CC Risk Policy'') and new Counterparty Credit Risk Procedures (the ''CC Risk Procedures'') and retire the existing Futures and Options Capital to Margin and Shortfall Margin Policy (the ''Capital to Margin Policy'') and existing Unsecured Credit Limits Procedures.[3] The proposed rule change was published for comment in the **Federal Register** on November 30, 2021.[4] The Commission did not receive comments regarding the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

i. Background

Both the CC Risk Policy and CC Risk Procedures would describe how ICE Clear Europe monitors and mitigates counterparty credit risk.[5] Both documents would define counterparty credit risk as (i) the risk that a Clearing Member misses its next payment to ICE Clear Europe, leaving ICE Clear Europe under-collateralized and therefore increasing the risk of using the Guaranty Fund contributions of other Clearing Members and ICE Clear Europe to manage a potential default of that Clearing Member and (ii) the risk that a Financial Service Provider (''FSP'') defaults without returning cash to ICE Clear Europe, leaving ICE Clear Europe with a loss on its investments or expected return of cash. Both the CC Risk Policy and CC Risk Procedures also would define ICE Clear Europe's overall objective with respect to counterparty credit risk as managing and minimizing this risk.

To achieve this objective, ICE Clear Europe, under both the CC Risk Policy and CC Risk Procedures, would (i) set and monitor credit eligibility criteria for Clearing Members and FSPs; (ii) establish credit scores for Clearing Members and FSPs; (iii) take mitigating actions to reduce ICE Clear Europe's exposure; (iv) perform trigger-based and periodic risk reviews of Clearing Members and FSPs; and (v) set and monitor exposure limits for Clearing Members and FSPs. The CC Risk Policy would explain in general how ICE Clear Europe would carry out these actions, and the CC Risk Procedures would supplement the CC Risk Policy with further detail regarding these actions. Thus, the description below is organized according to these five steps, with an explanation of those actions under both the CC Risk Policy and CC Risk Procedures.[6]

ii. Credit Eligibility Criteria

ICE Clear Europe would first assess prospective entities against certain credit eligibility criteria. The criteria that ICE Clear Europe would use for this assessment would be set forth in a new Counterparty Credit Risk Parameters and Reviews document, which would be a supporting document of the CC Risk Policy and CC Risk Procedures.[7] Overall, ICE Clear Europe would use this assessment against the credit criteria to assess the financial stability of Clearing Members and FSPs. ICE Clear Europe would assess prospective Clearing Members and FSPs against such criteria during onboarding and review existing Clearing Members and FSPs against such criteria at least annually.

After conducting the assessment, ICE Clear Europe would produce a credit recommendation for prospective Clearing Members based on financial

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Because the CC Risk Policy and CC Risk Procedures would incorporate the information currently found in the Capital to Margin Policy and Unsecured Credit Limits Procedures in substantially the same form, the proposed rule change would retire those two documents.

[4] Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to Amendments to the Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures, Exchange Act Release No. 93668 (Nov. 24, 2021); 86 FR 68014 (Nov. 30, 2021) (SR–ICEEU–2021–015) (''Notice'').

[5] Capitalized terms not otherwise defined herein have the meanings assigned to them in the CC Risk Policy and CC Risk Procedures.

[6] As noted further below, ICE Clear Europe is taking the processes described in section vi from the existing Capital to Margin Policy and Unsecured Credit Limits Procedures.

[7] ICE Clear Europe included the Counterparty Credit Risk Parameters and Reviews document as a confidential Exhibit 3 to the filing.

and qualitative information. For prospective FSPs, ICE Clear Europe would confirm that they are legal entities in approved jurisdictions and comply with the eligibility criteria and unsecured credit limits set forth in the Counterparty Credit Risk Parameters and Reviews document. Moreover, based on the assessment, ICE Clear Europe may disapprove a prospective Clearing Member or FSP or subject it to additional monitoring and potentially mitigating actions, such as requiring Clearing Members to provide a buffer margin and reducing or eliminating usage of a particular FSP.

iii. Credit Scores

In addition to this assessment against initial credit eligibility criteria, on a daily basis ICE Clear Europe would monitor Clearing Members and FSPs using its Counterparty Rating System (''CRS''). The CRS would calculate a credit score that represents a counterparty's credit quality. For FSPs, this credit score could take into account external ratings and ICE Clear Europe's exposure limits. ICE Clear Europe would use this credit score, along with its exposure to that counterparty, to identify Clearing Members and FSPs that have questionable financial standing, show signs of financial weakness, or are likely to default. ICE Clear Europe would calculate credit scores daily for all counterparties.

For each counterparty, the CRS would incorporate quantitative financial information, such as capitalization and leverage, and qualitative operational and conduct information, such as regulatory violations and pending litigation. ICE Clear Europe would analyze any material changes in a CRS score and would update the CRS at least quarterly with the latest financial statements from each counterparty.

iv. Mitigating Actions

ICE Clear Europe would rank Clearing Members by their CRS score in order to identify those with lower relative credit quality that may require further examination to determine whether additional actions are necessary to mitigate credit risk. ICE Clear Europe could place those Clearing Members and FSPs with the weakest CRS scores on a list of counterparties for further review and mitigating action known as the Watch List. If ICE Clear Europe placed any entity within a Clearing Member Family (meaning all of the Clearing Members that are linked by a common ownership that has a controlling stake in the entities) on the Watch List, then all members of that Clearing Member Family could also be added to the Watch List. ICE Clear Europe would be able remove counterparties from the Watch List if (i) their CRS score improves to a stronger classification or the reason for incorporation into the Watch List has ceased or (ii) their credit risk has been sufficiently mitigated. The Counterparty Credit Risk Parameters and Reviews document would set out the ICE Clear Europe personnel responsible for monitoring the Watch List and the reviews needed to place or not place counterparties on the Watch List and to remove counterparties from the Watch List.

If ICE Clear Europe added a Clearing Member or FSP to the Watch List, ICE Clear Europe would monitor the counterparty more closely and could take mitigating actions to reduce its exposure to the counterparty. These actions would depend on the size of the exposure and the circumstances and could include, among others: (i) Additional monitoring; (ii) requiring Clearing Members to post additional collateral to meet a buffer margin requirement; (iii) requiring Clearing Members to post different forms of collateral; (iv) requiring Clearing Members to reduce positions; (v) requiring Clearing Members to improve their capital position (such as by implementing a parental guarantee); (vi) lowering the materiality threshold for intra-day margin calls; and (vii) and reducing or removing ICE Clear Europe's usage of an FSP. As would be set out in the Counterparty Credit Risk Parameters and Reviews document, ICE Clear Europe's Head of Clearing Risk and Chief Risk Officer would determine which risk-mitigating actions to take for counterparties on the Watch List.

v. Trigger-Based and Periodic Risk Reviews

ICE Clear Europe would engage in continuous monitoring of Clearing Members and FSPs as well as additional trigger-based reviews. ICE Clear Europe would continuously monitor all Clearing Members and FSPs daily through the CRS credit scores, the Watch List, and exposure limits (as described below). In turn, ICE Clear Europe personnel and committees would review the CRS scores, the Watch List, and exposure limits as set out in the Counterparty Credit Risk Parameters and Reviews document.

In addition to continuous monitoring, ICE Clear Europe would review a Clearing Member or FSP when (i) it is added to the Watch List or (ii) there are concerns about its stability. Such a review could cover data and recent relevant news and an assessment of the incident and its impact. The depth of the review would depend on the circumstances and exposures.

While conducting these trigger-based reviews of higher risk counterparties, ICE Clear Europe also would periodically review lower risk counterparties that do not meet these triggers. Ultimately, the CC Risk Policy would require that ICE Clear Europe review all counterparties at least once every five years, and the CC Risk Procedures would require that ICE Clear Europe review all Clearing Members at least once every four years. ICE Clear Europe would tailor the reviews to the relationship and obligation of the counterparty, and reviews would cover such matters as capital metrics, credit scores, financials, business description, ownership structure, and risks to ICE Clear Europe.

vi. Exposure Limits

Clearing Members

ICE Clear Europe would monitor its uncollateralized exposure to each Clearing Member, assuming the Clearing Member were to default, at least daily against exposure limits. ICE Clear Europe would use a Clearing Member's Uncollateralised Stress Loss (''USL'') as a proxy for the exposures. ICE Clear Europe would set an exposure limit in relation to USL as a percentage of a Clearing Member's capital, subject to a minimum amount. Where exposure to a CM exceeds the exposure limit, ICE Clear Europe could (i) require additional buffer margin, (ii) require the Clearing Member to reduce positions leading to a reduction in their initial margin, or (iii) require the Clearing Member to increase its capital or implement a parental guarantee or subordinated debt to increase the exposure limit. The Counterparty Credit Risk Parameters and Reviews document would set forth the percentages of capital for the exposure limit, the minimum amount, types of eligible capital, the frequencies of review, and the approvals needed to change those values.

In addition to monitoring a Clearing Member's USL, ICE Clear Europe also would monitor a Clearing Member's initial margin relative to its capital at least daily against threshold limits. ICE Clear Europe, for each Clearing Member and on each business day, would monitor whether the size of a Clearing Member's positions are large relative to the Clearing Member by monitoring the ratio of its total margin to its capital (known as the margin to capital ratio). When a Clearing Member's margin to capital ratio is above a certain threshold, ICE Clear Europe would investigate the breach to understand its cause. If the

margin to capital ratio over a set period of time is above the threshold, then ICE Clear Europe would take mitigating actions including (i) enhanced monitoring of the Clearing Member to assess whether the increased ratio is temporary, (ii) requiring the Clearing Member to reduce positions leading to a reduction in its initial margin, and (iii) requiring the Clearing Member to increase its capital or implement a parental guarantee or subordinated debt to increase the exposure limit. The Counterparty Credit Risk Parameters and Reviews document would set forth the threshold, the period of time, and the frequency of reviews. This aspect of the CC Risk Policy and CC Risk Procedures would replace provisions of the Capital to Margin Policy, which would be retired.[8] Consistent with current practice, ICE Clear Europe would monitor the capital to margin ratio of Clearing Members in both ICE Clear Europe's CDS clearing service and ICE Clear Europe's Futures and Options clearing service.[9] With respect to Futures and Options Clearing Members, however, ICE Clear Europe would eliminate the use of two separate ratios based on house and customer margin, respectively, and would instead use a single combined margin ratio, which ICE Clear Europe believes is more representative of the overall risk.[10]

ICE Clear Europe also would monitor certain clients of Clearing Members. For a client that is not an affiliate of a Clearing Member, ICE Clear Europe would monitor the client against the Tiering Concentration Indicator, to consider whether default of the client could cause default of the Clearing Member. The Counterparty Credit Risk Parameters and Reviews document would set forth the Tiering Concentration Indicator, the frequency of reviews, and approvers.

Finally, ICE Clear Europe could also set a limit for collateral posted by Clearing Members, which would be further described in the Counterparty Credit Risk Parameters and Reviews document. With respect to issuers of collateral, the ICE Clear Europe could set an overall limit with sub-limits for CM collateral, Treasury (reverse repo and other collateral), and Finance (investment of ICE Clear Europe's own capital and Skin-in-the-Game). The overall limit would equal the sum of the sub-limits and could be borrowed between departments.

FSPs

Through its investment program, ICE Clear Europe aims to secure the cash that Clearing Members have transferred to ICE Clear Europe to cover margin and Guaranty Fund contributions. Given that, ICE Clear Europe's exposure to an FSP is primarily from leaving cash with that FSP unsecured overnight.[11] Thus, ICE Clear Europe would measure its exposure to an FSP in terms of time deposits and other cash deposits provided to a FSP that ICE Clear Europe can lose in the event of the FSP defaulting. ICE Clear Europe would set a maximum value on such exposure which would be the overall Unsecured Credit Limit for that FSP.

ICE Clear Europe would allocate and monitor Unsecured Credit Limits with respect to FSPs, based on a percentage of the FSP's capital, with a minimum and maximum total limit. ICE Clear Europe would reduce an FSP's limit by other exposures ICE Clear Europe may have to the FSP, such as the USL if the FSP is also a Clearing Member. The CC Risk Procedures would set out roles and responsibilities for ICE Clear Europe's Credit and Treasury teams in assessing FSPs and applying the limits, which would be the same as under the current Unsecured Credit Limits Procedures. Moreover, the Counterparty Credit Risk Parameters and Reviews document would set forth other information pertinent to these limits, such as the types of eligible capital, percentage of capital for the limits, the reverse repo exposure percentage, and the maximum and minimum values. The Counterparty Credit Risk Parameters and Reviews document also would set forth the reviewers, frequency of review, and the approvals needed to change those values.

Where exposure to an FSP breaches the limit, ICE Clear Europe's mitigating responses could include allocating unsecured cash to different FSPs, securing the cash exposure, and escalating material breaches.

Finally, an FSP would have to meet certain minimum requirements set out in the CC Risk Procedures. For example, the FSP would need to be regulated by a competent authority with valid jurisdiction and satisfy the credit eligibility criteria discussed above. Moreover, FSPs that are Committed Repo providers must be Legal Entities registered in the United States, the United Kingdom, or in countries in the European Union that satisfy the Minimum External Rating, and ICE Clear Europe would give preference to FSPs with direct access to central bank lending facilities for the currency of issue.

These provisions of the CC Risk Policy and CC Risk Procedures would replace, but not change the substance of, provisions of the existing Unsecured Credit Limits Procedures.

vii. Document Governance and Exception Handling

In addition to the steps that ICE Clear Europe would take to monitor and mitigate counterparty credit risk, both the CC Risk Policy and the CC Risk Procedures would describe ICE Clear Europe's procedures for governance of, and exceptions to, both documents. This document governance and exception handling section would be similar to those of other ICE Clear Europe policies and would be the same under both the CC Risk Policy and the CC Risk Procedures.[12] Specifically, the document owner would be responsible for maintaining up-to-date documents and reviewing documents in accordance with ICE Clear Europe's governance processes. The document owner would be required to report material breaches or unapproved deviations to the Head of

[8] Certain other provisions of the Capital to Margin Policy relating to shortfall margin are already part of ICE Clear Europe's existing Futures and Options Risk Procedures. ICE Clear Europe would retain those provisions relating to shortfall margin in the Futures and Options Risk Procedures but would not make any changes to the Futures and Options Risk Procedures. Notice, 86 FR 68015. ICE Clear Europe last filed amendments to the Futures and Options Risk Procedures with the Commission in filing 2021–007. *See* Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Futures and Options Risk Policy and Futures and Options Risk Procedures and Retirement of the Futures and Options Concentration Charge Policy, Exchange Act Release No. 91290 (Mar. 10, 2021); 86 FR 14478 (Mar. 16, 2021) (SR–ICEEU–2021–007).

[9] Notice, 86 FR 68015.

[10] Notice, 86 FR 68015.

[11] ICE Clear Europe would assume deposits left with central banks to be secured.

[12] *See, e.g.,* Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Futures and Options Stress Testing Policy and the Adoption of the Futures and Options Stress Testing Methodology Document, Exchange Act Release No. 89621 (Aug. 20, 2020); 85 FR 52650 (Aug. 26, 2020) (SR–ICEEU–2020–008); Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Partial Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Partial Amendment No. 1, Relating to the ICE Clear Europe Investment Management Procedures and Treasury and Banking Services Policy, Exchange Act Release No. 89211 (July 1, 2020); 85 FR 41082 (July 8, 2020) (SR–ICEEU–2020–002); Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Partial Amendment No. 2 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Partial Amendment No. 1 and Partial Amendment No. 2, To Revise the ICE Clear Europe Treasury and Banking Services Policy, Liquidity Management Procedures, Investment Management Procedures and Unsecured Credit Limits Procedures, Exchange Act Release No. 86891 (Sept. 6, 2019); 84 FR 48191 (Sept. 12, 2019) (SR–ICEEU–2019–012).

Department, the Chief Risk Officer, and the Head of Compliance (or their delegates) who would together determine if further escalation should be made to relevant senior executives, the Board, or competent authorities. Exceptions to the CC Risk Policy and CC Risk Procedures would be approved in accordance with ICE Clear Europe's governance process for approval of changes to the documents.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act 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.[13] For the reasons discussed below, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act,[14] and Rules 17Ad–22(e)(2)(i), (e)(2)(v), (e)(3)(i), and (e)(19).[15]

i. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of ICE Clear Europe be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, as well as to assure the safeguarding of securities and funds which are in the custody or control of ICE Clear Europe or for which it is responsible.[16]

As discussed above, the CC Risk Policy and the CC Risk Procedures [17] would describe how ICE Clear Europe monitors and mitigates counterparty credit risk by (i) setting and monitoring credit eligibility criteria for Clearing Members and FSPs; (ii) establishing a credit score for each Clearing Member and FSP; (iii) taking mitigating actions to reduce ICE Clear Europe's exposure; (iv) performing trigger-based and periodic risk reviews of Clearing Members and FSPs; and (v) setting and monitoring exposure limits for Clearing Members and FSPs. The Commission believes that through these actions, ICE Clear Europe would be in a position to monitor and mitigate the risk of default by a Clearing Member or FSP. For example, the Commission believes that setting and monitoring eligibility criteria would help to ensure that all Clearing Members and FSPs have a similar baseline of financial reliability and that establishing and monitoring CRS scores for Clearing Members and FSPs would help to identify those counterparties whose financial situation may be deteriorating and posing a risk to ICE Clear Europe.

Similarly, the Commission believes that trigger-based and periodic reviews, as well as setting and monitoring exposure limits, would help ICE Clear Europe to determine counterparties who may pose an increased risk and limit its exposure to those counterparties. Finally, the Commission believes that ICE Clear Europe's mitigating actions, such as requiring a Clearing Member to post additional margin or reducing usage of an FSP, would help to reduce or eliminate its exposure to a Clearing Member or FSP, as needed in response to a change in that counterparty's credit risk.

As discussed in the CC Risk Policy and CC Risk Procedures, counterparty credit risk poses a risk to ICE Clear Europe's financial resources because default by a Clearing Member could leave ICE Clear Europe under-collateralized and default by an FSP could cause ICE Clear Europe to lose its investments or expected return of cash. The Commission believes that such losses could, in turn, threaten ICE Clear Europe's ability to operate and therefore clear and settle transactions. Thus, the Commission believes that effective management of ICE Clear Europe's counterparty credit risk could help ICE Clear Europe control risks to the financial resources needed to continue clearing and settling transactions. The Commission therefore believes that, by establishing the actions ICE Clear Europe would take to manage and mitigate counterparty credit risk, the CC Risk Policy and CC Risk Procedures would help to manage counterparty credit risk and thereby would promote the prompt and accurate clearance and settlement of securities transactions.

Moreover, the Commission believes that the minimum requirements applicable to FSPs, as well as the setting of monitoring of exposure limits with respect to FSPs would be consistent with the assurance of safeguarding of securities and funds in ICE Clear Europe's custody or control or for which it is responsible. The Commission believes that the minimum requirements would help to ensure that FSPs are financially stable and subject to competent regulation, which should help to ensure that ICE Clear Europe is able to access securities and funds placed with such FSPs.

Therefore, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act.[18]

ii. Consistency With Rules 17Ad–22(e)(2)(i), (v) Under the Act

Rule 17Ad–22(e)(2)(i) requires that ICE Clear Europe establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent.[19] As discussed above, both the CC Risk Policy and the CC Risk Procedures would establish the general governance and exceptions process for those documents, identical to the governance and exceptions process that ICE Clear Europe has established in other policies and procedures. The Commission believes that, in doing so, the CC Risk Policy and CC Risk Procedures would establish clear and transparent arrangements for ensuring that ICE Clear Europe personnel adhere to the documents and for modifying the documents as needed.

Rule 17Ad–22(e)(2)(v) requires that ICE Clear Europe establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that specify clear and direct lines of responsibility.[20] As discussed above, the CC Risk Procedures would set out roles and responsibilities for ICE Clear Europe's Credit and Treasury teams in assessing FSPs and applying limits to FSPs. The Commission believes these provisions would specify clear and

[13] 15 U.S.C. 78s(b)(2)(C).

[14] 15 U.S.C. 78q–1(b)(3)(F).

[15] 17 CFR 240.17Ad–22(e)(2)(i), (e)(2)(v), (e)(3)(i), and (e)(19).

[16] 15 U.S.C. 78q–1(b)(3)(F).

[17] As discussed above, ICE Clear Europe is importing the processes described in Section II.vi above from its existing Capital to Margin Policy and Unsecured Credit Limits Procedures. The Commission published notice of the Capital to Margin Policy in 2019. *See* Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating To Adoption of a New Futures & Options Capital-to-Margin and Shortfall Margin Policy (the ''F&O Margin Shortfall Policy''), Exchange Act Release No. 85439 (Mar. 28, 2019); 84 FR 13087 (April 3, 2019) (SR–ICEEU–2019–005). Moreover, the Commission approved the Unsecured Credit Limits Procedures in 2019. *See* Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Partial Amendment No. 2 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Partial Amendment No. 1 and Partial Amendment No. 2, To Revise the ICE Clear Europe Treasury and Banking Services Policy, Liquidity Management Procedures, Investment Management Procedures and Unsecured Credit Limits Procedures, Exchange Act Release No. 86891 (Sept. 6, 2019); 84 FR 48191 (Sept. 12, 2019) (SR–ICEEU–2019–012).

[18] 15 U.S.C. 78q–1(b)(3)(F).

[19] 17 CFR 240.17Ad–22(e)(2)(i).

[20] 17 CFR 240.17Ad–22(e)(2)(v).

direct lines of responsibility for the Credit and Treasury teams.

Therefore, the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(e)(2)(i) and (e)(2)(v).[21]

iii. Consistency With Rule 17Ad–22(e)(3)(i) Under the Act

Rule 17Ad–22(e)(3)(i) requires that ICE Clear Europe establish, implement, maintain, and enforce written policies and procedures reasonably designed to, among other things, 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 ICE Clear Europe, 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 ICE Clear Europe, that are subject to review on a specified periodic basis and approved by the board of directors annually.[22] As discussed above, the CC Risk Policy and the CC Risk Procedures would describe how ICE Clear Europe monitors and mitigates counterparty credit risk. The Commission believes that together these documents would allow ICE Clear Europe to comprehensively measure the credit risk posed by Clearing Members and FSPs through, among other things, assessing prospective Clearing Members and FSPs against certain credit eligibility criteria. The Commission further believes that CRS scores, periodic reviews, trigger-based reviews, and exposure limits would provide ICE Clear Europe a comprehensive means of monitoring the credit risk posed by Clearing Members and FSPs. Finally, the Commission believes that the mitigating actions discussed above would reduce or eliminate ICE Clear Europe's exposure to a Clearing Member or FSP, thereby helping ICE Clear Europe manage overall credit risk.

Therefore, the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(e)(3)(i).[23]

iv. Consistency With Rule 17Ad–22(e)(19) Under the Act

Rule 17Ad–22(e)(19) requires that ICE Clear Europe establish, implement, maintain, and enforce written policies and procedures reasonably designed to identify, monitor, and manage the material risks to ICE Clear Europe arising from arrangements in which firms that are indirect participants in ICE Clear Europe rely on the services provided by direct participants to access ICE Clear Europe's payment, clearing, or settlement facilities.[24] As discussed above, the CC Risk Policy and the CC Risk Procedures would require that ICE Clear Europe monitor clients of Clearing Members that are not affiliates of the Clearing Member to consider whether default of the client could cause the default of the Clearing Member. The Commission believes this would help ICE Clear Europe to monitor and manage the risks that clients, as indirect participants, could pose to Clearing Members, as direct participants in ICE Clear Europe. The Commission further believes that such client/Clearing Member arrangements could pose material risks to ICE Clear Europe through its relationships with Clearing Members.

Therefore, the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(e)(19).[25]

IV. 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(b)(3)(F) of the Act,[26] and Rules 17Ad–22(e)(2)(i), (e)(2)(v), (e)(3)(i), and (e)(19).[27]

It is therefore ordered pursuant to Section 19(b)(2) of the Act[28] that the proposed rule change (SR–ICEEU–2021–015), be, and hereby is, approved.[29]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Eduardo A. Aleman,

Deputy Secretary.

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[21] 17 CFR 240.17Ad–22(e)(2)(i) and (e)(2)(v).

[22] 17 CFR 240.17Ad–22(e)(3)(i).

[23] 17 CFR 240.17Ad–22(e)(3)(i).

[24] 17 CFR 240.17Ad–22(e)(19).

[25] 17 CFR 240.17Ad–22(e)(19).

[26] 15 U.S.C. 78q–1(b)(3)(F).

[27] 17 CFR 240.17Ad–22(e)(2)(i), (e)(2)(v), (e)(3)(i), and (e)(19).

[28] 15 U.S.C. 78s(b)(2).

[29] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93881; File No. SR–MIAX–2021–63]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

December 30, 2021.

Pursuant to the provisions of 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 December 23, 2021, Miami International Securities Exchange LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a 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 is filing a proposal to amend the MIAX Options Fee Schedule (the ''Fee Schedule'') to: (1) Extend the waiver period for certain non-transaction fees applicable to Market Makers[3] that trade solely in Proprietary Products[4] until June 30, 2022; and (2) extend the SPIKES Options Market Maker Incentive Program (the ''Incentive Program'') until March 31, 2022.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxoptions.com/rule-filings,* at MIAX's principal office, 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Market Makers'' refers to ''Lead Market Makers'', ''Primary Lead Market Makers'' and ''Registered Market Makers'' collectively. *See* Exchange Rule 100.

[4] The term ''Proprietary Product'' means a class of options that is listed exclusively on the Exchange. *See* Exchange Rule 100.

places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to: (1) Extend the waiver period for certain non-transaction fees applicable to Market Makers that trade solely in Proprietary Products until June 30, 2022; and (2) extend the Incentive Program until March 31, 2022.

Background

On October 12, 2018, the Exchange received approval from the Commission to list and trade on the Exchange, options on the SPIKES® Index, a new index that measures expected 30-day volatility of the SPDR S&P 500 ETF Trust (commonly known and referred to by its ticker symbol, ''SPY'').[5] The Exchange adopted its initial SPIKES transaction fees on February 15, 2019 and adopted a new section of the Fee Schedule—Section (1)(a)(xi), SPIKES—for those fees.[6] Options on the SPIKES Index began trading on the Exchange on February 19, 2019.

On May 31, 2019, the Exchange filed its first proposal in a series of proposals with the Commission to amend the Fee Schedule to waive certain non-transaction fees applicable to Market Makers that trade solely in Proprietary Products (including options on the SPIKES Index) beginning September 30, 2019, through December 31, 2021.[7] In particular, the Exchange adopted fee waivers for Membership Application fees, monthly Market Maker Trading Permit fees, Application Programming Interface (''API'') Testing and Certification fees for Members,[8] and monthly MIAX Express Interface (''MEI'') Port[9] fees assessed to Market Makers that trade solely in Proprietary Products (including options on SPIKES) throughout the entire period of September 30, 2019 through December 31, 2021. The Exchange now proposes to extend the waiver period for the same non-transaction fees applicable to Market Makers that trade solely in Proprietary Products (including options on SPIKES) until June 30, 2022. In particular, the Exchange proposes to waive Membership Application fees, monthly Market Maker Trading Permit fees, Member API Testing and Certification fees, and monthly MEI Port fees assessed to Market Makers that trade solely in Proprietary Products (including options on SPIKES) until June 30, 2022.

Membership Application Fees

The Exchange currently assesses Membership fees for applications of potential Members. The Exchange assesses a one-time Membership Application fee on the earlier of (i) the date the applicant is certified in the membership system, or (ii) once an application for MIAX membership is finally denied. The one-time application fee is based upon the applicant's status as either a Market Maker or an Electronic Exchange Member (''EEM'').[10] A Market Maker is assessed a one-time Membership Application fee of $3,000.

The Exchange proposes that the waiver for the one-time Membership Application fee of $3,000 for Market Makers that trade solely in Proprietary Products (including options on SPIKES) will be extended from December 31, 2021 until June 30, 2022, which the Exchange proposes to state in the Fee Schedule. The purpose of this proposed change is to continue to provide an incentive for potential Market Makers to submit membership applications, which should result in an increase of potential liquidity in Proprietary Products, including options on SPIKES. Even though the Exchange proposes to extend the waiver of this particular fee, the overall structure of the fee is outlined in the Fee Schedule so that there is general awareness that the Exchange intends to assess such a fee after June 30, 2022.

Trading Permit Fees

The Exchange issues Trading Permits that confer the ability to transact on the Exchange. MIAX Trading Permits are issued to Market Makers and EEMs. Members receiving Trading Permits during a particular calendar month are assessed monthly Trading Permit fees as set forth in the Fee Schedule. As it relates to Market Makers, MIAX currently assesses a monthly Trading Permit fee in any month the Market Maker is certified in the membership system, is credentialed to use one or more MIAX MEI Ports in the production environment and is assigned to quote in one or more classes. MIAX assesses the monthly Market Maker Trading Permit fee for its Market Makers based on the greatest number of classes listed on MIAX that the MIAX Market Maker was assigned to quote in on any given day within a calendar month and the applicable fee rate is the lesser of either the per class basis or percentage of total national average daily volume measurements. A MIAX Market Maker is assessed a monthly Trading Permit Fee according to the following table:[11]

[5] *See* Securities Exchange Act Release No. 84417 (October 12, 2018), 83 FR 52865 (October 18, 2018) (SR–MIAX–2018–14) (Order Granting Approval of a Proposed Rule Change by Miami International Securities Exchange, LLC to List and Trade on the Exchange Options on the SPIKES® Index).

[6] *See* Securities Exchange Release No. 85283 (March 11, 2019), 84 FR 9567 (March 15, 2019) (SR–MIAX–2019–11). The Exchange initially filed the proposal on February 15, 2019 (SR–MIAX–2019–04). That filing was withdrawn and replaced with SR–MIAX–2019–11. On September 30, 2020, the Exchange filed its proposal to, among other things, reorganize the Fee Schedule to adopt new Section (1)(b), Proprietary Products Exchange Fees, and moved the fees and rebates for SPIKES options into new Section (1)(b)(i). *See* Securities Exchange Act Release No. 90146 (October 9, 2020), 85 FR 65443 (October 15, 2020) (SR–MIAX–2020–32); Securities Exchange Act Release No. 90814 (December 29, 2020), 86 FR 327 (January 5, 2021) (SR–MIAX–2020–39).

[7] *See* Securities Exchange Act Release Nos. 86109 (June 14, 2019), 84 FR 28860 (June 20, 2019) (SR–MIAX–2019–28); 87282 (October 10, 2019), 84 FR 55658 (October 17, 2019) (SR–MIAX–2019–43); 87897 (January 6, 2020), 85 FR 1346 (January 10, 2020) (SR–MIAX–2019–53); 89289 (July 10, 2020), 85 FR 43279 (July 16, 2020) (SR–MIAX–2020–22); 90146 (October 9, 2020), 85 FR 65443 (October 15, 2020) (SR–MIAX–2020–32); 90814 (December 29, 2020), 86 FR 327 (January 5, 2021) (SR–MIAX–2020–39); 91498 (April 7, 2021), 86 FR 19293 (April 13, 2021) (SR–MIAX–2021–06).

[8] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[9] Full Service MEI Ports provide Market Makers with the ability to send Market Maker simple and complex quotes, eQuotes, and quote purge messages to the MIAX System. Full Service MEI Ports are also capable of receiving administrative information. Market Makers are limited to two Full Service MEI Ports per matching engine. *See* Fee Schedule, note 27.

[10] The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is not a Market Maker. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[11] *See* Fee Schedule, Section (3)(b).

Type of trading permit	Monthly MIAX Trading Permit Fee	Market Maker assignments (the lesser of the applicable measurements below) Ω	
		Per class	% of National average daily volume
Market Maker (includes RMM, LMM, PLMM).	$7,000.00	Up to 10 Classes	Up to 20% of Classes by volume.
	12,000.00	Up to 40 Classes	Up to 35% of Classes by volume.
	* 17,000.00	Up to 100 Classes	Up to 50% of Classes by volume.
	* 22,000.00	Over 100 Classes	Over 50% of Classes by volume up to all Classes listed on MIAX.

Ω Excludes Proprietary Products.

* For these Monthly MIAX Trading Permit Fee levels, if the Market Maker's total monthly executed volume during the relevant month is less than 0.060% of the total monthly executed volume reported by OCC in the market maker account type for MIAX-listed option classes for that month, then the fee will be $15,500 instead of the fee otherwise applicable to such level.

MIAX proposes that the waiver for the monthly Trading Permit fee for Market Makers that trade solely in Proprietary Products (including options on SPIKES) will be extended from December 31, 2021, to June 30, 2022, which the Exchange proposes to state in the Fee Schedule. The purpose of this proposed change is to continue to provide an incentive for Market Makers to provide liquidity in Proprietary Products on the Exchange, which should result in increasing potential order flow and volume in Proprietary Products, including options on SPIKES. Even though the Exchange proposes to extend the waiver of this particular fee, the overall structure of the fee is outlined in the Fee Schedule so that there is general awareness by potential Members seeking a Trading Permit that the Exchange intends to assess such a fee after June 30, 2022.

The Exchange also proposes that Market Makers who trade Proprietary Products (including options on SPIKES) along with multi-listed classes will continue to not have Proprietary Products (including SPIKES) counted toward those Market Makers' class assignment count or percentage of total national average daily volume. This exclusion is noted with the symbol ''Ω'' following the table that shows the monthly Trading Permit fees currently assessed to Market Makers in Section (3)(b) of the Fee Schedule.

API Testing and Certification Fee

The Exchange assesses an API Testing and Certification fee to all Members depending upon Membership type. An API makes it possible for Members' software to communicate with MIAX software applications, and is subject to Members testing with, and certification by, MIAX. The Exchange offers four types of interfaces: (i) The Financial Information Exchange Port (''FIX Port''),[12] which enables the FIX Port user (typically an EEM or a Market Maker) to submit simple and complex orders electronically to MIAX; (ii) the MEI Port, which enables Market Makers to submit simple and complex electronic quotes to MIAX; (iii) the Clearing Trade Drop Port (''CTD Port''),[13] which provides real-time trade clearing information to the participants to a trade on MIAX and to the participants' respective clearing firms; and (iv) the FIX Drop Copy Port (''FXD Port''),[14] which provides a copy of real-time trade execution, correction and cancellation information through a FIX Port to any number of FIX Ports designated by an EEM to receive such messages.

API Testing and Certification fees for Market Makers are assessed (i) initially per API for CTD and MEI ports in the month the Market Maker has been credentialed to use one or more ports in the production environment for the tested API and the Market Maker has been assigned to quote in one or more classes, and (ii) each time a Market Maker initiates a change to its system that requires testing and certification. API Testing and Certification fees will not be assessed in situations where the Exchange initiates a mandatory change to the Exchange's system that requires testing and certification. The Exchange currently assesses a Market Maker an API Testing and Certification fee of $2,500. The API Testing and Certification fees represent costs incurred by the Exchange as it works with each Member for testing and certifying that the Member's software systems communicate properly with MIAX's interfaces.

MIAX proposes to extend the waiver of the API Testing and Certification fee for Market Makers that trade solely in Proprietary Products (including options on SPIKES) from December 31, 2021, until June 30, 2022, which the Exchange proposes to state in the Fee Schedule. The purpose of this proposed change is to continue to provide an incentive for potential Market Makers to develop software applications to trade in Proprietary Products, including options on SPIKES. Even though the Exchange proposes to extend the waiver of this particular fee, the overall structure of the fee is outlined in the Fee Schedule so that there is general awareness that the Exchange intends to assess such a fee after June 30, 2022.

MEI Port Fees

MIAX assesses monthly MEI Port fees to Market Makers in each month the Member has been credentialed to use the MEI Port in the production environment and has been assigned to quote in at least one class. The amount of the monthly MEI Port fee is based upon the number of classes in which the Market Maker was assigned to quote on any given day within the calendar month, and upon the class volume percentages set forth in the table below. The class volume percentage is based on the total national average daily volume in classes listed on MIAX in the prior calendar quarter. Newly listed option

[12] A FIX Port is an interface with MIAX systems that enables the Port user (typically an Electronic Exchange Member or a Market Maker) to submit simple and complex orders electronically to MIAX. *See* Fee Schedule, note 24.

[13] Clearing Trade Drop (''CTD'') provides Exchange members with real-time clearing trade updates. The updates include the Member's clearing trade messages on a low latency, real-time basis. The trade messages are routed to a Member's connection containing certain information. The information includes, among other things, the following: (i) Trade date and time; (ii) symbol information; (iii) trade price/size information; (iv) Member type (for example, and without limitation, Market Maker, Electronic Exchange Member, Broker-Dealer); (v) Exchange Member Participant Identifier (''MPID'') for each side of the transaction, including Clearing Member MPID; and (vi) strategy specific information for complex transactions. CTD Port Fees will be assessed in any month the Member is credentialed to use the CTD Port in the production environment. *See* Fee Schedule, Section (5)(d)(iii).

[14] The FIX Drop Copy Port (''FXD'') is a messaging interface that will provide a copy of real-time trade execution, trade correction and trade cancellation information for simple and complex orders to FIX Drop Copy Port users who subscribe to the service. FIX Drop Copy Port users are those users who are designated by an EEM to receive the information and the information is restricted for use by the EEM only. FXD Port Fees will be assessed in any month the Member is credentialed to use the FXD Port in the production environment. *See* Fee Schedule, Section (5)(d)(iv).

classes are excluded from the calculation of the monthly MEI Port fee until the calendar quarter following their listing, at which time the newly listed option classes will be included in both the per class count and the percentage of total national average daily volume. The Exchange assesses MIAX Market Makers the monthly MEI Port fee based on the greatest number of classes listed on MIAX that the MIAX Market Maker was assigned to quote in on any given day within a calendar month and the applicable fee rate that is the lesser of either the per class basis or percentage of total national average daily volume measurement. MIAX assesses MEI Port fees on Market Makers according to the following table: [15]

Monthly MIAX MEI fees	Market Maker assignments (the lesser of the applicable measurements below) Ω	
	Per class	% of National average daily volume
$5,000.00	Up to 5 Classes	Up to 10% of Classes by volume.
$10,000.00	Up to 10 Classes	Up to 20% of Classes by volume.
$14,000.00	Up to 40 Classes	Up to 35% of Classes by volume.
$17,500.00 *	Up to 100 Classes	Up to 50% of Classes by volume.
$20,500.00 *	Over 100 Classes	Over 50% of Classes by volume up to all Classes listed on MIAX.

Ω Excludes Proprietary Products.
* For these Monthly MIAX MEI Fees levels, if the Market Maker's total monthly executed volume during the relevant month is less than 0.060% of the total monthly executed volume reported by OCC in the market maker account type for MIAX-listed option classes for that month, then the fee will be $14,500 instead of the fee otherwise applicable to such level.

MIAX proposes to extend the waiver of the monthly MEI Port fee for Market Makers that trade solely in Proprietary Products (including options on SPIKES) from December 31, 2021, until June 30, 2022, which the Exchange proposes to state in the Fee Schedule. The purpose of this proposal is to continue to provide an incentive to Market Makers to connect to MIAX through the MEI Port such that they will be able to trade in MIAX Proprietary Products. Even though the Exchange proposes to extend the waiver of this particular fee, the overall structure of the fee is outlined in the Fee Schedule so that there is general awareness that the Exchange intends to assess such a fee after June 30, 2022.

The Exchange notes that for the purposes of this proposed change, other Market Makers who trade MIAX Proprietary Products (including options on SPIKES) along with multi-listed classes will continue to not have Proprietary Products (including SPIKES) counted toward those Market Makers' class assignment count or percentage of total national average daily volume. This exclusion is noted by the symbol ''Ω'' following the table that shows the monthly MEI Port Fees currently assessed for Market Makers in Section (5)(d)(ii) of the Fee Schedule.

The proposed extension of the fee waivers are targeted at market participants, particularly market makers, who are not currently members of MIAX, who may be interested in being a Market Maker in Proprietary Products on the Exchange. The Exchange estimates that there are fewer than ten (10) such market participants that could benefit from the extension of these fee waivers. The proposed extension of the fee waivers does not apply differently to different sizes of market participants, however the fee waivers do only apply to Market Makers (and not EEMs).

Market Makers, unlike other market participants, take on a number of obligations, including quoting obligations that other market participants do not have. Further, Market Makers have added market making and regulatory requirements, which normally do not apply to other market participants. For example, Market Makers have obligations to maintain continuous markets, engage in a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and to not make bids or offers or enter into transactions that are inconsistent with a course of dealing. Accordingly, the Exchange believes it is reasonable and not unfairly discriminatory to continue to offer the fee waivers to Market Makers because the Exchange is seeking additional liquidity providers for Proprietary Products, in order to enhance liquidity and spreads in Proprietary Products, which is traditionally provided by Market Makers, as opposed to EEMs.

Incentive Program Extension

On September 30, 2021, the Exchange filed its initial proposal to implement a SPIKES Options Market Maker Incentive Program for SPIKES options to incentivize Market Makers to improve liquidity, available volume, and the quote spread width of SPIKES options beginning October 1, 2021, and ending December 31, 2021.[16] Technical details regarding the Incentive Program were published in a Regulatory Circular on September 30, 2021.[17] On October 12, 2021, the Exchange withdrew SR–MIAX–2021–45 and refiled its proposal to implement the Incentive Program to provide additional details.[18] In that filing, the Exchange specifically noted that the Incentive Program would expire at the end of the period (December 31, 2021) unless the Exchange filed another 19b–4 Filing to amend the fees (or extend the Incentive Program).[19] The Exchange now proposes to extend the Incentive Program for three months, with the Incentive Program ending on March 31, 2022.[20]

The Exchange proposes to extend the Incentive Program for SPIKES options to continue to incentivize Market Makers to improve liquidity, available volume, and the quote spread width of SPIKES options. Currently, to be eligible to participate in the Incentive Program, a Market Maker must meet certain minimum requirements related to quote spread width in certain in-the-money (ITM) and out-of-the-money (OTM) options as determined by the Exchange and communicated to Members via

[15] *See* Fee Schedule (5)(d)(ii).

[16] *See* SR–MIAX–2021–45.

[17] *See* MIAX Options Regulatory Circular 2021–56, SPIKES Options Market Maker Incentive Program (September 30, 2021) available at *https://www.miaxoptions.com/sites/default/files/circularfiles/MIAX_Options_RC_2021_56.pdf.*

[18] *See* Securities Exchange Act Release No. 93424 (October 26, 2021), 86 FR 60322 (November 1, 2021) (SR–MIAX–2021–49).

[19] *See id.,* at note 4.

[20] The Exchange notes that at the end of the extension period, the Incentive Program will expire unless the Exchange files another 19b–4 Filing to amend the terms or extend the Incentive Program.

Regulatory Circular.[21] Market Makers must also satisfy a minimum time in the market in the front 2 expiry months of 70%, and have an average quote size of 25 contracts. The Exchange established two separate incentive compensation pools that are used to compensate Market Makers that satisfy the criteria pursuant to the Incentive Program.

The first pool (Incentive 1) has a total amount of $40,000 per month, which is allocated to Market Makers that meet the minimum requirements of the Incentive Program. Market Makers are required to meet minimum spread width requirements in a select number of ITM and OTM SPIKES option contracts as determined by the Exchange and communicated to Members via Regulatory Circular.[22] A complete description of how the Exchange calculates the minimum spread width requirements in ITM and OTM SPIKES options can be found in the published Regulatory Circular.[23] Market Makers are also required to maintain the minimum spread width, described above, for at least 70% of the time in the front two (2) SPIKES options contract expiry months and maintain an average quote size of at least 25 SPIKES options contracts. The amount available to each individual Market Maker is capped at $10,000 per month for satisfying the minimum requirements of the Incentive Program. In the event that more than four Market Makers meet the requirements of the Incentive Program, each qualifying Market Maker is entitled to receive a pro-rated share of the $40,000 monthly compensation pool dependent upon the number of qualifying Market Makers in that particular month.

The second pool (Incentive 2 Pool) is capped at a total amount of $100,000 per month which is used during the Incentive Program to further incentivize Market Makers who meet or exceed the requirements of Incentive 1 (''qualifying Market Makers'') to provide tighter quote width spreads. The Exchange ranks each qualifying Market Maker's quote width spread relative to each other qualifying Market Maker's quote width spread. Market Makers with tighter spreads in certain strikes, as determined by the Exchange and communicated to Members via Regulatory Circular,[24] are eligible to receive a pro-rated share of the compensation pool as calculated by the Exchange and communicated to Members via Regulatory Circular,[25] not to exceed $25,000 per Member per month. Qualifying Market Makers are ranked relative to each other based on the quality of their spread width (*i.e.,* tighter spreads are ranked higher than wider spreads) and the Market Maker with the best quality spread width receives the highest rebate, while other eligible qualifying Market Makers receive a rebate relative to their quality spread width.

The Exchange now proposes to extend the Incentive Program until March 31, 2022. The Exchange does not propose to make any amendments to how it calculates any of the incentives provided for in Incentive Pools 1 or 2. The details of the Incentive Program can continue to be found in the Regulatory Circular that was published on September 30, 2021 to all Exchange Members.[26] The purpose of this extension is to continue to incentivize Market Makers to improve liquidity, available volume, and the quote spread width of SPIKES options. The Exchange will announce the extension of the Incentive Program to all Members via a Regulatory Circular.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[27] in general, and furthers the objectives of Section 6(b)(4) of the Act[28] in particular, in that it is an equitable allocation of reasonable fees and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act 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 and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that the proposal to extend the fee waiver period for certain non-transaction fees for Market Makers in Proprietary Products is an equitable allocation of reasonable fees because the proposal continues to waive non-transaction fees for a limited period of time in order to enable the Exchange to improve its overall competitiveness and strengthen its market quality for all market participants in MIAX's Proprietary Products, including options on SPIKES. The Exchange believe the proposed extension of the fee waivers is fair and equitable and not unreasonably discriminatory because it applies to all market participants not currently registered as Market Makers at the Exchange. Any market participant may choose to satisfy the additional requirements and obligations of being a Market Maker and trade solely in Proprietary Products in order to qualify for the fee waivers.

The Exchange believes that the proposed extension of the fee waivers is equitable and not unfairly discriminatory for Market Makers as compared to EEMs because Market Makers, unlike other market participants, take on a number of obligations, including quoting obligations that other market participants do not have. Further, Market Makers have added market making and regulatory requirements, which normally do not apply to other market participants. For example, Market Makers have obligations to maintain continuous markets, engage in a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and to not make bids or offers or enter into transactions that are inconsistent with a course of dealing.

The Exchange believes it is reasonable and equitable to continue to waive the one-time Membership Application Fee, monthly Trading Permit Fee, API Testing and Certification Fee, and monthly MEI Port Fee for Market Makers that trade solely in Proprietary Products (including options on SPIKES) until June 30, 2022, since the waiver of such fees provides incentives to interested market participants to trade in Proprietary Products. This should result in increasing potential order flow and liquidity in MIAX Proprietary Products, including options on SPIKES.

The Exchange believes it is reasonable and equitable to continue to waive the API Testing and Certification fee assessable to Market Makers that trade solely in Proprietary Products (including options on SPIKES) until June 30, 2022, since the waiver of such fees provides incentives to interested Members to develop and test their APIs sooner. Determining system operability with the Exchange's system will in turn provide MIAX with potential order flow and liquidity providers in Proprietary Products.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory that Market Makers who trade in Proprietary Products along with

[21] *See supra* note 17.

[22] *See id.*

[23] *See id.*

[24] *See id.*

[25] *See id.*

[26] *See id.*

[27] 15 U.S.C. 78f(b).

[28] 15 U.S.C. 78f(b)(4) and (5).

multi-listed classes will continue to not have Proprietary Products counted toward those Market Makers' class assignment count or percentage of total national average daily volume for monthly Trading Permit Fees and monthly MEI Port Fees in order to incentivize existing Market Makers who currently trade in multi-listed classes to also trade in Proprietary Products, without incurring certain additional fees.

The Exchange believes that the proposed extension of the fee waivers constitutes an equitable allocation of reasonable fees and other charges among its members and issuers and other persons using its facilities. The proposed extension of the fee waivers means that all prospective market makers that wish to become Market Maker Members of the Exchange and quote solely in Proprietary Products may do so and have the above-mentioned fees waived until June 30, 2022. The proposed extension of the fee waivers will continue to not apply to potential EEMs because the Exchange is seeking to enhance the quality of its markets in Proprietary Products through introducing more competition among Market Makers in Proprietary Products. In order to increase the competition, the Exchange believes that it must continue to waive entry type fees for such Market Makers. EEMs do not provide the benefit of enhanced liquidity which is provided by Market Makers, therefore the Exchange believes it is reasonable and not unfairly discriminatory to continue to only offer the proposed fee waivers to Market Makers (and not EEMs). Further, the Exchange believes it is reasonable and not unfairly discriminatory to continue to exclude Proprietary Products from an existing Market Maker's permit fees and port fees, in order to incentive such Market Makers to quote in Proprietary Products. The amount of a Market Maker's permit and port fee is determined by the number of classes quoted and volume of the Market Maker. By excluding Proprietary Products from such fees, the Exchange is able to incentivize Market Makers to quote in Proprietary Products. EEMs do not pay permit and port fees based on the classes traded or volume, so the Exchange believes it is reasonable, equitable, and not unfairly discriminatory to only offer the exclusion to Market Makers (and not EEMs).

The Exchange believes that it is reasonable, equitable, and not unfairly discriminatory to extend the Incentive Program for Market Makers in SPIKES options. The Incentive Program is reasonably designed because it will continue to incentivize Market Makers to provide quotes and increased liquidity in select SPIKES options contracts. The Incentive Program is reasonable, equitably allocated and not unfairly discriminatory because all Market Makers in SPIKES options may continue to qualify for Incentive 1 and Incentive 2, dependent upon each Market Maker's quoting in SPIKES options in a particular month. Additionally, if a SPIKES Market Maker does not satisfy the requirements of Incentive Pool 1 or 2, then it simply will not receive the rebate offered by the Incentive Program for that month.

The Exchange believes that it is reasonable, equitable and not unfairly discriminatory to continue to offer this financial incentive to SPIKES Market Makers because it will continue to benefit all market participants trading in SPIKES. SPIKES Options is a Proprietary Product on the Exchange and the continuation of the Incentive Program encourages SPIKES Market Makers to satisfy a heightened quoting standard, average quote size, and time in market. A continued increase in quoting activity and tighter quotes may yield a corresponding increase in order flow from other market participants, which benefits all investors by deepening the Exchange's liquidity pool, potentially providing greater execution incentives and opportunities, while promoting market transparency and improving investor protection.

The Exchange believes that the Incentive Program is equitable and not unfairly discriminatory because it will continue to promote an increase in SPIKES options liquidity, which may facilitate tighter spreads and an increase in trading opportunities to the benefit of all market participants. The Exchange believes it is reasonable to operate the Incentive Program for a continued limited period of time to strengthen market quality for all market participants. The resulting increased volume and liquidity will benefit those Members who are eligible to participate in the Incentive Program and will also continue to benefit those Members who are not eligible to participate in the Incentive Program by providing more trading opportunities and tighter spreads.

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.

Intra-Market Competition

The Exchange believes that the proposal to extend certain of the non-transaction fee waivers until June 30, 2022 for Market Makers that trade solely in Proprietary Products would increase intra-market competition by incentivizing new potential Market Makers to quote in Proprietary Products, which will enhance the quality of quoting and increase the volume of contracts in Proprietary Products traded on MIAX, including options on SPIKES. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market liquidity for the Exchange's Proprietary Products. Enhanced market quality and increased transaction volume in Proprietary Products that results from the anticipated increase in Market Maker activity on the Exchange will benefit all market participants and improve competition on the Exchange.

The Exchange does not believe that the proposed rule change will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed changes for each separate type of market participant (new Market Makers and existing Market Makers) will be assessed equally to all such market participants. While different fees are assessed to different market participants in some circumstances, these different market participants have different obligations and different circumstances as discussed above. For example, Market Makers have quoting obligations that other market participants (such as EEMs) do not have.

The Exchange believes that the proposed extension of the Incentive Program would continue to increase intra-market competition by incentivizing Market Makers to quote SPIKES options, which will continue to enhance the quality of quoting and increase the volume of contracts available to trade in SPIKES options. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market liquidity for SPIKES options. Enhanced market quality and increased transaction volume in SPIKES options that results from the anticipated increase in Market Maker activity on the Exchange will benefit all market participants and improve competition on the Exchange.

Inter-Market Competition

The Exchange does not believe that the proposed rule changes will impose

any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed extension of the fee waivers and the extension of the Incentive Program apply only to the Exchange's Proprietary Products (including options on SPIKES), which are traded exclusively on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[29] and Rule 19b–4(f)(2)[30] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2021–63 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–MIAX–2021–63. 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 (*https://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–MIAX–2021–63, and should be submitted on or before January 26, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2021–28576 Filed 1–4–22; 8:45 am]

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[29] 15 U.S.C. 78s(b)(3)(A)(ii).

[30] 17 CFR 240.19b–4(f)(2).

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93883; File No. SR–IEX–2021–14]

Self-Regulatory Organizations; Investors Exchange LLC; Suspension of and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend Its Fee Schedule for Market Data Fees

December 30, 2021.

I. Introduction

On November 1, 2021, Investors Exchange LLC (''IEX'' or ''Exchange'') 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 modify its Fee Schedule to establish fees, as of January 3, 2022, for the receipt and distribution of proprietary market data feeds. The proposed rule change was published for comment in the **Federal Register** on November 17, 2021.[3] Pursuant to Section 19(b)(3)(C) of the Act,[4] the Commission is hereby temporarily suspending File No. SR–IEX–2021–14 and instituting proceedings to determine whether to approve or disapprove File No. SR–IEX–2021–14.

II. Description of the Proposed Rule Change

IEX offers two real-time proprietary market data feeds, ''TOPS''[5] and ''DEEP''[6] (collectively, ''IEX Data'' or the ''market data feeds'').[7] DEEP includes all resting displayed liquidity on the Exchange aggregated by price level and it therefore includes the top of book quotes contained in TOPS, as well as less aggressively priced displayed quotes. IEX has not previously imposed fees to access or redistribute its market data feeds.[8]

The Exchange proposes to modify its Fee Schedule to assess fees on Data Subscribers[9] that access IEX Data in real-time.[10] As discussed below, IEX would not itself provide or impose a fee for time-delayed IEX Data.[11] The Exchange proposes to implement these fees on January 3, 2022.

Specifically, IEX proposes to assess Data Subscribers $2,500 per month for its ''Real-Time'' DEEP feed and $500 per

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 93557 (November 10, 2021), 86 FR 64268 (November 17, 2021).

[4] 15 U.S.C. 78s(b)(3)(C).

[5] TOPS is an uncompressed data feed that offers aggregated top of book quotations for all displayed orders resting on the IEX Order Book and last sale information for executions on the Exchange. *See* Notice, *supra* note 3, at 64269. According to the Exchange, the data available through TOPS is also available through the securities information processor feed. *See id.*

[6] DEEP is an uncompressed data feed that provides aggregated depth of book quotations for all displayed orders resting on the IEX Order Book at each price level and last sale information for executions on the Exchange. *See* Notice, *supra* note 3, at 64269.

[7] *See* Notice, *supra* note 3, at 64269.

[8] *See id.*

[9] The Exchange proposes to define the term ''Data Subscriber'' as ''any natural person or entity that receives Real-Time IEX market data either directly from the Exchange or from another Data Subscriber.'' *See* Notice, *supra* note 3, at 64274. IEX will require Data Subscribers to enter into a Data Subscriber Agreement with IEX in order to receive Real-Time IEX Data. *See id.* at 64270, n.23.

[10] *See* Notice, *supra* note 3, at 64269.

[11] *See* Notice, *supra* note 3, at 64270, n.22.

month for its ''Real-Time'' TOPS feed. The Exchange proposes to define ''Real-Time'' as ''IEX market data that is accessed, used, or distributed less than fifteen (15) milliseconds after it was made available by the Exchange.'' [12]

Further, the Exchange proposes to assess a $500 per month ''Distribution Fee'' to each Data Subscriber that redistributes IEX Data in Real-Time to an external, non-affiliated third-party.[13] For Data Subscribers that redistribute IEX Data to others, IEX would not charge them a Distribution Fee if: (1) They only redistribute the IEX Data in Real-Time to internal, affiliated parties; or (2) they delay distribution of the data by at least fifteen milliseconds before redistributing it.

For recipients of IEX Data, IEX would not consider them a ''Data Subscriber'' and would not charge them the TOPS or DEEP fees if they only (1) receive IEX Data subject to a delay of at least a fifteen milliseconds [14] or (2) receive Real-Time IEX Data internally from an affiliate.

III. Suspension of the Proposed Rule Change

Pursuant to Section 19(b)(3)(C) of the Act,[15] at any time within 60 days of the date of filing of an immediately effective proposed rule change pursuant to Section 19(b)(1) of the Act,[16] the Commission summarily may temporarily suspend the change in the rules of a self-regulatory organization (''SRO'') 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. As described below, the Commission believes a temporary suspension of the proposed rule change is necessary and appropriate to allow for additional analysis of the proposed rule change's consistency with the Act and the rules thereunder.

In support of its proposed market data fees, the Exchange states ''its belief that the fees each equities exchange charges for its proprietary market data are not subject to competitive forces'' [17] and therefore has proposed fees that it believes are ''fair and reasonable as a form of cost recovery plus the possibility of a reasonable return for IEX's aggregate costs of offering IEX Data to its Data Subscribers.'' [18] With respect to its proposed cost-based fees, IEX provides a summary of its annual market data infrastructure costs ($2,483,644 for 2021), with a breakdown of selected line-item costs including direct costs, enhancement initiative costs, and personnel costs.[19] IEX states that its proposed fees are reasonable under the Act because they are ''based both on the relative costs to IEX to generate TOPS and DEEP, as well as IEX's objective to make TOPS broadly available to a range of market participants including long-term investors.'' [20] IEX further asserts that its proposed fees ''are reasonable because they are designed to generate annual revenue of approximately $3.1 million (reflecting a 25% markup over costs),'' [21] though IEX acknowledges a potential markup from ''break even'' or even below aggregate costs to an aggregate markup of 95%, depending on the number of paying subscribers it ultimately will have.[22] IEX further states that it ''is only charging Data Subscribers who use IEX Data in real time'' and argues that its proposed fees ''are significantly less than the fees charged by competing equities exchanges'' and that its fee proposal ''will not impose onerous audit requirements on Data Subscribers.'' [23]

When an Exchange files a proposed rule change with the Commission, including fee filings, it is required to provide a statement supporting the proposal's basis under the Act and the rules and regulations thereunder applicable to the exchange.[24] The instructions to Form 19b–4, on which exchanges file their proposed rule changes, specify that such statement ''should be sufficiently detailed and specific to support a finding that the proposed rule change is consistent with [those] requirements.'' [25]

Section 6 of the Act, including Sections 6(b)(4), (5), and (8), requires, among other things, that the rules of an exchange: (1) Provide for the equitable allocation of reasonable fees among members, issuers, and other persons using the exchange's facilities; [26] (2) be designed to perfect the mechanism of a free and open market and a national market system and to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers; [27] and (3) not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[28]

In temporarily suspending the Exchange's proposed rule change, the Commission intends to further consider whether the proposed fees are consistent with the statutory requirements applicable to a national securities exchange under the Act. In particular, the Commission will consider whether the proposed rule change satisfies the standards under the Act and the rules thereunder requiring, among other things, that an exchange's rules provide for the equitable allocation of reasonable fees among members, issuers, and other persons using its facilities; are designed to perfect the mechanism of a free and open market and a national market system and to protect investors and the public interest, and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers; and do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[29]

Therefore, the Commission finds that it is appropriate in the public interest, for the protection of investors, and otherwise in furtherance of the purposes of the Act, to temporarily suspend the proposed rule change.[30]

IV. Proceedings To Determine Whether To Approve or Disapprove SR–IEX–2021–14 and Grounds for Disapproval Under Consideration

In addition to temporarily suspending the proposal, the Commission also hereby institutes proceedings pursuant to Sections 19(b)(3)(C) [31] and

[12] *See* Notice, *supra* note 3, at 64274. IEX will consider ''market data that is accessed, used, or distributed at least fifteen (15) milliseconds after it was made available by the Exchange'' as ''Delayed'' IEX Data. *See id.* IEX only provides Real-Time IEX Data and will not itself delay the dissemination of IEX Data to Data Subscribers. *See* Notice, *supra* note 3, at 64269, n.22.

[13] *See* Notice, *supra* note 3, at 64269.

[14] *See* Notice, *supra* note 3, at 64270. The Exchange notes that a recipient of Delayed IEX Data may be subject to fees imposed by the redistributor of the Delayed IEX Data pursuant to the contract between the recipient of the Delayed IEX Data and the third-party provider of such market data. *See id.* at 64270, n.24.

[15] 15 U.S.C. 78s(b)(3)(C).

[16] 15 U.S.C. 78s(b)(1).

[17] *See* Notice, *supra* note 3, at 64274.

[18] *See* Notice, *supra* note 3, at 64274.

[19] *See* Notice, *supra* note 3, at 64271.

[20] *See* Notice, *supra* note 3, at 64274–75.

[21] *See* Notice, *supra* note 3, at 64275.

[22] *See* Notice, *supra* note 3, at 64273.

[23] *See* Notice, *supra* note 3, at 64275.

[24] See 17 CFR 240.19b–4 (General Instructions for Form 19b–4—Information to be Included in the Complete Form—Item 3 entitled ''Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change'').

[25] *See id.*

[26] 15 U.S.C. 78f(b)(4).

[27] 15 U.S.C. 78f(b)(5).

[28] 15 U.S.C. 78f(b)(8).

[29] See 15 U.S.C. 78f(b)(4), (5), and (8), respectively.

[30] For purposes of temporarily suspending the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[31] 15 U.S.C. 78s(b)(3)(C). Once the Commission temporarily suspends a proposed rule change,

19(b)(2)(B) [32] of the Act to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[33] the Commission is providing notice of the grounds for possible disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of whether the Exchange has sufficiently demonstrated how the proposed rule change is consistent with Sections 6(b)(4),[34] 6(b)(5),[35] and 6(b)(8) [36] of the Act. Section 6(b)(4) of the Act requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. Section 6(b)(5) of the Act requires that the rules of a national securities exchange be designed, among other things, 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, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Section 6(b)(8) of the Act requires that the rules of a national securities exchange not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following aspects of the proposal and asks commenters to submit data where appropriate to support their views:

1. *Cost Allocation.* IEX states it ''does not believe that exchange market data fees are constrained by competitive market forces,'' [37] and that ''each exchange has a natural monopoly over its own market data.'' [38] Consequently, for market data fee filings, IEX believes that exchanges ''should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements'' and that ''each exchange should demonstrate that these fees bear a reasonable relationship to its costs and reasonable business needs and that it is not taking unfair advantage of its unique position as the sole provider of its own proprietary market data.'' [39] In proposing its fees, IEX says it used a ''cost-plus model'' and ''sought to determine such fees in a transparent way in relation to its own aggregate costs of providing the related service. . . .'' [40] IEX says it used a ''conservative methodology (*i.e.,* that strictly considers only those costs that are most clearly directly related to the production and distribution of IEX Data) to estimate such costs, as well as the relative costs of compiling the TOPS and DEEP feeds . . .'' [41] and also considered its ''objective to make TOPS broadly available to a range of market participants including long-term investors.'' [42] IEX summarizes its cost components according to (1) direct costs (servers, infrastructure, monitoring), (2) enhancement initiative costs (new functionality and capacity), and (3) personnel.[43] IEX asserts that direct costs are those that are specifically dedicated to IEX Data and that physical assets and software are valued at cost and depreciated over three years.[44] For direct costs, IEX notes that ''servers included were limited to those specifically dedicated to IEX Data'' and that ''[a]ll physical assets and software, which also includes assets used for testing and monitoring of market data infrastructure, were valued at cost, and depreciated over three years.'' [45] Do commenters believe IEX has provided sufficient detail about the specific direct costs it has assigned to market data to justify its proposal? For enhancement initiative costs, IEX asserts that, though they are one-time costs, it expects to incur ''annual enhancement costs on an ongoing basis'' that ''will be similar'' to what it incurred in 2021.[46] Do commenters believe enhancement costs are sufficiently clear and defined? Further, do commenters expect costs (enhancement costs as well as all other costs) incurred in 2021 to be generally representative of an exchange's expected costs going forward (to the extent commenters consider 2021 to be an atypical year), or should an exchange present an estimated range of costs with an explanation of how profit margins could vary along with estimates costs? For personnel costs, IEX ''calculated an allocation of employee time for employees whose functions include providing and maintaining IEX Data and/or the proprietary market data feeds used to transmit IEX Data, and used a blended rate of compensation reflecting salary, stock and bonus compensation, bonuses, benefits, payroll taxes, and 401(k) matching contributions.'' [47] IEX estimates 6.15 FTEs who ''work in support of compiling and disseminating IEX Data,'' [48] but does not identify the department and job title of all employees it counted as ''work[ing] in support of compiling and disseminating IEX Data'' nor does it explain the methodology it used to determine how much of an employee's time is devoted to that specific activity (*e.g.,* are finance, legal, HR, administrative personnel included in this estimate and what portion of their time did IEX count towards market data costs and why?). Further, IEX uses a ''blended compensation rate . . . to determine the personnel costs associated with compiling and disseminating IEX Data,'' [49] which includes salary, stock compensation, annual cash bonus, benefits, payroll taxes, and 401(k) matching contributions.[50] Do commenters believe those are appropriate criteria? In particular, would it be appropriate to include stock compensation and annual cash bonuses in a blended compensation rate for

Section 19(b)(3)(C) of the Act requires that the Commission institute proceedings under Section 19(b)(2)(B) to determine whether a proposed rule change should be approved or disapproved.

[32] 15 U.S.C. 78s(b)(2)(B).

[33] 15 U.S.C. 78s(b)(2)(B). Section 19(b)(2)(B) of the Act also provides that proceedings to determine whether to disapprove a proposed rule change must be concluded within 180 days of the date of publication of notice of the filing of the proposed rule change. *See id.* The time for conclusion of the proceedings may be extended for up to 60 days if the Commission finds good cause for such extension and publishes its reasons for so finding, or if the exchange consents to the longer period. *See id.*

[34] 15 U.S.C. 78f(b)(4).

[35] 15 U.S.C. 78f(b)(5).

[36] 15 U.S.C. 78f(b)(8).

[37] Notice, *supra* note 3 at 64272.

[38] Notice, *supra* note 3 at 64269.

[39] Notice, *supra* note 3 at 64269.

[40] Notice, *supra* note 3 at 64269–70.

[41] Notice, *supra* note 3 at 64270.

[42] Notice, *supra* note 3 at 64274–75.

[43] Notice, *supra* note 3 at 64270–71.

[44] Notice, *supra* note 3 at 64271.

[45] Notice, *supra* note 3 at 64271.

[46] Notice, *supra* note 3 at 64270, n.31.

[47] Notice, *supra* note 3 at 64271.

[48] Notice, *supra* note 3 at 64271, n.33.

[49] Notice, *supra* note 3 at 64271, n.33.

[50] *See, e.g.,* Cost Study at 3.

purposes of assessing market data costs if those items are based on an exchange's overall profitability or performance and not the individual employee's performance (and thus not directly attributable to market data)? Across all of these costs, what are commenters' views on whether the Exchange has provided sufficient detail on the elements that go into its market data costs, including how it allocated and attributed shared costs to market data expenses, to permit an independent review of its costs and meaningfully assess the reasonableness of purported cost-based fees and the corresponding profit margin thereon?

2. *TOPS versus DEEP.* IEX states that its proposed market data fee structure is ''designed to make real time access to IEX's top of book widely available to a broad base of market participants'' and, to accomplish that goal, IEX ''proposes to allocate its cost plus structure so that TOPS is materially more affordable than DEEP.'' IEX notes that ''because it contains multiple price levels, DEEP requires more processing (and related costs) for IEX to generate than TOPS.'' [51] As proposed, DEEP ($2,500) is five times more expensive than TOPS ($500). However, IEX does not assert in its filing that DEEP is five times more costly for it to produce than TOPS, nor does IEX present its separate costs to produce DEEP and TOPS individually. Rather, IEX appears to be subsidizing TOPS, though it has not presented a cost-based explanation for how it is doing so or explained the extent to which it is subsidizing TOPS through the proposed fees for DEEP or some other source of revenue. Do commenters believe that the price difference between TOPS and DEEP is consistent with IEX's assertions that it set the level of its proposed fees ''in relation to its own aggregate costs of providing the related service. . .'' [52] and according to the ''relative costs of compiling the TOPS and DEEP feeds?'' [53] Do commenters believe that IEX should provide more detail about the types of market participants that subscribe to TOPS and DEEP in order to assess, among other things, IEX's statement that ''fees also do not depend on any distinctions between Members, customers, broker-dealers, or any other entity, because they are solely determined by the individual Data Subscriber's business needs?'' [54]

3. *Subscribers.* IEX acknowledges that imposing a fee on the proprietary market data it previously offered for free may cause some of its current market data subscribers to terminate or modify their current subscriptions.[55] Specifically, IEX says it ''currently has 70 Data Subscribers who it believes are individuals and expects that most, if not all, of the individual Data Subscribers will terminate their subscriptions for IEX Data'' once IEX charges for Real-Time data (though ''if they choose to continue to receive IEX Data, [they] can opt to receive Delayed IEX Data from a third-party vendor or through HIST'').[56] IEX says (without providing supporting numbers) that the ''remaining, non-individual, Data Subscribers are made up of approximately one-third IEX Members, one-third professional market participants that are not IEX Members (*e.g.,* hedge funds and broker-dealers), and one-third data vendors'' and ''[b]ased on IEX's general understanding of many of its current Data Subscribers' business models, IEX projects at least half of the data vendors will retain all of their existing subscriptions for IEX Data while the others may cancel their real-time data subscriptions, and also anticipates that several Members and non-Members will cancel their real-time data subscriptions for either TOPS, DEEP, or both.'' [57] IEX did not offer any further explanation of its basis for these projections. For example, how many non-individual Data Subscribers does IEX have that subscribe to each of TOPS, DEEP, or TOPS and DEEP, and on what basis does IEX estimate they will alter their current subscriptions? Has IEX received any verbal or written indication of such subscribers' likely intent? Do commenters believe IEX has provided sufficient information regarding its current market data subscriber base as well as sufficient information to support its projections regarding what types of current subscribers (*i.e.,* individuals, vendors, members, and non-members) may terminate or modify their current subscriptions and why? Do commenters believe that additional detail on estimated subscribers to TOPS, DEEP, or TOPS and DEEP is necessary and useful to assess the Exchange's estimated profit margin on market data?

4. *Profit Margin Range.* IEX states that its proposed fee structure is ''designed to recoup its costs and limit any revenue in excess of cost to an amount that represents no more than what IEX believes is a reasonable rate of return over such costs.'' [58] Depending on how many paying subscribers IEX will have once the fees take effect, IEX projects that the proposed market data fees will generate revenue of up to 95% above cost, though it has targeted and projects a 25% return over costs based on its estimate of subscribers.[59] IEX attributes the wide range to its inability to know beforehand who will subscribe to TOPS or DEEP (or both or neither). If IEX is incorrect and all people that currently obtain IEX Data (for free) keep that data and pay the fee, IEX estimates it could generate revenue of 95% above cost. On the other hand, IEX also acknowledges that ''revenues could range from 'break even' (or even below aggregate costs)'' if its projections are incorrect.[60] However, IEX does not specify the circumstances under which it would receive zero or negative profit margins or the likelihood of that occurring. Further, IEX does not specifically explain why it believes that profit margins of up to 95% are appropriate nor does it provide an argument to support a finding that fees within that range would be reasonable under the Act. Do commenters find IEX's projected range to be appropriately narrow for a cost-based fee filing, or should IEX provide a more detailed and precise estimate in order to facilitate consideration of whether the proposed fees are reasonable and equitably allocated? Do commenters believe that the top-end of the range (95%) would constitute a reasonable rate of return over cost for proprietary market data?

5. *Reasonable Rate of Return.* IEX believes that a 95% return ''is unlikely'' and ''is targeting a return of 25% over its costs'' [61] because ''market participants that do not need real-time data will have the option to receive Delayed IEX Data (at a minimal delay of only 15 milliseconds) in lieu of real-time data, without paying a fee to IEX.'' [62] IEX states that its proposed fees are reasonable because, among other things, ''IEX is only charging Data Subscribers who use IEX Data in real time'' and the fees ''are significantly less than the fees charged by competing equities exchanges. . . .'' [63] If IEX's subscriber estimates are correct, do commenters agree with IEX that its targeted 25% profit margin would constitute a reasonable rate of return over cost for proprietary market data? If not, what would commenters consider

[51] Notice, *supra* note 3 at 64270.

[52] Notice, *supra* note 3 at 64269.

[53] Notice, *supra* note 3 at 64270.

[54] Notice, *supra* note 3 at 64275.

[55] *See* Notice, *supra* note 3 at 64273 (discussing IEX's projections regarding how fees are likely to impact IEX market data subscriptions).

[56] Notice, *supra* note 3 at 64273.

[57] *See id.*

[58] Notice, *supra* note 3 at 64271.

[59] Notice, *supra* note 3 at 64273.

[60] Notice, *supra* note 3 at 64273.

[61] Notice, *supra* note 3 at 64271.

[62] Notice, *supra* note 3 at 64272.

[63] Notice, *supra* note 3 at 64275.

to be a reasonable rate of return for proprietary market data fees? The rate of return is dependent on the accuracy of the cost allocations which, if inflated (intentionally or unintentionally), may render the projected profit margin meaningless. What are commenters' views regarding what factors should be considered in determining what constitutes a reasonable rate of return for proprietary market data fees?

6. *Periodic Reevaluation.* IEX represented that ''[i]f the revenue IEX receives from the proposed fees materially deviates from IEX's projections described herein, IEX will assess whether it is appropriate to make a rule filing pursuant to Section 19(b) of the Act to increase or decrease the fees accordingly.'' [64] In light of the impact that the number of subscribers has on market data profit margins (because market data costs do not necessarily linearly change as the number of subscribers increase or decrease), what are commenters' views on the need for exchanges to commit to reevaluate, on an ongoing and periodic basis, their cost-based proprietary market data fees to ensure that they stay in line with their stated profitability target and do not become unreasonable over time, for example, by failing to adjust for efficiency gains, cost increases or decreases, and changes in subscribers? How formal should that process be, how often should that reevaluation occur, and what metrics and thresholds should be considered? How soon after a new market data fee change is implemented should an exchange assess whether its subscriber estimates were accurate and at what threshold should an exchange commit to file a fee change if its estimates were inaccurate? Should an initial review take place within the first 30 days after a proprietary market data fee becomes operative?

7. *Real-Time.* IEX is only proposing to assess fees for market data that is made available in ''Real-Time.'' The Exchange is proposing to define ''Real-Time'' market data as IEX market data that is accessed, used, or distributed less than *fifteen milliseconds* after it was made available by the Exchange. IEX states that it ''sought informal feedback from Members and other Data Subscribers'' and, ''[b]ased upon that informal feedback, IEX believes that most, if not all, non-electronic trading desks would be able to continue to use IEX Data if it was received subject to at least a fifteen-millisecond delay.'' [65] What are commenters' views on this threshold and whether this definition accurately reflects and correlates to IEX's assertion that ''it is the very demand for real-time, low latency data that drives much of the costs associated with creating and distributing'' such data? [66] Do commenters agree with IEX's statement that ''most, if not all, non-electronic trading desks would be able to continue to use IEX Data if it was received subject to at least a fifteen-millisecond delay,'' and that (conversely) electronic trading desks that need IEX Data for trading purposes require the data to have less than a 15 millisecond delay? [67] Similarly, do commenters agree with IEX's statement that a fifteen-millisecond delay is ''a time frame that is usable for most trading purposes'' (*i.e.,* does usefulness to ''non-electronic trading desks'' cover ''most trading purposes''), while the fifteen-minute delay offered by other exchanges ''makes the data stale for any subscribers using the data to make trading decisions''? [68]

8. *Distribution Fee.* IEX proposes a $500 redistribution fee because ''[e]nabling redistribution in real time adds to IEX's administrative expenses related to the need to identify and track the recipients of IEX Data.'' [69] IEX does not, however, provide any estimate of such administrative expenses, nor does it mention its targeted profit margin on the proposed Distribution Fee. IEX also justifies the proposed Distribution Fee by noting that ''if it allowed Data Subscribers to redistribute IEX Data in real time without any additional fees, it could enable Data Subscribers to circumvent IEX's fees for providing IEX Data, which would conflict with IEX's objective to recover its costs of producing IEX Data.'' [70] IEX does not explain how the proposed Distribution Fee would discourage Data Subscribers from circumventing the TOPS and/or DEEP fees. What are commenters' views on the adequacy of the information IEX provides regarding its proposed Distribution Fee?

9. *Delayed IEX Data.* IEX does not propose to itself directly offer Delayed IEX Data, nor does it propose to charge persons that access, receive, or distribute Delayed IEX Data from third parties. IEX states that its proposal will continue ''to allow market participants to access IEX Data free of charge if they can wait at least fifteen milliseconds to receive it'' [71] but acknowledges that ''[d]istributors of Delayed IEX Data may charge a fee for the data, but that fee is not payable to IEX.'' [72] What do commenters think will be the end costs to consumers of Delayed IEX Data? While IEX itself will not charge for Delayed IEX Data, do commenters think there is sufficient competition among data vendors such that market participants will have access to Delayed IEX Data for a reasonable fee?

10. *Sharing with Affiliates.* In an example discussing the other exchanges that charge for proprietary market data, IEX explains that ''the aggregate monthly cost for those 11 equity exchanges [to obtain IEX Data] would be $3,000 per exchange family.'' [73] That statement, however, appears to be inconsistent with the rule text and the proposed definition of Data Subscriber. Specifically, IEX's proposed rule text defines ''Data Subscriber'' as ''any natural person or entity that receives Real-Time IEX market data either directly from the Exchange or from another Data Subscriber.'' [74] Further, it states that each Data Subscriber ''must enter into a Data Subscriber Agreement with IEX in order to receive Real-Time IEX market data'' [75] as well as pay the applicable fee. Yet, IEX's example of affiliated exchanges states that an exchange family would only be assessed $3,000 in fees (*i.e.,* $2,500 for DEEP and $500 for TOPS), despite the fact that each exchange within a family would independently meet the proposed definition of Data Subscriber. IEX's filing appears incomplete with respect to how the proposed fees would apply in the case of internal sharing of TOPS and/or DEEP with an affiliate.

Under 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 [SRO] that proposed the rule change.'' [76] 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,[77] and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the applicable rules

[64] Notice, *supra* note 3 at 64271, n.44.

[65] Notice, *supra* note 3 at 64273.

[66] Notice, *supra* note 3 at 64270.

[67] Notice, *supra* note 3 at 64273.

[68] Notice, *supra* note 3 at 64275.

[69] Notice, *supra* note 3 at 64270.

[70] Notice, *supra* note 3 at 64270.

[71] Notice, *supra* note 3 at 64275.

[72] Notice, *supra* note 3 at 64276, n.75.

[73] Notice, *supra* note 3 at 64272.

[74] Notice, *supra* note 3 at 64274.

[75] *See id.*

[76] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[77] *See id.*

and regulations.[78] Moreover, ''unquestioning reliance'' on an SRO's representations in a proposed rule change would not be sufficient to justify Commission approval of a proposed rule change.[79]

The Commission believes it is appropriate to institute proceedings to allow for additional consideration and comment on the issues raised herein, including as to whether the proposed fees are consistent with the Act, any potential comments or supplemental information provided by the Exchange, and any additional independent analysis by the Commission.

V. Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the concerns and issues identified above, as well as any other relevant concerns. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Sections 6(b)(4), 6(b)(5), and 6(b)(8), or any other provision of the Act, or the rules and regulations thereunder. The Commission asks that commenters address the sufficiency and merit of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change. 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, any request for an opportunity to make an oral presentation.[80]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by January 26, 2022. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by February 9, 2022.

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–IEX–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–IEX–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 IEX–2021–14 and should be submitted on or before January 26, 2022. Rebuttal comments should be submitted by February 9, 2022.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(3)(C) of the Act,[81] that File No. SR–IEX–2021–14 be, and hereby is, temporarily suspended. In addition, the Commission is instituting proceedings to determine whether the proposed rule change should be approved or disapproved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[82]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2021–28577 Filed 1–4–22; 8:45 am]

BILLING CODE 8011–01–P

[78] *See id.*

[79] *See Susquehanna Int'l Group, LLP* v. *Securities and Exchange Commission,* 866 F.3d 442, 446–47 (D.C. Cir. 2017) (rejecting the Commission's reliance on an SRO's own determinations without sufficient evidence of the basis for such determinations).

[80] Section 19(b)(2) of the Exchange Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[81] 15 U.S.C. 78s(b)(3)(C).

[82] 17 CFR 200.30–3(a)(57) and (58).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93885; File No. SR–DTC–2021–018]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Reorganizations Guide and the Fee Guide

December 30, 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 December 29, 2021, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rules 19b–4(f)(2) and (f)(4) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change[5] consists of amendments to the Reorganizations Guide and the Fee Guide to (i) postpone the retirement of DTC's legacy computer to computer facility (''CCF'') files for corporate actions entitlements and allocations (''CCF Entitlements and Allocations Files'')[6] to January 1, 2023,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2) and (f)(4).

[5] Each term not otherwise defined herein has its respective meaning as set forth in the Rules, By-Laws and Organization Certificate of DTC (the ''Rules''), the Guide to the DTC Fee Schedule (''Fee Guide''), and the Reorganizations Service Guide (''Reorganizations Guide''), *available at http://www.dtcc.com/legal/rules-and-procedures.aspx.*

[6] Each of the CCF Entitlements and Allocations Files falls into one of two categories (each, a ''File Category''): (i) Pre-allocation (''Pre-Allocation CCF Files''), which includes files containing a Participant's allocation projections and entitlements, or (ii) allocation/post-allocation (''Allocation/Post-Allocation CCF Files''), which

and (ii) amend the Fee Guide to apply the CCF File Fee to Participants that consume CCF Entitlements and Allocations Files [7] between January 1, 2022 and December 31, 2022, as more fully described below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed rule change would amend the Reorganizations Guide and the Fee Guide to (i) postpone the retirement of CCF Entitlements and Allocations Files to January 1, 2023, and (ii) amend the Fee Guide to apply the CCF File Fee to Participants that consume CCF Entitlements and Allocations Files between January 1, 2022 and December 31, 2022, as more fully described below.

(i) Retirement of CCF Entitlements and Allocations Files and CCF File Fee

A. Background

On November 19, 2020, DTC filed a rule change (the ''CCF Retirement Filing'') [8] that amended the Reorganizations Guide and the Fee Guide to (i) set a retirement date for CCF Entitlements and Allocations Files of January 1, 2022, and (ii) apply a $50,000,000 CCF File Fee, per File Category (Pre-Allocation or Allocation/Post-Allocation) of CCF Entitlements and Allocations Files, to Participants that continued to consume CCF Entitlements and Allocations Files between January 1, 2021 and December 31, 2021 (''Original Fee Period'').

As discussed in the CCF Retirement Filing, DTC has been informing Participants that corporate actions CCF files [9] will be retired and will be replaced by ISO 20022 messaging since 2011.[10] ISO 20022 messaging offers enhanced efficiency and transparency in the corporate action lifecycle because, in contrast to the proprietary function and activity codes of CCF Files, ISO 20022 is a business-model-based standard for the development of messages for the international financial services industry.

DTC has been working with Participants to specifically support their orderly transition from CCF Entitlements and Allocations Files to ISO 20022 messaging since 2013. DTC began providing Participants with parallel entitlements and allocations ISO 20022 messaging in 2013 (Distributions), 2015 (Redemptions) and 2017 (Reorganizations). In addition, since 2016, DTC had been communicating with Participants about the deadline for retirement of the CCF Entitlements and Allocation Files and postponed the projected retirement date multiple times.[11] Finally, in 2020, DTC filed the CCF Retirement Filing and continued to work with Participants to support their orderly migration away from the CCF Entitlements and Allocations Files to ISO 20022 messaging before the January 1, 2022.

B. Proposed Rule Change

Most Participants have successfully migrated from CCF Entitlements and Allocations Files to ISO 20022 messaging. However, DTC understands that a few Participants are still testing the ISO 20022 messages and that not all will be ready to transition away from the CCF Entitlements and Allocations Files before January 1, 2022.

Therefore, pursuant to this proposed rule change, DTC would postpone the retirement date of the CCF Entitlements and Allocation Files to January 1, 2023, and would charge Participants the $50,000 CCF File Fee for each File Category of CCF Entitlements and Allocations Files that they consume between January 1, 2022 and December 31, 2022 (the ''New Fee Period''). The CCF File Fee would be charged to the Account of the Participant, upon the Participant's first receipt of CCF Entitlements and Allocations Files in a particular File Category during the New Fee Period. The CCF File Fee would cover all CCF Entitlements and Allocations Files within that File Category during the New Fee Period.

Pursuant to the proposed rule change, DTC would amend the description of the CCF File Fee in the Fee Guide to conform with the proposed rule change. DTC would also amend the Reorganizations Guide to reflect the January 1, 2023 retirement date for CCF Entitlements and Allocations Files. Specifically, in the ''Preparing to Use the Services'' subsection of the ''How Reorganizations Work'' section of the Reorganizations Guide, DTC is proposing to replace ''*CCF files associated with entitlements and allocations will be retired as of January 1, 2022'' with ''*CCF files associated with entitlements and allocations will be retired as of January 1, 2023.''

Implementation Date

DTC will implement the proposed changes on January 1, 2022. DTC will announce the implementation date of the proposed rule change in an Important Notice posted on its website.

As proposed, a legend would be added to the Reorganizations Guide and the Fee Guide stating there are changes that became effective upon filing with the Commission but have not yet been implemented. The proposed legend also would include that the implementation date will be January 1, 2022. In addition, the proposed legend would state that the legend would automatically be removed upon the implementation of the proposed changes.

2. Statutory Basis

Section 17A(b)(3)(F) of the Act requires, *inter alia,* that the Rules be designed to promote the prompt and

includes files containing information on a Participant's allocations and pending allocations. *See* Important Notice 13851–20 (August 27, 2020), *available at https://www.dtcc.com/legal/important-notices.*

[7] There are three types of CCF files representing the corporate actions lifecycle: Corporate actions announcements (''CCF Announcements Files''); the CCF Entitlements and Allocations Files; and corporate actions instructions from Participants through CCF files (''CCF Corporate Actions Instructions Files''). All CCF Announcement Files were retired as of December 31, 2018. *See* Securities Exchange Act Release No. 79746 (January 5, 2017), 82 FR 3372 (January 11, 2017) (SR–DTC–2016–014). CCF Corporate Actions Instructions Files have not yet been retired and are not subject to this proposed rule change.

[8] *See* Securities Exchange Act Release No. 90490 (November 23, 2020), 85 FR 76645 (November 30, 2020) (SR–DTC–2020–016).

[9] There are three event groups for CCF files for corporate actions. Participants subscribe to the CCF files for each event group separately. The event groups are (i) distributions (''Distributions''), such as cash and stock dividends, principal and interest, and capital gain distributions; (ii) redemptions (''Redemptions''), such as full and partial calls, final paydowns, and maturities; and (iii) reorganizations (''Reorganizations''), which include both mandatory and voluntary reorganizations such as exchange offers, conversions, Dutch auctions, mergers, puts, reverse stock splits, tender offers, and warrant exercises.

[10] *See* Securities Exchange Act Release No. 63886 (February 10, 2011), 76 FR 9070 (February 16, 2011) (SR–DTC–2011–02) (indicating that DTC will continue to support its legacy proprietary CCF files until 2015.)

[11] *See* Important Notice 2538–16 (January 21, 2016), *supra* note 6; Important Notice 4381–16 (November 4, 2016), *supra* note 6; Important Notice 5099–17 (February 2017), *supra* note 6; Important Notice 7488–18 (February 28, 2018), *supra* note 6; Important Notice 9861–18 (October 9, 2018), *supra* note 6.

accurate clearance and settlement of securities transactions.[12]

As described above, the proposed rule change would (i) postpone the retirement of CCF Entitlements and Allocations Files to January 1, 2023, and (ii) apply the CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files during the New Fee Period. By postponing the retirement of CCF Entitlements and Allocations Files to January 1, 2023, the proposed rule change would allow Participants to minimize potential business interruptions by undertaking an orderly and organized migration from CCF files to the more efficient ISO 20022 standard. Similarly, by charging a CCF File Fee to those Participants that continue to receive CCF Entitlements and Allocations Files after December 31, 2021, the proposed rule change would encourage Participants to accelerate system development and the adoption of the ISO 20022 standard. In this manner, the proposed rule change would encourage and facilitate the transition to the ISO 20022 standard, which provides efficiencies and enhanced transparency in processing corporate actions and the settlement activities related thereto. Accordingly, DTC believes that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, consistent with the requirements of Section 17A(b)(3)(F) of the Act, cited above.

Section 17A(b)(3)(D) of the Act requires that the Rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Participants.[13] DTC believes that the proposed rule change to apply the CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files during the New Fee Period would provide for the equitable allocation of reasonable fees.

DTC believes that the proposed application of the CCF File Fee would be equitably allocated because the CCF File Fee (i) would only be charged to those Participants that have delayed their migration from CCF Entitlements and Allocations Files beyond December 31, 2021[14] and (ii) would be applied in accordance with the Participant's use of a particular File Category.

Further, DTC believes that the application of the $50,000 CCF File Fee would be reasonable. As discussed above, Participants that did not complete their migration to ISO 20022 by January 1, 2021 were charged the $50,000 CCF File Fee for each File Category of CCF Entitlements and Allocations Files that they consumed during the Original Fee Period. Most Participants completed their migration during the Original Fee Period, which DTC believes is due, in part, to the application of the CCF Fee. Based on this prior experience with the CCF File Fee, DTC believes that the CCF File Fee in the amount of $50,000 provides the necessary encouragement for Participants to accelerate their system development for their adoption of the ISO 20022 standard for entitlements and allocations information.[15] Further, during the application of the CCF File Fee to CCF Entitlements and Allocations Files during the Original Fee Period, DTC had not received any negative feedback from Participants suggesting that the $50,000 fee was overly burdensome.[16]

Therefore, DTC believes that the proposed rule change regarding the CCF File Fee provides for the equitable allocation of reasonable dues, fees, and other charges among its Participants, consistent with Section 17A(b)(3)(D) of the Act, cited above.

(B) Clearing Agency's Statement on Burden on Competition

DTC believes that the proposed rule change with respect to postponing the retirement of CCF Entitlements and Allocations Files to January 1, 2023 would not have any impact on competition. The proposed rule change would provide any Participant that has not completed its migration from CCF Entitlements and Allocation Files with additional time to complete its testing and development of its systems, and finalize the transition to ISO 20022 messaging. Therefore, DTC believes that the proposed rule change with respect to postponing the retirement of CCF Entitlements and Allocations Files to January 1, 2023 would not have a burden on competition.[17]

DTC believes that the proposed rule change with respect to amending the Fee Guide to apply the CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files during the New Fee Period could have an impact on competition because it could create a burden on competition.[18] Although the proposed application of the CCF File Fee is designed to incentivize Participants to accelerate their adoption of the ISO 20022 standard, DTC recognizes and appreciates that charging the fee could negatively affect such Participants' operating costs. However, DTC believes that any burden on competition would not be significant and would be necessary and appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.[19]

DTC believes any burden on competition would not be significant because (i) the fee would only be charged once per File Category, upon the Participant's first receipt of CCF Entitlements and Allocations Files for a File Category during the New Fee Period, and (ii) the application of the CCF File Fee for a File Category would cover the consumption of all CCF Entitlements and Allocations Files within that File Category during the New Fee Period. In addition, based on DTC's prior use of the CCF File Fee for CCF Announcements Files[20] and CCF Entitlements and Application Files, DTC has no indication that the amount of the fee creates a significant burden on any Participant.

DTC believes that any burden on competition that may be created by the proposed change to amend the Fee Guide to apply the CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files during the New Fee Period would be

[12] 15 U.S.C. 78q–1(b)(3)(F).

[13] 15 U.S.C. 78q–1(b)(3)(D).

[14] As discussed above, DTC has been communicating with Participants about the migration from CCF files to the ISO 20022 standard for corporate actions events since 2011. Since 2013, DTC has been communicating with Participants about targeted retirement dates for CCF Entitlements and Allocations Files and has, at the request of Participants, postponed the projected dates numerous times. Before October 2018, DTC had always told Participants that there would not be any charges for the continued consumption of CCF Entitlements and Allocations Files. After the CCF Retirement Filing most Participants did complete development and fully adopted the ISO 20022 standard for entitlements and allocations information, illustrating the effectiveness of the CCF File Fee.

[15] The CCF File Fee is not designed to cover costs incurred by DTC as a result of continuing to service CCF files.

[16] DTC also had charged a similar $50,000 CCF File Fee to Participants that continued to receive the CCF Announcements Files between 2016–2018, in order to encourage Participants to migrate from CCF Announcements Files to ISO 20022 messaging. DTC believes that the CCF File Fee provided a strong incentive for Participants to accelerate their migration from the CCF format to the ISO 2002 standard, thereby allowing DTC to retire all of the CCF Announcements Files by December 31, 2018. *See* Securities Exchange Act No. 76811 (December 31, 2015), 81 FR 826 (January 7, 2016) (SR–DTC–2015–013) (postponing retirement of CCF Announcements Files and implementation of a $50,000 CCF File Fee to encourage prompt transition to the ISO 20022 standard); and see also Securities Exchange Act Release No. 79746 (January 5, 2017), 82 FR 3372 (January 11, 2017) (SR–DTC–2016–014) (establishing the retirement date for CCF Announcement Files).

[17] 15 U.S.C. 78q–1(b)(3)(I).

[18] *Id.*

[19] *Id.*

[20] *See supra* note 16.

necessary and appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.[21] DTC believes that this proposed change would be necessary because some Participants have yet to adopt the ISO 20022 standard, despite at least seven years of communication and prompting on the issue.[22] As noted above, the ISO 20022 standard provides efficiencies and enhanced transparency in processing corporate actions and the settlement activities related thereto. Thus, DTC believes that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.[23]

DTC believes that the proposed rule change to apply the CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files during the New Fee Period would be appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.[24] DTC's prior experience with the $50,000 CCF File Fee and the successful retirement of CCF Announcements Files illustrates that a $50,000 CCF File Fee provides the necessary encouragement for Participants to accelerate their system development for the full adoption of the ISO 20022 standard. Further, during the application of the CCF File Fee to CCF Announcements Files, DTC had not received any negative feedback from Participants that suggested that the $50,000 fee was overly burdensome; nor did DTC receive any objections during the application of the CCF File Fee to CCF Entitlements and Allocations Files during the Original Fee Period that suggested that the $50,000 fee was overly burdensome. Accordingly, DTC believes that application of the $50,000 CCF File Fee would be appropriate here in order to incentivize Participants to accelerate their migration to the ISO 20022 standard. In addition, as discussed above, DTC believes that the proposed application of the CCF File Fee would be equitably allocated because the CCF File Fee (i) would only be charged to those Participants that have delayed their migration from CCF Entitlements and Allocations beyond December 31, 2021 and (ii) would be applied in accordance with the Participant's use of a particular File Category.

Therefore, for these reasons, DTC believes that a perceived competitive burden of the proposed rule change to apply the CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files during the Fee Period would be necessary and appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.[25]

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DTC has not received or solicited any written comments relating to this proposal. If any written comments are received, DTC will amend this filing to publicly file such comments as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting written comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on *How to Submit Comments,* available at *https://www.sec.gov/regulatory-actions/how-to-submit-comments.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

DTC reserves the right to not respond to any comments received.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)[26] of the Act and paragraph (f)[27] of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–DTC–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.

All submissions should refer to File Number SR–DTC–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 (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of DTC and on DTCC's website (*https://dtcc.com/legal/sec-rule-filings.aspx*). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–DTC–2021–018 and should be submitted on or before January 26, 2022.

[21] *Id.*

[22] *See supra* notes 10 and 11.

[23] 15 U.S.C. 78q–1(b)(3)(F).

[24] 15 U.S.C. 78q–1(b)(3)(I).

[25] 15 U.S.C. 78q–1(b)(3)(I).

[26] 15 U.S.C 78s(b)(3)(A).

[27] 17 CFR 240.19b–4(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2021–28569 Filed 1–4–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93888; SR–CboeBZX–2021–086]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend the Opening Auction Process Provided Under Rule 11.23(b)(2)(B)

December 30, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 21, 2021, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes a rule change to amend the Opening Auction process provided under Rule 11.23(b)(2)(B) to better align the Opening Auction Process with current market conditions, and, where certain market conditions are not optimal, to delay the Opening Auction from occurring until those market conditions have improved.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 11.23(b)(2)(B) to make the Opening Auction process more dynamic by, under certain circumstances delaying the Opening Auction in order to incorporate additional information into the determination of the Opening Auction price. Specifically, as proposed the Rule would provide that when there is no Valid NBBO[3] in a BZX-listed security and there is an Indicative Price[4] that is not within the Collar Price Range,[5] the Opening Auction will be delayed until there is a Valid NBBO or the delay period has lapsed, as further described below. The Exchange believes that the proposal will make the Opening Auction price in less liquid securities more representative of current market conditions making the Opening Auction process a more meaningful price formation event in such BZX-listed securities.

Background

Rule 11.23(b)(2)(B) sets forth the process by which the BZX Official Opening Price[6] is determined for BZX-listed securities during the Opening Auction Process. Specifically, as provided in Rule 11.23(b)(2)(B), the Opening Auction price will be the price level within the Collar Price Range that maximizes the number of shares executed between the Continuous Book[7] and Auction Book[8] in the Opening Auction. In the event of a volume based tie at multiple price levels, the Opening Auction price will be the price which results in the minimum total imbalance. In the event of a volume based tie and a tie in minimum total imbalance at multiple price levels, the Opening Auction price will be the price closest to the Volume Based Tie Breaker.[9]

The Volume Based Tie Breaker for an Opening Auction will be the midpoint of the NBBO where there is a Valid NBBO. Where there is no Valid NBBO, the FLSET will be used as the Volume Based Tie Breaker. Because the FLSET is typically based on the most recent execution in a security during Regular Trading Hours, its value may be significantly away from the Indicative Price at the time of the Opening Auction process, especially in more thinly traded securities. As a result, the Exchange has observed instances where auction eligible orders priced in-line with the Indicative Price were not executed in the Opening Auction because they were outside the Collar Price Range established using the FLSET. Based on analysis by the Exchange and feedback from market participants, certain of these instances resulted in orders not receiving executions in the Opening Auction that would have otherwise occurred at prices that would have been acceptable to both parties to the execution. To illustrate this point, the Exchange presents the following example: Consider a security with a prevailing NBBO at 9:30:00 a.m. of $27.10 × $29.54 and an Indicative Price of $27.90. Because the midpoint of the NBBO (*i.e.,* $28.32) is more than the Maximum Percentage away from both the NBB and NBO, the NBBO is not a Valid NBBO. Accordingly, the FLSET would be used as the Volume Based Tie Breaker, which would by definition be the BZX Official Closing Price from the previous business day. For purposes of this example, that price is $26.52. Using the FLSET as the Collar Midpoint, the Collar Price Range would be $25.19 × $27.85. Because the Indicative Price is outside of the Collar Price Range, the auction would occur at the upper most price that is included in the Collar Price Range (*i.e.,* $27.85) even though more shares could have executed at $27.90. Because the Opening Auction was forced into the Collar Price Range and occurred at $27.85, a contingent of auction eligible orders that would have executed at $27.90 that were priced

[28] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] As provided in Rule 11.23(a)(23), an NBBO is a Valid NBBO where: (i) There is both a NBB and NBO for the security; (ii) the NBBO is not crossed; and (iii) the midpoint of the NBBO is less than the Maximum Percentage away from both the NBB and the NBO. *See* Exchange Rule 11.23(a)(23).

[4] The term ''Indicative Price'' shall mean the price at which the most shares from the Auction Book and the Continuous Book would match. In the event of a volume based tie at multiple price levels, the Indicative Price will be the price which results in the minimum total imbalance. In the event of a volume based tie and a tie in minimum total imbalance at multiple price levels, the Indicative Price will be the price closest to the Volume Based Tie Breaker. *See* Exchange Rule 11.23(a)(10).

[5] *See* Exchange Rule 11.23(a)(6).

[6] *See* Exchange Rule 11.23(a)(5).

[7] *See* Exchange Rule 11.23(a)(7).

[8] *See* Exchange Rule 11.23(a)(1).

[9] The Volume Based Tie Breaker is the midpoint of the NBBO for a particular security where the NBBO is a Valid NBBO. Where the NBBO is not a Valid NBBO, the price of the FLSET is used as the Volume Based Tie Breaker, which for the Opening Auction process is the previous BZX Official Closing Price. *See* Exchange Rule 11.23(a)(23).

equally to or more aggressive than the Indicative Price and within the NBBO (*i.e.,* sell orders priced between $27.86 and $27.90) would be canceled without execution.[10]

Proposal

Based on the scenario described above, the Exchange is proposing to amend its Opening Auction process such that rather than immediately forcing the Opening Auction to occur at either the lowest or highest end of the Collar Price Range and cancelling auction eligible orders that were willing to execute at the Indicative Price but outside of the Collar Price Range, the System would instead wait for the first of a Valid NBBO, the Indicative Price to be within the Collar Price Range, or the passage of a certain amount of time before initiating the Opening Auction process, as described in additional detail below. Proposed Rule 11.23(b)(2)(B)(i) would set forth the ''Standard Opening Process'', which mirrors the current process described in Rule 11.23(b)(2)(B). Proposed Rule 11.23(b)(2)(B)(ii) would provide that if there is no Valid NBBO and the Indicative Price is within the Collar Price Range, the Opening Auction price will be established pursuant to the Standard Opening Process. Proposed Rule 11.23(b)(2)(B)(iii) would delay and set forth an alternative Opening Auction Process in the event there is no Valid NBBO and the Indicative Price is not within the Collar Price Range. The proposal is designed to prevent the cancellation of auction eligible orders priced equally or more aggressively than the Indicative Price which the Exchange believes will facilitate the presence of sufficient liquidity and information to make the Opening Auction a meaningful price formation event in BZX-listed securities.

Proposed Rule 11.23(b)(2)(B)(iii) would provide that the Opening Auction price will be delayed as set forth in subparagraphs (a) and (b) as follows:

(a) If after the one-second delay there is a Valid NBBO or the Indicative Price is within the Collar Price Range, the Opening Auction price will be established pursuant to the Standard Opening Auction Process. If there is no Valid NBBO and the Indicative Price is not within the Collar Price Range after the one-second delay, the Opening Auction will be delayed by one additional second, at which point if there is a Valid NBBO or the Indicative Price is within the Collar Price Range, the Opening Auction price will be established pursuant to the Standard Opening Process. If after the additional one-second delay there is a Valid NBBO or the Indicative Price is not within the Collar Price Range, the process described in this paragraph (a) will continue to be applied in one-second increments until either the Opening Auction occurs or until five seconds has lapsed (*i.e.,* 9:30:05 a.m.).

(b) If the Opening Auction has not occurred by 9:30:05, the System will widen the Collar Price Range in the direction of the auction imbalance by 5% of the Final Last Sale Eligible Trade as of 9:30:05 a.m. (the ''Widening Amount''). If the Indicative Price is within the widened Collar Price Range, the Opening Auction price will be established pursuant to the Standard Opening Auction Process. If the Indicative Price is not within the widened Collar Price Range, the Opening Auction will be further delayed, as discussed below.

Proposed Rules 11.23(b)(2)(B)(iii)(b)(1) through (4) would set forth the delay of the Opening Auction if no auction has occurred between 9:30:05 and 9:34:30. Specifically, the proposed Rules would provide:

(1) The System will check to see whether the Indicative Price is inside the widened Collar Price Range every second between 9:30:05 and 9:30:30 a.m. If an Indicative Price is inside the widened Collar Price Range during a check, the Opening Auction price will be established pursuant to the Standard Opening Auction Process.

(2) If by 9:30:30 a.m. the Indicative Price is not within the widened Collar Price Range, the Collar Price Range will again widen by the Widening Amount. The System will check to see whether the Indicative Price is inside the widened Collar Price Range every second between 9:30:30 and 9:31:30 a.m. If an Indicative Price is inside the widened Collar Price Range during a check, the Opening Auction price will be established pursuant to the Standard Opening Auction Process.

(3) If by 9:31:30 a.m. the Indicative Price is not within the widened Collar Price Range, the System will check to see whether the Indicative Price is inside the widened Collar Price Range every second between 9:31:30 and 9:34:30 a.m. If an Indicative Price is inside the widened Collar Price Range during a check, the Opening Auction price will be established pursuant to the Standard Opening Auction Process. Unless the Opening Auction has occurred, the Collar Price Range will widen in the direction of the auction imbalance by the Widening Amount each minute from 9:31:30 to 9:34:30.

(4) If no Opening Auction has occurred by 9:34:30 a.m., the Opening Auction will occur pursuant to the Standard Opening Auction Process using the expanded Collar Price Range as of 9:34:30.

The Exchange also proposes to move the last two sentences of existing Rule 11.23(b)(2)(B) to proposed Rules 11.23(b)(2)(B)(iv) and (v), respectively. Specifically, proposed Rule 11.23(b)(2)(B)(iv) would provide that the Opening Auction Price will be the BZX Official Opening Price. Proposed Rule 11.23(b)(2)(B)(v) would provide that in the event that there is no Opening Auction for an issue, the BZX Official Opening Price will be the price of the FLSET.

Based on the above proposed amendments, the Exchange proposes to amend Rules 11.23(b)(1)(A) and (B) to reflect that the Opening Auction may occur at a time other than 9:30 a.m. Specifically, the Exchange proposes to amend paragraph (A) to provide the following: Users may submit orders to the Exchange as set forth in Rule 11.1. Any Eligible Auction Orders[11] designated for the Opening Auction will be queued for participation in the Opening Auction. Users may submit limit-on-open (''LOO'') and market-on-open (''MOO'') orders until 9:28 a.m., at which point any additional LOO and MOO orders submitted to the Exchange will be rejected. Regular Hours Only[12] (''RHO'') market orders will also be rejected from 9:28 a.m. until the Opening Auction has concluded. Users may submit late-limit-on-open[13] (''LLOO'') orders from 9:28 a.m. until the Opening Auction has concluded. Any LLOO orders submitted before 9:28 a.m. or after the Opening Auction has concluded will be rejected. RHO limit orders submitted from 9:28 a.m. until the Opening Auction has concluded will be treated as LLOO orders.

The Exchange proposes to amend Rule 11.23(b)(1)(B) to provide that Eligible Auction Orders designated for the Opening Auction may not be cancelled or modified from 9:28 a.m. until the Opening Auction has concluded except that RHO limit orders designated for the Opening Auction may be modified, but not cancelled, from 9:28 a.m. until the time the Opening Auction has concluded. Any such RHO limit orders modified from 9:28 a.m. until the Opening Auction has

[10] *See* Exchange Rule 11.23(b)(3)(C).

[11] *See* Exchange Rule 11.23(a)(8).

[12] *See* Exchange Rule 11.9(b)(7).

[13] *See* Exchange Rule 11.23(a)(12).

concluded will be treated as LLOO orders.

Applying the example discussed above, the Opening Auction would be delayed at 9:30:00 as there was no Valid NBBO and the Indicative Price was outside of the Collar Price Range. Under the proposal, the Opening Auction would be delayed until either (1) the NBBO becomes a Valid NBBO, (2) the Indicative Price is within the Collar Price Range (*i.e.,* if the Opening Auction occurred between 9:30:01 and 9:30:05) or within the widened Collar Price Range (*i.e.,* if the Opening Auction occurred between 9:30:06 and 9:34:30), or (3) the delay period of four minutes and 30 seconds lapsed. While the proposal does not guarantee that certain order priced equally or more aggressive to the Indicative Price will execute in the Opening Auction, it provides for additional time for the market to develop at the beginning of the trading day before conducting the Opening Auction.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act.[14] Specifically, the proposed change is consistent with Section 6(b)(5) of the Act,[15] because it would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest. Generally, the Exchange believes that the proposed changes will improve the price discovery process in the Opening Auction for securities listed on the Exchange along with additional benefits set forth below.

First, the Exchange believes proposed Rules 11.23(b)(2)(B)(i) and (ii) will contribute to the protection of investors and the public interest by memorializing the circumstances under which the Exchange will continue to operate the Opening Auction in the same way that it does today. Second, the Exchange believes proposed Rule 11.23(b)(2)(B)(iii) would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest. The proposal is designed to increase the likelihood that auction eligible orders that are priced equally or more aggressive than the Indicative Value of the security are able to participate in the Opening Auction instead of being canceled because they are priced outside the Collar Price Range established using the FLSET. As stated above, current Rule 11.23(b)(2)(B) provides that in the event there is no Valid NBBO, the FLSET will be used as the Volume Based Tie Breaker and basis for calculating the Collar Price Range. Because the current Opening Auction process occurs at 9:30:00 a.m., such a Collar Price Range is based on an FLSET that may not have occurred recently or may not otherwise be reflective of current market conditions. As a result, the Exchange has observed instances where auction eligible orders priced equally or more aggressive than the Indicative Price were canceled without execution because they were outside the Collar Price Range established using the FLSET. The Exchange believes that the proposed approach would maximize the execution of auction eligible orders priced equally or more aggressive than the Indicative Price of the security while still [sic]. As such, the Exchange believes that the proposal would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest by allowing the execution of orders in the Opening Auction with limit prices reflect current market conditions.

The Exchange notes that the concept of delaying an auction and widening the Collar Price Range is similar to the Twelfth Amendment of the Plan to Address Extraordinary Market Volatility[16] (the ''Plan''). Specifically, Amendment 12 was created to improve re-openings following a trading pause,[17] with an eye towards carefully balancing halt auction price quality and the speed with which continuous trading can be resumed. Amendment 12 provided that auction halt periods would be extended if either the auction price at which the most shares would be traded is outside the range of the pre-defined price threshold collars (the ''price threshold collars'') or there is a market order share imbalance. Further, Amendment 12 provided that the price threshold collars would be widened in the event that the auction's halt period is extended. In its approval of Amendment 12, the Commission stated that it is appropriate in the public interest, for the protection of investors and the maintenance of a fair and orderly market to provide that a trading pause continue until the primary listing exchange has reopened trading using its established reopening procedures, even if such reopening is more than 10 minutes after the beginning of a trading pause, and to require that trading centers may not resume trading in an NMS Stock following a trading pause without Price Bands in such NMS Stock. The Commission believes that these two provisions together support a more standardized process for reopening trading after a trading pause has been declared. Further, these provisions ensure that trading would not resume after a trading pause without Price Bands. Given the similarity of the proposal to Amendment 12, the Exchange believes the proposal is appropriate, in the public interest, for the protection of investors and the maintenance of a fair and orderly market.

Finally, the Exchange believes its proposed clarifications to Rules 11.23(b)(1)(A) and (B) to reflect that the Opening Auction may occur at a time other than 9:30 a.m. will contribute to the protection of investors and the public interest. Specifically, the Exchange believes the proposed amendments to Rules 11.23(b)(1)(A) and (B) will add clarity, transparency and internal consistency to Exchange rules making them easier to navigate, in light of the other proposed Rule changes described herein.

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. To the contrary, allowing the Exchange to make the above proposed modifications will allow the Exchange to better compete with other exchanges as a listing venue by improving the Exchange's auction process by allowing more executions to occur at more reasonable prices that are based on the current value of the security. As mentioned above, the Exchange has received feedback from market participants regarding the issue under the current process, and the proposed amendments will both address this feedback and improve the Exchange's auction process, allowing it

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] *See* Securities and Exchange Act no. 79410 (November 28, 2016) 81 FR 87114 (December 2, 2016) (Notice of Filing of the Twelfth Amendment to the National Market System Plan To Address Extraordinary Market Volatility (''Amendment 12'')).

[17] A ''trading pause'' refers to a function of the Limit Up-Limit Down (''LULD'') mechanism provided under the Plan. Specifically, the Plan sets for procedures that provide for market-wide LULD requirements that prevent trades in individual NMS stocks from occurring outside of the specified price bands and provides for trading pauses to accommodate more fundamental price moves.

to better compete as both a listing and execution venue.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2021–086 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2021–086. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–CboeBZX–2021–086 and should be submitted on or before January 26, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2021–28572 Filed 1–4–22; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

SBA Council on Underserved Communities Meeting

AGENCY: Small Business Administration (SBA).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for the first meeting of the SBA Council on Underserved Communities. The meeting will be virtual and streamed live to the public.

DATES: The meeting will be held on Tuesday, January 11th, 2022, from 9:00 a.m. to 1:00 p.m. Eastern Standard Time.

ADDRESSES: The meeting will be live streamed on Zoom. To Register sign up here: *https://www.zoomgov.com/webinar/register/WN_v29I1eLlT22orc7Yi0opkQ.*

FOR FURTHER INFORMATION CONTACT: The meeting will be live streamed and open to the public, and anyone wishing to submit questions to the SBA Council on Underserved Communities can do so by submitting them via email to *underservedcouncil@sba.gov.*

Additionally, if you need accommodations because of a disability or require additional information, please contact Bajeyah Eaddy, SBA, Office of the Administrator, 409 Third Street SW, Washington, DC 20416, 202–941–5997 or *Bajeyah.Eaddy@sba.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., appendix 2), SBA announces the meeting of the SBA Council on Underserved Communities (the ''Council''). The Council is tasked with providing advice, ideas and opinions on SBA programs and services and issues of interest to small businesses in underserved communities. For more information, please visit *http://www.sba.gov/cuc.*

The purpose of the meeting is to provide the Council with information on SBA's efforts to support small businesses in underserved communities, as well as provide an opportunity for the Council to discuss its goals for the coming months. The Council will provide insights based on information they've heard from their communities and discuss areas of interest for further research and recommendation development.

Dated: December 29, 2021.

Andrienne Johnson,

SBA Committee Management Officer.

[FR Doc. 2021–28501 Filed 1–4–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice: 11616]

Notice of Determinations; Culturally Significant Objects Being Imported for Conservation and Exhibition—Determinations: ''Henri Matisse: The Red Studio'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary conservation and display in the exhibition ''Henri Matisse: The Red Studio'' at The Museum of Modern Art, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary conservation and exhibition or display within the United States as aforementioned are in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of

State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2021–28511 Filed 1–4–22; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 765; Docket No. EP 755; Docket No. EP 665 (Sub-No. 2)]

Joint Petition for Rulemaking To Establish a Voluntary Arbitration Program for Small Rate Disputes; Final Offer Rate Review; Expanding Access to Rate Relief

AGENCY: Surface Transportation Board.

ACTION: Extending time to submit reply comments.

SUMMARY: The Board grants, in part, a motion for an extension of time to file comments in Docket No. EP 765, extending the deadline for reply comments until April 15, 2021. The Board also will extend the deadline for reply comments in Docket Nos. EP 755 and EP 665 (Sub-No. 2) until April 15, 2022.

DATES: The reply comment periods established by the notices published on November 26, 2021, at 86 FR 67622 and 86 FR 67588 are extended until April 15, 2022.

FOR FURTHER INFORMATION CONTACT: Amy Ziehm at (202) 245–0391. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision, which is available at *www.stb.gov.*

Decided: December 28, 2021.

By the Board, Board Members Fuchs, Oberman, Primus, and Schultz.

Andrea Pope-Matheson,

Clearance Clerk.

[FR Doc. 2021–28528 Filed 1–4–22; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Youth Access to American Jobs in Aviation Task Force; Notice of Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: This notice announces a meeting of the Youth Access to American Jobs in Aviation Task Force (YIATF).

DATES: The meeting will be held on January 20, 2022, from 9:00 a.m.–11:30 a.m. Eastern Time.

Requests for accommodations to a disability must be received by January 10, 2022.

Requests to submit written materials to be reviewed during the meeting must be received no later than January 10, 2022.

ADDRESSES: The meeting will be held virtually. Members of the public who wish to observe the virtual meeting may access the event live on the FAA's *Twitter, Facebook* and *YouTube* channels. For copies of meeting minutes along with all other information, please visit the YIATF internet website at *https://www.faa.gov/regulations_policies/rulemaking/committees/documents/index.cfm/committee/browse/committeeID/797.*

FOR FURTHER INFORMATION CONTACT: Ms. Aliah Duckett, Federal Aviation Administration, by email at *S602YouthTaskForce@faa.gov* or phone at 202–267–8361. Any committee-related request should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

I. Background

On October 3, 2019, FAA established the Task Force under the Federal Advisory Committee Act (FACA) in accordance with section 602 of the FAA Reauthorization Act of 2018 (Pub. L. 115–254). The Task Force is required by statute to develop and provide independent recommendations and strategies to the FAA Administrator to: (1) Facilitate and encourage high school students in the United States to enroll in and complete career and technical education courses, including science, technology, engineering, and mathematics (STEM), that will prepare them to pursue a course of study related to an aviation career at an institution of higher education, a community college, or trade school; (2) facilitate and encourage these students to enroll in a course of study related to an aviation career, including aviation manufacturing, engineering and maintenance, at an institution of higher education, including a community college or trade school; and (3) identify and develop pathways for students to secure registered apprenticeships, workforce development programs, or careers in the aviation industry of the United States.

The charter was renewed on October 4, 2021.

II. Agenda

At the meeting, the agenda will cover the following topics:

- Welcome/Opening Remarks
- Approval of Previous Meeting Minutes
- Subcommittee Presentations
- Review of Action Items
- Closing Remarks

A detailed agenda will be posted on the YIATF internet website address listed in the **ADDRESSES** section at least 15 days in advance of the meeting. Copies of the meeting minutes will also be available on the YIATF internet website.

III. Public Participation

The meeting will be open to the public and livestreamed. Members of the public who wish to observe the virtual meeting can access the livestream on the FAA social media platforms listed in the **ADDRESSES** section on the day of the event.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

The FAA is not accepting oral presentations at this meeting due to time constraints. However, the public may present written statements to the Task Force by providing a copy to the Designated Federal Officer via the email listed in the **FOR FURTHER INFORMATION CONTACT** section.

Issued in Washington, DC.

Timothy R. Adams,

Acting Executive Director, Office of Rulemaking, Federal Aviation Administration.

[FR Doc. 2021–28517 Filed 1–4–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

[Docket No. DOT–OST–2021–0038]

Request for Comments on a Previously Approved Information Collection: Information Associated With the Aviation Manufacturing Jobs Protection (AMJP) Program

AGENCY: Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on September 21, 2021. No comments were received.

DATES: Comments must be submitted on or before February 4, 2022.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW, Washington, DC 20503.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Information related to this ICR, including applicable supporting documentation may be obtained by contacting Alexus Jenkins-Reid in the Office of the Secretary of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, via telephone at (202) 366–5112, or via email at *AMJP@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Information Associated with the Aviation Manufacturing Jobs Protection (AMJP) Program.

Form Numbers: New collection, Forms AMJP–1A.2.2, AMJP–1A.2.3, AMJP–1A.2.4, AMJP–1A.6.4, AMJP–1A.6.5, AMJP–1A.6.6, AMJP–1A6.7 (available at *https://www.transportation.gov/amjp/resources-recipients*).

OMB Control Number: 2106–0048.

Type of Request: Renewal and update of Information Collection previously approved.

Abstract: The Department of Transportation (DOT) hereby asks the Office of Management and Budget (OMB) approval to renew and revise an information collection that was approved under an emergency clearance approval by OMB through November 30, 2021.

On March 11, 2021, the ''American Rescue Plan Act of 2021'' (ARPA), Public Law (P.L.) 117–2, was enacted. Sections 7201 and 7202 established the ''Aviation Manufacturing Jobs Protection'' (AMJP) program. The stated purpose of the program is ''to provide public contributions to supplement compensation of an eligible employee group'' (which is defined in the statute), by entering into agreements with qualifying business entities to pay up to half of the payroll costs for that group of employees for up to six months, in return for several commitments, including a commitment that the company will not involuntarily furlough or lay off employees within that group. Individual employees (including contract employees) are not eligible to apply for assistance under this program.

Application for assistance under the AMJP was voluntary. No business was required to apply. To be eligible, however, businesses were required to meet all the requirements set forth in the law. Therefore, DOT was required to collect certain information from applicants to determine eligibility. DOT must also verify the accuracy of specific payment requests from approved applicants, in accordance with other laws and regulations governing Federal financial assistance programs, including (but not limited to) the Antideficiency Act, the Federal Funding Accountability and Transparency Act (FFATA), the Payment Integrity Information Act of 2019, and applicable provisions in 2 CFR part 200, among others.

The ARPA required DOT to reduce funding on a *pro rata* basis if eligible requests exceeded available funds. Therefore, DOT originally planned to conduct a single-round, expedited application process to identify all eligible requests before beginning the award process. Accordingly, DOT developed a process and system to enable businesses to apply for financial assistance under the AMJP. DOT used an online, web-based system to collect the information outlined in the notice at 86 FR 19695. OMB provided emergency approval on May 26, 2021, with information collection control number 2106–0048.

DOT subsequently announced the beginning of the application process on June 14, 2021, via notice at 86 FR 31573. DOT posted the application instructions online at *https://www.transportation.gov/AMJP/apply.* The application process was open for four weeks, from June 14, 2021 through July 13, 2021. DOT subsequently reopened the application process for another four-week period ending September 1, 2021. On November 8, 2021, DOT made the decision to reopen the application process for one final period ending December 13, 2021.

DOT has publicly announced more than 470 offers of financial assistance under the AMJP, totaling more than $666 million, resulting from the first two application processes. As of the signature date of this notice, DOT has awarded 446 financial assistance agreements, totaling approximately $597 million. DOT is renewing and updating this information collection. DOT will continue to require eligible recipients to attest that they continue to meet all the original eligibility requirements as previously outlined, as well as the following information:

- A sworn certification as to the complete and accurate nature of all information provided, including all supporting documentation, subject to civil or criminal penalties. The specific certification language is in the forms referenced above and section 4.8 of the General Terms And Conditions Under The Aviation Manufacturing Jobs Protection Program.[1]
- After DOT determines eligibility and enters into an agreement with the applicant (referred to hereafter as ''the recipient''), DOT will also require the recipient to provide the actual aggregate total cost of compensation for the Eligible Employee Group during the period of the agreement with DOT, in order for DOT to review and approve actual disbursements pursuant to the agreement. Recipients will be required to provide supporting documentation in sufficient detail to substantiate the

[1] See *https://www.transportation.gov/amjp/resources-recipients* for text of a sample AMJP agreement, including the General Terms and Conditions.

actual costs, specifically excluding any Personally Identifiable Information (PII) for any individual employees. Recipients will also be required to provide additional supporting information and certifications in support of disbursement requests. See Forms AMJP–1A–6.4, AMJP–1A–6.6, and AMJP–1A–6.7.

• DOT may also ask recipient businesses to submit voluntary reports regarding demographic data associated with the workforce that is and is not included in the Eligible Employee Group. This would be voluntary on the part of the employer and based solely on voluntary data self-reported by employees, disaggregated from any Personally Identifiable Information in order to avoid any potential privacy concerns. If a statistically valid sample can be developed, then it may be possible to extrapolate for reporting and program evaluation purposes. Such information may be used to support program evaluation.

• DOT may also ask recipient businesses to identify how they first learned about the AMJP program. Such information may be useful in implementation of future financial assistance programs.

DOT has updated the following estimated public burden figures based on the actual number of applications received as well as observations during the application review process. In order to help reduce the burden on recipients (and particularly on small businesses), DOT decided to make an initial disbursement shortly after award of each agreement. The initial disbursement is up to 50 percent of the award amount. This provides the recipient businesses with an immediate cash infusion, while also reducing the total number of disbursements and the cumulative paperwork required. DOT announced this decision in the application package published on June 15, 2021.

Estimated Number of Respondents: 600 eligible business entities in the aviation manufacturing, maintenance, repair, and overhaul services based in the United States.

Estimated Number of Responses: See ''Annual Estimated Total Burden Hours,'' below.

Frequency of Collection: One-time application (already completed), to be followed by disbursement requests and final closeout reports (including supporting payroll documentation and reporting requirements).

Estimated Total Annual Burden Hours: Total burden, 16,800 hours (28 hours per respondent including 4 hours for each of 2 disbursement requests; 14 hours for required forms; 2 hours for voluntary demographic data; and 4 hours for closeout documentation).[2]

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued in Washington, DC, on December 12, 2021.

Brian Elliott Black,

Program Director, Aviation Manufacturing Jobs Protection (AMJP) Program.

[FR Doc. 2021–27329 Filed 1–4–22; 8:45 am]

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[2] DOT published these figures in the 60-day notice on September 21, 2021. As of that date, DOT believed that the application process had been concluded, and therefore no longer included figures associated with the AMJP application process (which DOT did include in the original request for emergency approval published on April 14, 2021). DOT subsequently reopened the application process for a third and final round, with an application deadline of December 13, 2021. If another 150 applicants apply, then this would represent an additional burden of 2,400 hours at an estimated cost of $89,740.50.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Covered Savings Associations

AGENCY: Office of the Comptroller of the Currency, Treasury (OCC).

ACTION: Notice and request for comment.

SUMMARY: The Office of the Comptroller of the Currency (OCC) as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on an information collection renewal as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The OCC is soliciting comment concerning the renewal of its information collection titled ''Covered Savings Associations.''

DATES: Comments must be received by March 7, 2022.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

• *Email: prainfo@occ.treas.gov.*

• *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0341, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

• *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

• *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0341'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet. Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period.

• *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0341'' or ''Covered Savings Associations.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.

• For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR

1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the proposed collection of information set forth in this document.

Abstract: The Home Owners' Loan Act (HOLA), as amended by the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA), allows an FSA with total consolidated assets of $20 billion or less, as of December 31, 2017, to elect to operate as a CSA. This section of HOLA requires the OCC to issue rules that, among other things, establish streamlined standards and procedures for FSA elections to operate as CSAs and clarify the requirements for the treatment of CSA. A CSA has the same rights and privileges as a national bank and is subject to the same duties and restrictions as a national bank.

Twelve CFR part 101 allows Federal savings associations (FSAs) to elect national bank powers and operate as covered savings associations (CSAs). An FSA seeking to operate as a CSA is required under 12 CFR 101.3(a) to submit a notice making an election to the OCC that: (1) Is signed by a duly authorized officer of the FSA; and (2) identifies and describes any nonconforming subsidiaries, assets, or activities that the FSA operates, holds, or conducts at the time its submits its notice.

Under 12 CFR 101.5(a), the OCC may require a CSA to submit a plan to divest, conform, or discontinue a nonconforming subsidiary, asset, or activity.

A CSA may submit a notice to terminate its election to operate as a CSA under 12 CFR 101.6 using similar procedures to those for an election. In addition, after a period of five years, an FSA that has terminated its election to operate as a CSA may submit a notice under 12 CFR 101.7 to reelect using the same procedures used for its original election.

Title of Collection: Covered Savings Associations.

OMB Control No.: 1557–0341.

Election, Termination, Reelection:

Estimated Number of Respondents: 267.

Estimated Burden per Respondent: 1 hour.

Estimated Annual Burden: 267 hours.

Plan to Divest:

Estimated Number of Respondents: 25.

Estimated Burden per Respondent: 2 hours.

Estimated Annual Burden: 50 hours.

Total Annual Burden: 317 hours.

Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: December 6, 2021.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2021–28591 Filed 1–4–22; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been removed from the Specially Designated Nationals and Blocked Persons List (SDN List). Their property and interests in property are no longer blocked, and U.S. persons are no longer generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date.

FOR FURTHER INFORMATION CONTACT:

OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On December 30, 2021, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are unblocked and they have been removed from the SDN List under the relevant sanctions authorities listed below.

Individuals

1. GUTIERREZ RESTREPO, Luis Fernando (a.k.a. ''LUIFER''); DOB 13 Aug 1958; POB Belmira, Antioquia, Colombia; citizen Colombia; Cedula No. 70550107 (Colombia) (individual) [SDNTK] (Linked To: ROBIREPUESTOS; Linked To: IMPORTADORA MARENOL LIMITADA).

2. ABRIL CORTEZ, Oliverio (a.k.a. ABRIL CORTES, Oliverio; f.k.a. CORTEZ, Oliverio Abril), c/o INVERSIONES EL PENON S.A., Cali, Colombia; c/o CONSTRUCTORA DIMISA LTDA., Cali, Colombia; c/o AGROPECUARIA BETANIA LTDA., Cali, Colombia; c/o VALLADARES LTDA., Cali, Colombia; c/o INVERSIONES GEMINIS S.A., Cali, Colombia; c/o W. HERRERA Y CIA. S. EN C., Cali, Colombia; Calle 18A No. 8A–20, Jamundi, Colombia; c/o INVERSIONES EL GRAN CRISOL LTDA., Cali, Colombia; DOB 20 Aug 1956; Cedula No. 3002003 (Colombia); Passport AF368431 (Colombia) (individual) [SDNT].

3. ACERO PIEDRAHITA, Cesar Augusto, Avenida 7N No. 17A–48, Cali, Colombia; c/o AGROPECUARIA LA ROBLEDA S.A., Cali, Colombia; DOB 20 May 1965; Cedula No. 70564947 (Colombia) (individual) [SDNT].

4. AMEZQUITA MENESES, Salustio, c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia; c/o INVERSIONES GEMINIS S.A., Cali, Colombia; DOB 01 Jul 1946; Cedula No. 14943885 (Colombia) (individual) [SDNT].

5. ANGULO OROBIO (SEGUNDO), Jose Francisco, Avenida 4N No. 17–43 apt. 801, Cali, Colombia; c/o INVERSIONES Y CONSTRUCCIONES VALLE S.A., Cali, Colombia; DOB 08 Sep 1964; Cedula No. 16706561 (Colombia) (individual) [SDNT].

6. ARBOLEDA ROMERO, Julio Cesar, c/o INVERSIONES BETANIA LTDA., Cali, Colombia; c/o INVERSIONES EL PENON S.A., Cali, Colombia; DOB 01 Dec 1953; Cedula No. 16205508 (Colombia) (individual) [SDNT].

7. ARIZABALETA ARZAYUS, Phanor (a.k.a. ARIZABALETA ARZAYUS, Fanor), Avenida 39 No. 15–22, Bogota, Colombia; c/o CONSTRUCTORA ALTOS DEL RETIRO LTDA., Bogota, Colombia; c/o INVERSIONES ARIO LTDA., Cali, Colombia; Carrera 9 No. 9S–35, Buga, Colombia; Carrera 4 No. 12–41 of. 710, Cali, Colombia; Calle 110 No. 30–45, Bogota, Colombia; DOB 12 May 1938; Cedula No. 2879530 (Colombia) (individual) [SDNT].

8. BANDERAS, Aracelly, c/o AGROPECUARIA LA ROBLEDA S.A., Cali,

Colombia; DOB 30 Nov 1955 (individual) [SDNT].

9. BECERRA BECERRA, Alvaro, c/o AGROPECUARIA LA ROBLEDA S.A., Cali, Colombia; Cedula No. 2730788 (Colombia) (individual) [SDNT].

10. BUITRAGO DE HERRERA, Luz Mery, c/o AGROPECUARIA BETANIA LTDA., Cali, Colombia; c/o AGROPECUARIA Y REFORESTADORA HERREBE LTDA., Cali, Colombia; c/o CONSTRUEXITO S.A., Cali, Colombia; c/o INVERSIONES BETANIA LTDA., Cali, Colombia; c/o INVERSIONES INVERVALLE S.A., Cali, Colombia; c/o VALLADARES LTDA., Cali, Colombia; c/o SOCOVALLE, Cali, Colombia; c/o W. HERRERA Y CIA., Cali, Colombia; c/o INVERSIONES GEMINIS S.A., Cali, Colombia; c/o INVERSIONES HERREBE LTDA., Cali, Colombia; c/o INVERSIONES EL GRAN CRISOL LTDA., Cali, Colombia; DOB 24 Aug 1924; Cedula No. 29641219 (Colombia) (individual) [SDNT].

11. BUITRAGO MARIN, Adiela, c/o CONSTRUEXITO S.A., Cali, Colombia; c/o INDUSTRIA AVICOLA PALMASECA S.A., Cali, Colombia; DOB 28 Feb 1951; Cedula No. 31137617 (Colombia) (individual) [SDNT].

12. BUITRAGO MARIN, Nubia, c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia; DOB 05 Apr 1948; Cedula No. 31132922 (Colombia) (individual) [SDNT].

13. CASTRILLON CRUZ, Maria Leonor, c/o AGROPECUARIA LA ROBLEDA S.A., Cali, Colombia; DOB 25 Oct 1922; Cedula No. 31138584 (Colombia) (individual) [SDNT].

14. CHAVARRO, Hector Fabio, c/o VALLADARES LTDA., Cali, Colombia; c/o AGROPECUARIA BETANIA LTDA., Cali, Colombia; c/o INVERSIONES VILLA PAZ S.A., Cali, Colombia; DOB 28 Sep 1959; Cedula No. 16263212 (Colombia) (individual) [SDNT].

15. CORREA PULGARIN, Ernesto, c/o AGROPECUARIA LA ROBLEDA S.A., Cali, Colombia; Cedula No. 2510585 (Colombia) (individual) [SDNT].

16. CUARTES MORALES, Juan Carlos, c/o INVERSIONES Y CONSTRUCCIONES VALLE S.A., Cali, Colombia; DOB 09 Nov 1968; Cedula No. 16757375 (Colombia) (individual) [SDNT].

17. CUERO MARTINEZ, Otalvaro, c/o INVHERESA S.A., Cali, Colombia; c/o ALKALA ASOCIADOS S.A., Cali, Colombia; DOB 17 Aug 1955; Cedula No. 16599979 (Colombia) (individual) [SDNT].

18. CULZAT LUGSIR, Rafael Alberto, c/o CONSTRUCTORA ALTOS DEL RETIRO LTDA., Bogota, Colombia; Calle 7 Oeste No. 2–228, Cali, Colombia; Transversal 3 No. 86–73, Bogota, Colombia; c/o INVERSIONES CULZAT GUEVARA Y CIA. S.C.S., Cali, Colombia; DOB 23 Oct 1940; Cedula No. 14962523 (Colombia); Passport P551220 (Colombia) (individual) [SDNT].

19. DIAZ, Manuel, c/o INMOBILIARIA GALES LTDA, Bogota, Colombia; c/o COMERCIAL DE NEGOCIOS CLARIDAD Y CIA., Bogota, Colombia; c/o COMERCIALIZADORA EXPERTA Y CIA. S. EN C., Bogota, Colombia; DOB 10 Feb 1954; Cedula No. 396358 (Colombia) (individual) [SDNT].

20. DIAZ, Rosa Isabel, c/o INVHERESA S.A., Cali, Colombia (individual) [SDNT].

21. ESCOBAR BUITRAGO, Walter, c/o INMOBILIARIA BOLIVAR LTDA., Cali, Colombia; c/o SERVIAUTOS UNO A 1A LIMITADA, Cali, Colombia; DOB 08 Feb 1971; Cedula No. 16785833 (Colombia); Passport AD254557 (Colombia) (individual) [SDNT].

22. FIGUEROA DE BRUSATIN, Dacier, c/o W. HERRERA Y CIA. S. EN C., Cali, Colombia; c/o INVERSIONES EL GRAN CRISOL LTDA., Cali, Colombia; DOB 07 Nov 1930; Cedula No. 29076093 (Colombia) (individual) [SDNT].

23. GALINDO, Gilmer Antonio (a.k.a. GUZMAN TRUJILLO, Carlos Arturo), c/o CONSTRUEXITO S.A., Cali, Colombia; c/o INDUSTRIA AVICOLA PALMASECA S.A., Cali, Colombia; Carrera 4C No. 53–40 apt. 307, Cali, Colombia; c/o COMERCIAL DE NEGOCIOS CLARIDAD Y CIA., Bogota, Colombia; c/o INMOBILIARIA GALES LTDA., Bogota, Colombia; c/o COMERCIALIZADORA EXPERTA Y CIA. S. EN C., Bogota, Colombia; DOB 28 Dec 1948; Cedula No. 16245188 (Colombia); Passport AC824879 (Colombia) (individual) [SDNT].

24. GALINDO HERRERA, Diana Paola, c/o INMOBILIARIA GALES LTDA., Bogota, Colombia; c/o INDUSTRIA AVICOLA PALMASECA S.A., Cali, Colombia; c/o COMERCIAL DE NEGOCIOS CLARIDAD Y CIA., Bogota, Colombia; c/o COMERCIALIZADORA EXPERTA Y CIA. S. EN C., Bogota, Colombia; c/o AGROPECUARIA Y REFORESTADORA HERREBE LTDA., Cali, Colombia; c/o INVERSIONES HERREBE LTDA., Cali, Colombia; c/o CONSTRUEXITO S.A., Cali, Colombia; DOB 08 Jul 1978; Cedula No. 31538790 (Colombia); Passport AF127300 (Colombia) (individual) [SDNT].

25. GALINDO HERRERA, Diego Alexander, c/o CONSTRUEXITO S.A., Cali, Colombia; c/o INVERSIONES HERREBE LTDA., Cali, Colombia; c/o AGROPECUARIA Y REFORESTADORA HERREBE LTDA., Cali, Colombia; c/o COMERCIALIZADORA EXPERTA Y CIA. S. EN C., Bogota, Colombia; c/o COMERCIAL DE NEGOCIOS CLARIDAD Y CIA., Bogota, Colombia; c/o INMOBILIARIA GALES LTDA., Bogota, Colombia; c/o INDUSTRIA AVICOLA PALMASECA S.A., Cali, Colombia; DOB 09 Feb 1977; Cedula No. 16836449 (Colombia); Passport AF246678 (Colombia) (individual) [SDNT].

26. GARCIA, Freddy (a.k.a. GARCIA, Fredy), c/o COMERCIALIZADORA INTERNACIONAL VALLE DE ORO S.A., Cali, Colombia; Calle 11 No. 1–07 of. 405, Cali, Colombia; c/o PROCESADORA DE POLLOS SUPERIOR S.A., Cali, Colombia; Cedula No. 79376230 (Colombia) (individual) [SDNT].

27. GARCIA ROMERO, Audra Yamile, c/o INVHERESA S.A., Cali, Colombia; c/o ALKALA ASOCIADOS S.A., Cali, Colombia; DOB 23 Jul 1971; Cedula No. 66765096 (Colombia) (individual) [SDNT].

28. GIRALDO SARRIA, Octavio, c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia; DOB 15 Nov 1967; Cedula No. 16281770 (Colombia) (individual) [SDNT].

29. GOMEZ BERRIO, Olmes de Jesus (a.k.a. GOMEZ BERRIO, Holmes de Jesus), Carrera 1 No. 18–52, Cali, Colombia; c/o INVERSIONES INVERVALLE S.A., Cali, Colombia; c/o INVERSIONES Y CONSTRUCCIONES VALLE S.A., Cali, Colombia; DOB 15 Dec 1961; Cedula No. 73105133 (Colombia) (individual) [SDNT].

30. HENAO HINESTROZA, Maria Nohelio, c/o INVHERESA S.A., Cali, Colombia; DOB 20 Mar 1954; Cedula No. 26271587 (Colombia) (individual) [SDNT].

31. HERNANDEZ CANOBAS, Hector Fabio, c/o INVERSIONES BETANIA LTDA., Cali, Colombia; c/o INVERSIONES EL PENON S.A., Cali, Colombia; DOB 21 Jun 1958; Cedula No. 16615804 (Colombia) (individual) [SDNT].

32. HERRERA BUITRAGO, Helmer (a.k.a. ''H7''; a.k.a. ''PACHO''), Cali, Colombia; DOB 24 Aug 1951; alt. DOB 05 Jul 1951; Cedula No. 16247821 (Colombia); Passport J287011 (Colombia) (individual) [SDNT].

33. HERRERA BUITRAGO, Alvaro, Avenida 6N No. 25–14, Cali, Colombia; c/o INDUSTRIA AVICOLA PALMASECA S.A., Cali, Colombia; DOB 10 Oct 1955; Cedula No. 16258303 (Colombia) (individual) [SDNT].

34. HERRERA BUITRAGO, Stella, c/o SOCOVALLE LTDA., Cali, Colombia; c/o INVERSIONES GEMINIS S.A., Cali, Colombia; c/o CONSTRUCTORA DIMISA LTDA., Cali, Colombia; c/o INVERSIONES HERREBE LTDA., Cali, Colombia; c/o AGROPECUARIA Y REFORESTADORA HERREBE LTDA., Cali, Colombia; c/o CONCRETOS CALI S.A., Cali, Colombia; c/o COMERCIALIZADORA EXPERTA Y CIA. S. EN C., Bogota, Colombia; c/o INMOBILIARIA GALES LTDA., Bogota, Colombia; c/o INDUSTRIA AVICOLA PALMASECA S.A., Cali, Colombia; c/o COMERCIAL DE NEGOCIOS CLARIDAD Y CIA., Bogota, Colombia; Avenida 1B Oeste No. 1–44 apt. 602, Medeira Building, Cali, Colombia; DOB 07 Oct 1953; Cedula No. 31143871 (Colombia); Passport AD031302 (Colombia) (individual) [SDNT].

35. HERRERA BUITRAGO, William, c/o W. HERRERA Y CIA. S. EN C., Cali, Colombia; DOB 29 Nov 1964; Cedula No. 16716887 (Colombia); Passport P046550 (Colombia) (individual) [SDNT].

36. IBANEZ LOPEZ, Raul Alberto; DOB 11 Apr 1960; Cedula No. 16640123 (Colombia) (individual) [SDNT] (Linked To: AGROPECUARIA LA ROBLEDA S.A.; Linked To: GANADERIAS DEL VALLE S.A.; Linked To: INMOBILIARIA U.M.V. S.A.; Linked To: DISTRIBUIDORA DE ELEMENTOS PARA LA CONSTRUCCION S.A.).

37. LARRANAGA CALVACHE, Juan Carlos, c/o INVERSIONES EL PENON S.A., Cali, Colombia; c/o COMERCIALIZADORA INTERNACIONAL VALLE DE ORO S.A., Cali, Colombia; c/o INMOBILIARIA BOLIVAR LTDA., Cali, Colombia; c/o ADMINISTRACION INMOBILIARIA BOLIVAR S.A., Cali, Colombia; DOB 18 Mar 1964; Cedula No. 12982064 (Colombia) (individual) [SDNT].

38. LIBREROS DIEZ, Orlando, c/o CONSTRUCTORA DIMISA LTDA., Cali, Colombia; c/o INDUSTRIA AVICOLA PALMASECA S.A., Cali, Colombia; c/o VALLE COMUNICACIONES LTDA., Cali, Colombia; c/o DISTRIBUIDORA DE ELEMENTOS PARA LA CONSTRUCCION S.A., Cali, Colombia; DOB 06 Dec 1960;

Cedula No. 16651068 (Colombia) (individual) [SDNT].

39. LINARES REYES, Ricardo Jose (a.k.a. LLENARES REYES, Jose Ricardo), c/o INVERSIONES INVERVALLE S.A., Cali, Colombia; c/o CONCRETOS CALI S.A., Cali, Colombia; c/o W. HERRERA Y CIA. S. EN C., Cali, Colombia; c/o ADMINISTRACION INMOBILIARIA BOLIVAR S.A., Cali, Colombia; c/o INVHERESA S.A., Cali, Colombia; c/o INCOVALLE, Cali, Colombia; c/o CONSTRUEXITO S.A., Cali, Colombia; c/o INVERSIONES EL PENON S.A., Cali, Colombia; c/o INVERSIONES HERREBE LTDA., Cali, Colombia; c/o VIAJES MERCURIO LTDA, Cali, Colombia; c/o INVERSIONES BETANIA LTDA., Cali, Colombia; DOB 08 Mar 1955; alt. DOB 03 Mar 1955; Cedula No. 14440139 (Colombia); Passport PO466638 (Colombia) (individual) [SDNT].

40. LINDO HURTADO, Edgar, c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia; DOB 23 Mar 1927; Cedula No. 6061717 (Colombia) (individual) [SDNT].

41. LONDONO DE UPEGUI, Maria del Carmen, c/o INVERSIONES VILLA PAZ S.A., Cali, Colombia; DOB 16 Oct 1927; Cedula No. 29652262 (Colombia) (individual) [SDNT].

42. LOPERA LONDONO, Vicente de Jesus, c/o INVERSIONES Y CONSTRUCCIONES VALLE S.A., Calle, Colombia; Cedula No. 1393107 (Colombia) (individual) [SDNT].

43. LOPEZ RODRIGUEZ, Cecilia, c/o COMERCIALIZADORA INTERNACIONAL VALLE DE ORO S.A., Cali, Colombia; DOB 04 Jul 1965; Cedula No. 31171066 (Colombia) (individual) [SDNT].

44. LOPEZ ZAPATA, Hernan de Jesus, c/o AGROPECUARIA LA ROBLEDA S.A., Cali, Colombia; c/o INDUSTRIA MADERERA ARCA LTDA., Cali, Colombia; Cedula No. 16344058 (Colombia) (individual) [SDNT].

45. MAFLA, Carlos Obeymar (a.k.a. MAFLA, Carlos Obeimar; f.k.a. OBEYMAR MAFLA, Carlos), c/o MERCAVICOLA LTDA., Cali, Colombia; Carrera 11 No. 9–11, Villagorgon, Candelaria, Colombia; DOB 05 Aug 1955; Cedula No. 6226643 (Colombia) (individual) [SDNT].

46. MONROY ARCILA, Francisco Jose, c/o INVERSIONES GEMINIS S.A., Cali, Colombia; c/o CONSTRUCTORA DIMISA LTDA., Cali, Colombia; c/o INVERSIONES EL PENON S.A., Cali, Colombia; c/o COMPANIA ADMINISTRADORA DE VIVIENDA S.A., Cali, Colombia; DOB 02 Aug 1942; Cedula No. 79153691 (Colombia) (individual) [SDNT].

47. MORENO, Carlos Arturo, c/o INVERSIONES EL PENON S.A., Cali, Colombia; Cedula No. 14264233 (Colombia) (individual) [SDNT].

48. MOSQUERA, Juan Carlos, c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia; Calle 24N No. 6–17, Cali, Colombia; Avenida 2 Norte No. 7N–55 of. 601, Cali, Colombia; Cedula No. 16692007 (Colombia) (individual) [SDNT].

49. MUNOZ PAZ, Joaquin Emilio, c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia; Avenida 4AN No. 47–89, Cali, Colombia; c/o CONSTRUCTORA DIMISA LTDA., Cali, Colombia; c/o INVERSIONES Y CONSTRUCCIONES VALLE S.A., Cali, Colombia; DOB 18 Jan 1971; Cedula No. 16789012 (Colombia) (individual) [SDNT].

50. MURILLO MURILLO, Jose Tolentino, c/o AGROPECUARIA LA ROBLEDA S.A., Cali, Colombia; Cedula No. 2240779 (Colombia) (individual) [SDNT].

51. PATINO RINCON, Octavio, c/o INVERSIONES VILLA PAZ S.A., Cali, Colombia; DOB 20 Sep 1916; Cedula No. 2438955 (Colombia) (individual) [SDNT].

52. PEREZ ORTEGA, Publio Eliecer, c/o INVERSIONES VILLA PAZ S.A., Cali, Colombia; DOB 23 Jul 1954; Cedula No. 16597479 (Colombia) (individual) [SDNT].

53. PEREZ SERNA, Wilmar Armando, c/o INVHERESA S.A., Cali, Colombia (individual) [SDNT].

54. PIEDRAHITA GIRALDO, Gustavo Adolfo, c/o AGROPECUARIA LA ROBLEDA S.A., Cali, Colombia; Calle 1A No. 62A–120, Cali, Colombia; Cedula No. 16764002 (Colombia) (individual) [SDNT].

55. POSSO DE LONDONO, Maria del Carmen, c/o INVERSIONES VILLA PAZ S.A., Cali, Colombia; Cedula No. 29664243 (Colombia) (individual) [SDNT].

56. QUINTERO SALAZAR, Lisimaco, c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia (individual) [SDNT].

57. RAMIREZ BUITRAGO, Placido, c/o COMERCIALIZADORA INTERNACIONAL VALLE DE ORO S.A., Cali, Colombia; DOB 16 Nov 1950; Cedula No. 10219387 (Colombia) (individual) [SDNT].

58. RAMIREZ CORTES, Delia Nhora (a.k.a. RAMIREZ CORTES, Delia Nora), c/o INVERSIONES GEMINIS S.A., Cali, Colombia; c/o AGROPECUARIA Y REFORESTADORA HERREBE LTDA., Cali, Colombia; c/o INDUSTRIA AVICOLA PALMASECA S.A., Cali, Colombia; c/o VIAJES MERCURIO LTDA., Cali, Colombia; c/o ADMINISTRACION INMOBILIARIA BOLIVAR S.A., Cali, Colombia; c/o CONSTRUCTORA ALTOS DEL RETIRO LTDA., Bogota, Colombia; c/o INMOBILIARIA BOLIVAR LTDA., Cali, Colombia; c/o INVERSIONES INVERVALLE S.A., Cali, Colombia; c/o SOCOVALLE LTDA., Cali, Colombia; c/o INVERSIONES HERREBE LTDA., Cali, Colombia; c/o CONSTRUEXITO S.A., Cali, Colombia; c/o COMPANIA ADMINISTRADORA DE VIVIENDA S.A., Cali, Colombia; DOB 20 Jan 1959; Cedula No. 38943729 (Colombia) (individual) [SDNT].

59. RAMIREZ VALENCIANO, William, c/o IMCOMER LTDA., Cali, Colombia; c/o INVERSIONES EL PENON S.A., Cali, Colombia; c/o ADMINISTRACION INMOBILIARIA BOLIVAR S.A., Cali, Colombia; c/o INVERSIONES BETANIA LTDA., Cali, Colombia; c/o CONCRETOS CALI S.A., Cali, Colombia; c/o CONSTRUCTORA DIMISA LTDA., Cali, Colombia; Calle 3C No. 72–64 10, Cali, Colombia; c/o INVERSIONES GEMINIS S.A., Cali, Colombia; DOB 07 Feb 1964; Cedula No. 16694719 (Colombia) (individual) [SDNT].

60. RAMOS RAYO, Heriberto, c/o INVERSIONES VILLA PAZ S.A., Cali, Colombia; DOB 19 Aug 1946; Cedula No. 6186403 (Colombia) (individual) [SDNT].

61. REYES MURCIA, Edgar, c/o CONSTRUVIDA S.A., Cali, Colombia; DOB 03 Feb 1947; Cedula No. 17181081 (Colombia) (individual) [SDNT].

62. RIZO MORENO, Jorge Luis, Transversal 11, Diagonal 23–30 apt. 304A, Cali, Colombia; DOB 17 May 1960; Cedula No. 16646582 (Colombia) (individual) [SDNT] (Linked To: SERVIAUTOS UNO A 1A LIMITADA; Linked To: INVERSIONES EL PENON S.A.; Linked To: CONSTRUVIDA S.A.; Linked To: IMPORTADORA Y COMERCIALIZADORA LTDA.; Linked To: CONSTRUCTORA DIMISA LTDA.; Linked To: PROCESADORA DE POLLOS SUPERIOR S.A.; Linked To: CRIADERO DE POLLOS EL ROSAL S.A.).

63. ROZO CLAVIJO, Miguel Antonio, c/o CONSTRUCTORA ALTOS DEL RETIRO LTDA., Bogota, Colombia; DOB 18 Aug 1943; Cedula No. 17093270 (Colombia) (individual) [SDNT].

64. SAAVEDRA RESTREPO, Jesus Maria, c/o CONCRETOS CALI S.A., Cali, Colombia; Calle 5 No. 46–83 Local 119, Cali, Colombia; c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia; c/o CONSTRUCTORA DIMISA LTDA., Cali, Colombia; DOB 10 Jul 1958; Cedula No. 16603482 (Colombia) (individual) [SDNT].

65. SALCEDO RAMIREZ, Nhora Clemencia, c/o ADMINISTRACION INMOBILIARIA BOLIVAR S.A., Cali, Colombia; c/o INMOBILIARIA BOLIVAR LTDA., Cali, Colombia; DOB 20 Nov 1956; Cedula No. 31273613 (Colombia) (individual) [SDNT].

66. SEPULVEDA SEPULVEDA, Manuel Salvador, c/o INVHERESA S.A., Cali, Colombia; c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia; c/o ALKALA ASOCIADOS S.A., Cali, Colombia; DOB 02 Feb 1956; Cedula No. 16855038 (Colombia) (individual) [SDNT].

67. SERNA, Maria Norby (a.k.a. SERNA DE PEREZ, Maria Norbi), c/o INVHERESA S.A., Cali, Colombia; c/o ALKALA ASOCIADOS S.A., Cali, Colombia; Carrera 30A No. 67–45, Palmira, Colombia; DOB 14 Jul 1945; Cedula No. 29475049 (Colombia) (individual) [SDNT].

68. URIBE GONZALEZ, Jose Abelardo, c/o CONSULTORIA EMPRESARIAL ESPECIALIZADA LTDA., Cali, Colombia; c/o SERVICIOS INMOBILIARIAS LTDA., Cali, Colombia; c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia; c/o COMERCIALIZADORA INTERNACIONAL VALLE DE ORO S.A., Cali, Colombia; Cedula No. 16647906 (Colombia) (individual) [SDNT].

69. VALDIVIESO FONTAL, Diego, c/o VALLADARES LTDA., Cali, Colombia; DOB 13 Dec 1959; Cedula No. 16662362 (Colombia) (individual) [SDNT].

70. VALENCIA, Reynel (a.k.a. VALENCIA, Reinel), c/o GANADERIAS DEL VALLE S.A., Cali, Colombia; c/o INMOBILIARIA U.M.V. S.A., Cali, Colombia; c/o COMERCIALIZADORA INTERNACIONAL VALLE DE ORO S.A., Cali, Colombia; DOB 19 Nov 1954; Cedula No. 16258610 (Colombia) (individual) [SDNT].

71. VALENCIA ARIAS, Jhon Gavy (a.k.a. VALENCIA ARIAS, John Gaby), Carrera 76 No. 6–200 102, Cali, Colombia; Avenida 7N No. 17A–46, Cali, Colombia; c/o INVERSIONES EL PENON S.A., Cali, Colombia; c/o INVERSIONES BETANIA LTDA., Cali, Colombia; Cedula No. 16741491 (Colombia) (individual) [SDNT].

72. VALENCIA ARIAS, Luis Fernando, c/o INVERSIONES EL PENON S.A., Cali,

Colombia; c/o INVERSIONES BETANIA LTDA., Cali, Colombia; c/o INVERSIONES GEMINIS S.A., Cali, Colombia; DOB 24 Sep 1962; Cedula No. 71626881 (Colombia) (individual) [SDNT].

73. VALENCIA DE JARAMILLO, Maria Diocelina, c/o AGROPECUARIA LA ROBLEDA S.A., Cali, Colombia; DOB 08 May 1959; Cedula No. 31162155 (Colombia) (individual) [SDNT].

74. VALENCIA FRANCO, Manuel, c/o GANADERIAS DEL VALLE S.A., Cali, Colombia (individual) [SDNT].

75. VARGAS LOPEZ, Gustavo Adolfo, c/o INDUSTRIA MADERERA ARCA LTDA., Cali, Colombia; c/o AGROPECUARIA LA ROBLEDA S.A., Cali, Colombia; c/o INVERSIONES VILLA PAZ S.A., Cali, Colombia; c/o COLOMBIANA DE CERDOS LTDA., Pereira, Colombia; c/o MATADERO METROPOLITANO LTDA., Pereira, Colombia; DOB 03 Nov 1955; Cedula No. 6457925 (Colombia) (individual) [SDNT].

76. VILLEGAS ARIAS, Maria Deisy (a.k.a. VILLEGAS ARIAS, Maria Deicy), c/o CONCRETOS CALI S.A., Cali, Colombia; c/o CONSTRUEXITO S.A., Cali, Colombia; c/o INDUSTRIA MADERERA ARCA LTDA, Cali, Colombia; Calle 66 No. 1A–6 51, Cali, Colombia; c/o GANADERIAS DEL VALLE S.A., Cali, Colombia; c/o SOCOVALLE LTDA., Cali, Colombia; DOB 16 Jul 1961; Cedula No. 31200871 (Colombia) (individual) [SDNT].

77. ZAMBRANO CERON, Maria Concepcion, c/o AGROPECUARIA LA ROBLEDA S.A., Cali, Colombia; DOB 04 Aug 1928; Cedula No. 29488292 (Colombia) (individual) [SDNT].

78. ZAMORA, Jose Hernan, c/o GANADERIAS DEL VALLE S.A., Cali, Colombia (individual) [SDNT].

79. MARIN TOBON, Bernardo Antonio, Calle 14 No. 18–62, La Union, Valle, Colombia; Calle 14 No. 18–64, La Union, Valle, Colombia; Carrera 16 No. 13–29 Piso 2, La Union, Valle, Colombia; Carrera 16 No. 13–31, La Union, Valle, Colombia; c/o ALMACAES S.A., Bogota, Colombia; c/o GRAJALES S.A., La Union, Valle, Colombia; c/o HOTEL LOS VINEDOS, La Union, Valle, Colombia; c/o ILOVIN S.A., Bogota, Colombia; c/o TRANSPORTES DEL ESPIRITU SANTO S.A., La Union, Valle, Colombia; c/o DOXA S.A., La Union, Valle, Colombia; c/o FUNDACION CENTRO DE INVESTIGACION HORTIFRUTICOLA DE COLOMBIA, La Union, Valle, Colombia; c/o MANUFACTURAS REAL S.A., Bogota, Colombia; DOB 18 Jan 1954; POB La Union, Valle, Colombia; Cedula No. 6355508 (Colombia) (individual) [SDNT].

80. TOVAR ZULETA, Jorge Eduardo; DOB 09 Oct 1964; POB Cali, Colombia; Cedula No. 79324921 (Colombia) (individual) [SDNTK] (Linked To: INDUITEX LTDA.; Linked To: SBT S.A.).

81. VALENCIA COSSIO, Guillermo Leon; DOB 24 Jun 1958; Cedula No. 70115707 (Colombia) (individual) [SDNTK].

82. VILLANUEVA MADRID, Mario Ernesto; DOB 02 Jul 1949; POB Quintana Roo, Mexico (individual) [SDNTK].

83. NINO CARDENAS, Julio Cesar, c/o MI CARRO E.U., Medellin, Colombia; POB Colombia; nationality Colombia; citizen Colombia; Cedula No. 70513214 (Colombia) (individual) [SDNTK].

84. SALAZAR CARDENAS, Carlos Mario, c/o MI CARRO E.U., Medellin, Colombia; POB Colombia; nationality Colombia; citizen Colombia; Cedula No. 13485023 (Colombia) (individual) [SDNTK].

85. GARCIA ROJAS, Javier (a.k.a. ''EL PARIENTE''; a.k.a. ''MARACUYA''), Medellin, Colombia; DOB 27 Oct 1960; POB Florencia, Caqueta, Colombia; citizen Colombia; Gender Male; Cedula No. 12971151 (Colombia) (individual) [SDNTK] (Linked To: AGROCONSTRUCCIONES LAS PALMERAS S.A.S.; Linked To: MMAG AGRICULTURA GLOBAL S.A.S.).

86. GARCIA ROJAS, Ruth, Colombia; DOB 20 Dec 1967; POB Puerto Asis, Putumayo, Colombia; citizen Colombia; Gender Female; Cedula No. 31971911 (Colombia); Tarjeta Profesional 186785 (Abogado) (Colombia) (individual) [SDNTK] (Linked To: INVERSORA PINZON Y GARCIA S. EN C.S. EN LIQUIDACION).

87. BUENDIA CUELLAR, Luis Alfonso, c/o GALAPAGOS S.A., Cali, Colombia; Cedula No. 6044411 (Colombia) (individual) [SDNT].

88. GARAVITO, Doris Amelia, c/o GALAPAGOS S.A., Cali, Colombia; Cedula No. 31233463 (Colombia) (individual) [SDNT].

89. GARCIA PIZARRO, Gentil Velez, Cali, Colombia (individual) [SDNT] (Linked To: GALAPAGOS S.A).

90. HERRAN SAAVEDRA, Victor Hugo, c/o GALAPAGOS S.A., Cali, Colombia; Cedula No. 16447166 (Colombia) (individual) [SDNT].

91. MORENO DAZA, Ricardo Alfredo, Carrera 38D No. 4B–57, Cali, Colombia; c/o GALAPAGOS S.A., Cali, Colombia; c/o TAURA S.A., Cali, Colombia; Cedula No. 16631400 (Colombia) (individual) [SDNT].

92. RAMIREZ ESCUDERO, Pedro Emilio, Calle 6A No. 48–36, Cali, Colombia; c/o GALAPAGOS S.A., Cali, Colombia; Cedula No. 16820602 (Colombia) (individual) [SDNT].

93. GILMAN FRANCO, Maria, c/o TAURA S.A., Cali, Colombia; Cedula No. 22103099 (Colombia) (individual) [SDNT].

94. GONGORA ALARCON, Hernando, c/o TAURA S.A., Cali, Colombia; Cedula No. 19298944 (Colombia) (individual) [SDNT].

95. HERNANDEZ, Oscar, Mz. 21 Casa 5 Barrio San Fernando, Pereira, Colombia; c/o TAURA S.A., Cali, Colombia; Cedula No. 6157940 (Colombia) (individual) [SDNT].

96. VILLADA ZUNIGA, Elmer, Calle 15 No. 20–10, Cali, Colombia; c/o TAURA S.A., Cali, Colombia; Cedula No. 14988902 (Colombia) (individual) [SDNT].

97. CAVIEDES CRUZ, Leonardo, Calle 21 Norte No. 3N–84, Cali, Colombia; c/o CAVIEDES DILEO Y CIA S.C.S., Cali, Colombia; DOB 23 Nov 1952; Cedula No. 16593470 (Colombia); Passport AB151486 (Colombia); alt. Passport AC444270 (Colombia); alt. Passport OC444290 (Colombia) (individual) [SDNT].

98. SANTACRUZ LONDONO, Jose (a.k.a. ''CHEPE''; a.k.a. ''DON CHEPE''; a.k.a. ''EL GORDO CHEPE''), Cali, Colombia; DOB 01 Oct 1943; Passport AB149814 (Colombia) (individual) [SDNT].

99. GALVIS MARIN, Samuel Gustavo (a.k.a. GALVEZ, Samuel), c/o PALMERAS SANTA BARBARA, Calamar, Guaviare, Colombia; Calle 39 No. 19A–33, Villavicencio, Colombia; Cedula No. 6001464 (Colombia) (individual) [SDNTK].

100. USUGA DAVID, Juan de Dios, Colombia; POB Monteria, Cordoba; nationality Colombia; citizen Colombia; Cedula No. 71938240 (Colombia) (individual) [SDNTK].

101. VARGAS GUTIERREZ, Roberto, Colombia; POB Colombia; nationality Colombia; citizen Colombia; Cedula No. 71981878 (Colombia) (individual) [SDNTK].

Entities

1. IMPORTADORA MARENOL LIMITADA, Carrera 50 No. 39–71, Medellin, Colombia; NIT # 800104353–4 (Colombia) [SDNTK].

2. ROBIREPUESTOS, Carrera 50 No. 41–41 Local 112, Medellin, Colombia; Matricula Mercantil No 21–438991–02 (Medellin) [SDNTK].

3. ADMINISTRACION INMOBILIARIA BOLIVAR S.A., Calle 17N No. 6N–28, Cali, Colombia; Avenida 2CN No. 24N–92, Cali, Colombia; NIT # 800149060–5 (Colombia) [SDNT].

4. AGROPECUARIA BETANIA LTDA., Calle 70N No. 14–31, Cali, Colombia; Carrera 61 No. 11–58, Cali, Colombia [SDNT].

5. AGROPECUARIA LA ROBLEDA S.A., Avenida 2DN No. 24N–76, Cali, Colombia; Carrera 61 No. 11–58, Cali, Colombia; NIT # 800160353–2 (Colombia) [SDNT].

6. AGROPECUARIA Y REFORESTADORA HERREBE LTDA., Avenida 2N No. 7N–55 of. 501, Cali, Colombia [SDNT].

7. ALKALA ASOCIADOS S.A. (f.k.a. INVHERESA S.A.), Calle 1A No. 62A–130, Cali, Colombia; Calle 1A No. 62A–120, Cali, Colombia; Avenida 2N No. 7N–55 of. 501, Cali, Colombia; Calle 70N No. 14–31, Cali, Colombia; NIT # 800108121–0 (Colombia) [SDNT].

8. COMERCIAL DE NEGOCIOS CLARIDAD Y CIA., Avenida Caracas No. 59–77 of. 201A, 401B y 405B, Bogota, Colombia; NIT # 800080719–0 (Colombia) [SDNT].

9. COMERCIALIZADORA EXPERTA Y CIA. S. EN C., Avenida Caracas No. 59–77 of. 201A, 401B, 405B y 407B, Bogota, Colombia; NIT # 800075687–3 (Colombia) [SDNT].

10. COMPANIA ADMINISTRADORA DE VIVIENDA S.A. (f.k.a. INVERSIONES GEMINIS S.A.), Carrera 40 No. 6–24 of. 402B, Cali, Colombia; Carrera 41 No. 6–15/35, Cali, Colombia; NIT # 800032419–1 (Colombia) [SDNT].

11. CONCRETOS CALI S.A., Calle 7 No. 82–65, Cali, Colombia [SDNT].

12. CONSTRUCTORA ALTOS DEL RETIRO LTDA., Carrera 7 No. 72–28 of. 301, Bogota, Colombia; Carrera 4 No. 86–88, Bogota, Colombia; Transversal 3 No. 85–10 apt. 401 Interior 1, Bogota, Colombia; NIT # 890329139–8 (Colombia) [SDNT].

13. CONSTRUCTORA DIMISA LTDA., Calle 70N No. 14–31, Cali, Colombia [SDNT].

14. CONSTRUCTORA EL NOGAL S.A. (f.k.a. CONE S.A.; f.k.a. CONSTRUEXITO S.A.), Avenida 2N No. 7N–55 of. 501, Cali, Colombia; Calle 2A No. 65A–110, apto. 501 B3, Cali, Colombia; NIT # 800051378–9 (Colombia) [SDNT].

15. CONSTRUVIDA S.A., Avenida 2N No. 7N–55 of. 521, Cali, Colombia; Carrera 68 No. 13B–61 of. 104B, Cali, Colombia; Calle 70N No. 14–31, Cali, Colombia; NIT # 800108122–8 (Colombia) [SDNT].

16. CONSULTORIA EMPRESARIAL ESPECIALIZADA LTDA., Avenida 2N No. 7N–55 of. 421, Cali, Colombia; NIT # 800109042–1 (Colombia) [SDNT].

17. CRIADERO DE POLLOS EL ROSAL S.A. (f.k.a. INDUSTRIA AVICOLA PALMASECA S.A.), Carretera Central via Aeropuerto Palmaseca, Colombia; Carrera 61 No. 11–58, Cali, Colombia; NIT # 800146749–7 (Colombia) [SDNT].

18. GANADERIAS DEL VALLE S.A., Avenida 2FN No. 24N–92, Cali, Colombia; Carrera 83 No. 6–50, Cali, Colombia; Carrera 61 No. 11–58, Cali, Colombia; NIT # 800119808–9 (Colombia) [SDNT].

19. IMPORTADORA Y COMERCIALIZADORA LTDA. (a.k.a. IMCOMER), Avenida 6N y Avenida 4 No. 13N–50 of. 1201, Cali, Colombia; NIT # 800152058–0 (Colombia) [SDNT].

20. INDUSTRIA MADERERA ARCA LTDA., Calle 11 No. 32–47 Bodega 41 Arroyohondo, Cali, Colombia; Calle 32 No. 11–41 Bodega 4 Arroyohondo, Cali, Colombia; NIT # 800122866–7 (Colombia) [SDNT].

21. INMOBILIARIA BOLIVAR LTDA., Calle 17N No. 6N–28, Cali, Colombia; Calle 24N No. 6N–21, Cali, Colombia; NIT # 890330573–3 (Colombia) [SDNT].

22. INMOBILIARIA GALES LTDA., Avenida Caracas No. 59–77 of. 201A, 401B y 405B, Bogota, Colombia; NIT # 800061287–1 (Colombia) [SDNT].

23. INMOBILIARIA U.M.V. S.A., Carrera 83 No. 6–50, Edificio Alqueria, Torre C, of. 302, Cali, Colombia [SDNT].

24. INVERSIONES AGRICOLAS AVICOLAS Y GANADERAS LA CARMELITA LTDA., Carrera 61 Nos. 11–58 y 11–62, Cali, Colombia; NIT # 800052898–1 (Colombia) [SDNT].

25. INVERSIONES ARIO LTDA., Carrera 4 No. 12–41 of. 608 y 701, Cali, Colombia; NIT # 890328888–1 (Colombia) [SDNT].

26. INVERSIONES CULZAT GUEVARA Y CIA. S.C.S., Avenida 4A Oeste No. 5–107 apt. 401, Cali, Colombia; Avenida 7N No. 23N–39, Cali, Colombia; Avenida 4A Oeste No. 5–187 apt. 401, Cali, Colombia; NIT # 860065523–1 (Colombia) [SDNT].

27. INVERSIONES EL GRAN CRISOL LTDA. (f.k.a. W. HERRERA Y CIA. S. EN C.), Avenida 2N 7N–55 of. 501, Cali, Colombia; Carrera 24D Oeste No. 6–237, Cali, Colombia; NIT # 800001330–2 (Colombia) [SDNT].

28. INVERSIONES EL PENON S.A., Avenida 2N, Cali, Colombia [SDNT].

29. INVERSIONES HERREBE LTDA., Avenida 2N No. 7N–55 of. 501, Cali, Colombia; Carrera 25 No. 4–65, Cali, Colombia [SDNT].

30. INVERSIONES VILLA PAZ S.A., Avenida 2DN No. 24N–76, Cali, Colombia; Avenida 2CN No. 24N–92, Cali, Colombia; Carrera 61 No. 11–58, Cali, Colombia; Calle 70N No. 14–31, Cali, Colombia; NIT # 800091083–2 (Colombia) [SDNT].

31. INVERSIONES Y CONSTRUCCIONES VALLE S.A. (a.k.a. INCOVALLE), Avenida 2N No. 7N–55 of. 501, Cali, Colombia [SDNT].

32. MANAURE S.A. (f.k.a. AGROPECUARIA LA ROBLEDA S.A.), Avenida 2D Norte No. 24N–76, Cali, Colombia; Carrera 61 No. 11–58, Cali, Colombia; NIT # 800160353–2 (Colombia) [SDNT].

33. MERCAVICOLA LTDA., Calle 47AN, Cali, Colombia; Calle 34 No. 5A–25, Cali, Colombia; NIT # 800086338–5 (Colombia) [SDNT].

34. PROCESADORA DE POLLOS SUPERIOR S.A. (a.k.a. COMERCIALIZADORA INTERNACIONAL VALLE DE ORO S.A.), Avenida 2N No. 7N–55 of. 521, Cali, Colombia; Carrera 3 No. 12–40, Cali, Colombia; A.A. 1689, Cali, Colombia; Km 17 Recta Cali-Palmira, Palmira, Colombia; NIT # 800074991–3 (Colombia) [SDNT].

35. PROHUEVO DE COLOMBIA LTDA., Calle 34 No. 5A–25, Cali, Colombia; 1 Km Antes de Cavasa Palmira-Cali, Colombia; Granja Pio Pio Carretera Cali-Candelaria Km 12, Cali, Colombia; NIT # 800089683–5 (Colombia) [SDNT].

36. SAN MATEO S.A. (f.k.a. INVERSIONES BETANIA LTDA.; f.k.a. INVERSIONES BETANIA S.A.), Avenida 2N No. 7N–55 of. 501, Cali, Colombia; Carrera 53 No. 13–55 apt. 102B, Cali, Colombia; Carrera 3 No. 12–40, Cali, Colombia; NIT # 890330910–2 (Colombia) [SDNT].

37. SOCIEDAD CONSTRUCTORA Y ADMINISTRADORA DEL VALLE LTDA. (a.k.a. SOCOVALLE LTDA.), Avenida 2N No. 7N–55 of. 601–602, Cali, Colombia [SDNT].

38. VALLADARES LTDA. (f.k.a. AGROPECUARIA BETANIA LTDA.), Calle 70N No. 14–31, Cali, Colombia; Carrera 61 No. 11–58, Cali, Colombia; NIT # 890329123–0 (Colombia) [SDNT].

39. VALLE COMUNICACIONES LTDA. (a.k.a. VALLECOM), Carrera 60 No. 2A–107, Cali, Colombia [SDNT].

40. VALLE DE ORO S.A., Pollo Tanrico Km 17 Recta Cali-Palmira, Palmira, Colombia; Cali, Colombia; NIT # 890331067–2 (Colombia) [SDNT].

41. VIAJES MERCURIO LTDA., Carrera 3 No. 10–02 Local 113, Cali, Colombia [SDNT].

42. MI CARRO E.U., Calle 33 No. 75C–40, Medellin, Colombia; NIT # 9000750838 (Colombia) [SDNTK].

43. AGROCONSTRUCCIONES LAS PALMERAS S.A.S., Carrera 43 A 1 Sur 220 Interior 706, Medellin, Antioquia, Colombia; NIT # 900609147–4 (Colombia) [SDNTK].

44. MMAG AGRICULTURA GLOBAL S.A.S. (f.k.a. JAVIER GARCIA ROJAS E.U.; a.k.a. MAG AGRICULTURA GLOBAL S.A.S.), Carrera 43 A 1 Sur 220 Oficina 706, Medellin, Antioquia, Colombia; NIT # 813003117–6 (Colombia) [SDNTK].

45. INVERSORA PINZON Y GARCIA S. EN C.S. EN LIQUIDACION (a.k.a. INVERSORA PINZON Y GARCIA S. EN C.S.), Cl. 15A Nro. 106 13 13 Casa, Cali, Valle, Colombia; Cl. 15A Nro. 106 13 13C, Cali, Valle, Colombia; NIT # 805024080–3 (Colombia) [SDNTK].

46. TAURA S.A., Calle 13 No. 68–06, Of. 204, Cali, Colombia; Calle 13 No. 68–26, Of. 214, 313 & 314, Cali, Colombia; Carrera 115 No. 16B–121, Cali, Colombia; NIT # 800183713–1 (Colombia) [SDNT].

47. PALMERAS SANTA BARBARA, Entrada Casco Urbano Calamar, Calamar, Guaviare, Colombia; Matricula Mercantil No 109214 (Colombia) [SDNTK].

Dated: December 30, 2021.

Gregory T. Gatjanis,

Associate Director, Office of Global Targeting, Office of Foreign Assets Control, U.S. Department of the Treasury.

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BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been removed from the Specially Designated Nationals and Blocked Person List (SDN List).

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date.

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2480; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Actions

OFAC previously determined the individuals listed below met one or more of the criteria under the Cuban Assets Control Regulations, 31 CFR part 515 (CACR) and Sections 5 and 16 of the Trading With the Enemy Act, 50 U.S.C. App. §§ 5, 16 (TWEA) to be added to the SDN List. On December 30, 2021, OFAC determined that circumstances no longer warrant the inclusion of the following individuals on the SDN List under this authority.

Individuals

1. NORIEGA, Manuel Antonio, Panama (individual) [CUBA].

2. SIEIRO DE NORIEGA, Felicidad, Panama (individual) [CUBA].

Dated: December 30, 2021.

Gregory T. Gatjanis,

Associate Director, Office of Global Targeting, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2021–28588 Filed 1–4–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Work Opportunity Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning guidance on the work opportunity credit.

DATES: Written comments should be received on or before March 7, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or to *omb.unit@irs.gov.* Please include, ''OMB Number: 1545–1522—Public Comment Request Notice'' in the Subject line.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis at (202) 317–5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Work Opportunity Credit.

OMB Number: 1545–0219.

Form Number: 5884.

Abstract: Internal Revenue Code section 38(b)(2) allows a credit against income tax to employers hiring individuals from certain targeted groups such as welfare recipients, etc. The employer uses Form 5884 to compute this credit. The IRS uses the information on the form to verify that the correct amount of credit was claimed.

Current Actions: There is no change to the existing form or burden at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations and farms.

Estimated Number of Respondents: 10,000.

Estimated Time per Respondent: 6 hours, 57 minutes.

Estimated Total Annual Burden Hours: 69,400 hours.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 30, 2021.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2021–28590 Filed 1–4–22; 8:45 am]

BILLING CODE 4830–01–P

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Part II

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Panama City Crayfish and Designation of Critical Habitat; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket Nos. FWS–R4–ES–2017–0061 and FWS–R4–ES–2020–0137; FF09E2100 FXES1111090FEDR 223]

RIN 1018–BC14; 1018–BD50

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Panama City Crayfish and Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), list the Panama City crayfish (*Procambarus econfinae*), a terrestrial crayfish species native to Bay County, Florida, as a threatened species with a rule issued under section 4(d) of the Endangered Species Act of 1973 (Act), as amended. We also designate critical habitat for the species under the Act. In total, approximately 4,138 acres (1,675 hectares (ha)) in Bay County, Florida, fall within eight units of critical habitat. This rule extends the Act's protections to the species and its designated critical habitat.

DATES: This rule is effective February 4, 2022.

ADDRESSES: This final rule is available on the internet at *https://www.regulations.gov.* Comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *https://www.regulations.gov at* Docket Nos. FWS–R4–ES–2017–0061 and FWS–R4–ES–2020–0137.

The coordinates or plot points or both from which the maps are generated are included in the decision file for this critical habitat designation and are available at *https://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0137 and at the Florida Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**, below). The critical habitat shapefile is available on the Service's Environmental Conservation Online System (ECOS) portal at *https://www.ecos.fws.gov.*

FOR FURTHER INFORMATION CONTACT: Lourdes Mena, Classification and Recovery Division Manager, Florida Ecological Services Field Office, U.S. Fish and Wildlife Service, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256; telephone 904–731–3134. 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 Act, a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become endangered in the foreseeable future throughout all or a significant portion of its range). If we determine that a species warrants listing, we must list the species promptly and designate the species' critical habitat to the maximum extent prudent and determinable. We have determined that the Panama City crayfish meets the definition of a threatened species; therefore, we are listing it as such and finalizing a designation of its critical habitat. Listing a species as an endangered or threatened species and designation of critical habitat can be completed only by issuing a rule.

What this document does. This rule lists the Panama City crayfish (*Procambarus econfinae*) as a threatened species with a rule issued under section 4(d) of the Act (a ''4(d) rule'') and designates critical habitat in eight units totaling approximately 4,138 acres (1,675 ha) in Bay County, Florida.

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 habitat loss and fragmentation from development (Factor A) is the primary threat to the Panama City crayfish.

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.

Economic analysis. In accordance with section 4(b)(2) of the Act, we prepared an economic analysis of the impacts of designating critical habitat. On April 15, 2021, we published an announcement of, and solicited public comments on, the draft economic analysis (86 FR 19838). We received general comments that the designation would harm the local economy, but we received no specific or substantial information that would require altering the draft economic analysis. Therefore, we have adopted the draft economic analysis as final. As noted below in Summary of Changes from Proposed Rule, we revised the critical habitat designation and removed 3,039 acres (1,230 hectares (ha)) from the proposed designation. Accordingly, the estimated costs presented in the draft economic analysis will likely be reduced as a result of a smaller final designation of critical habitat.

Peer review and public comment. Prior to our development of our January 3, 2018, and April 15, 2021, proposed rules (83 FR 330 and 86 FR 19838, respectively), we received peer reviews of the Species Status Assessment (SSA) report from eight experts, which informed our assessment that we used for this rulemaking. We also considered all comments and information we received from the public during the two public comment periods for the proposed rules.

Previous Federal Actions

Please refer to the Panama City crayfish proposed listing rule (83 FR 330) published on January 3, 2018, and the reopening of the comment period for the proposed listing rule with a proposed 4(d) rule and critical habitat designation (86 FR 19838) published on April 15, 2021, for detailed descriptions of previous Federal actions concerning this species.

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the Panama City crayfish. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a

compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species.

Summary of Changes From the Proposed Rule

This final rule incorporates several changes to our proposed 4(d) rule and critical habitat designation (86 FR 19838; April 15, 2021).

For the 4(d) rule, we removed the incidental take exception for conservation and restoration efforts by the Service or State wildlife agencies because the provisions of 50 CFR 17.31(b), which amount to the same or similar allowances, apply to the Panama City crayfish. In addition, based on comments we received, we clarified the incidental take exception for maintenance activities associated with rights-of-way to include mowing, use of herbicides, and mechanical side trimming, and we added the replacement of critical structural components, such as crossarms, insulators, conductors, etc., to this take exception in the 4(d) rule.

For the critical habitat designation, we made changes based on updated aerial photography, new information about permitted developments, and more recent information about Panama City crayfish habitat use in secondary soils. By using 2020 aerial photography (Bay County Property Appraiser 2020, unpaginated), we removed unsuitable or developed parcels, resulting in removal of approximately 473 acres (191 ha) from the critical habitat designation. The new aerial photography also revealed an additional 1.9 acres (0.8 ha) of habitat, confirmed by the occurrence of hydric soils, suitable grasses, and a high concentration of Panama City crayfish, which we added to Unit 1 (19th Street). We also revised our critical habitat delineation protocol based on new information with respect to how Panama City crayfish uses secondary soils. In the April 15, 2021, proposed rule, we used a 100-meter (m) (328-foot) buffer from the core soils into the secondary soils, but our more recent analysis uses a 15-m (50-foot) buffer from the core soils into the secondary soils, capturing 71 percent of all Panama City crayfish occurrences, and reducing the amount of designated critical habitat by 2,566 acres (1,038 ha). We have determined that the 50-foot buffer provides a better method to focus protection on lands that are likely occupied more consistently than those that may be occupied only during seasons or years with high rainfall events. Therefore, in this rule, we use the refined 50-foot buffer boundary to capture lands likely used by the Panama City crayfish all of the time versus land used only during a shorter portion of the crayfish's life cycle when rainfall is high. This approach better represents the habitat containing the primary biological features and supporting the Panama City crayfish a majority of the time. Given current information, Panama City crayfish are not likely to persist during drought years. Activities authorized, funded, or carried out by a Federal agency that may affect areas occupied by the species for part of its life cycle will still be subject to section 7 of the Act. As a result of these modifications, the final amount of designated critical habitat is 4,138 acres (1,675 ha), a decrease of 3,039 acres (1,230 ha) from the proposed designation.

I. Final Listing Determination

Background

A thorough review of the taxonomy, life history, and ecology of the Panama City crayfish is presented in the SSA report, version 2.0 (Service 2019). The full SSA report can be found on the Service's Environmental Conservation Online System (ECOS) portal at *https://ecos.fws.gov/ecp/species/8915* and at *http://www.regulations.gov* under Docket Nos. FWS–R4–ES–2017–0061 and FWS–R4–ES–2020–0137.

Species Description

The Panama City crayfish is a small, semi-terrestrial crayfish that grows to about 2 inches (in) (50.8 millimeters (mm)) in length (minus claws), and is found in south-central Bay County, Florida. The species' color pattern consists of a medium dark-brown background color, lighter brown mid-dorsal stripe, and darker brown dorsolateral stripes (Florida Fish and Wildlife Conservation Commission (FWC) 2016, p. 1). The Panama City crayfish was first described by Hobbs in 1942, from Bay County, Panama City, Florida. The Panama City crayfish is classified in the family Cambaridae and is a recognized taxon by the scientific community (Taylor et al. 2007; Integrated Taxonomic Information System 2017).

The life history of the Panama City crayfish specifically is not well known. Cambarid crayfish may live about 2.5 to 3 years (Hobbs 2001, p. 977), with a generation period of 2 years. For this family of crayfish, the majority breed more than once, with mating among mature yearlings frequent; however, many individuals do not become sexually active until late summer or fall. Females may produce between 30 and 160 eggs and have been found with eggs and/or young from March through September. Juveniles are most frequently found in the summer and have been observed through December, so juveniles appear to be produced from at least March through December. Juveniles can be carried overland by moving water during rainy periods, which aids in dispersal (Keppner and Keppner 2002, p. 11).

Eight crayfish species occur within the range of the Panama City crayfish, although only the hatchet crayfish and the jackknife crayfish are found in the same habitat as the Panama City crayfish and may co-occur with it (FWC 2017, p. 1). The Panama City crayfish is not known to hybridize with other species of crayfish.

Historically, the species inhabited natural and often temporary bodies of shallow fresh water within open pine flatwoods and wet prairie-marsh communities. However, most of these communities have been cleared for residential or commercial development or replaced with slash pine plantations. The Panama City crayfish currently inhabits the waters of grassy, gently sloped ditches and swales, slash pine plantations, utility rights-of-way, and a few remnant parcels protected under wetland and private easements (FWC 2016, p. 2).

The highest densities of Panama City crayfish have been recorded in areas with little to no shrub or tree cover (FWC 2016, p. 2). Suitable habitat is normally dominated by herbaceous vegetation. Lowest population densities have occurred in small, open sites where shrubs or trees were present, or in the furrows between bedding rows in some pine plantations (Keppner and Keppner 2005). When encountered in dense titi (*Cyrilla racemiflora* and *Cliftonia monophylla*) swamps, the species was associated with temporarily inundated areas open to the sun with some herbaceous vegetation. Such sites may be considered secondary or suboptimal habitat for the species. On sites where mixed habitat features are present (*e.g.,* partially wooded sites or sites with permanent, deep-water ponds), the Panama City crayfish appears to select favorable areas dominated by herbaceous vegetation, with shallow or fluctuating water levels (FWC 2016, p. 3; Keppner and Keppner 2005, p. 2).

The Panama City crayfish relies on particular soil types for burrow construction and supporting herbaceous vegetation; these soil types are categorized as core or secondary soils.

Core soils, or those that sustain long hydropattern wetlands, provide the best substrate to support the species; secondary soils, or those that support short hydropattern wetlands, are less ideal but still used (Service 2019, p. 23). Because they must have wet conditions for survival, Panama City crayfish rely on the dynamics of the flow of water and wetness of the soils for dispersal. These habitat restrictions and limited dispersal ability make the crayfish have low adaptive ability. The core and secondary soil types that support Panama City crayfish within the species' known range are described in more detail in the SSA report (Service 2019, pp. 23–24).

Panama City crayfish build burrows for shelter, which are normally in or adjacent to surface water when it is present in the hydric soils they inhabit (Hobbs 1981, entire). They construct burrows that contact the water table as the surface water of their habitat recedes, and they occupy burrows when surface water is absent or during periods of extreme water temperatures. They emerge from the burrows when surface water is present again or water temperatures are favorable. It appears that they can survive significant periods of drought in their burrows when they can maintain contact with the water table. During these dry periods, the Panama City crayfish excavates and lives in unbranched burrows up to 3 feet long that extend down to the water table, thereby enabling the species to remain adequately hydrated to survive (FWC 2016, p. 3).

Little is known about the specific feeding habits of the Panama City crayfish. Observations of Panama City crayfish that were held in aquaria spanning 1.5 plus years (Keppner and Keppner 2014, entire) indicate that they are detritivores and herbivores. Specimens were offered dead animal material, but they avoided it in favor of processing the substrate for particles of prepared fish food and the fresh aquatic vegetation that were provided as primary food sources. Herbaceous vegetation likely serves as a food source for the Panama City crayfish.

The Panama City crayfish historically ranged throughout south-central Bay County, Florida, within a 56-square-mile area (14,504 ha; see figure, below). The historical range likely created one population connected by core and secondary soils. As urban growth came to Panama City, the range of the Panama City crayfish became fragmented into isolated patches. Today, the species has 12 localized (*i.e.,* isolated) populations that can be divided into two groups, based on patterns in fragmentation from urban development: The western group and eastern group, using Transmitter Road as the primary division. Localized populations were delineated using a landscape genetic analysis based on a pattern of isolation-by-distance, where increasing geographic separation tends to reflect increasing genetic differentiation (Duncan et al. 2017, entire). A genetic analysis describes eight localized populations occurring in a western grouping and four localized populations occurring in an eastern grouping (Duncan et al. 2017, entire). The 12 populations are described in more detail in the SSA report (Service 2019, pp. 32–52), and are referred to as 19th Street, Old Airport, 390 West, Talkington, Minnesota, Edwards, Transmitter West, College Point, Deer Point, High Point, Star, and Transmitter East. Three of the populations are considered functionally extirpated (Old Airport, Minnesota, and College Point).

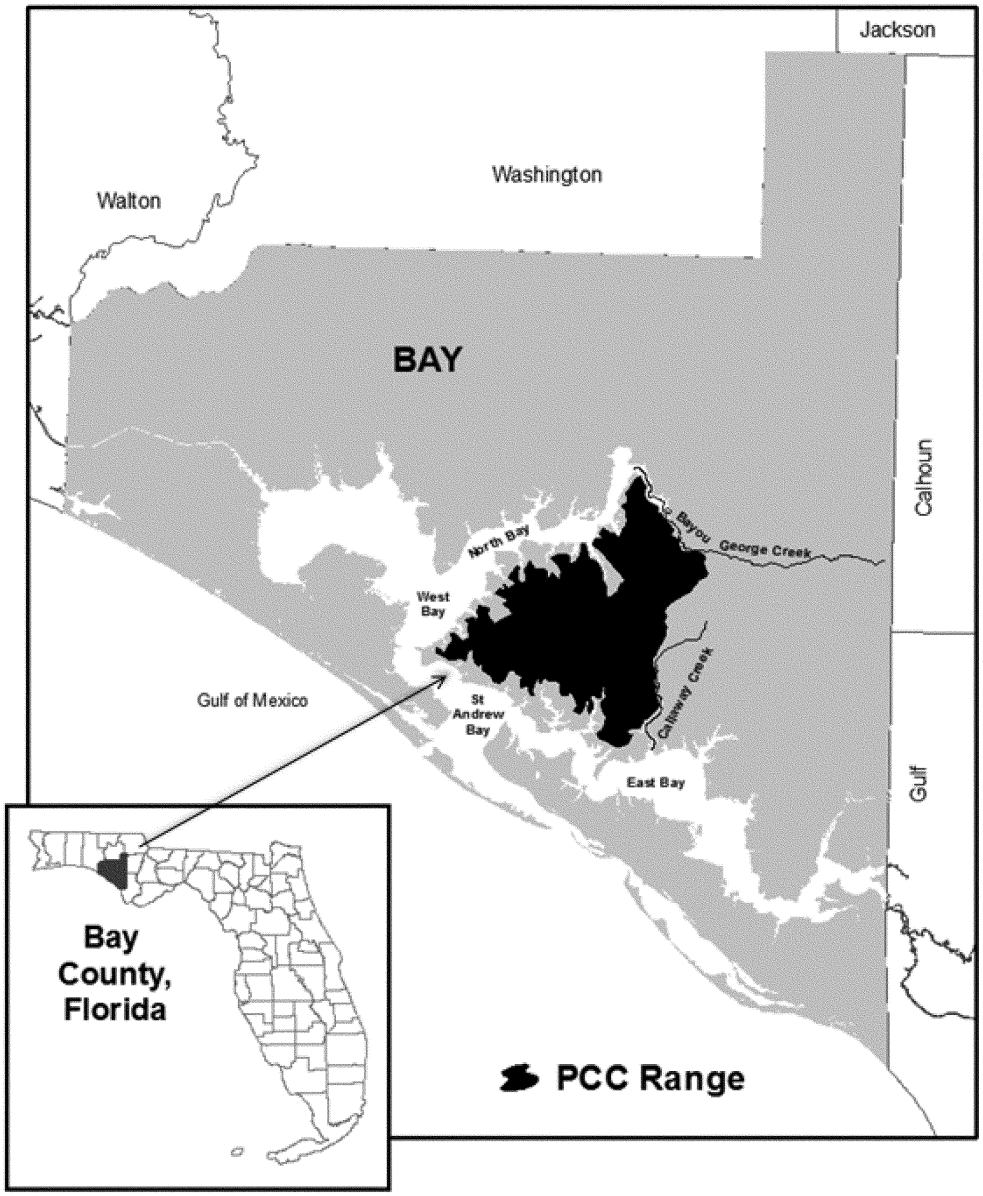


Figure: Range of the Panama City crayfish.

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. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the 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 January 3, 2018, proposed rule (83 FR 330) described ''foreseeable future'' for the Panama City crayfish as 20 to 30 years, which encompasses 10 to 15 generations, which we stated in that proposal is more than sufficient time to determine the species' response to stressors. On August 27, 2019, the Service published a final rule (84 FR 45020) codifying its understanding of ''foreseeable future'' at 50 CFR 424.11(d). 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.

The regulations at 50 CFR 424.11(d) did not significantly modify the Service's interpretation; rather, they codified a framework that sets forth how the Service will determine what constitutes the foreseeable future based on our long-standing practice. Accordingly, although the regulations at 50 CFR 424.11(d) do not apply to this final rule for the Panama City crayfish because the crayfish's listing was proposed prior to the effective date of the August 27, 2019, final rule, application of the regulations at 50 CFR 424.11(d) would not change the Service's assessment of foreseeable future for the Panama City crayfish as contained in our January 3, 2018, proposed rule and in this final rule.

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 listed 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.

To assess Panama City crayfish viability, 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 influences. 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.

The Panama City crayfish needs freshwater wetlands that support herbaceous vegetation, which is important to the Panama City crayfish for food, shelter, and detritus formation. The species needs core or secondary soils to provide the proper sediment structure for burrow construction and to support the herbaceous vegetation. The Panama City crayfish needs access to groundwater (through burrowing) or surface water to prevent desiccation of individuals and populations. The species needs both adequate water quality and quantity to fulfill its life history.

To evaluate the current and future viability of the Panama City crayfish, we assessed a range of conditions to allow us to consider the species' resiliency, representation, and redundancy. For the Panama City crayfish to maintain viability, its populations or some portion thereof must be adequately resilient. To assess resiliency, we analyzed data related to two population factors (inbreeding rate and isolation) and three habitat factors (urbanization, protection/management, and suitable area) (see Table 1, below). Population condition rankings and habitat condition rankings were determined by combining these five factors, and then overall condition rankings were

categorized as high, medium, or low condition. High condition equates to a healthy condition with a high likelihood of persistence in the near term, low is declining condition with a low likelihood of persistence in the near term, and moderate condition is in between high and low (Service 2019, p. 60).

TABLE 1—POPULATION AND HABITAT FACTORS FOR PANAMA CITY CRAYFISH (PCC)
[Service 2019, p. 60]

PCC condition rankings	Population factors		Habitat factors		
	Inbreeding rate [1]	Population isolation	Urbanization [2]	Protection and management [3]	Suitable area [4]
High	<or = 0	Large site with multiple sub-populations and shares a border with another habitat unit.	<33% developed and unsuitable.	Easements or rights-of-way (ROWs) with >15 acres in suitable habitat.	>1,000 acres.
Moderate	0–0.1	Small or moderately sized site that shares a border with another habitat unit.	33–66% developed and unsuitable.	Easements or ROWs with ≤15 acres in suitable habitat.	100–1,000 acres.
Low	>0.1	Small or moderately sized site that is not connected to another.	>66% developed and unsuitable.	No habitat protections	<100 acres.

[1] "Inbreeding Rate" refers to outbreeding and random mating result in a F_{IS} coefficient less than or equal to 0; a high rate of inbreeding is generally thought to be $F_{IS} > 0.1$.
[2] "Urbanization" is the percentage of developed and unsuitable acres within the area supporting each population.
[3] "Protection and Management" considers whether the site has had any easements or rights-of-way (ROWs) in suitable habitat that are protected against development, and then the easements and ROWs are ranked by size.
[4] "Suitable Area" means the acres of undeveloped core and secondary soils within the habitat unit.

We described representation for the Panama City crayfish in terms of a single meta-population with low adaptive ability that was once connected through core and secondary soils but is currently inhabiting "islands" of habitat due to fragmentation of habitat from urbanization, resulting in limited dispersal and low adaptive ability. We assessed Panama City crayfish redundancy in the context of the species' historical range compared to its current range, and the relative risk of the distribution throughout the range to catastrophic events.

Factors Influencing Panama City Crayfish Viability

Freshwater aquatic systems face a multitude of natural and anthropogenic threats and stressors (Neves et al. 1997, p. 44). The FWC has identified multiple factors that have impacts on Panama City crayfish populations and habitats, most of which are related to human activities (FWC 2016, entire). Due to its persistence within a rapidly urbanizing landscape, the Panama City crayfish has adapted and is presently found in or near habitats that have been altered to varying degrees, which are no longer considered natural or wild. These include roadside ditches, rights-of-way, clearings in silvicultural land, and residential property. Potential threats to Panama City crayfish include further habitat loss and degradation, habitat fragmentation, and isolation. Other possible factors affecting survival include direct mortality related to construction activities, incompatible applications of chemicals or spills, off-road vehicle use, illegal harvest, and direct competition with indigenous and/or nonindigenous species.

Generally, these factors can fall into two categories: population-scale (localized) threats and rangewide stressors or systematic changes. Current and potential future effects, along with current distribution and abundance, help inform viability and, therefore, vulnerability to extinction. Below, we describe the primary stressors to the Panama City crayfish, which are habitat degradation, loss, and fragmentation; water quality; bait collection; climate change; and sea level rise. Other factors, such as direct mortality, disease, predation, competition, or impacts from off-road vehicle use, were not considered to have species-level impacts (see 83 FR 330, January 3, 2018), and therefore are not discussed further here.

Threats and Environmental Stressors

Habitat Degradation, Loss, and Fragmentation: Development projects and land conversion can result in direct loss of habitat, leading to fragmentation and isolation of populations. Historically, the Panama City crayfish inhabited natural and often temporary bodies of shallow fresh water within open pine flatwoods and wet prairie-marsh communities. The Panama City crayfish's natural habitat (wet pine flatwoods) has been lost or degraded through residential, commercial, and industrial development, as well as conversion to intensive pine silviculture, and for ranching and farming uses. No unaltered natural pine flatwoods remain within the Panama City crayfish's current range. Most known Panama City crayfish current occurrences are in human-altered habitats and are vulnerable to further loss or alteration. Although artificial habitats such as roadside ditches and rights-of-way have allowed the Panama City crayfish to survive in areas from which they would otherwise likely have been extirpated, human activities can alter the hydrology and configuration of these sites, making them unsuitable for long-term Panama City crayfish survival. For example, roadside ditch maintenance and construction activities have resulted in the destruction of several crayfish sites.

Infrastructure development has impacted, or is anticipated to impact, several known crayfish sites. For example, several road construction or expansion projects, such as the widening of Star Avenue and Kern Avenue and the widening and hardening of Tram Road, may impact Panama City crayfish habitat in the future. Infrastructure development can eliminate suitable Panama City crayfish habitat by removing the required herbaceous vegetation and digging up the surrounding soils.

Silvicultural practices such as ditching and bedding, roller chopping, installing fire breaks, and constructing roads can alter the hydrology of Panama City crayfish sites, create physical barriers to crayfish movement, and destroy underground burrows. These activities may contribute to the isolation of Panama City crayfish populations. Fire suppression and high tree density on silvicultural sites can reduce herbaceous groundcover necessary for suitable crayfish habitat. Similarly, removal of tree canopy cover, changes in ground cover vegetation, and associated changes in water quality and surface water availability are all possible changes associated with the effects of conversion to farming and ranching practices, such as cattle grazing. These activities reduce the

suitability of the habitat for the Panama City crayfish. Although minimal changes to habitat in the future are expected to occur from farming and ranching practices, conversion from silviculture to grazing use has historically occurred on lands adjacent the crayfish's range.

Ditching and draining urban areas is a common practice in efforts to control local flooding events and reduce mosquito outbreaks but could have accidental impacts, especially to populations with small amounts of available habitat, by artificially draining or decreasing the amount of time that surface waters are available. The majority of known Panama City crayfish occurrences, particularly in the western part of the range, are in roadside ditches and swales and thus are vulnerable to impacts from ditching and draining activities. Additionally, nearly all populations are isolated from other Panama City crayfish populations by roads and development. Fragmentation and isolation can increase vulnerability to local extirpation due to adverse genetic, demographic, and environmental events. Further, when Panama City crayfish are extirpated from an area, lack of habitat connections between sites can prevent Panama City crayfish from recolonizing (FWC 2016, p. 10). Recent genetic work indicates the isolation throughout the range has resulted in inbreeding and drift (Duncan et al. 2017, p. 17).

Water Quality: Freshwater crayfish may be sensitive to declines in water quality, and these water quality declines have been identified as a threat to the Panama City crayfish. Water quality declines can range from oxygen-deficient conditions resulting from algal blooms or sewage spills to pollution originating from roadway runoff, pesticide applications, or chemical spills. Given the level of development throughout the range of the Panama City crayfish and the occurrences of Panama City crayfish adjacent to private properties, runoff from roads or incompatible application of chemicals, such as pesticides or fertilizers, negatively impacts water quality and has direct impacts on the species.

Mosquitocides are used within the range of the Panama City crayfish to treat both larval and adult mosquitos. The mosquitocides registered for use within the range of the Panama City crayfish do not pose known threats to water quality if applied per label directions (FWC 2016, p. 10). If incorrectly applied, however, the consequences to the Panama City crayfish can be fatal. Similarly, fertilizers, insecticides, and herbicides may pose a risk to Panama City crayfish if applied inappropriately. Many substances commonly used around the home or business can be toxic to Panama City crayfish and other wildlife if used or disposed of improperly. Since Panama City crayfish often inhabit ditches and swales close or adjacent to private properties, they are at risk if landowners do not ensure that fertilizers, insecticides, and herbicides are applied and disposed of properly per label directions. Potentially toxic substances such as petroleum products and paint should be properly disposed of at hazardous waste disposal facilities. Accidental spills of large volumes of toxic substances such as petroleum products and acids occasionally occur in urban areas. If spills overflow into ditches, swales, or other areas inhabited by Panama City crayfish, substantial localized impacts to the population are possible.

Bait Collection: Collecting Panama City crayfish for fish bait or other uses may have long-term effects on populations if large numbers of adults are taken from a population. Several lines of evidence indicate that current occupied sites are used as sources for catching crayfish for fish bait. Although this activity is occurring, the magnitude of the impact of recreational harvest on the Panama City crayfish is unknown (Keppner and Keppner 2001, p. 14; Keppner and Keppner 2005, p. 11).

Systematic Changes

Climate Change and Sea Level Rise: The Panama City crayfish was included in a Statewide vulnerability assessment for approximately 1,000 species in Florida (Reece et al. 2013, entire; Hocter et al. 2014, entire) using a Standardized Index of Vulnerability and Value Assessment (SIVVA; Reece and Noss 2014, entire). Based on the data used in this assessment, little suitable habitat for Panama City crayfish will be affected by sea level rise under the A1B scenario (Hocter et al. 2014, p. 10). To further evaluate potential impacts from sea level rise, we used two products to map predicted future changes due to sea level rise in 2025, 2050, and 2075 under a low scenario (0.5 meter) and high scenario (2.0 meters) (Service 2019, pp. 71–74). We used the University of Florida digital elevation sea level rise model to predict habitat loss (Hocter et al. 2014, entire). This model predicts inundation changes based on elevation. We also used the Sea Level Rise Affecting Marshes Model (SLAMM) to predict changes in sea level rise that would affect habitat suitability inland from inundated areas (Clough et al. 2010, entire). Using a 5–30 meter pixel size, SLAMM simulates the dominant process involved in wetland conversions and shoreline modifications during long-term sea level rise. We assumed these vegetation changes would adequately represent the water quality changes from saltwater intrusion that would affect crayfish survival in affected areas. We looked at overall changes in habitat rangewide as well as within the suitable habitat supporting each individual population.

Overall, little suitable habitat for Panama City crayfish will be directly affected by sea level rise, which confirms prior analyses (Hocter et al. 2014, p. 10). By the year 2075, suitable habitat (in terms of suitable acres of core and secondary soils) within the range of the Panama City crayfish is predicted to be reduced by 1.28 acres (0.01 percent) with 0.5-meter sea level rise and by 40.2 acres (0.26 percent) with 2.0-meter sea level rise (see table 4.1 in Service 2019, p. 73). However, two populations were affected by sea level rise, Deer Point and Old Airport, which respectively sustained loss of 21.02 and 5.89 acres of suitable habitat by the year 2075 with 2.0-meter sea level rise. Indirect effects of sea level rise on Panama City crayfish could be substantial, however. Saltwater intrusion into freshwater habitats will occur far beyond areas that are completely inundated, potentially changing the hydrology and vegetation in Panama City crayfish habitats that are outside the predicted direct sea level rise impact areas. Crayfish spend their entire life in fresh water. Research on crayfish report some levels of saltwater tolerance, but it is believed that their abilities to colonize in the estuarine environment may be restricted to areas of low salinity due to adverse effects of sea water on egg development and hatching (Susanto and Charmantier, 2000, in Yildiz et al. 2004, p. 1271).

Synergistic and Cumulative Effects

Synergistic interactions are possible between the effects of climate change and the effects of other potential threats, such as development. Increases in temperature and changes in precipitation are likely to affect water quality and vegetation, and the Panama City crayfish needs good water quality to survive and is closely associated with the presence of herbaceous vegetation. However, it is difficult to project how climate change will affect herbaceous vegetation because certain plant species may increase in cover, while other species may decrease. Uncertainty about how different plant species will respond to climate change, combined with uncertainty about how changes in plant species composition would affect

suitability of Panama City crayfish habitat, make projecting possible synergistic effects of climate change on the Panama City crayfish highly speculative.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. To assess the current and future condition of the species, we undertake an iterative analysis that encompasses and incorporates the threats individually and then accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Conservation Strategy

We developed a conservation strategy for Panama City crayfish to identify critical conservation needs (Service 2017b, entire). In this conservation strategy, we rely on the known survival over time of small populations and a published meta-analysis (Traill 2007, entire) to estimate the amount of habitat needed to support population viability. The results of the analysis indicate that a minimum viable population size (MVP) for Panama City crayfish of 5,137 individuals and 2,200 acres of actively managed habitat across the range that is permanently protected and managed across at least seven population units should ensure the Panama City crayfish maintains viability for the foreseeable future. Currently, we have estimated population sizes at three sites (19th Street, Transmitter West, Talkington). Abundance ranges from 34 to 623 Panama City crayfish and 3 to 232 acres (1.2 to 93.9 ha) of suitable habitat, yielding 3 to 9 crayfish per acre. Applying these density values across the currently occupied range yields a rangewide population of 6,600 to 19,800 Panama City crayfish.

The Panama City crayfish needs multiple, adequately resilient populations spread across its range to avoid extinction. We currently estimate that 2,200 acres (890 ha) of permanently protected Panama City crayfish habitat would sustain the viability of multiple (two to four) populations depending on habitat quality. We estimate that protecting 3 to 4 large core habitat units with between 200 and 800 acres (81 and 324 ha), in addition to 3 smaller habitat units (less than 200 acres (81 ha) in size), to be managed with fire or mowing every 2 to 3 years, along with a plan to restore existing conservation easements that have suitable soils for the crayfish will sustain the crayfish into the future (Service 2017b, entire). We determined the conservation goal of 2,200 acres (890 ha) secured with conservation easements or under public ownership would support Panama City crayfish for the foreseeable future. However, at this time, agreements are not in place to ensure the necessary protections.

Current Conditions of the Panama City Crayfish

The Panama City crayfish historically ranged throughout south-central Bay County, Florida, as one population connected by core and secondary soils. Today, the species has 12 localized populations divided into a western group with 8 populations and an eastern group with 4 populations. While the Panama City crayfish continues to occur within its historical range, only 42 percent of core soils and 43 percent of secondary soils remain undeveloped from historical levels, indicating a loss of 57 percent of historical habitat (Service 2019, p. 58). Population resiliency was estimated as high for 2 populations, moderate for 2 populations, low for 5 populations, and functionally extirpated for three populations (see Table 2).

TABLE 2—SUMMARY OF CURRENT RESILIENCY CONDITION FOR 12 POPULATIONS OF PANAMA CITY CRAYFISH

[Service 2019, p. 61]

Habitat area	Inbreeding rate condition	Population isolation	Urbanization	Habitat protection	Suitable habitat area	Overall current resiliency condition
19th Street	Low	Low	Moderate	Moderate	Low	Low.
Old Airport	Low	Low	Moderate	Moderate	Low	Extirpated.
390 West	Low	Low	Low	Moderate	Low	Low.
Talkington	Low	Low	Moderate	Moderate	Low	Low.
Minnesota	Low	Low	High	Moderate	Low	Extirpated.
Edwards	Low	Low	Low	Low	Low	Low.
Transmitter West	Low	Low	High	High	Moderate	Moderate.
College Point	Low	Low	Low	Low	Low	Extirpated.
High Point	Low	Low	High	Moderate	Low	Low.
Deer Point	Low	Low	High	High	Moderate	Moderate.
Star	Low	High	High	High	High	High.
Transmitter East	Low	High	High	High	High	High.

The representation, or adaptive capacity, of the Panama City crayfish has been diminished. Historically, it was one population and now has been fragmented and genetically isolated into 9 extant localized populations (and 3 functionally extirpated populations). The genetic differences across the range correspond to patterns in fragmentation from urban development, resulting in small crayfish population sizes and poor dispersal ability. Consequently, genetic variation is low, gene flow is limited, and inbreeding is high across the range. Additionally, genetic isolation coupled with presumably low abundance poses risk of further reductions in genetic diversity through genetic drift (random chance by removing rare genotypes completely when some individuals die without reproducing). Without intervention, the combined effects of prolonged inbreeding and genetic drift can consign a population to a genetic ''extinction vortex,'' in which lethal mutations and infertility occur in a positive feedback loop, potentially resulting in localized extirpation regardless of other factors.

Redundancy for the Panama City crayfish is low. The current fragmented landscape poses a vulnerability to potential catastrophic hurricanes, sea level rise, salt water intrusion, and large-scale droughts. Panama City crayfish populations are now isolated; thus, recolonization or demographic rescue is unlikely following population-level disturbances. Additionally, the Panama City crayfish occupies an increasing smaller area, thereby increasing the risk of a single event, or series of events, affecting a large portion of extant populations.

Future Conditions of Panama City Crayfish

For the purpose of this assessment, we define viability as the ability of the species to sustain populations in the wild over time. This discussion explains how the stressors associated with habitat loss, fragmentation, and degradation from residential and commercial development will influence resiliency, redundancy, and representation for the Panama City crayfish throughout its current known range using a series of plausible scenarios out to 2030, 2050, and 2070. We predicted both future population factors (inbreeding and population isolation) and habitat factors (urbanization, protections from development, and suitable habitat) and evaluated these to inform our future conditions.

To predict potential future changes related to urban growth, we used layers from the Southeast Regional Assessment Project (SERAP, from the Biodiversity and Spatial Analysis Center at North Carolina State University; 60m resolution), a modification of the SLEUTH Projected Urban Growth model (Jantz et al. 2010, entire; Terando et al. 2014, entire). SERAP identifies the parameters in global and regional models that are most likely to affect the Southeast region's climate and local landscape dynamics, with the goal of providing decision makers with information about low-probability, high-impact climate extremes through downscaled models and threats analysis. This tool helps inform where the biggest threats from climate change will be on the landscape and, accordingly, identifies high-risk areas for conservation lands and development. We then used these products to map future predicted changes in urbanization in 2030, 2050, and 2070. The uncertainty associated with the SLEUTH model increases over time, and as a result, the species' response to the dynamic nature of the variables becomes less predictive. There is a greater confidence in predicting potential development and the species' response to changes in the landscape in the near future rather than the distant future.

To adequately capture uncertainty associated with the degree and extent of potential future stressors and their impacts on species' requisites, resiliency, redundancy, and representation were assessed using three scenarios: Status quo development (*i.e.,* minimum degree of urbanization that has a high probability of occurring), intermediate development (*i.e.,* moderate degree of urbanization that has a low probability of occurring), and high development (*i.e.,* high degree of urbanization that has a very low probability of occurring). The scenarios included projecting possible future development using the SERAP model (Jantz et al. 2010, entire; Terando et al. 2014, entire). They also describe the predicted effects of the development on loss and fragmentation of suitable habitat rangewide and on each of 12 known populations, and draw inferences about population health (Duncan et al. 2017, entire). We excluded three populations (College Point, Old Airport, and Minnesota) from our scenario analysis because Panama City crayfish are currently extirpated at these sites and they will not be able to maintain viability in these locations in the future without deliberate introduction or translocation efforts. Although we provide all three scenarios, initial changes in patterns of development following Hurricane Michael (2018) indicate that the high development scenario is more likely than we previously thought because of the housing damage and subsequent shortage caused by this Category 5 storm. Please refer to the SSA report for the full analysis of the future scenarios (Service 2019, pp. 79–92).

Under the range of plausible future development scenarios, habitat loss ranges from 1,401 to 6,130 acres of habitat rangewide as developed land increases from 20,221 to 28,899 acres between 2030 and 2070. Under all three scenarios, the loss and degradation (fragmentation) of habitat reduce the number of sufficiently resilient populations in high or moderate condition from four to three by 2030. This loss of resiliency comes from both a reduction in habitat elements as well as the effects of isolation and genetic drift for all 12 populations. Under each of the three future scenarios, all western populations are categorized as low condition by 2030 (see Table 3, below), resulting in a near total loss of redundancy and representation. In the eastern group, three of four populations are projected to maintain moderate or high resiliency through 2070.

TABLE 3—FUTURE CONDITION SUMMARY OF PANAMA CITY CRAYFISH

[Populations above the double line are in the western group; populations below the double line are in the eastern group.]

Population name	Current	Year	Status quo	Intermediate development	High development
19th Street	Low	2030	Low	Low	Low.
		2050	Low	Low	Low.
		2070	Low	Low	Low.
Old Airport	Extirpated	2030	Extirpated	Extirpated	Extirpated.
		2050	Extirpated	Extirpated	Extirpated.
		2070	Extirpated	Extirpated	Extirpated.
390 West	Low	2030	Low	Low	Low.
		2050	Low	Low	Low.
		2070	Low	Low	Low.
Talkington	Low	2030	Low	Low	Low.
		2050	Low	Low	Low.
		2070	Low	Low	Low.
Minnesota	Extirpated	2030	Extirpated	Extirpated	Extirpated.
		2050	Extirpated	Extirpated	Extirpated.
		2070	Extirpated	Extirpated	Extirpated.
Edwards	Low	2030	Low	Low	Low.

TABLE 3—FUTURE CONDITION SUMMARY OF PANAMA CITY CRAYFISH—Continued

[Populations above the double line are in the western group; populations below the double line are in the eastern group.]

Population name	Current	Year	Status quo	Intermediate development	High development
		2050	Low	Low	Low.
		2070	Low	Low	Low.
Transmitter West	Moderate	2030	Low	Low	Low.
		2050	Low	Low	Low.
		2070	Low	Low	Low.
College Point	Extirpated	2030	Extirpated	Extirpated	Extirpated.
		2050	Extirpated	Extirpated	Extirpated.
		2070	Extirpated	Extirpated	Extirpated.
High Point	Low	2030	Low	Low	Low.
		2050	Low	Low	Low.
		2070	Low	Low	Low.
Deer Point	Moderate	2030	Moderate	Moderate	Moderate.
		2050	Moderate	Moderate	Moderate.
		2070	Moderate	Moderate	Moderate.
Star	High	2030	High	High	High.
		2050	High	High	High.
		2070	High	High	High.
Transmitter East	High	2030	High	High	High.
		2050	High	High	High.
		2070	High	High	High.

We also evaluated a ''conservation scenario,'' which is based on a conservation strategy that includes permanent protection and management of approximately 2,200 acres (890 ha) of habitat across seven populations (Service 2017b, entire). The predicted outcomes of the conservation scenario are straightforward, with populations with higher resiliency continuing to maintain or have improved resiliency in the future as land management efforts improve. Although anticipated habitat protection and habitat management will not immediately change any of the overall current condition ranks, it should, when coupled with the population management measures agreed to by FWC and the Service, ensure that populations with high resiliency will remain so regardless of future development, which is the primary threat to the Panama City crayfish. Additionally, population management measures (*e.g.,* translocation) detailed in this scenario should improve the genetic health and population size of several managed populations. Finally, improved monitoring and applied research agreed to by the Service and FWC should also improve our knowledge of the status of each population to better adjust management actions as needed in the future. However, at this time, agreements are not in place to ensure the necessary protections, and we do not have certainty about whether and where, or in what configuration, those protections may occur on the landscape.

All plausible future scenarios had similar outcomes for the species. Our overall estimate of the Panama City crayfish's current viability is low across the majority of its geographic range, particularly in the urbanized western portion. Ongoing and future development will likely result in low resiliency across 70 percent of the species' range by as soon as 2030. If the remainder (30 percent) of its range is protected from development and conservation efforts are focused in this less developed area, we project the species will maintain resiliency in three populations for the foreseeable future.

As Panama City crayfish are endemic to a small area with limited variation in local conditions prior to modern urbanization, a large-scale disturbance will impact all habitats and populations similarly, putting the species at risk of extinction due to a single event larger than the 10 linear miles its range covers. As such, its redundancy will never be high relative to more widely distributed species. Historical trends in the area have further reduced redundancy for Panama City crayfish, as its geographic extent and habitat area have both been shrunk by development, further decreasing the likelihood that a single population of Panama City crayfish will find refuge during a catastrophe and survive.

Due to small, isolated populations with low genetic diversity and high rates of inbreeding, we estimate that the Panama City crayfish currently has low adaptive potential across its small range. As inbreeding can drive a population to extinction regardless of other variables, we should consider the possibility that some Panama City crayfish populations are already in an extinction vortex due to an ongoing loss of genetic diversity.

Summary of Comments and Recommendations

In the January 3, 2018, and April 15, 2021, proposed rules (83 FR 330 and 86 FR 19838, respectively), we requested that all interested parties submit written comments. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposed rules. Newspaper notices inviting general public comment were published in the legal notice section of The News Herald on December 31, 2017, and April 24, 2021. On February 22, 2018, we held a public meeting for the proposed listing, and on May 4, 2021, we held a virtual public informational meeting and public hearing for the reopening of the comment period on the January 3, 2018, proposed listing, as well as the proposed 4(d) rule and critical habitat designation. All substantive information received during both comment periods has either been incorporated directly into this final determination or is addressed below.

Peer Reviewer Comments

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 sought review from nine experts regarding version 1.1 of the SSA report, and four experts regarding version 2.0 of

the SSA report. We received responses from four experts for each version (total of eight peer reviews).

We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the information contained in the SSA report. The peer reviewers generally concurred with our methods and conclusions, and they provided additional information, clarifications, and suggestions to improve the SSA report. Peer reviewer comments are addressed in the following summary and were incorporated into the SSA report as appropriate.

(1) Comment: Peer reviewers of version 1.1 of the SSA report recommended modifications to the habitat ranking analysis, suggested dropping the use of crayfish counts as a proxy for relative abundance, and suggested adding genetics information.

Our response: Version 2.0 of the SSA report reflects changes suggested by peer reviewers (summarized in Appendix IV of the SSA report (Service 2019, p. 112)). We replaced abundance as a population factor with a principal components analysis (*i.e.,* an exploratory data analysis used for making predictive models) from the genetics study (Duncan et al. 2017, entire; Service 2019, p. 63).

Comments From States

(2) Comment: The Florida Fish and Wildlife Conservation Commission (FWC) provided several comments, suggesting revisions to version 1.0 of the SSA report. Specifically, similar to the peer review comment about crayfish counts as proxy for relative abundance, FWC emphasized that the surveys conducted by FWC were intended to determine Panama City crayfish presence at a site and not a population size, and suggested that catch per unit of survey effort would yield better comparative information between populations. In addition, FWC recommended the Service clarify that, with the exception of the infiltration into a small portion of the Panama City crayfish's range by the hatchet crayfish (*Procambarus kilbyi*) and the jackknife crayfish (*P. hubbelli*), the most frequent crayfish species found co-occurring in the same habitat (and within the water column) with the Panama City crayfish is the stud crayfish (*P. pycnogonopodus*). FWC also pointed out some minor errors regarding generation time calculations and suggested edits to the presentation of the 2030 scenario in Tables 5.3, 5.4, and 5.5 (Service 2017a, pp. 87–94).

Our response: The SSA report was revised (Service 2019, version 2.0) to reflect these suggested changes. We did not intend to confuse population presence with that of relative abundance but believed that abundance numbers could be used as an indicator of the resiliency of populations. In the revised SSA report (Service 2019, version 2.0), we removed abundance as a criterion used to rank resiliency of the crayfish populations. Further, using the Act's section 6 funds and a staff position provided by FWC, we have attempted to gather mark-recapture data in the field to estimate population size and the factors that affect detection probability. We continue to work with FWC biologists to develop a monitoring plan that accurately assesses population trends or estimates.

(3) Comment: FWC staff concurred with the proposed take exceptions described in our proposed 4(d) rule, but they also recommended that we consider an exception to the take prohibitions for emergency actions to relieve flooding.

Our response: The 4(d) rule for the Panama City crayfish that we are adopting in this final rule excepts incidental take associated with ditch mowing and maintenance actions that may be necessary to relieve flooding when following best management practices (BMPs) that have been coordinated with the Service.

Public Comments

(4) Comment: Several commenters state that listing the Panama City crayfish will hurt the local economy by delaying the growth and development of infrastructure that is needed for the community. These commenters are therefore opposed to listing the Panama City crayfish. They stated we have not adequately addressed the economic impacts of listing the Panama City crayfish as required by Florida law.

Our response: Determinations of whether a species is placed on the Federal List of Endangered and Threatened Wildlife and Plants are based on whether the species meets the definition of ''endangered species'' or of ''threatened species'' in the Act (16 U.S.C. 1531 *et seq.*). The Act directs the Service to make these determinations solely on the basis of the best scientific and commercial data available. Therefore, we may not consider economic impacts when determining the status of a species. We do consider economic impacts when designating critical habitat (see *Consideration of Economic Impacts,* below).

Additionally, infrastructure and growth are not prohibited by this rule. The Service developed a 4(d) rule for the Panama City crayfish to streamline the permitting process by excepting certain actions from the take prohibitions. For example, residents who want to install sheds, driveways, or pools likely will not need a permit from the Service. The 4(d) rule allows streamlining of project reviews to focus on those activities that are expected to have the most potential impact to the Panama City crayfish or its habitat, thus reducing staff workload by eliminating the need to review *de minimus* impact projects and enabling more focus on targeted conservation efforts that are expected to have the most benefit to the species.

(5) Comment: One commenter suggested that protecting and managing 2,200 acres in perpetuity, with 3-year rotational prescribed burns and other management activities, will cost approximately $20 million and is not feasible. They questioned the overall conservation strategy and expressed concern about whether perpetual maintenance would be required in conservation areas and how that maintenance would be funded.

Our response: The conservation strategy identifies goals that may need to be met in order to ensure recovery of the Panama City crayfish and states that a minimum viable population size (MVP) for Panama City crayfish of 5,137 individuals and 2,200 acres of actively managed habitat across the range that is permanently protected and managed across at least seven population units should ensure the Panama City crayfish maintains viability for the future. In order to accomplish this goal, Bay County staff worked with the Florida Department of Environmental Protection (FDEP) to place optimal lands on the Florida Forever Land acquisition list. Placement on the Florida Forever list will allow future expenditures of State funds to purchase lands important for the protection of the Panama City crayfish when funds and ranking priorities are aligned, and will place them in permanent conservation or into State of Florida ownership to enable perpetual maintenance for the species. Federal grants are also available via the Recovery and Land Acquisition grants program. Lastly, minimization and mitigation through the Act's section 7 process provide another mechanism to achieve conservation actions such as habitat protection.

(6) Comment: On commenter expressed concerns that all known techniques to measure Panama City crayfish populations are harmful to the crayfish and will invariably lead to population extirpations. Another commenter stated that the crayfish

cannot be positively identified without a postmortem examination.

Our response: The FWC and Service biologists regularly collect samples of the Panama City crayfish to confirm presence and for genetic testing. We conduct crayfish captures by use of a dip net or by placement of funnel traps. Each time, crayfish are captured, they are counted, measured, and released alive. Rarely are they injured, and more rarely are they killed with either trapping method used. Crayfish can easily be identified by trained biologists from their physical characteristics and location of collection. At newly discovered sites, a voucher specimen of a male in breeding phase is confirmed by a species expert and preserved for future reference.

(7) Comment: One commenter requested that any final rule promulgated by the Service clarify that the total habitat available to the Panama City crayfish is the 56 square-mile area identified in Figure 1 of the January 3, 2018, proposed rule (see 83 FR 333) and that Callaway Creek and Bayou George Creek form an absolute barrier to any eastward expansion by the crayfish.

Our response: The Service has taken the range description from the SSA report and used it in this final rule. We, with assistance from the FWC, have projected boundaries based on existing survey data. To our knowledge, Callaway Creek and Bayou George Creek form barriers and restrict access by the Panama City crayfish on opposite creek or stream banks. However, the northeastern portion of the species' range is not bordered by any well-defined water body, and the current delineator is only defined by the locations of the Panama City crayfish identified during surveys where access was allowed by the landowner. Thus, some uncertainty remains with respect to the boundaries in the northeastern-most habitats. Accordingly, we cannot state Callaway Creek and Bayou George are absolute barriers to eastward expansion.

(8) Comment: One commenter claimed that the eastern side of the Panama City crayfish's range has been surveyed more than the western side of the range. Another commenter stated that we have insufficient data regarding the Panama City crayfish to prove a decline in the species. Both commenters encouraged the Service to conduct more surveys within the western portion of the range.

Our response: Survey effort varies across the species' range. Survey access is limited by landowner permission, so the majority of surveys occur only where we received landowner permission to access their land or along public rights-of-way. We agree that additional surveys within the western range of the species would assist with our understanding of the species' distribution. As access is allowed, we will continue to fill in survey gaps. Despite these potential survey gaps, the Act requires us to make a listing determination based on the best available information. Using current data and our knowledge of the Panama City crayfish's habitat use, we are able to define where populations of the species may occur. Overlaying these areas with land use layers, we used Geographic Information System (GIS) mapping to refine areas that remain suitable for the species and compared it to past habitat availability. From this analysis, we found that approximately 50 percent of the remaining habitat is potentially suitable for the species. Because of the known relationship between the crayfish and its habitat, we can make inferences that declines of the crayfish have occurred based on loss of habitat to development.

(9) Comment: One commenter expressed concern that the Service may allow destruction of mature hardwood swamp vegetation and mature baygall communities as a method to create new habitat for the Panama City crayfish.

Our response: On lands that may be secured for Panama City crayfish protection, we do not intend to alter natural communities such as mature hardwood swamps or baygall communities to benefit the Panama City crayfish. Fire historically sculpted the ecosystem boundaries of the species, but with limitations in developing city boundaries on where prescribed fires may be implemented, the ecotones between differing habitat types may not be as clear as they were historically when wildfires burned unimpeded. There are often differing viewpoints among ecologists on what habitat type a specific area historically was intended to function as; however, we consult with habitat experts and review literature before removal of certain plant species to encourage growth of other plant species.

(10) Comment: One commenter stated that it has yet to be determined whether Panama City crayfish is a native species.

Our response: Based on the best available data, the species is considered to be a valid species native to Bay County, Florida (Taylor et al. 2007; Integrated Taxonomic Information System 2017; Service 2019, p. 12).

(11) Comment: One commenter questioned whether critical habitat should be extended to the remaining 30 percent of the lands that do not contain the preferred hydric soils, because there is evidence that juvenile crayfish are transported overland by sheet flow rains. Any alteration in the upland landscape (driveway, building) could create an impediment to this sheet flow and therefore create an impediment to crayfish survival.

Our response: We agree that crayfish are likely dispersed via sheet flow during heavy rain events. However, because these areas are not used consistently either on a per-event basis or by a specific lifestage, and do not provide features (such as core, hydric soils) that are essential to the species' conservation, we have not included these soil types in our critical habitat designation. Connectivity of conservation parcels that have been designated as critical habitat and are consistent with our conservation strategy will further allow for natural dispersal events via sheet flow.

(12) Comment: Commenters noted that the Panama City crayfish is already protected by the State of Florida and expressed concern about the potential for unnecessary regulatory duplication should the Service finalize the listing of the Panama City crayfish. They requested that entities only need to coordinate with one agency.

Our response: We have determined that the Panama City crayfish warrants listing as a threatened species, despite existing State protections. With the intent to streamline the regulatory process, in January 2020, FDEP assumed permitting authority under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) for dredge and fill activities throughout Florida, including within the range of the Panama City crayfish. FDEP is required to coordinate with us prior to authorizing permits for species listed under the Act, species proposed for listing under the Act, candidate species, and species petitioned for listing under the Act. We support minimizing the regulatory burden on the public, while also ensuring the conservation of the species. Through the FDEP assumption of permitting authorities, entities will deal directly with one process that will cover all permits, thereby simplifying the consultation process for applicants.

(13) Comment: One commenter expressed concern with the continuing status quo for development projects that do not require Federal permits, citing that State and local protections for the species are inadequate as demonstrated by the species' continuing decline.

Our response: Our 4(d) rule extends the prohibitions of section 9 of the Act to the Panama City crayfish, with certain exceptions. Projects or actions

that are likely to cause take of the Panama City crayfish but that are not subject to section 7 review under the Act will require a permit and habitat conservation plan (HCP) under section 10 of the Act, unless they otherwise qualify for an exception in the 4(d) rule.

(14) Comment: One commenter expressed concern that spraying for mosquitos will be prohibited to prevent pesticide drift into protected habitat, and, therefore, Panama City crayfish will be prioritized over the health of Bay County residents with respect to mosquito-borne illnesses.

Our response: We encourage the use of mosquito control methods that do not result in take of the species. Mosquito control often uses pyrethroid insecticide, which has been shown to be toxic to aquatic wildlife (Paul and Simonin 2006, p. 614). There are alternative methods to control mosquitos other than through the use of aerial pesticide applications, such as donut blocks placed directly into neighborhood ditches that prevent the larvae from maturing to adult mosquitos. We encourage alternative applications that are not detrimental to the Panama City crayfish.

(15) Comment: One commenter noted that Panama City crayfish habitat will create additional mosquito breeding areas.

Our response: We do not agree; protecting habitat for the Panama City crayfish will not alter the amount of standing water that exists in the environment today. Restoration actions may reduce the amount of water standing in furrowed habitats and normalize the water table. The Panama City crayfish prefers ephemeral pools of water less than a foot deep. The Panama City crayfish feeds mostly on decaying vegetation, but as generalist feeders, they are likely to feed on mosquito larvae, too.

(16) Comment: One commenter requested that the Service list the Panama City crayfish as endangered instead of threatened. They cite endangered ranks from the International Union for the Conservation of Nature (IUCN) and the American Fisheries Society (AFS).

Our response: The definitions, criteria, and analyses under the Act are not equivalent to those used by IUCN and other organizations. The Act defines ''endangered species'' and ''threatened species'' and mandates five factors for consideration when determining a species' status under the Act. The definitions and analysis conducted under the Act do not necessarily equate with those used by other organizations who have different ranking systems, and, accordingly, a species' status may vary depending on the source. As noted, we are required to apply the definitions of the Act and consider the factors the Act identifies. We have determined that endangered species status under the Act is not appropriate for the Panama City crayfish because the species maintains multiple, moderate or high resiliency populations across its historical range, with low risk of significantly declining in the near term. Further, given its distribution and health of populations, the Panama City crayfish has sufficient redundancy and representation to withstand catastrophic events and novel changes in its environment in the near term. For these reasons, Panama City crayfish is not currently in danger of extinction. See Determination of Panama City Crayfish's Status, below.

(17) Comment: Several commenters had questions about the buffer width used to delineate critical habitat. One commenter questioned the percentage of Panama City crayfish documented on core soils. One commenter asserted existing forestry BMPs in Florida and biodiversity standards in forest certification programs are effective for protecting at-risk species, regardless of buffer width.

Our Response: As described in the Summary of Changes from the Proposed Rule and the Criteria Used to Identify Critical Habitat sections of this rule, we have modified the buffer width based on additional analysis of Panama City crayfish occupancy of secondary soils. We reduced the buffer to 50 feet rather than the proposed 328 feet. Our original analysis conducted for the April 15, 2021, proposed rule (86 FR 19838) used a 328-foot buffer from core soils into secondary soils, which captured 96 percent of known occurrence records. Later in 2021, we looked at varying scales relative to presence points. Using a 50-foot buffer from the core soils' boundary line into secondary soils, we capture close to 71 percent of known occurrence records. Based on our knowledge of how the crayfish moves across the landscape, it is likely that the additional occurrence records may have been from points in time where there was high rainfall, however we lack recorded rainfall amounts or ground water levels to confirm this assumption. We have determined that the 50-foot buffer provides a better method to focus protection on lands that are likely occupied more consistently, rather than those that may only be temporarily occupied during months or years with high rainfall events. Therefore, this final rule includes the refined 50-foot buffer boundary to capture lands used most consistently versus lands that may be used only during a small portion of the crayfish's life cycle when there is high rainfall. We include an exception for forestry BMPs in secondary soils as part of our 4(d) rule because forestry practices that follow BMPs in secondary soils will have *de minimus* impacts on the species.

(18) Comment: Several commenters focused on concerns that private landowners will need to hire consultants and pay for mitigation for activities on their properties. Concerns were expressed over the potential loss of use or value of their property, and these commenters requested that all landowners in the proposed critical habitat units be notified about the proposed listing and critical habitat rule.

Our response: As described under *Takings—Executive Order 12630,* below, the Act does not authorize the Service to regulate private actions on private lands as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. Accordingly, any potential impact to land value results from perceptions and is expected to be small.

We placed notifications in the local newspaper informing the public of the proposed rule, and we held two public informational meetings and one public hearing. In general, a 4(d) rule allows the Service to target the take prohibitions to those that provide conservation benefits for a threatened species; we may choose to except take for certain activities (*i.e.,* allow incidental take without a permit for certain activities) if we conclude the exceptions are necessary and advisable to provide for the conservation of the species. For this species' 4(d) rule, one exception removes permit requirements with respect to the following activities for individual homeowners: Maintenance of existing structures and construction or reconstruction activities that occur within the existing footprint of previously developed areas; construction of new structures that occur within 100 feet of existing structures on an individual private landowner's property and with a new footprint less than 1,000 square feet (ft^2), such as a pool or shed associated

with an existing house; and culvert installations for individual landowners not associated with larger developments. Therefore, small (*i.e.,* individual home) landowners will not need to hire consultants or pay for mitigation for activities on their properties.

(19) Comment: One commenter expressed concern that only occupied habitat is included in the critical habitat designation and indicated that more areas are needed in the designation to meet the resilience, redundancy, and representation under which the Service evaluates requirements of the Act.

Our response: It appears that the commenter may be confusing our use of the conservation biology principles of resiliency, redundancy, and representation (*i.e.,* the 3Rs) in the SSA report and how we identify areas that meet the definition of critical habitat under section 3(5)(A) of the Act. We are designating more than 4,000 acres of land, all considered occupied, as critical habitat. In addition, our analysis of land needed to recover the species is a subset of the currently occupied habitat rather than all, as reflected in this final designation. We did not find that unoccupied habitat should be designated, as no other habitat was deemed essential to the conservation of the species. Based on occupied critical habitat, the species maintains multiple, adequately resilient populations across its historical range, with low risk of significantly declining in the near term. Further, given its distribution and the health of its populations, the Panama City crayfish has sufficient redundancy and representation to withstand catastrophic events and novel changes in its environment in the near term. Accordingly, we determined occupied critical habitat is sufficient to conserve the species.

(20) Comment: Two commenters expressed concerns with proposing a 4(d) rule that would allow activities, such as sustainable silvicultural practices, that do not have positive effects on the Panama City crayfish.

Our response: Section 4(d) of the Act provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of a threatened species. Under section 4(d) of the Act, we may extend some or all of the prohibitions of section 9(a)(1) of the Act to threatened wildlife species. In considering whether to extend the section 9(a)(1) prohibitions, we may consider whether the benefits of allowing certain activities, including habitat management activities and some silvicultural practices when implemented with conservation measures to reduce impacts, are expected to have overall *de minimus* impacts or be beneficial to the species such that prohibiting those activities or take associated with those activities may be unnecessary. One example is reduced bedding depths used during silvicultural activities. Silvicultural row thinning increases groundcover that is beneficial to the Panama City crayfish. The 4(d) rule exceptions will allow us to streamline routine actions that have minimal impacts or benefits to the crayfish, especially when implemented with conservation measures, by excepting the take associated with them.

(21) Comment: One commenter stated that they are unaware of any ranching or farming uses that have resulted in the loss or degradation of the Panama City crayfish's natural habitat. They disagreed with the statement, ''conversion from silviculture to grazing use has occurred on lands adjacent the crayfish's range.'' They are also unaware of any plans to convert any land to ranching or farming uses in the crayfish's range. The commenter stated that land conversion to ranching and or farming is simply not an issue, and that these activities may provide an overall benefit to the crayfish through the creation of artificial habitat. The commenter, therefore, requested that the Service remove the statements associated with the potential for ranching and farming uses to impact the Panama City crayfish's habitat. This commenter also supported use of the 4(d) rule for all activities, such as agriculture, if water quality BMPs are followed.

Our response: On the few individual family farms and ranches that occur within the range of the crayfish, little habitat remains that is suitable for the crayfish. These properties lack sufficient herbaceous vegetation and have muddied and compacted soils. The 4(d) rule includes an incidental take exception for agricultural maintenance activities in pasture and rangelands (including cattle operations) that were established prior to January 3, 2018, and that implement State and Federal BMPs for existing farms and ranches if they have no indirect impacts to adjacent Panama City crayfish habitat. The Service agrees that no corporate-scale ranching or farming of lands currently occurs within the Panama City crayfish's range. We clarify that currently the closest large-scale ranching is more than 5 miles from the eastern border of the species' range. However, we have concerns with future corporate-scale ranching or farming of lands that might occur within the range of the Panama City crayfish. Current practices for these operations often include conversion of the groundcover to a nonnative grass cover, which is not suitable for the crayfish.

(22) Comment: One commenter stated that the 4(d) rule should include exceptions for take associated with conservation management practices for a suite of activities that occur in Panama City crayfish habitat, including maintenance of ditches, roads, and utility and transmission line rights-of-way, and an exception for entities using water quality BMPs for silviculture and agriculture.

Our response: As described under Provisions of the 4(d) Rule, below, we provide exceptions for take associated with certain development practices, select land management activities, and some utility actions that are expected to have negligible impacts to the Panama City crayfish and its habitat.

(23) Comment: One commenter requested revising the 4(d) rule to remove the limitation of excepting take only if it is associated with forestry activities ''located in secondary soils.''

Our response: Because of the close association of the Panama City crayfish to core soils, and the species' need for intact, unaltered core soils, we are not excepting take associated with forestry practices in core soils. As indicated in the SSA report, silvicultural practices such as ditching and bedding, roller chopping, installing fire breaks, and constructing roads can alter the hydrology of Panama City crayfish sites, create physical barriers to Panama City crayfish movement, and destroy underground burrows (Service 2019, p. 67). Fire suppression and high tree-density on silvicultural sites reduce or eliminate herbaceous groundcover necessary for suitable crayfish habitat (Service 2019, p. 67). For these reasons, we are not excepting incidental take associated with activities employing forestry BMPs on core soils; however, we do provide the exception for incidental take associated with these activities on secondary soils because the soils are less hydric, so ditching and bedding is greatly reduced thereby likely reducing the effects to a *de minimus* level for the Panama City crayfish.

(24) Comment: One commenter stated that any level of take allowed by the 4(d) rule will lead to the extinction of the Panama City crayfish and requested that all incidental take exceptions be removed from the 4(d) rule.

Our response: Small, isolated pockets of Panama City crayfish occurrences located within individual homeowners' backyards do not contribute

significantly to the overall recovery of the species, therefore incidental take for specified activities in these small pockets of habitat is warranted. The exceptions detailed in the 4(d) rule target activities that will have minimal impacts on populations of Panama City crayfish and the species' recovery; therefore, we found that the exceptions are necessary and advisable for the conservation of the crayfish.

Determination of Panama City Crayfish's 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 ''endangered species'' or ''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 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

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Panama City crayfish. Our analysis of this information indicates that, at the species level, habitat loss, degradation, and fragmentation due to human development (Factor A) is the primary factor affecting the Panama City crayfish now and into the future. There may be additional infrastructure projects (*e.g.,* roads and ditches) that affect the hydrology within the range of the Panama City crayfish as a result of forest clearing for permanent rights-of-way or silviculture. Additionally, the current level of habitat fragmentation (Factor A) further isolates populations, which reduces gene flow and limits the potential for the species to disperse. The existing regulatory mechanisms (Factor D) do not address these threats to the level that the species is not warranted for listing. We have no evidence that off-road vehicle use (Factor A), overutilization (Factor B), or disease (Factor C) are affecting populations of Panama City crayfish.

We find that an endangered species status is not appropriate for the Panama City crayfish because despite its narrow and isolated distribution making it susceptible to catastrophic events and having low adaptive ability, the species maintains multiple resilient populations across its historical range and the risk of extinction is low in the near term. While only 43 percent of the original lands historically available to the Panama City crayfish remain suitable for use by the Panama City crayfish, the species currently has four highly or moderately resilient populations. Further, despite changes to the crayfish's natural habitat of wet pine flatwoods, the species currently uses artificial habitats such as roadside ditches and rights-of-way, although these sites may become unsuitable in the long term due to anthropogenic activities that can alter their hydrology or configuration. Therefore, we conclude that the current risk of extinction of the Panama City crayfish is sufficiently low that it does not meet the Act's definition of an endangered species.

In determining whether Panama City crayfish is likely to become endangered in the foreseeable future, we assessed the plausible scenarios, including the scope and magnitude of threats and the expected species' response to these changes. The foreseeable future is the period of time for which we determined we could make reliable predictions about the threats to the species and the species' response to those threats. Based on the biology of the species and the threats acting on it, the foreseeable future timeframe used in the determination is approximately 30 years. The generation time for the species is 2 years with a lifespan up to 3.5 years; the period to 30 years encompasses up to 15 generations, which is sufficient time to determine the species' response to the stressors. During this timeframe, we determined we can make reliable predictions about the threats to the species and the species' response to those threats. Although the future scenarios extend through 2070, the uncertainty regarding the species' response to the stressors becomes so great as to render the scenarios too unreliable beyond 2050.

While the Panama City crayfish faces a variety of threats, only one threat, habitat loss and degradation due to urban development causing habitat fragmentation and subpopulation isolation, was considered an important factor in our assessment of the future viability of the Panama City crayfish. Based on our future scenarios for urban development, we projected losses of resiliency, representation, and redundancy for Panama City crayfish in the foreseeable future. Especially problematic is the projected complete loss of resiliency and redundancy in the western group of populations. Losses of western Panama City crayfish populations substantially reduce the range and genetic diversity of the species, as well as increasing vulnerability to catastrophic events such as hurricanes. The current circumstances are already precarious, and the loss of any more adequately resilient populations would put the species in danger of extinction.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Panama City crayfish. Habitat loss from development is occurring rangewide and has resulted in the fragmentation of the landscape. The fragmentation of suitable habitat has caused the isolation of existing populations, limiting them to ditches, swales, slash pine plantations, and utility rights-of-way. The Panama City crayfish has been fragmented into 12 smaller populations. In the future, two populations are projected to maintain high resiliency, one moderate resiliency, and six low resiliency, while three will be considered functionally extirpated.

Of the eight western populations, six populations are projected to be in low condition and three are functionally extirpated in the future. These three functionally extirpated populations represent 25 percent of the known populations overall and 38 percent of the western group, and, although still in existence, they are not expected to contribute to the future redundancy of Panama City crayfish because they are already experiencing genetic drift and the habitat that supports them is susceptible to future development.

All future scenarios project a similar negative impact on the redundancy and representation of Panama City crayfish, with three populations projected to be extirpated, and of the remaining nine populations, six will be in low condition by 2030 under all scenarios. The greatest loss of redundancy for the Panama City crayfish is projected to occur in the western group. In this group, all of the populations are predicted to be extirpated or in low condition by 2030, including the Transmitter West population, which is the largest population in this group. Loss of viability within this population is significant for the species. In the eastern group, three populations are

projected to remain strongholds for Panama City crayfish. These three eastern populations will maintain resiliency and constitute only 33 percent of the remaining populations.

The Panama City crayfish currently has low adaptive potential across its range, and all of the future scenarios project an impact on the species' representation during the 30-year foreseeable future time horizon. The species has very low resiliency in the western portion of its range, with only one of the eight populations currently in moderate condition. None of the western populations are projected to maintain adequate resiliency in the future; thus, adaptive capacity is projected to be completely lost in the western portion. Furthermore, a population (High Point) in the eastern portion contains unique genetic diversity not found in other populations (Duncan et al. 2017a, p. 19), but it is expected to remain in low condition and thus has a low likelihood of persistence, thereby further reducing the species' ability to adapt to changes in its environment.

Thus, after assessing the best available information, and based on analysis of the species' current and future conditions, we conclude that the resiliency, representation, and redundancy for the Panama City crayfish will continue to decline such that it is likely to become in danger of extinction within the foreseeable future throughout its range.

Panama City Crayfish's 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. The court in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020) (*Center for Biological Diversity*), 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 that 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. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant, and (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Center for Biological Diversity,* we now consider whether there are any significant portions of the species' range where the species is in danger of extinction now (*i.e.,* endangered). In undertaking this analysis for the Panama City crayfish, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered.

For the Panama City crayfish, we considered whether the threats are geographically concentrated in any portion of the species' range at a biologically meaningful scale. We examined the following threats: Habitat loss and degradation from development, including cumulative effects. The threat from development and future urbanization of the landscape in Bay County, Florida, affects the species throughout its entire narrow range. The species is a narrow endemic that historically functioned as a single population occurring in a very small area, and has since been fragmented into multiple small populations divided into western and eastern groupings based on a road. While we can separate the species' range into western and eastern portions, the threats that the species faces, particularly development and subsequent isolation and lack of connectivity, affect the species throughout its entire narrow range. Therefore, there is no concentration of threats in any portion of the Panama City crayfish's range at a biologically meaningful scale, and accordingly, there are no portions of the species' range where the species is likely to have a different status from its rangewide status. Thus, no portion of the species' range provides a basis for determining that the species is in danger of extinction in a significant portion of its range, and we determine that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that the Panama City crayfish meets the Act's definition of a threatened species. Therefore, we are listing the Panama City crayfish as a threatened species in accordance with sections 3(20) 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 includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. 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 ECOS portal (*https://www.fws.gov/ecos*), or from our Florida 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. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

Following publication of this final rule, 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 Florida will be eligible for Federal funds to implement management actions that promote the protection or recovery of the Panama City crayfish. Information on our grant programs that are available to aid species recovery can be found at: *https://www.fws.gov/grants.*

Please let us know if you are interested in participating in recovery efforts for the Panama City crayfish. 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 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)(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 any endangered or threatened 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; issuance of section 404 Clean Water Act permits by the U.S. Army Corps of Engineers; and construction and maintenance of roads or highways by the Federal Highway Administration.

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 final listing on proposed and ongoing activities within the range of a listed species. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy.

II. Final Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the Secretary shall issue such regulations as she deems necessary and advisable to provide for the conservation of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife, or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him [or her] with regard to the permitted activities for those species. He [or she] may, for example, permit taking, but not importation of such species, or he [or she] may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising the authority under section 4(d), we have developed a rule that is designed to address the Panama City crayfish's specific threats and conservation needs. Although the statute does not require us to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the Panama City crayfish. As discussed above under Summary of Biological Status and Threats, we have concluded that the Panama City crayfish is likely to become in danger of extinction within the foreseeable future primarily due to habitat loss and degradation, habitat fragmentation, and subpopulation isolation due to development.

The provisions of this 4(d) rule will promote conservation of the Panama City crayfish by encouraging management of the landscape in ways that meet the conservation needs of the

Panama City crayfish and are consistent with land management considerations. The provisions of this rule are one of many tools that the Service will use to promote the conservation of the Panama City crayfish.

Provisions of the 4(d) Rule

This 4(d) rule will provide for the conservation of the Panama City crayfish by prohibiting the following activities, except as otherwise authorized or permitted: Importing or exporting; take; possession and other acts with unlawfully taken specimens; delivering, receiving, transporting, or shipping in interstate or foreign commerce in the course of commercial activity; or selling or offering for sale in interstate or foreign commerce.

Multiple factors are affecting the status of the Panama City crayfish, with the primary threats resulting in habitat loss and degradation, habitat fragmentation, and population isolation. A range of activities have the potential to affect these species, including farming and grazing practices, some silvicultural practices, creation and maintenance of roadside ditches and rights-of-way, development of residential or commercial properties, and collection for bait (Service 2019, pp. 65–66). These threats, which are expected to be exacerbated by continued development along with the effects of climate change, were central to our assessment of the future viability of the Panama City crayfish. As a result, we are prohibiting take associated with these threats to conserve the species unless they are managed in such a way that results in minor take. Further, import or export, sale, and possession are all activities that could be associated with bait collection and, therefore, are prohibited.

Under the Act, ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulation at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. Regulating incidental and intentional take will help preserve the species' remaining populations, slow their rate of decline, and decrease synergistic, negative effects from other stressors. Therefore, we prohibit intentional and incidental take of the Panama City crayfish, except that take associated with those actions and activities discussed below is specifically excepted by the 4(d) rule.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

The 4(d) rule will also provide for the conservation of the species by allowing exceptions to actions and activities that, while they may have some minimal level of disturbance or take to the Panama City crayfish, are not expected to rise to the level that would negatively impact the species' conservation and recovery efforts. The exceptions to these prohibitions include conservation efforts by the Service or State wildlife agencies; certain other general exceptions allowed for take of endangered wildlife as set forth in 50 CFR 17.21 (see the rule portion of this document); and certain development practices, select land management activities, and some utility actions (described below) that are expected to have negligible impacts to the Panama City crayfish and its habitat.

The first exception is for take associated with certain development activities that will have negligible or beneficial effects on the Panama City crayfish and its habitat, including: Maintenance of existing structures and construction or reconstruction activities that occur within the existing footprint of previously developed areas; construction of new structures that occur within 100 feet of existing structures on an individual private landowner's property and have a new footprint less than 1,000 square feet (ft^2), such as a pool or shed associated with an existing house; installation of culverts for individual landowners not associated with larger developments; installation of platforms or boardwalks for recreational purposes on conservation lands that allow sunlight of sufficient levels to maintain herbaceous groundcover; and construction of paths used for nonmotorized activities as long as the project footprint, including construction impacts, impacts no more than 5 percent of the acreage in core or secondary soils within properties under a conservation easement.

The second exception is for take associated with select land management activities related to silvicultural (forestry) activities and invasive species control that help maintain habitat for the Panama City crayfish and to agricultural maintenance activities, and that have *de minimus* effects. Silviculture activities within secondary soils including tree thinning, harvest (including clearcutting), site preparation, planting, and replanting following State BMPs (Florida Department of Agriculture and Consumer Services (FDACS) 2008, entire) are excepted as the species has remained viable in lands under timber management where native groundcover species recolonize naturally. As a practice, ditching and bedding from forestry occurs less often in secondary soils than in primary soils, and therefore is considered to have *de minimus* effects. Take associated with prescribed burning and wildfire control efforts is excepted when following all State BMPs, guidelines, or permit conditions, and take associated with herbicide applications targeting exotic plants or shrub species is excepted when following all other State and Federal BMPs, guidelines, or permit conditions, associated with these actions. Finally, take associated with agricultural maintenance activities in pasture and rangelands (including cattle operations) that were established prior to publication of the proposed listing rule (January 3, 2018) and that implement State and Federal BMPs will be excepted.

The third exception is for take associated with some utility actions that are expected to have minimal impacts to the Panama City crayfish or its habitat. These include ditch mowing and maintenance activities outside of critical habitat units, or ditch mowing and maintenance within critical habitat units after development of BMPs in coordination with the local Service office. Take associated with culvert replacements or maintenance that do not adversely affect, but improve or restore, the natural hydrology is excepted. In coordination with the local Service office, take associated with the following activities is also excepted: Maintenance associated with rights-of-way (including mowing, use of herbicides, and mechanical side trimming); powerline and pole placements and replacements; replacement of critical structural components, such as crossarms, insulators, conductors, etc.; and directional boring by utility owners.

We reiterate that these actions and activities may have some minimal level of take of the Panama City crayfish, but any such take is expected to be rare and

insignificant, and is not expected to negatively impact the species' conservation and recovery efforts. We expect the restoration activities to have a net beneficial effect on the species. Across the species' range, habitat has been degraded and fragmented by development and land use changes. The habitat restoration activities in the 4(d) rule are intended to improve habitat conditions for the species in the long term.

We recognize our special and unique relationship with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist the Services in implementing all aspects of the Act. In this regard, section 6 of the Act provides that the Services shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, will be able to conduct activities designed to conserve the Panama City crayfish that may result in otherwise prohibited take without additional authorization. In addition, Federal and State wildlife law enforcement officers, working in coordination with Service field office personnel, may possess, deliver, carry, transport, or ship Panama City crayfish taken in violation of the Act as necessary.

Nothing in this 4(d) rule will change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of the Panama City crayfish. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service.

III. Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Designation also does not allow the government or public to access private lands, nor does designation 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 will 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 only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species; 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.

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 (HCPs), or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features that are essential to the conservation of the species and that may require special management considerations or protection. The regulations at 50 CFR 424.02 define ''physical or biological features essential to the conservation of the species'' as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, we may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance. These characteristics are described below for the Panama City crayfish:

(1) Space for individual and population growth and for normal behavior: The Panama City crayfish naturally inhabits shallow, ephemeral, freshwater wetlands that are associated with early successional wet prairie-marsh and wet pine flatwoods and their communities. These locations historically supported a native herbaceous plant community dominated by native wetland grasses and sedges with an accompanying overstory of no to low-density pines and were naturally maintained by periodic wildfire.

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements: Native herbaceous vegetation is important to the Panama City crayfish for food, detritus formation, and shelter. Absence of vegetation increases exposure of this small crayfish to predation and reduced availability of food. Although Panama City crayfish are facultative air breathers, moisture is required to facilitate the respiratory process. Burrowing to groundwater or access to surface water are both important habitat features needed to prevent desiccation of individuals and populations. The Panama City crayfish cannot burrow much deeper than 3 feet below the surface and prefer surface waters less than 1 foot deep (FWC 2006, p. 3).

(3) Cover or shelter: The Panama City crayfish relies mostly on herbaceous vegetation that grow on core and secondary soils, which allow them to burrow for shelter and to rear young. The ability to burrow to the water table during times of drought is essential to the persistence of the species. Core soils have depth to water tables that meet the depth threshold that is important for long-term Panama City crayfish

population persistence. These core soils provide the sediment structure needed for burrow construction to the water table and also support the herbaceous vegetation upon which the species relies for food and shelter. Young crayfish are often captured clinging to vegetation in emergent, yet shallow, water bodies.

Secondary soil types are drier, and it is believed the species cannot persist when only secondary soils are available with below-average water tables. They are mentioned here because they may support Panama City crayfish after recent rainfalls and longer periods of time after above-average rainfall that influences water table depths, and they may provide connectivity between two patches of core soils. Seventy percent of known occurrences of Panama City crayfish occur within either core soils or within secondary soils that are within 50 feet (15 m) of core soils. These secondary soils also provide the sediment structure needed for burrow construction to the water table and also support the herbaceous vegetation upon which the species relies for food and shelter except during times of drought.

(4) Sites for breeding, reproduction, or rearing (or development) of offspring: Shelters, such as burrows, are an important resource for crayfish as they provide for protection from predation and space for mating and for rearing hatchlings. Burrows also help to maintain hydration and preferred body temperatures. Surface waters provide shelter for juveniles to grow prior to being large enough to burrow. These surface water locations also provide for breeding and feeding grounds. Surface water must be sufficiently deep, but usually less than 1 foot (0.3 meters) deep, to support the species but shallow enough to sustain herbaceous vegetation. Waters greater than 1 foot (0.3 meters) deep sustain other crayfish species that may outcompete the Panama City crayfish.

(5) Habitats that are protected from disturbance or are representative of the historical, geographical, and ecological distributions of a species: The Panama City crayfish's historical range is estimated to cover a 56-square-mile area (Service 2019, entire). Hardwood swamps fall within the core soil category but are not actually suitable for the Panama City crayfish (except the transition edge habitat). Land acreages within the Panama City crayfish's range total 35,658 acres, with a composition of the following soils: (1) Core with 14,880 acres (6,022 ha; 42 percent of the land area); (2) secondary with 12,379 acres (5,010 ha; 35 percent of the land area); and (3) unsuitable soils with 8,399 acres (3,399 ha; 23 percent of the land area). We estimate that approximately 9,180 acres (3,715 ha) of core and 5,647 acres (2,285 ha) of secondary soils remain undeveloped (using 2016 data) and are therefore suitable for the Panama City crayfish. We estimate that 3,606 acres (1,459 ha) of the core (3,242 acres (1,312 ha, or 22 percent)) and secondary (364 acres (147 ha, or 3 percent)) soils are hardwood swamp, which are not directly used by the Panama City crayfish but are included within acreage totals because they provide transition habitat.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of Panama City crayfish from studies of the species' habitat, ecology, and life history as described below. Additional information can be found in the proposed listing rule published in the **Federal Register** on January 3, 2018 (83 FR 330), and the Panama City Crayfish SSA report (version 2.0; Service 2019, entire). We have determined that the following physical or biological features are essential to the conservation of the Panama City crayfish:

(1) Undeveloped lands, including cropland, utilities rights-of-way, timberlands, and grazing lands, that support open wet pine flatwoods and wet prairie habitats that contain the following:

(a) Appropriate herbaceous groundcover vegetation;

(b) Permanent or temporary pools of shallow (usually less than 1 foot) freshwater locations; and

(c) Gently-sloped ground level swales with a 3:1 or shallower slope ratio along ecotonal or transitional areas.

(2) Soil types within undeveloped lands that provide sediment structure needed for burrow construction and that support mostly native herbaceous vegetation needed for additional food and shelter, and where the ground water is always within 3 feet of the ground surface and surface waters occur on occasion. These soil types include:

(a) Core soils for Panama City crayfish, including (note: Prefix numbers refer to map units in the Soil Survey for Bay County, Florida (U.S. Department of Agriculture (USDA) 1984, entire)): (22) Pamlico-Dorovan Complex, (29) Rutlege Sand, (32) Plummer Sand, (33) Pelham Sand, (39) Pantego Sandy Loam, and (51) Rutledge-Pamlico Complex;

(b) Secondary soils within 50 feet (15 m) of core soils: (1) Albany Sand, (12) Leefield Sand, (13) Leon Fine Sand, (31) Osier Fine Sand, and (36) Alapaha Loamy Sand; and

(c) Soils that currently, or can eventually, support native herbaceous vegetation such as, but not limited to, wiregrass (*Aristida beyrichiana*), redroot (*Lachnanthes caroliniana*), beakrushes (*Rhynchospora* spp.), pitcher plants (*Sarracenia* spp.), sundews (*Drosera* spp.), butterworts (*Pinguicula* spp.), and lilies (*Hymenocallis* spp.).

(3) Undeveloped lands that contain surface and groundwater of sufficient quality to support all life stages of the Panama City crayfish and the herbaceous vegetation on which they rely, specifically surface waters with:

(a) Oxygen levels that range between 2 and 9 milligrams per liter;

(b) pH levels between 4.1 and 9.2; and

(c) Temperatures between 42 and 94 degrees Fahrenheit (°F) (5 and 34.4 degrees Celsius (°C)), although optimum temperatures are thought to be in the range of 68 to 79 °F (20 to 26 °C) (Butler et al. 2003).

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. The features essential to the conservation of this species may require special management considerations or protection to reduce the following threats: Habitat loss and destruction due to residential and commercial development, as well as habitat loss due to changes in the natural disturbance and hydrological regimes that maintain the wet prairie and flatwoods that Panama City crayfish originally inhabited. Historically, the Panama City crayfish inhabited natural and often temporary bodies of shallow fresh water within open pine flatwoods and prairie-marsh communities (as described in the SSA report (version 2.0; Service 2019, p. 56)). However, most of these communities have been cleared for residential or commercial development or replaced with slash pine (*Pinus elliottii*) plantations. Thus, the Panama City crayfish currently is known to inhabit the waters of grassy, gently-sloped ditches and swales; furrows within slash pine plantations; and utility rights-of-way.

Special management considerations or protections are required within critical habitat areas to address these habitat loss and destruction threats. The occupied units we are designating as

critical habitat for Panama City crayfish will require some level of management to address the current and future threats to the physical or biological features. Management activities that could ameliorate these threats include (but are not limited to): (1) Protection of lands from development through purchase, easement, or other conservation agreements that will prevent permanent conversion of Panama City crayfish habitat to other land uses; and (2) restoration and management of habitat to maintain the appropriate vegetative and hydrological characteristics for the Panama City crayfish.

These management activities will protect the physical or biological features for the species by protecting currently suitable habitat from being converted to other land uses and by promoting the appropriate vegetative and hydrological characteristics that the Panama City crayfish needs for survival. Additionally, management of habitat to protect the physical or biological features on occupied critical habitat will help achieve recovery of the Panama City crayfish.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat. When designating critical habitat, the Secretary will first evaluate areas occupied by the species. The Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied would be inadequate to ensure the conservation of the species. We are not designating any areas outside the geographical area occupied by the species because we have not identified any unoccupied areas that meet the definition of critical habitat and because occupied areas are sufficient to ensure the conservation of the species.

We reviewed available information that pertains to the habitat requirements of this species using information that was cited within the SSA report (Service 2019, entire) and information presented in the Service's conservation strategy for Panama City crayfish critical conservation needs (Service 2017b, entire); sources of information on habitat requirements include existing State management plans, endangered species reports, studies conducted at occupied sites and published in peer-reviewed articles, agency reports, and data collected during monitoring efforts (Service 2019, entire). Based on known occurrences and habitat requirements, critical habitat units were mapped in ArcMap (ESRI, Inc.) using the U.S. Department of Agriculture, Natural Resources Conservation Service, Soil Survey Geographic Database (USDA 2019, unpaginated). ArcGIS software was used to calculate the acreage of core and secondary soils within the historical range of the Panama City crayfish prior to anthropogenic habitat disturbances. Core soil types (as described in *Species Description* in the proposed listing rule (83 FR 330, January 3, 2018, pp. 332–333) and in Physical or Biological Features Essential to the Conservation of the Species, above) were buffered by 50 feet (15 m). We used 50 feet as our buffer because we found that more than 70 percent of known occurrences of Panama City crayfish occur within 50 feet of core soils and this buffer encompasses the majority of secondary soil types used by the species. In geographic information systems (GIS) mapping, the buffered soils were spatially processed by clipping to the population buffer of one-quarter mile, and developed areas were excluded based on 2020 Bay County Property Appraiser aerial imagery (Bay County Property Appraiser 2020, unpaginated).

In summary, for areas within the geographic area occupied by the species at the time of listing and with sufficient availability of land, we delineate critical habitat unit boundaries using the following criteria:

(1) Suitable habitat surrounding each of eight known populations of Panama City crayfish, delineated by polygons using one-quarter mile (0.4 kilometer (km)) circles around sample points with known species occurrences, based on the movement patterns of small crayfishes (note: Habitat surrounding four populations was not included for critical habitat designation, as explained below);

(2) Core and secondary soils within 50 feet (15 m) of core soils that contain one or more of the physical or biological features to support life-history functions essential for conservation of the Panama City crayfish.

Hardwood swamps found within core soils are considered unsuitable for the crayfish, and this habitat type was removed to the maximum extent possible.

The total acreage calculated for critical habitat based upon the above criteria amounted to 4,138 acres (1,675 ha). Accordingly, we designate as critical habitat those areas that contain the physical and biological features essential to the Panama City crayfish and that are currently occupied by the species.

For the purposes of critical habitat designation, we determined a unit to be occupied if it contains recent (*i.e.,* observed since 2015) observations of Panama City crayfish. We used 2015 as the cutoff because those surveys were the most recent comprehensive, landscape-scale surveys done, and successful crayfish reproduction was observed during those efforts, indicating it is reasonable to assume the areas are still occupied. The critical habitat designation does not include all lands known to have been occupied by the species historically; instead, it focuses on currently occupied lands that have retained the necessary physical or biological features that will allow for the maintenance and expansion of existing populations. The following locations (*i.e.,* populations as defined in the SSA report) meet the criteria of areas occupied by the species at the time of listing and that present sufficient availability of lands to support a population: 19th Street, Talkington, Minnesota, Transmitter West, Deer Point, High Point, Star, and Transmitter East. College Point and Old Airport populations were not consistently occupied, nor was there sufficient suitable habitat within the one-quarter-mile (0.4-km) polygon to support recovery, and these populations, therefore, are not included in the final designation. We also do not include Edwards, a population representing an original collection site from 1942, nor 390 West given that the fragmentation of that population by the industrial park resulted in too little remaining habitat to support population viability over time. While both areas are still occupied by Panama City crayfish, Edwards is surrounded by industrial buildings and bordered by U.S. Route 231 on its west edge, and 390 West will soon be bisected by a four-lane highway currently under construction. Potential habitat for recovery in either of these locations is limited and potentially fragmented. Long-term management will be challenging given proximity to major roadways and industrial development. As mentioned above, we exclude developed areas within the designation to the extent possible in the mapping exercise and in the text of the rule, as explained below. Designating critical

habitat in these eight occupied areas of the Panama City crayfish will sufficiently conserve the species, leading to its recovery.

We are not designating any areas outside the geographical area occupied by the species because we have not identified any unoccupied areas that are essential to the conservation of the species. In addition, based on our conservation strategy, the protection of the eight occupied units (as further described below) are sufficient for the conservation of the species.

When determining critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the Panama City crayfish. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this final rule have been excluded by text in the rule and are not designated as critical habitat. Therefore, a Federal action involving these lands will not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

We designate as critical habitat areas that we have determined are occupied at the time of listing (*i.e.,* currently occupied), that contain one or more of the physical or biological features that are essential to support life-history processes of the species, and which may require special management considerations or protections.

All units contain all of the identified physical or biological features and support multiple life-history processes.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation below. We will make the coordinates, plot points, or shapefiles on which each map is based available to the public on *https://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0137, on our ECOS portal site *https://ecos.fws.gov,* or at the Florida Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Final Critical Habitat Designation

We are designating eight units as critical habitat for the Panama City crayfish. The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for the Panama City crayfish. In total, they comprise 4,138 acres (1,675 ha) of land, entirely within Bay County, Florida. Table 4 below summarizes the approximate area and ownership of the units, which are described in detail below.

TABLE 4—CRITICAL HABITAT UNITS FOR THE PANAMA CITY CRAYFISH

Group	Unit	Unit name	Occupied	Proposed critical habitat area (in acres)	Land ownership of final critical habitat (in acres)		Final total critical habitat area (in acres)	Percent of total critical habitat designation (%)
					Private	State/local		
Western	1	19th Street	Yes	24.3	19.45	3.7	23.17	0.6
	2	Talkington	Yes	53.1	33.08	4.09	37.17	0.9
	3	Minnesota	Yes	65.0	19.07	29.96	49.02	1.2
	4	Transmitter West	Yes	248.4	179.61	2.21	181.82	4.4
Eastern	5	Deer Point	Yes	414.6	274.31	4.51	278.82	6.7
	6	High Point	Yes	38.4	36.28	0.51	36.79	0.9
	7	Star	Yes	2,761.4	1,417.8	6.49	1,424.29	34.4
	8	Transmitter East	Yes	3,571.5	2,057.47	49.92	2,107.38	50.9
Total				7,176.8	4,037.07	101.40	4,138.47	100
Percent of Total					98%	2%	100%	

Note: Area estimates reflect all land within critical habitat unit boundaries; area sizes may not sum due to rounding.

The eight units we are designating as critical habitat are broken into two groups, based on the western (Units 1 through 4) and eastern (Units 5 through 8) groups described in the SSA report (Service 2019, pp. 37–52). These two groups are distinguished by east-west genetic differentiation based on proximity to other populations and amounts of fragmentation within a population polygon. Below we describe each unit, and reasons why they meet the definition of critical habitat for the Panama City crayfish.

Western Group

The western group is comprised of four units supporting geographically isolated populations scattered throughout the species' range primarily in the cities of Panama City and Lynn Haven in Bay County, Florida. The Service designates 291.2 acres (117.8 ha) in total for the western group. These populations have been isolated by residential and commercial development, which resulted in habitat loss and fragmentation. These populations are currently supported by an average of 72.8 acres (29.5 ha) of habitat (range 23.2–181.8 acres (9.4–73.4 ha)). However, the Transmitter West population is by far the largest at 181.8 acres (73.4 ha), and this population may have historically been a critical link both genetically and geographically between the western and eastern representative groups. The remaining three populations are supported by an average of 36.5 acres (14.8 ha) (range 23.2–49.0 acres (9.4–19.8 ha)). Limited habitat area needed to support each population and lack of habitat connectivity to other populations in this group are the greatest management challenges.

Unit 1: 19th Street

The 19th Street unit includes the southwestern-most population located off 19th Street in Panama City, Florida. It is located on both sides of an active railroad track with habitat totaling 23.2 acres (9.4 ha). Land ownership is mostly private, but 3.7 acres (1.5 ha) is owned by Bay County. Only secondary soils remain undeveloped, but the elevated railroad track has artificially provided a water barrier, often keeping the site ponded when all others have dried up. Maintenance (*i.e.,* mowing and woody vegetation removal) for the railroad has kept the adjacent right-of-way covered in dense, herbaceous vegetation that is ideal for the Panama City crayfish. Adjacent unmanaged slash pine stands,

where burrows have been documented, and a mowed grass field also provide habitat.

Panama City crayfish occurrence and reproduction were documented as recently as 2016–2018. All of the essential physical or biological features are found within the unit. The essential features (*e.g.,* appropriate herbaceous groundcover vegetation and permanent or temporary pools of shallow fresh water) for this unit may require special management, particularly with respect to mowing, to ensure maintenance or improvement of the existing habitat.

Unit 2: Talkington

The Talkington unit is located off of Jenks Avenue in Panama City, Florida, with habitat totaling 37.2 acres (15.1 ha). Land ownership is entirely private, although 4.1 acres (1.7 ha) is under easement for conservation. The Talkington Family Nature Preserve forms the centerpiece of this population, with land ownership held by the Bay County Conservancy (BCC), and the associated conservation easement held by FDEP. The preserve is primarily pine flatwoods with a cluster of pond pine trees in the center portion. The Service and FWC have a management agreement in place with BCC that allows for mowing to manage the habitat on a 2- to 3-year interval, to mimic the natural fire regime and maintain ideal conditions for the Panama City crayfish. The remaining 33.1 acres (13.4 ha) of core and secondary soils in the vicinity provide opportunity for additional land protections and management, although much of this area will require restoration of vegetation.

Panama City crayfish occurrence was consistently documented since 2000, and most recently in 2016–2018. All essential physical and biological features are found within the unit. The essential features, especially appropriate herbaceous groundcover vegetation and permanent or temporary pools of shallow fresh water, in this unit may require special management; establishment of sloped swales and removal of dense shrub thickets would improve conditions for the Panama City crayfish in this unit.

Unit 3: Minnesota

The Minnesota unit is located off Minnesota Avenue in Lynn Haven, Florida, with undeveloped habitat totaling 49.0 acres (19.8 ha). Land ownership is a mix of private and public, and some area is under easement for conservation. This site is largely hardwood-cypress swamp with some possibilities for improving the habitat along 6 acres (2.4 ha) near and adjacent to the swamp ecotone. The City of Lynn Haven owns 30 acres (12.1 ha), which is under a conservation easement held by FDEP.

The Service and FWC have a management agreement with the City of Lynn Haven that allows the agencies to manage the property when funding is available. Minimal actions have occurred to date to remove some of the pine canopy layer. Other core and secondary soils surrounding the easement consist of dense slash pine plantations. The property has deep rutting from off-road vehicles, horses, and heavy equipment, which may affect the hydrology of the habitat.

Panama City crayfish occurrence was documented in 2015 and 2016. All essential physical and biological features are found within the unit. Achieving the right mosaic of water and grasses may require special management such as improving the hydrological functions to reduce flooding at depths not conducive to persistence of the Panama City crayfish.

Unit 4: Transmitter West

The Transmitter West unit is located off Transmitter Road in Lynn Haven and Panama City, Florida, with habitat totaling 181.8 acres (73.6 ha). Land ownership is a mix of private and public, with approximately 40 percent under easement for conservation. The FDEP holds multiple conservation easements for private landowners with a total 100.5 acres (40.7 ha) of pine flatwoods. The easements are managed as required by permit with either mowing or burning, and are in good condition for the Panama City crayfish. The remaining habitats, including the 2.2 acres (0.9 ha) in public ownership owned by the City of Lynn Haven and Bay County, are in mixed condition and in need of regular management (*e.g.,* prescribed fire or mowing).

Panama City crayfish occurrence was documented most recently in 2016. All essential physical and biological features are found within the unit, with grasses maintained by fire in the past and mowing more recently. Different depths of water bodies occur that provide a mosaic of water features with herbaceous grasses to make this a good area for the Panama City crayfish. Management may be required to reduce encroaching shrubs and to remove tree debris caused by Hurricane Michael in October 2018.

Eastern Group

The eastern group is comprised of four units supporting populations scattered throughout the species' range primarily in the unincorporated portions of Bay County, Florida. The Service designates 3,847.3 acres (1,556.9 ha) in total for the eastern group. These populations are currently supported by an average of 961.8 acres (389.2 ha) of habitat (range 36.8–2,107.4 acres (14.9–852.8 ha)). However, the Star and Transmitter East populations are the largest at 1,424.3 and 2,107.4 acres (576.4 and 852.8 ha), respectively. These two populations represent the largest connected blocks of core and secondary soils with appropriate vegetation. Although the vegetation and hydrology have been altered from native wet prairie and pine flatwoods habitats by silvicultural and agricultural uses, the geographic extent of these two populations forms the basis for the species' long-term resilience.

Unit 5: Deer Point

The Deer Point unit occurs on a peninsula located near Bay County Road 2321 in Lynn Haven and Panama City, Florida, and is supported by 278.8 acres (112.8 ha) of habitat. The land is bordered by Willams Bayou on the northeast, Mill Bayou on the southwest, and North Bay to the north. Land ownership is almost entirely private, although some areas are under easement for conservation. Only 0.9 acres (0.4 ha) is in public ownership by Bay County.

Four privately owned easements lie within or are adjacent to areas included in this unit. These easements protect 95.0 acres (38.4 ha) of core and secondary soil habitat, although some of the secondary soil habitats do not meet the criteria for inclusion within critical habitat due to distance from core soils. The Trust for Public Lands holds 90.0 acres (36.4 ha) under easement, but that easement is to be transferred to the City of Lynn Haven in the near future. FDEP holds three easements totaling 35.0 acres (14.2 ha) that are still owned by a private landowner (D&H Properties, LLC). The Service and FWC hold a management agreement with D&H Properties, LLC, and have mowed and burned 24.0 acres (9.7 ha) of this 35.0-acre (14.2-ha) property that are held in easements by FDEP. The remaining habitat is on lands that are heavily timbered and unmanaged, resulting in dense overgrowth of titi and slash pine, and hydrology may be affected by these activities as well as borrow pits and dirt roads that traverse the unit. Only the portions of these easements that meet the criteria are included as critical habitat. All need regular management, especially the lands with dense vegetation, for the crayfish to thrive.

Panama City crayfish occurrence was documented on easement lands in 2012 and 2014–2018. All of the essential

physical or biological features are found within the unit. Herbaceous groundcover is spotty, and shallow pools of water are small and unreliable, often caused by vehicle tracks, and too deep for Panama City crayfish. Special management considerations may be required to remove Hurricane Michael tree debris and to improve the hydrological impacts from timber management, borrow pits, and roads.

Unit 6: High Point

The High Point unit includes the northern-most population and is located off Bay County Road 2311 in Bay County, Florida. The population is supported by habitat totaling 36.8 acres (14.9 ha), and land ownership is almost entirely private, with some acreage under easement for conservation. Only 0.5 acres (0.2 ha) is in public ownership by Bay County. The 11-acre (4.5 hectare) Marjorie's Magical Marsh-Symone's Sanctimonious Swamp conservation easement owned by BCC contains most of the known Panama City crayfish population.

Panama City crayfish occupy 6.0 (2.4 ha) of the 11-acre (4.5 hectare) easement, which is in the process of being restored by the Service and FWC under a management agreement with BCC. These 6 acres are being restored to primarily herbaceous vegetation from a more recent dense mixture of titi shrub thicket in the under- and mid-story and slash pines in the overstory, which has lacked fire management. The remaining core and secondary soil habitat surrounding the easement was historically managed for timber but currently contains dense titi with an intermittent slash pine overstory.

Panama City crayfish occurrence was documented in 2010, 2012–2014, and 2015–2017. All essential physical and biological features are found within the unit. This population, albeit small, has herbaceous ground cover vegetation, pools of shallow water, and appropriate slope ratios, but the unit may require management to maintain the ground cover and keep shrubs from encroaching.

Unit 7: Star

This unit consists of 1,424.3 acres (576.4 ha) of habitat for Panama City crayfish. A portion of this unit is located north of the intersection of Bay County Road 2321 and U.S. Highway 231 in Bay County, Florida. Land ownership is a mix of private and public. There are no conservation easements in place, but one 1.4-acre (0.6-hectare) parcel is owned by the State of Florida and used by the Florida Highway Patrol. Although the appropriate core and secondary soil habitat exists, the lands that run parallel to the county road are mostly in dense slash pine plantations for timber production with overgrown ground cover. The plantations east of the county road have been harvested recently. This management is sub-optimal for the Panama City crayfish because of the dense overstory canopy, lack of herbaceous ground cover, infrequent (>3 year) fire management, and bedding that may additionally affect the hydrology of the unit.

The remainder of this habitat unit is adjacent and south of U.S. Highway 231. It forms the farthest east-northeast boundary of the species' geographic range in Bay County, Florida. The population is bordered on the west by U.S. Highway 231, the north by Bayou George Creek, and the south by an unnamed tributary of Mill Bayou. These lands are mostly under timber management since the mid-1980s and in various stages of management from recent harvest to dense slash pines with dense titi shrub layers. The current timber management is sub-optimal for Panama City crayfish because of the dense overstory canopy, lack of herbaceous ground cover, infrequent (>3 year) fire management, and bedding that may additionally affect the hydrology of the unit. Land ownership is predominantly private, with approximately 5 acres (2 ha) in public ownership by Bay County. Gulf Power Company manages rights-of-way along 86 acres (34.8 ha). The Service and FWC have a management agreement with Gulf Power Company incorporating best management practices, primarily regular mowing, that have stimulated herbaceous vegetation as the primary ground cover. Currently a two-lane road, Star Avenue, bisects this population.

The population in the unit is supported by 1,424.3 acres (576.4 ha). Panama City crayfish occurrence was documented most recently in 2016. All essential physical and biological features are found within the unit. Intermittent herbaceous groundcover vegetation and temporary pools of shallow water with hardwood swamp ecotone areas do occur, but special management may be required to maintain and improve these biological features needed for increased or more connected populations. Much tree debris remains throughout the unit as a result of Hurricane Michael's 2018 impact to the landscape. It is assumed that some debris will be removed from timber company land and on other small tracts of land, but it is unknown at this time what impacts are likely to occur to Panama City crayfish populations as lands are cleared at large-scale levels.

Unit 8: Transmitter East

The Transmitter East unit forms the farthest south-southeast boundary of the species' geographic range in Bay County, Florida. The population is bordered on the west by Transmitter Road, the south by U.S. Highway 98 and State Highway 22, the east by Callaway Creek, and the north by an unnamed tributary of Mill Bayou. The population in this unit is supported by 2,107.4 acres (852.8 ha) of habitat, which has been primarily under timber management since the mid-1980s and in various stages of management from recent harvest to dense slash pines with dense titi shrub layers.

The current management regime is sub-optimal for Panama City crayfish because of the dense overstory canopy, lack of herbaceous ground cover, infrequent (>3 year) fire management, and bedding that may additionally affect the hydrology of the unit. Land ownership is predominantly private, with only 49.9 acres (20.2 ha) in public ownership by the City of Springfield, Bay County, and the State of Florida. Gulf Power Company manages rights-of-way along approximately 114 acres (46.1 ha) of land that is populated with the Panama City crayfish. The Service and FWC have a management agreement with Gulf Power incorporating best management practices, primarily regular mowing, that have stimulated herbaceous vegetation as the primary groundcover.

Two conservation easements, 11.3 and 7.3 acres (4.6 and 3.0 ha) in size, are held by FDEP for two separate landowners. Currently, a two-lane road, Star Avenue, bisects this population. Tram Road also bisects the lower third of the area. It is currently a dirt road and there are plans for converting it to a four-lane asphalt road.

Panama City crayfish occurrence was confirmed in surveys as recent as 2016. All essential physical and biological features are found within the unit. Much tree debris, which may require management, remains throughout as a result of Hurricane Michael's 2018 impact to the landscape. It is assumed that some debris will be removed from timber company land and on other small tracts of land, but it is unknown at this time what impacts are likely to occur on the Panama City crayfish populations as lands are cleared at large-scale levels.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species.

We published a final rule revising the definition of destruction or adverse modification on August 27, 2019 (84 FR 44976). Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on Federal lands, on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation.

Compliance with the requirements of section 7(a)(2) is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinitiate consultation on previously reviewed actions. These requirements apply when the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law) and, subsequent to the previous consultation: (1) If the amount or extent of taking specified in the incidental take statement is exceeded; (2) if new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; (3) if the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion; or (4) if a new species is listed or critical habitat designated that may be affected by the identified action.

In such situations, Federal agencies sometimes may need to request reinitiation of consultation with us, but the regulations also specify some exceptions to the requirement to reinitiate consultation on specific land management plans after subsequently listing a new species or designating new critical habitat. See the regulations for a description of those exceptions.

Application of the ''Adverse Modification'' Standard

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat as a whole for the conservation of the listed species. As discussed above, the role of critical habitat is to support physical or biological features essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may violate section 7(a)(2) of the Act by destroying or adversely modifying such habitat, or that may be affected by such designation.

Activities that the Service may, during a consultation under section 7(a)(2) of the Act, consider likely to destroy or adversely modify critical habitat include, but are not limited to:

(1) Actions that would significantly alter hydrological and soil characteristics. Such activities could include, but are not limited to, those that result in wetland fill or draining or, conversely, provide additional waters to the wetland. Activities drying the wetland (via fill or draining) can result in changes in depth to water tables that are less than the depth threshold that is important for long-term Panama City crayfish population persistence. These activities can also alter soils from those that provide the sediment structure needed to allow for burrow construction down to the water table and also support the herbaceous vegetation upon which the species relies for food and shelter. Activities providing additional water can allow other crayfish species that persist in deeper waters to outcompete the Panama City crayfish.

(2) Actions that would significantly alter water quality parameters including oxygen content, temperature, and chemical composition. Such activities could include, but are not limited to, release of chemicals, excess nutrients, pesticides, and biological or other pollutants into the surface water or connected groundwater at a point source or by dispersed release (non-point source). These activities could alter water conditions to levels that are beyond the tolerances of the crayfish and result in direct or cumulative adverse effects to these individuals and their life cycles.

(3) Actions that would significantly and permanently alter vegetative characteristics. Such activities could include, but are not limited to, residential and commercial construction; road construction; and draining, filling, or otherwise destroying or altering wetlands. These activities may lead to changes in hydrology and soil characteristics that prevent the appropriate vegetation from growing.

These activities can result in an absence or reduced levels of herbaceous vegetation that is important to the Panama City crayfish for food, detritus formation, and shelter.

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation. There are no Department of Defense (DoD) lands with a completed INRMP within the final critical habitat designation.

Consideration of Exclusions Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise discretion to exclude the area only if such exclusion would not result in the extinction of the species. In making the determination to exclude a particular area, the plain language of the statute, as well as the legislative history, make clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

We describe below the process that we undertook for taking into consideration each category of impacts and our analyses of the relevant impacts.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. To assess the probable economic impacts of a designation, we must first evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. We then must evaluate the impacts that a specific critical habitat designation may have on restricting or modifying specific land uses or activities for the benefit of the species and its habitat within the areas proposed. We then identify which conservation efforts may be the result of the species being listed under the Act versus those attributed solely to the designation of critical habitat for this particular species. The probable economic impact of a critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.''

The ''without critical habitat'' scenario represents the baseline for the analysis, which includes the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat (*e.g.,* under the Federal listing as well as other Federal, State, and local regulations). Therefore, the baseline represents the costs of all efforts attributable to the listing of the species under the Act (*i.e.,* conservation of the species and its habitat incurred regardless of whether critical habitat is designated). The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts are not expected without the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs. These are the costs we use when evaluating the benefits of inclusion and exclusion of particular areas from the final designation of critical habitat should we choose to conduct a discretionary 4(b)(2) exclusion analysis.

For this particular designation, we developed an incremental effects memorandum (IEM) considering the probable incremental economic impacts that may result from this designation of critical habitat. The information contained in our IEM was then used to develop a screening analysis of the probable effects of the designation of critical habitat for the Panama City crayfish (Industrial Economics, Inc. (IEc) 2018). We began by conducting a screening analysis of the proposed designation of critical habitat in order to focus our analysis on the key factors that are likely to result in incremental economic impacts. The purpose of the screening analysis is to filter out particular geographic areas of critical habitat that are already subject to such protections and are, therefore, unlikely to incur incremental economic impacts. In particular, the screening analysis considers baseline costs (*i.e.,* absent critical habitat designation) and includes any probable incremental economic impacts where land and water use may already be subject to conservation plans, land management plans, best management practices, or regulations that protect the habitat area as a result of the Federal listing status of the species. Ultimately, the screening analysis allows us to focus our analysis on evaluating the specific areas or sectors that may incur probable incremental economic impacts as a result of the designation. If the proposed critical habitat designation contains any unoccupied units, the screening analysis assesses whether those units require additional management or conservation efforts that may incur incremental economic impacts. This screening analysis combined with the information contained in our IEM constitute what we consider to be our draft economic analysis (DEA) of the critical habitat designation for the Panama City crayfish. As stated earlier in this document, during the comment period on the April 15, 2021, proposed rule (86 FR 19838), we received general comments that the designation would harm the local economy, but we received no specific or substantial information that would require altering the DEA. Therefore, we have adopted our DEA as our final economic analysis, and we summarize it in the narrative below.

Executive Orders (E.O.s) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with the E.O. regulatory analysis requirements, our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess to the extent practicable the probable impacts to both directly and indirectly affected entities. As part of our screening analysis, we considered the types of economic activities that are

likely to occur within the areas likely affected by the critical habitat designation. In our evaluation of the probable incremental economic impacts that may result from the designation of critical habitat for the Panama City crayfish, first we identified, in the IEM dated July 13, 2018, probable incremental economic impacts associated with the following categories of activities: Agriculture, forest management (silviculture, timber), development, recreation, restoration and conservation management activities, transportation, and utilities. We considered each industry or category individually. Additionally, we considered whether their activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. In areas where the Panama City crayfish is present, Federal agencies will be required to consult with the Service under section 7 of the Act on activities they fund, permit, or implement that may affect the species. Consultation will ensure the Federal action avoids the destruction or adverse modification of critical habitat.

In our IEM, we attempted to clarify the distinction between the effects that result from the species being listed and those attributable to the critical habitat designation (*i.e.,* difference between the jeopardy and adverse modification standards) for the Panama City crayfish's critical habitat. Because the critical habitat for the Panama City crayfish coincides with currently occupied areas by the species, it has been our experience that it is more difficult to discern which conservation efforts are attributable to the species being listed and those which will result solely from the designation of critical habitat. However, the following specific circumstances in this case help to inform our evaluation: (1) The essential physical or biological features identified for critical habitat are the same features essential for the life requisites of the species, and (2) any actions that will adversely affect the essential physical or biological features of critical habitat will also likely result in sufficient harm or harassment to constitute jeopardy to the Panama City crayfish. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this designation of critical habitat.

The critical habitat designation for the Panama City crayfish includes eight units, each of which contains one geographically and/or genetically distinct population of the Panama City crayfish. All of these units are in Bay County, Florida, and none occur on Federal lands. For the purposes of our critical habitat designation, we determined a unit to be occupied if it contains recent (*i.e.,* observed since 2015) observations of Panama City crayfish. All units are occupied because they contain populations of Panama City crayfish at the time of proposed listing, and each unit has features that are essential to the conservation of the species. In total, we are designating 4,138 acres (1,675 ha) as critical habitat for the Panama City crayfish. In occupied areas, any actions that may affect the critical habitat will also likely affect the species, and it is unlikely that any additional conservation efforts would be recommended to address the adverse modification standard over and above those recommended as necessary to avoid jeopardizing the continued existence of the Panama City crayfish. Incremental costs of the critical habitat designation for the Panama City crayfish are likely to be limited to additional administrative costs to consider adverse modification in consultations in all units. We anticipate that the consideration of critical habitat for the species in occupied units may increase consultation costs by 10 to 15 percent. The incremental administrative burden resulting from the designation of critical habitat for the Panama City crayfish is not anticipated to reach an annual effect of $100 million (which is the economic threshold for a ''significant regulatory action'' (see section 3(f)(1) of Executive Order 12866)) based on the anticipated annual number of consultations (no more than 12) and associated consultation costs, which are not expected to exceed $60,000 in any year. These estimates assume that consultations will occur even in the absence of critical habitat due to the presence of Panama City crayfish, and the amount of administrative effort needed to address the crayfish critical habitat during this process is relatively small. The designation is unlikely to trigger additional requirements under State or local regulations and is not expected to have perceptional effects.

Consideration of National Security Impacts

Section 4(a)(3)(B)(i) of the Act may not cover all DoD lands or areas that pose potential national-security concerns (*e.g.,* a DoD installation that is in the process of revising its INRMP for a newly listed species or a species previously not covered). If a particular area is not covered under section 4(a)(3)(B)(i), then national-security or homeland-security concerns are not a factor in the process of determining what areas meet the definition of ''critical habitat.'' However, the Service must still consider impacts on national security, including homeland security, on those lands or areas not covered by section 4(a)(3)(B)(i), because section 4(b)(2) requires the Service to consider those impacts whenever it designates critical habitat. Accordingly, if DoD, Department of Homeland Security (DHS), or another Federal agency has requested exclusion based on an assertion of national-security or homeland-security concerns, or we have otherwise identified national-security or homeland-security impacts from designating particular areas as critical habitat, we generally have reason to consider excluding those areas.

In preparing this final rule, we have determined that the lands within the designation of critical habitat for Panama City crayfish are not owned or managed by the DoD or DHS, and we received no requests for exclusions based on national security concerns by any agency responsible for national security or homeland security. Therefore, we anticipate no impact on national security or homeland security. Consequently, the Secretary is not exercising her discretion to exclude any areas from the final designation based on impacts on national security.

Consideration of Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security discussed above. Other relevant impacts may include, but are not limited to, impacts to Tribes, States, local governments, public health and safety, community interests, the environment (such as increased risk of wildfire or pest and invasive species management), Federal lands, and conservation plans, agreements, or partnerships. To identify other relevant impacts that may affect the exclusion analysis, we consider a number of factors, including whether there are permitted conservation plans covering the species in the area—such as HCPs, safe harbor agreements (SHAs), or candidate conservation agreements with assurances (CCAAs)—or whether there are non-permitted conservation agreements and partnerships that may

be impaired by designation of, or exclusion from, critical habitat. In addition, we look at whether Tribal conservation plans or partnerships, Tribal resources, or government-to-government relationships of the United States with Tribal entities may be affected by the designation. We also consider any State, local, public-health, community-interest, environmental, or social impacts that might occur because of the designation.

In preparing this final rule, we have determined that there are currently no HCPs or other management plans for the Panama City crayfish, and the designation does not include any Tribal lands or trust resources. We anticipate no impact on Tribal lands, partnerships, or HCPs from this critical habitat designation. Accordingly, the Secretary is not exercising her discretion to exclude any areas from the final designation based on other relevant impacts.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Under the RFA, as amended, and as understood in light of recent court decisions, Federal agencies are required to evaluate only the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies will be directly regulated by this critical habitat designation. There is no requirement under the RFA to evaluate the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities will be directly regulated by this rulemaking, the Service certifies that this final critical habitat designation will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether the final designation will result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that this final critical habitat designation does not have a significant economic impact on a substantial number of small business entities. Therefore, a regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. In our economic analysis, we did not find that the designation of this critical habitat will significantly affect energy supplies, distribution, or use because these were not identified as land use sectors within the critical habitat areas. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following finding:

(1) This final rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates

to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or Tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule will significantly or uniquely affect small governments. Small governments will be affected only to the extent that any programs having Federal funds, permits, or other authorized activities must ensure that their actions will not adversely affect the critical habitat. Therefore, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the Panama City crayfish in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed for the designation of critical habitat for the Panama City crayfish, and it concludes that this designation of critical habitat does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this final rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this critical habitat designation with, appropriate State resource agencies. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the final rule does not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary for the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist State and local governments in long-range planning because they no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) of the Act will be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the order. We have designated critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this final rule identifies the elements of physical or biological features essential to the conservation of the species. The areas of designated critical habitat are presented on maps, and the final rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with 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. We have determined that no Tribal lands fall within the boundaries of the critical habitat for the Panama City crayfish, so no Tribal lands will be affected by the designation.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the Florida Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this final rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Florida Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h), the List of Endangered and Threatened Wildlife, by adding an entry for ''Crayfish, Panama City'' in alphabetical order under CRUSTACEANS to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
CRUSTACEANS				
*	*	*	*	*
Crayfish, Panama City	*Procambarus econfinae*	Wherever found	T	86 FR [INSERT **FEDERAL REGISTER** PAGE WHERE THE DOCUMENT BEGINS], 1/5/22; 50 CFR 17.46(b);[4d] 50 CFR 17.95(h).[CH]
*	*	*	*	*

■ 3. Amend § 17.46 by adding paragraph (b) to read as follows:

§ 17.46 Special rules—crustaceans.

* * * * *

(b) Panama City crayfish (*Procambarus econfinae*)—(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the Panama City crayfish. Except as provided under paragraph (b)(2) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

(i) Import or export, as set forth at § 17.21(b) for endangered wildlife.

(ii) Take, as set forth at § 17.21(c)(1) for endangered wildlife.

(iii) Possession and other acts with unlawfully taken specimens, as set forth at § 17.21(d)(1) for endangered wildlife.

(iv) Interstate or foreign commerce in the course of a commercial activity, as set forth at § 17.21(e) for endangered wildlife.

(v) Sale or offer for sale, as set forth at § 17.21(f) for endangered wildlife.

(2) *Exceptions from prohibitions.* In regard to this species, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Take, as set forth at § 17.21(c)(2) through (4) for endangered wildlife.

(iii) Take as set forth at § 17.31(b).

(iv) Take incidental to an otherwise lawful activity caused by:

(A) Development practices that:

(*1*) Maintain existing structures, and build or rebuild structures that occur within the existing footprint of previously developed areas;

(*2*) Build new structures that occur within 100 feet of existing structures on an individual private landowner's property and with a new footprint less than 1,000 square feet, such as a pool or shed associated with an existing house;

(*3*) Install culverts for individual landowners not associated with housing developments on lands greater than one acre;

(*4*) Build platforms or boardwalks for recreational purposes on conservation lands that allow sunlight of sufficient levels to maintain herbaceous groundcover; and

(*5*) Build paths used for nonmotorized activities as long as the project footprint, including construction impacts, alter no more than 5 percent of the acreage in core or secondary soils within lands under a conservation easement.

(B) Certain land management activities, including:

(*1*) Silvicultural (forestry) activities located in secondary soils that follow State best management practices (BMPs);

(*2*) Prescribed burning and wildfire control efforts when following State BMPs, guidelines, or permit conditions;

(*3*) Herbicide application activities targeting exotic plants or shrub species when following all other State and Federal BMPs, guidelines, or permit conditions; and

(*4*) Agricultural maintenance activities in pasture and rangelands (including cattle operations) that were established prior to January 3, 2018, and that implement State and Federal BMPs for existing farms and ranches if they have no indirect impacts to adjacent Panama City crayfish habitat.

(C) Utility actions, including:

(*1*) Ditch mowing and maintenance outside of critical habitat units;

(*2*) Ditch mowing or maintenance within critical habitat units after development of BMPs in coordination with the local Service office;

(*3*) Culvert replacements or maintenance on individual landowner properties that do not adversely affect, but improve or restore, the natural hydrology; and

(*4*) After coordination with the local Service office, the following activities: Maintenance associated with rights-of-way (including mowing, use of herbicides, and mechanical side trimming); powerline and pole placements and replacements; replacement of critical structural components, such as crossarms, insulators, conductors, etc.; and directional boring by utility owners.

(v) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife.

■ 4. Amend § 17.95(h) by adding an entry for ''Panama City Crayfish (*Procambarus econfinae*)'' immediately following the entry for ''Pecos Amphipod (*Gammarus pecos*)'' to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(h) *Crustaceans.*

* * * * *

Panama City Crayfish (*Procambarus econfinae*)

(1) Critical habitat units are depicted for Bay County, Florida, on the maps in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of Panama City crayfish consist of the following components:

(i) Undeveloped lands, including cropland, utilities rights-of-way, timberlands, and grazing lands, that support open wet pine flatwoods and wet prairie habitats that contain the following:

(A) Appropriate herbaceous ground cover vegetation;

(B) Permanent or temporary pools of shallow (usually less than 1 foot) freshwater locations; and

(C) Gently sloped ground-level swales with a 3:1 or shallower slope ratio along ecotonal or transitional areas.

(ii) Soil types within undeveloped lands that provide sediment structure needed for burrow construction and that support mostly native herbaceous vegetation needed for additional food and shelter, and where the ground water is always within 3 feet of the ground surface and surface waters occur on occasion. These soil types include:

(A) Core soils for Panama City crayfish, including Pamlico-Dorovan Complex, Rutlege Sand, Plummer Sand, Pelham Sand, Pantego Sandy Loam, and Rutledge-Pamlico Complex;

(B) Secondary soils within 50 feet (15 meters) of core soils: Albany Sand, Leefield Sand, Leon Fine Sand, Osier Fine Sand, and Alapaha Loamy Sand; and

(C) Soils that currently, or can eventually, support native herbaceous vegetation such as, but not limited to, wiregrass (*Aristida beyrichiana*), redroot (*Lachnanthes caroliniana*), beakrushes (*Rhynchospora* spp.), pitcher plants (*Sarracenia* spp.), sundews (*Drosera* spp.), butterworts (*Pinguicula* spp.), and lilies (*Hymenocallis* spp.).

(iii) Undeveloped lands that contain surface and groundwater of sufficient quality to support all life stages of the Panama City crayfish and the herbaceous vegetation on which they rely, specifically surface waters with:

(A) Oxygen levels that range between 2 and 9 milligrams per liter;

(B) pH levels between 4.1 and 9.2; and

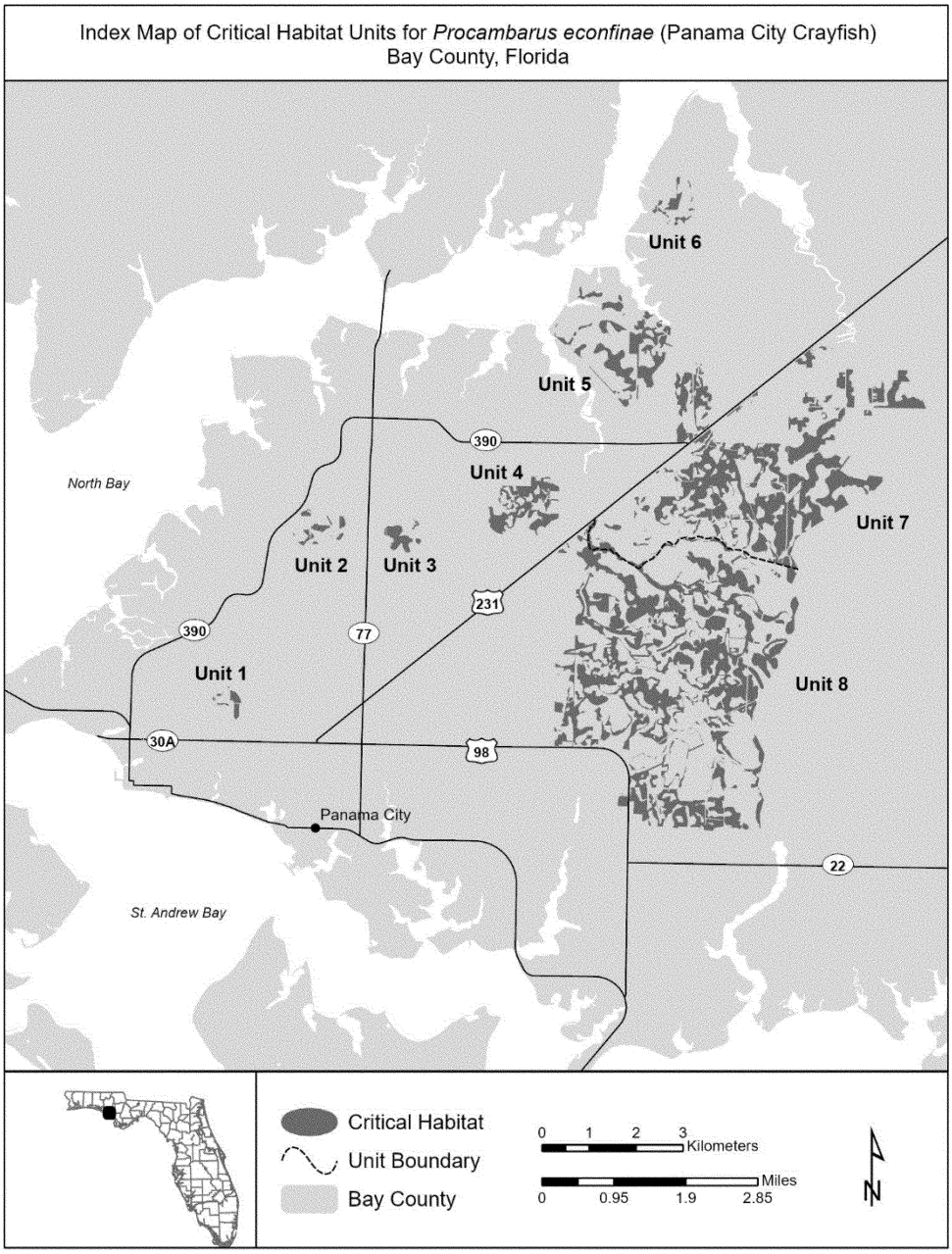
(C) Temperatures between 42 and 94 degrees Fahrenheit (°F) (5 and 34.4 degrees Celsius (°C)), although optimum temperatures are thought to be in the range of 68 to 79 °F (20 to 26 °C).

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on February 4, 2022.

(4) Data layers defining map units were created based on known occurrences and habitat requirements. Critical habitat units were mapped in ArcMap (ESRI, Inc.) using the U.S. Department of Agriculture, Natural Resources Conservation Service, Soil Survey Geographic Database dataset. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at *https://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0137 and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Note: Index map follows:

Figure 1 to Panama City Crayfish *(Procambarus econfinae)* paragraph (5)

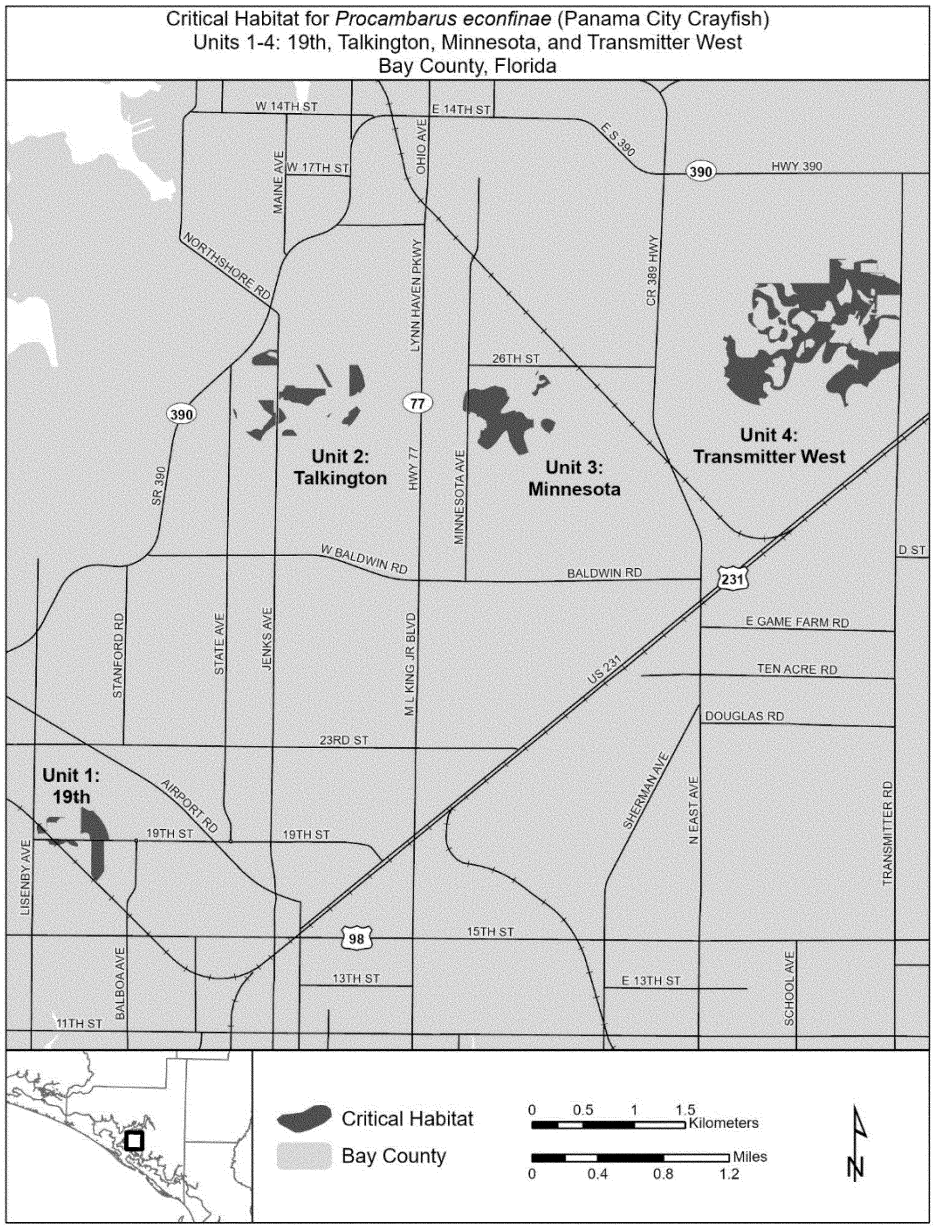


(6) Unit 1: 19th Street, Bay County, Florida.

(i) Unit 1 consists of 23.2 acres (9.4 ha) and is composed of lands in State, county, or city ownership (3.7 ac (1.5 ha)), and private ownership (19.5 ac (7.9 ha)).

(ii) Map of Units 1, 2, 3, and 4 follows:

Figure 2 to Panama City Crayfish *(Procambarus econfinae)* paragraph (6)(ii)



(7) Unit 2: Talkington, Bay County, Florida.

(i) Unit 2 consists of 37.2 acres (15.1 ha) and is composed of lands in State, county, or city ownership (4.09 ac (1.7 ha)), and private ownership (33.08 ac (13.4 ha)).

(ii) Map of Unit 2 is provided at paragraph (6)(ii) of this entry.

(8) Unit 3: Minnesota, Bay County, Florida.

(i) Unit 3 consists of 49.0 acres (19.8 ha) and is composed of lands in State, county, or city ownership (30.0 ac (12.1 ha)), and private ownership (19.1 ac (7.7 ha)).

(ii) Map of Unit 3 is provided at paragraph (6)(ii) of this entry.

(9) Unit 4: Transmitter West, Bay County, Florida.

(i) Unit 4 consists of 181.8 acres (73.6 ha) and is composed of lands in State, county, or city ownership (2.2 ac (0.9 ha)), and private ownership (179.6 ac (72.7 ha)).

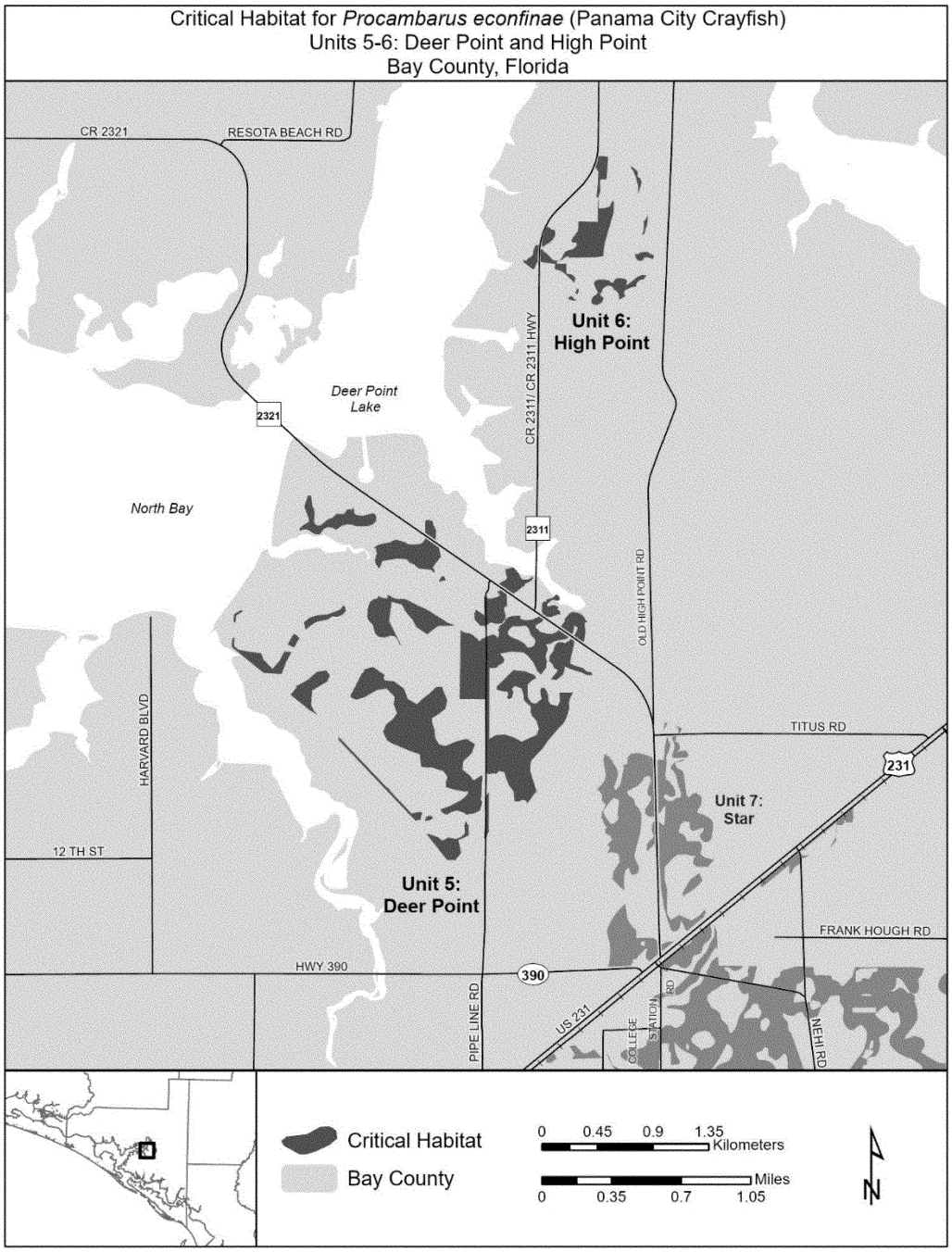
(ii) Map of Unit 4 is provided at paragraph (6)(ii) of this entry.

(10) Unit 5: Deer Point, Bay County, Florida.

(i) Unit 5 consists of 278.8 ac (112.8 ha) and is composed of lands in State, county, or city ownership (4.5 ac (1.8 ha)), and private ownership (274.3 ac (111.0 ha)).

(ii) Map of Units 5 and 6 follows:

Figure 3 to Panama City Crayfish *(Procambarus econfinae)* paragraph (10)(ii)



(11) Unit 6: High Point, Bay County, Florida.

(i) Unit 6 consists of 36.8 ac (14.9 ha) and is composed of lands in State, county, or city ownership (0.5 ac (0.2 ha)), and private ownership (36.3 ac (14.7 ha)).

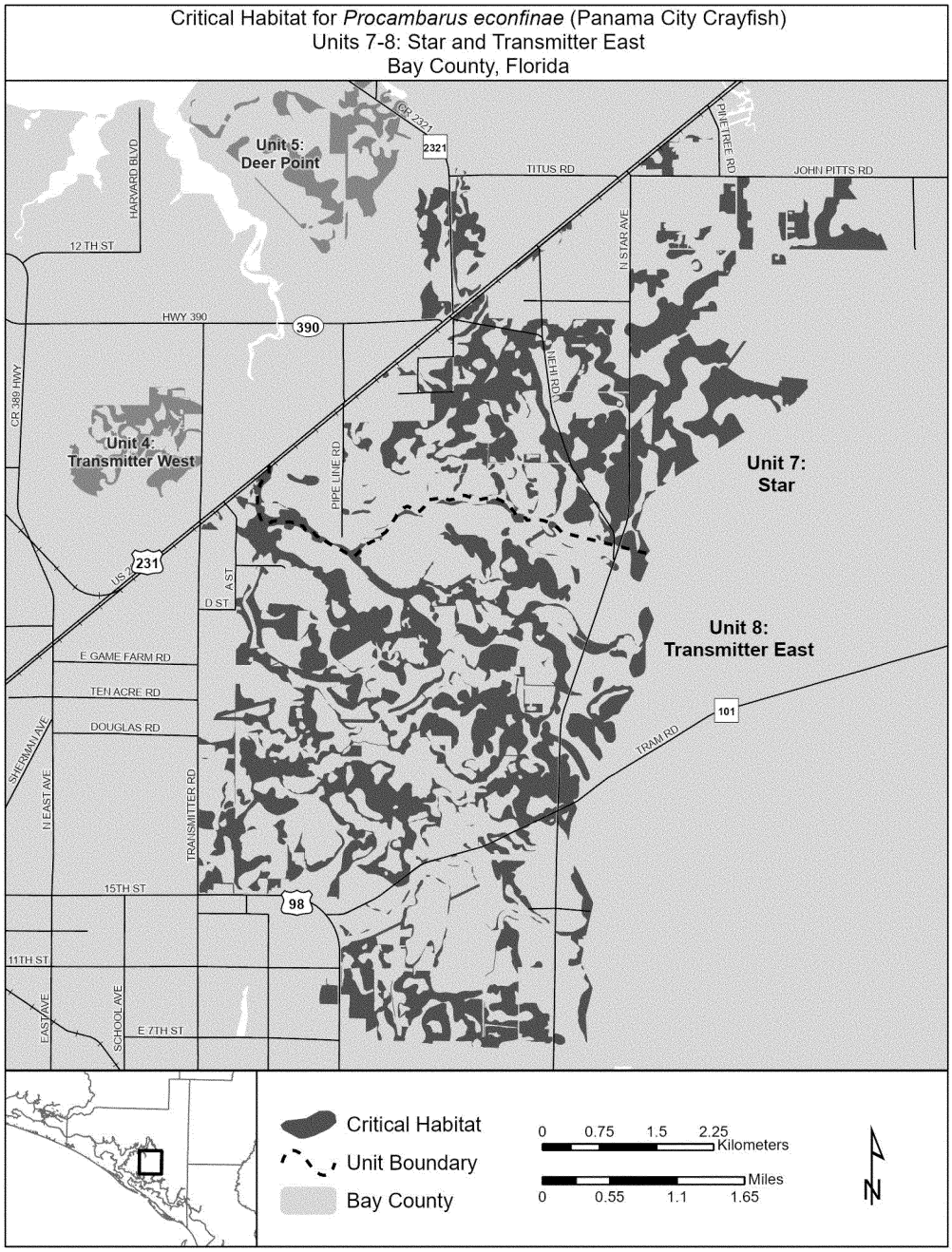
(ii) Map of Unit 6 is provided at paragraph (10)(ii) of this entry.

(12) Unit 7: Star, Bay County, Florida.

(i) Unit 7 consists of 1,424.3 ac (576.4 ha) and is composed of lands in State, county, or city ownership (6.5 ac (2.6 ha)), and private ownership (1,417.8 ac (573.8 ha)).

(ii) Map of Units 7 and 8 follows:

Figure 4 to Panama City Crayfish *(Procambarus econfinae)* paragraph (12)(ii)



(13) Unit 8: Transmitter East, Bay County, Florida.

(i) Unit 8 consists of 2,107.4 ac (852.8 ha) and is composed of lands in State, county, or city ownership (49.9 ac (20.2 ha)), and private ownership (2,057.5 ac (832.6 ha)).

(ii) Map of Unit 8 is provided at paragraph (12)(ii) of this entry.

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Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

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45 CFR Parts 144, 147, 153, et al.

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 147, 153, 155, 156 and 158

[CMS–9911–P]

RIN 0938–AU65

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule includes proposed payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs, as well as proposed 2023 user fee rates for issuers offering qualified health plans (QHPs) through federally-facilitated Exchanges and State-based Exchanges on the Federal platform. This proposed rule also proposes requirements related to prohibiting discrimination based on sexual orientation and gender identity; guaranteed availability; the offering of QHP standardized options through Exchanges on the Federal platform; requirements for agents, brokers, web-brokers, and issuers assisting consumers with enrollment through Exchanges that use the Federal platform; verification standards related to employer sponsored coverage; Exchange eligibility determinations during a benefit year; special enrollment period verification; cost-sharing requirements; Essential Health Benefits (EHBs); Actuarial Value (AV); QHP issuer quality improvement strategies; accounting for quality improvement activity (QIA) expenses and provider incentives for medical loss ratio (MLR) reporting and rebate calculation purposes; re-enrollment, and requirements related to a new State Exchange improper payment measurement program. This proposed rule also seeks comment on how HHS can advance health equity through QHP certification standards and otherwise in the individual and group health insurance markets, and how HHS might address plan choice overload in the Exchanges.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 27, 2022.

ADDRESSES: In commenting, please refer to file code CMS–9911–P.

You may submit comments in one of three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9911–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9911–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Jeff Wu, (301) 492–4305, Rogelyn McLean, (301) 492–4229, Grace Bristol, (410) 786–8437, Sara Rosta, (301) 492–4223, or Kaye Wells, (301) 492–4301, for general information.

Cam Moultrie Clemmons, (206) 615–2338, or Anthony Galace, (301) 492–4400, for matters related to past-due premiums.

Allison Yadsko, (410) 786–1740, John Barfield, (301) 492–4433, or Jacqueline Wilson, (301) 492–4286 for matters related to risk adjustment or risk adjustment data validation (HHS–RADV).

Aaron Franz, (410) 786- 8027, or John Barfield, (301) 492–4433, for matters related to federally-facilitated Exchange (FFE) and State-based Exchange on the Federal platform (SBE–FP) user fees.

Nora Simmons, (410) 786–1981, for matters related to advance payment of the premium tax credit (APTC) proration.

Aaron Franz, (410) 786- 8027, or Hi'ilei Haru, 301–492–4363, for matters related to cost-sharing reduction reconciliation.

Josh Van Drei, (410) 786–1659, for matters related to actuarial value (AV).

Becca Bucchieri, (301) 492–4341, for matters related to essential health benefit (EHB)-benchmark plans and defrayal of state-required benefits.

Marisa Beatley, (301) 492–4307, for matters related to employer sponsored coverage verification.

Susan Kalmus, (301) 492–4275, for matters related to agent, broker, and web-broker guidelines. Dena Nelson, 240–401–3535, or Carly Rhyne, 301–492–4188, for matters related to income calculation for eligibility for advance payments of premium tax credits.

Katherine Bentley, (301) 492–5209, or Ariel Kennedy, (301) 492–4306, for matters related to special enrollment period verification.

Leigha Basini, (301) 492–4380, for matters related to nondiscrimination based on sexual orientation and gender identity; and EHB nondiscrimination.

Christina Whitefield, (301) 492–4172, for matters related to the medical loss ratio (MLR) program.

Nidhi Singh Shah, (301) 492–5110, for matters related to quality improvement strategy standards for Exchanges.

Erika Ourisman, (301) 492–4170, for matters related to downstream and delegated entities.

Nikolas Berkobien, (301) 492–4400, or Leigha Basini, (301) 492–4380 for matters related to standardized options.

Erika Melman, (301) 492–4348, Deborah Hunter, (443) 386–3651, or Whitney Allen, (667) 290–8748, for matters related to network adequacy and essential community providers.

Linus Bicker, (803) 931–6185, for matters related to State Exchange improper payment measurement.

Phuong Van, (202) 570–5594, for matters related to advancing health equity through qualified health plans (QHPs).

Angelica Torres-Reid, (410) 786–1721, and Robert Yates, (301) 492–5151, for matters related to State Exchange general program integrity and oversight requirements.

Zarah Ghiasuddin, (301) 492–4308, for matters related to re-enrollment in the Exchanges.

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 comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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I. Executive Summary

American Health Benefit Exchanges, or ''Exchanges,'' are entities established under the Patient Protection and Affordable Care Act (ACA) [1] through which qualified individuals and qualified employers can purchase health insurance coverage in qualified health plans (QHPs). Many individuals who enroll in QHPs through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. The ACA also established the risk adjustment program, which transfers funds from issuers that attract lower-than-average risk populations to issuers that attract higher-than-average risk populations to reduce incentives for issuers to avoid higher-risk enrollees.

In previous rulemakings, we established provisions and parameters to implement many ACA requirements and programs. In this proposed rule, we propose to amend some of these provisions and parameters, with a focus on maintaining a stable regulatory environment. These proposed changes are intended to provide issuers with greater predictability for upcoming plan years (PYs), while simultaneously enhancing the role of states in these programs. The proposals would provide states with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability.

On January 20, 2021, the President issued an Executive Order which stated the Administration's policy on preventing and combating discrimination on the basis of gender identity and sexual orientation.[2] This Executive Order instructed the Secretary of Health and Human Services (Secretary of HHS, or HHS Secretary) to review all existing regulations, guidance documents, and other agency actions to determine whether they are consistent with the aforementioned policy, and to consider whether to suspend, revise, or rescind any agency actions that are inconsistent with it. In consideration of this Executive Order, and as a result of our review of certain regulations, we propose to amend HHS regulations such that Exchanges, issuers, and agents and brokers are prohibited from discriminating based on sexual orientation and gender identity. The provisions in this proposed rule reflect the aspects of the Executive Order 13988 and aligns with the HHS' Notice, released on May 10, 2021, that HHS interprets and enforces section 1557's and Title IX's prohibition on discrimination on the basis of sex to include: (1) Discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity, based on the Supreme Court's decision in *Bostock* v. *Clayton County.*[3]

Risk adjustment continues to be a core program in the individual, small group, and merged markets both on and off Exchanges, and we propose recalibrated parameters for the HHS-operated risk adjustment methodology. We published a technical paper, the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes [4] in October 2021, and sought comment on potential updates to the risk adjustment models. Consistent with the model changes discussed in the October 2021 Risk Adjustment (RA) Technical Paper, in this rule, we propose the following three updates to the HHS risk adjustment models beginning with the 2023 benefit year: (1) Adding a two-stage weighted approach to the adult and child models; (2) removing the current severity illness factors from the adult models and adding an interacted hierarchical condition category (HCC) count model specification to the adult and child models; and (3) replacing the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors. These proposals are intended to improve prediction in the adult and child risk adjustment models for the lowest-risk enrollees, the highest-risk enrollees, and partial-year enrollees, whose plan liabilities are underpredicted in the

[1] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rulemaking, the two statutes are referred to collectively as the ''Patient Protection and Affordable Care Act'', ''Affordable Care Act'', or ''ACA.''

[2] Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, January 20, 2021, *see* 86 FR 7023.

[3] U.S. Dep't of Health & Hum. Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 FR 27984 (May 25, 2021). *Also see, Bostock* v. *Clayton County,* 140 S. Ct. 1731 (2020). *https://www.supremecourt.gov/opinions/19pdf/17-1618_hfci.pdf.*

[4] Available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

current models. We also propose to recalibrate the 2023 benefit year risk adjustment models using the 2017, 2018, and 2019 enrollee-level External Data Gathering Environment (EDGE) data. We further propose to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models, consistent with the approach adopted beginning with the 2020 models. We discuss our consideration of the targeted removal of the mapping of hydroxychloroquine sulfate to Immune Suppressants and Immunomodulators (RXC 09) in the 2018 and 2019 benefit year enrollee-level EDGE data used for the 2023 benefit year model recalibration,[5] as well as the targeted removal of Descovy® from mapping to Anti-HIV Agents (RXC 01) in all three benefit years' enrollee-level EDGE datasets used for the 2023 benefit year model recalibration. We also propose for the 2024 benefit year and beyond to recalibrate the adult models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the current year's model recalibration. We propose to begin to use this approach for recalibration of the 2023 adult risk adjustment models, with the exception of the 2017 enrollee-level EDGE data year, for which we propose to use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018).

Additionally, we propose to repeal the ability of states to request a reduction in risk adjustment state transfers starting with the 2024 benefit year, while proposing to provide an exception for states that previously requested a reduction to transfers under § 153.320(d). In addition, we solicit comments on the requests from Alabama to reduce risk adjustment state transfers for the 2023 benefit year in the individual (including the catastrophic and non-catastrophic risk pools) and small group markets.

We also propose the 2023 benefit year risk adjustment user fee for states where HHS operates the risk adjustment program. We also propose to collect and extract five new data elements including ZIP code, race, ethnicity, individual coverage health reimbursement arrangement (ICHRA) indicator, and a subsidy indicator as part of the required risk adjustment data that issuers must make accessible to HHS in states where HHS is operating the risk adjustment program. We also propose to extract three new data elements issuers already provide to HHS as part of the required risk adjustment data submissions (plan ID, rating area, and subscriber indicator) and to expand the permitted uses of the risk adjustment data and reports. Finally, we propose that whenever HHS recoups high-cost risk pool funds as a result of audits of risk adjustment covered plans, actionable discrepancies, or successful appeals, the recouped funds would be used to reduce high-cost risk pool charges for that national high-cost risk pool for the next applicable benefit year for which high-cost risk pool payments have not already been calculated.

We propose further refinements to the HHS–RADV error estimation methodology beginning with the 2021 benefit year to (1) extend the application of Super HCCs (which are currently based on the coefficient estimation groups defined in the applicable benefit year's ''Additional Adult Variables'' Table of the ''Do It Yourself (DIY)'' software (Table 6 in the 2021 Benefit Year DIY Software), which is published on the CCIIO website)[6] from their current application only in the sorting step that assigns HCCs to failure rate groups to broader application throughout the HHS–RADV error rate calculation process, (2) specify that Super HCCs will be defined separately according to the age group model to which an enrollee is subject, and (3) constrain to zero any failure rate group outlier with a negative failure rate, regardless of whether the outlier issuer has a negative or positive error rate.

As we do every year in the HHS notice of benefit and payment parameters, we propose updated parameters applicable in the individual and small group markets. We propose the PY 2023 user fee rates for issuers offering plans through the Exchanges using the Federal platform. We propose maintaining the Federal-facilitated Exchange (FFE) and State-based Exchange on the Federal platform (SBE–FP) user fees at the current PY 2022 rates, 2.75 and 2.25 percent of total monthly premiums, respectively, in order to preserve and ensure that the FFEs and Federal platform have sufficient funding to cover the cost of all special benefits provided to FFE and SBE–FP issuers during PY 2023. We also note that HHS will issue the 2023 benefit year premium adjustment percentage index and related payment parameters in guidance, consistent with the policy finalized in part 2 of the 2022 Payment Notice.

We also propose to require all Exchanges to prorate premiums and advance payments of the premium tax credit (APTC) when administering APTC for enrollees enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month.

We are proposing changes to clarify that the cost-sharing reduction (CSR) data submission process is mandatory only for those issuers that received CSR payments from HHS for any part of the benefit year, and voluntary for other issuers. We propose a technical correction to the definition of large group market in § 144.103 to delete the concluding phrase ''unless otherwise provided under state law.''

We propose new display requirements for web-broker non-Exchange websites, including requirements related to QHP comparative information and standardized disclaimer language; a prohibition on displaying QHP advertisements or otherwise providing favored or preferred display of QHPs based on compensation agents, brokers, or web-brokers receive from QHP issuers; and a requirement to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on web-broker non-Exchange websites to better inform and protect consumers using such websites.

We propose a number of policies to address certain agent, broker, and web-broker practices. These policies would be added as part of the FFE standards of conduct codified at § 155.220(j)(2), improving CMS's ability to enforce existing responsibilities agents, brokers, and web-brokers utilizing the Exchange are required to adhere to without substantially burdening other agents, brokers, and web-brokers, while also providing more detail about specific business practices that are prohibited. We believe the proposed new regulatory text would protect consumers, ensure the efficient operation of the Exchange, minimize the risk of future tax discrepancies, reduce unauthorized enrollments in Exchange coverage, and provide a stronger basis for CMS to take enforcement action against agents, brokers, and web-brokers for violations of these requirements.

We propose revising our interpretation of the guaranteed availability requirement to prohibit

[5] The same concern was not present for the 2016 or 2017 enrollee-level EDGE data because hydroxychloroquine was not included in the crosswalk until 2018.

[6] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.* The August 3, 2021 version of the 2021 DIY Software Tables is available at *https://www.cms.gov/files/document/cy2021-diy-tables-07092021.xlsx.*

issuers from applying a premium payment to an individual's or employer's past debt owed for coverage and refusing to effectuate enrollment in new coverage. We believe this proposal would have a positive impact on the risk pool by removing barriers to enrollment for low-income individuals who lost prior coverage due to nonpayment of premiums. In addition, this proposal would promote more equitable access to health insurance coverage by ensuring that enrollment is not delayed as a result of non-payment of past-due premiums to the same issuer or control group, regardless of an individual's or employee's status as an APTC recipient.

Stable and affordable Exchanges with healthy risk pools are necessary for ensuring consumers maintain stable access to health insurance options. In order to minimize the potential for adverse selection in the Exchanges, we propose to allow Exchanges to conduct risk-based employer sponsored coverage verification.

We propose to clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. We also propose to specify that only expenses directly related to activities that improve health care quality may be included as quality improvement activity (QIA) expenses for MLR reporting and rebate calculation purposes.

In addition, we propose to make a technical amendment to remove a reference to a provision that was vacated by the United States District Court for the District of Maryland in *City of Columbus, et al.* v. *Cochran,* 523 F. Supp. 3d 731 (D. Md. 2021), and thus deleted in part 2 of the 2022 Payment Notice final rule.

With regards to the essential health benefits (EHB), we propose an evergreen deadline for EHB-benchmark plan applications by states, as well as proposing to remove the ability for states to permit issuers to substitute benefits between EHB categories. In addition, we propose changed de minimis thresholds for the actuarial value (AV) for plans subject to EHB requirements, as well as narrower de minimis thresholds for individual market silver QHPs and income-based CSR plan variations. We also propose to remove the state annual reporting requirement to report state-required benefits in addition to the EHB to HHS. We believe there may be ways to achieve compliance with the defrayal policy without imposing the rigid submission requirements on states that exist under the annual reporting requirement.

We propose policies to strengthen and clarify our network adequacy standards, including expanding the provider specialty list for time and distance standards and adding appointment wait time standards. For plans with tiered networks, we propose that, to count toward the issuer's satisfaction of the network adequacy and essential community provider (ECP) standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. We also propose to require issuers to submit information about whether providers offer telehealth services. We propose to increase the ECP threshold from 20 percent to 35 percent.

We also propose to amend the current regulation, which provides that, notwithstanding any relationship or relationships a QHP issuer may have with delegated or downstream entities, the QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities with all applicable Federal standards related to Exchanges. Specifically, HHS proposes adding a requirement that all agreements between QHP issuers and their downstream and delegated entities include language stating that any Exchange authority, including State Exchanges, may demand and receive records related to the QHP issuers' obligations and compliance with applicable Federal standards related to Exchanges. We also propose other amendments to extend the obligation to oversee compliance of delegated and downstream entities to QHP issuers in all models of Exchange. These proposals would hold QHP issuers in all models of Exchange responsible for their downstream and delegated entities' adherence to applicable Federal standards, and make their oversight obligations, and the obligations of their downstream and delegated entities, explicit. We also propose to amend the title of subpart D of 45 CFR part 156 from ''Standards for Qualified Health Plan Issuers on Federally Facilitated Exchanges and State-Based Exchanges on the Federal platform'' to ''Standards for Qualified Health Plan Issuers on Specific Types of Exchanges'' to more accurately reflect the applicability of the regulations within the subpart.

We solicit comments on incorporating the net premium, maximum out-of-pocket (MOOP), deductible, and annual out-of-pocket costs (OOPC) of a plan into the Exchange re-enrollment hierarchy as well as additional criteria or mechanisms HHS could consider to ensure the Exchange hierarchy for re-enrollment aligns with plan generosity and consumer needs, such as, re-enrolling a current bronze QHP enrollee into an available silver QHP with a lower net premium and higher plan generosity offered by the same QHP issuer. We also propose to update the quality improvement strategy (QIS) standards to require QHP issuers to address health and health care disparities as a specific topic area within their QIS beginning in 2023.

We also propose to require issuers of QHPs in FFEs and SBE–FPs to offer through the Exchange standardized QHP options beginning in PY 2023.

Finally, we solicit comments regarding additional ways HHS could incentivize QHP issuers to design plans that improve health equity and health conditions in enrollees' environments, as well as how QHP issuers could address other social determinants of health (SDOH) outside of the QHP certification process.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the Public Health Service Act (PHS Act) to establish various reforms to the group and individual health insurance markets.

These provisions of the PHS Act were later augmented by other laws, including the ACA. Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The term ''group health plan'' includes both insured and self-insured group health plans.[7]

Section 2702 of the PHS Act, as added by the ACA, establishes requirements for guaranteed availability of coverage in the group and individual markets.

Section 2718 of the PHS Act, as added by the ACA, generally requires health insurance issuers to submit an annual MLR report to HHS, and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds.

Section 2791 of the PHS Act defines several terms, including ''large group market''.

[7] The term ''group health plan'' is used in title XXVII of the PHS Act and is distinct from the term ''health plan'' as used in other provisions of title I of ACA. The term ''health plan'' does not include self-insured group health plans.

Section 1301(a)(1)(B) of the ACA directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the ACA, including coverage of the services described in section 1302(b) of the ACA, adherence to the cost-sharing limits described in section 1302(c) of the ACA, and meeting the AV levels established in section 1302(d) of the ACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the requirement to cover the EHB package to non-grandfathered individual and small group health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in sections 1302(c)(1) of the ACA.

Section 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHBs (as defined by the Secretary of HHS), cost-sharing limits, and AV requirements. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. Section 1302(d) of the ACA describes the various levels of coverage based on their AV. Consistent with section 1302(d)(2)(A) of the ACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the ACA directs the Secretary of HHS to develop guidelines that allow for de minimis variation in AV calculations. Sections 1302(b)(4)(A) through (D) establish that the Secretary must define EHB in a manner that: (1) Reflects appropriate balance among the 10 categories; (2) is not designed in such a way as to discriminate based on age, disability, or expected length of life; (3) takes into account the health care needs of diverse segments of the population; and (4) does not allow denials of EHBs based on age, life expectancy, disability, degree of medical dependency, or quality of life.

Section 1311(c) of the ACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs. Section 1311(c)(1)(B) of the ACA requires among the criteria for certification that the Secretary must establish by regulation that QHPs ensure a sufficient choice of providers. Section 1311(e)(1) of the ACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the state. Section 1311(c)(6)(C) of the ACA establishes special enrollment periods and section 1311(c)(6)(D) of the ACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.[8]

Section 1311(c)(1)(E) of the ACA specifies that to be certified as a QHP, each health plan must implement a QIS, which is described in section 1311(g)(1) of the ACA. Section 1311(g)(1) of the ACA describes this strategy as a payment structure that provides increased reimbursement or other incentives to improve health outcomes of plan enrollees, to prevent hospital readmissions, improve patient safety and reduce medical errors, promote wellness and health, and reduce health and health care disparities.

Section 1311(d)(3)(B) of the ACA permits a state, at its option, to require QHPs to cover benefits in addition to EHB. This section also requires a state to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional state-required benefits.

Section 1312(c) of the ACA generally requires a health insurance issuer to consider all enrollees in all health plans (except grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual and small group market risk pools under section 1312(c)(3) of the ACA.

Section 1312(e) of the ACA provides the Secretary with the authority to establish procedures under which a state may allow agents or brokers to (1) enroll qualified individuals and qualified employers in qualified health plans offered through Exchanges and (2) assist individuals in applying for PTC and CSRs for qualified health plans sold through an Exchange.

Sections 1313 and 1321 of the ACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1313(a)(5)(A) of the ACA provides the Secretary with the authority to implement any measure or procedure that the Secretary determines is appropriate to reduce fraud and abuse in the administration of the Exchanges. Section 1321 of the ACA provides for state flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of the ACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the ACA, including such other requirements as the Secretary determines appropriate. When operating an FFE under section 1321(c)(1) of the ACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the ACA to collect and spend user fees. Office of Management and Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public.

Section 1321(d) of the ACA provides that nothing in title I of the ACA must be construed to preempt any state law that does not prevent the application of title I of the ACA. Section 1311(k) of the ACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1343 of the ACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than-average risk populations, such as those with chronic conditions, funded by payments from those that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees.

Section 1401(a) of the ACA amended the Internal Revenue Code (the Code) to add Section 36B, which, among other things, requires that a taxpayer reconcile APTC for a year of coverage with the amount of the PTC the taxpayer is allowed for the year.

[8] The Indian Health Care Improvement Act (IHCIA), the cornerstone legal authority for the provision of health care to American Indians and Alaska Natives, was made permanent when President Obama signed the bill on March 23, 2010, as part of the Patient Protection and Affordable Care Act.

Section 1402 of the ACA provides for, among other things, reductions in cost sharing for EHB for qualified low- and moderate-income enrollees in silver level qualified health plans offered through the individual market Exchanges. This section also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

Section 1411(c) of the ACA requires the Secretary to submit certain information provided by applicants under section 1411(b) of the ACA to other federal officials for verification, including income and family size information to the Secretary of the Treasury. Section 1411(d) of the ACA provides that the Secretary must verify the accuracy of information provided by applicants under section 1411(b) of the ACA for which section 1411(c) does not prescribe a specific verification procedure, in such manner as the Secretary determines appropriate.

Section 1411(f) of the ACA requires the Secretary, in consultation with the Treasury and Homeland Security Department Secretaries and the Commissioner of Social Security, to establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations. Section 1411(f)(1)(B) of the ACA requires the Secretary to establish procedures to redetermine eligibility on a periodic basis, in appropriate circumstances, including eligibility to purchase a QHP through the Exchange and for APTC and CSRs.

Section 1411(g) of the ACA allows the use of applicant information only for the limited purposes of, and to the extent necessary to, ensure the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs, and limits the disclosure of such information.

Section 1557 of the ACA applies certain long-standing civil rights nondiscrimination requirements to ''any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive agency, or any entity established under'' Title I of the ACA (or amendments). It did so by referencing statutes that specify prohibited grounds of discrimination, namely, race, color, national origin, sex, age, or disability, in an array of federally funded and administered programs or activities.[9] In addition, HHS has previously finalized rules unrelated to section 1557 of the ACA to address populations that have historically been subject to discrimination.

Section 5000A of the Code, as added by section 1501(b) of the ACA, requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to $0, effective for months beginning after December 31, 2018.[10] Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under §§ 155.305(h) and 156.155(a)(5).

1. Premium Stabilization Programs

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs.[11] We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409). In the June 19, 2013 **Federal Register** (78 FR 37032), we proposed a modification to the HHS-operated methodology related to community rating states. In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the proposed modification to the HHS-operated methodology related to community rating states. We published a correcting amendment to the 2014 Payment Notice final rule in the November 6, 2013 **Federal Register** (78 FR 66653) to address how an enrollee's age for the risk score calculation would be determined under the HHS-operated risk adjustment methodology.

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13743). In the May 27, 2014 **Federal Register** (79 FR 30240), the 2015 fiscal year sequestration rate for the risk adjustment program was announced.

In the November 26, 2014 **Federal Register** (79 FR 70673), we published a proposed rule outlining the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2016 Payment Notice). We published the 2016 Payment Notice final rule in the February 27, 2015 **Federal Register** (80 FR 10749).

In the December 2, 2015 **Federal Register** (80 FR 75487), we published a proposed rule outlining the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2017 Payment Notice). We published the 2017 Payment Notice final rule in the March 8, 2016 **Federal Register** (81 FR 12203).

In the September 6, 2016 **Federal Register** (81 FR 61455), we published a proposed rule outlining the benefit and payment parameters for the 2018 benefit year and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology, new policies around the use of external data for recalibration of our risk adjustment models, and amendments to the HHS–RADV process (proposed 2018 Payment Notice). We published the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058).

In the November 2, 2017 **Federal Register** (82 FR 51042), we published a proposed rule outlining the benefit and payment parameters for the 2019 benefit year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology and amendments to the HHS–RADV process (proposed 2019 Payment Notice). We published the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 16930). We published a correction to the 2019 risk adjustment coefficients in the 2019 Payment Notice final rule in the May 11, 2018 **Federal Register** (83 FR 21925). On July 27,

[9] 42 U.S.C. 18116.

[10] Public Law 115–97, 131 Stat. 2054 (2017).

[11] The term premium stabilization programs refers to the risk adjustment, risk corridors, and reinsurance programs established by the ACA. See 42 U.S.C. 18061, 18062, and 18063.

2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level External Data Gathering Environment (EDGE) dataset.[12]

In the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17220 through 17252) and March 8, 2016 editions of the **Federal Register** (81 FR 12204 through 12352). That final rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2017 benefit year, including the reasons why the program is operated in a budget-neutral manner. That final rule also permitted HHS to resume 2017 benefit year risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of the final rule.[13]

In the August 10, 2018 **Federal Register** (83 FR 39644), we published a proposed rule seeking comment on adopting the 2018 benefit year risk adjustment methodology in the final rules published in the March 23, 2012 (77 FR 17219) and in the December 22, 2016 editions of the **Federal Register** (81 FR 94058). The proposed rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner. In the December 10, 2018 **Federal Register** (83 FR 63419), we issued a final rule adopting the 2018 benefit year HHS-operated risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17219) and the December 22, 2016 (81 FR 94058) editions of the **Federal Register**. That final rule sets forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner.

In the January 24, 2019 **Federal Register** (84 FR 227), we published a proposed rule outlining updates to the calibration of the risk adjustment methodology, the use of EDGE data for research purposes, and updates to HHS–RADV audits. We published the 2020 Payment Notice final rule in the April 25, 2019 **Federal Register** (84 FR 17454).

In the February 6, 2020 **Federal Register** (85 FR 7088), we published a proposed rule that included updates to the risk adjustment models' HCCs and a modification HHS–RADV error rate calculation methodology. We published the 2021 Payment Notice final rule in the May 14, 2020 **Federal Register** (85 FR 29164).

In the June 2, 2020 **Federal Register** (85 FR 33595), we published a proposed rule that proposed updates to various aspects of the HHS–RADV methodologies and processes. We published a final rule titled, the Amendments to the HHS-Operated Risk Adjustment Data Validation Under the Patient Protection and Affordable Care Act's HHS-Operated Risk Adjustment Program (2020 HHS–RADV Amendments Rule) in the December 1, 2020 **Federal Register** (85 FR 76979). That final rule revised the failure rate grouping algorithm, finalized a sliding scale adjustment in HHS–RADV error rate calculation, and a constraint on risk score adjustments for low-side failure rate outliers. The final rule also established a transition from the prospective application of HHS–RADV adjustments to apply HHS–RADV results to risk scores from the same benefit year as that being audited.

In the September 2, 2020 **Federal Register** (85 FR 54820), HHS issued an interim final rule containing certain policy and regulatory revisions in response to the COVID–19 public health emergency (PHE), wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year (interim final rule on COVID–19).

In the January 20, 2021 **Federal Register** (86 FR 6138), HHS issued a final rule containing certain policy and regulatory revisions related to the risk adjustment program (hereinafter referred to as ''part 1 of the 2022 Payment Notice final rule''). In the May 5, 2021 **Federal Register** (86 FR 24140), HHS issued another final rule containing policy and regulatory revisions related to the risk adjustment program, including approval of the request from Alabama to reduce risk adjustment transfers by 50 percent in the individual and small group markets for the 2022 benefit year (hereinafter referred to as ''part 2 of the 2022 Payment Notice final rule''). In addition, part 2 of the 2022 Payment Notice final rule established a revised schedule of collections for HHS–RADV and updated the provisions regulating second validation audit (SVA) and initial validation audit (IVA) entities.

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the ''first Program Integrity Rule'' published in the August 30, 2013 **Federal Register** (78 FR 54069) and the ''second Program Integrity Rule'' published in the October 30, 2013 **Federal Register** (78 FR 65045).

3. Market Rules

An interim final rule relating to the HIPAA health insurance reforms was published in the April 8, 1997 **Federal Register** (62 FR 16894). A proposed rule relating to the 2014 health insurance market rules was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing the health insurance market rules was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule). The 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058) provided additional guidance on guaranteed availability and guaranteed renewability. In the Market Stabilization final rule that was published in the April 18, 2017 **Federal Register** (82 FR 18346), we further interpreted the guaranteed availability provision. In the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 17058), we clarified that certain exceptions to the special enrollment periods only apply with respect to coverage offered outside of the Exchange in the individual market.

[12] ''Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients.'' July 27, 2018. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf.*

[13] ''Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year.'' July 27, 2018. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf.*

In the Nondiscrimination in Health and Human Education Programs or Activities final rule on section 1557 of the ACA, published in the June 19, 2020 **Federal Register** (85 FR 37160), we removed nondiscrimination protections on the basis of gender identity and sexual orientation from the guaranteed availability regulation.

In part 2 of the 2022 Payment Notice final rule in the May 5, 2021 **Federal Register** (86 FR 24140), we made additional amendments to the guaranteed availability regulation regarding special enrollment periods and finalized new special enrollment periods related to untimely notice of triggering events, cessation of employer contributions or government subsidies to COBRA continuation coverage, and loss of APTC eligibility. In the final rule Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond published in the September 27, 2021 **Federal Register** (86 FR 53412) (part 3 of the 2022 Payment Notice) by HHS and the Department of the Treasury, HHS finalized additional amendments to the guaranteed availability regulations regarding special enrollment periods.

4. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to states on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market and Small Business Health Options Program (SHOP), eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges, as well as network adequacy and ECP certification standards, was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

In the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541), we set forth standards related to Exchange user fees. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In the 2016 Payment Notice, we also set forth the ECP certification standard at § 156.235, with revisions in the 2017 Payment Notice in the March 8, 2016 **Federal Register** (81 FR 12203) and the 2018 Payment Notice in the December 22, 2016 **Federal Register** (81 FR 94058).

In an interim final rule, published in the May 11, 2016 **Federal Register** (81 FR 29146), we made amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice final rule, published in the December 22, 2016 **Federal Register** (81 FR 94058).

In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we modified parameters around certain special enrollment periods. In the April 25, 2019 **Federal Register** (84 FR 17454), the final 2020 Payment Notice established a new special enrollment period.

In the February 6, 2020 **Federal Register** (85 FR 7088), we published a proposed rule (proposal 2021 Payment Notice). We published the final rule in the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice).

In the December 4, 2020 **Federal Register** (85 FR 78572), we issued a proposed rule containing certain policy and regulatory revisions related to user fees (proposed 2022 Payment Notice). In the January 19, 2021 **Federal Register** (86 FR 6138), HHS issued a rule finalizing certain of the provisions in the proposed 2022 Payment Notice (part 1 of the 2022 Payment Notice final rule). In the May 5, 2021 **Federal Register** (86 FR 24140), HHS published a second final rule addressing the remainder of the proposed provisions (part 2 of the 2022 Payment Notice final rule). In the July 1, 2021 **Federal Register** (86 FR 35156), HHS and the Department of the Treasury released a proposed rule proposing to amend certain policies in part 1 of the 2022 Payment Notice final rule, and finalized the rule in the September 27, 2021 **Federal Register** (86 FR 53412) (part 3 of the 2022 Payment Notice final rule).

5. Essential Health Benefits

On December 16, 2011, HHS released a bulletin that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework.[14] A proposed rule relating to EHBs was published in the November 26, 2012 **Federal Register** (77 FR 70643). We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), we added § 156.111 to provide states with additional options from which to select an EHB-benchmark plan for PYs 2020 and beyond.

6. Medical Loss Ratio (MLR)

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules published in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), the April 17, 2018 **Federal Register** (83 FR 16930), the May 14, 2020 **Federal Register** (85 FR 29164), and the May 5, 2021 **Federal Register** (86 FR 24140), and an interim final rule that was published in the September 2, 2020 **Federal Register** (85 FR 54820).

7. Quality Improvement Strategy

We promulgated regulations in 45 CFR 155.200(d) to direct Exchanges to evaluate quality improvement strategies, and 45 CFR 156.200(b) that direct QHP issuers to implement and report on a quality improvement strategy or strategies consistent with section 1311(g) standards as a QHP certification criteria for participation in an Exchange. In the 2016 Payment Notice, published in the February 27, 2015 **Federal Register** (80 FR 10749), we finalized

[14] ''Essential Health Benefits Bulletin.'' December 16, 2011. Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

regulations at § 155.1130 to establish standards and the associated timeframe for QHP issuers to submit the necessary information to implement QIS standards for QHPs offered through an Exchange.

8. Nondiscrimination

Section 1311(b) and section 1321(b) of the ACA provide that each state has the opportunity to establish an Exchange. In the July 15, 2011 **Federal Register** (76 FR 41866), HHS published the ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans'' proposed rule to implement section 1311(b) and section 1321(b) of the ACA. In the March 27, 2012 **Federal Register** (77 FR 18310), HHS published the ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers'' final rule and interim final rule (hereinafter referred to as the ''Exchange Standards final rule''), which included nondiscrimination protections.

Section 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHB and actuarial value requirements. In the November 26, 2012 **Federal Register** (77 FR 70644), HHS published the ''Patient Protections and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation'' proposed rule to implement section 1302 of the ACA. In the February 25, 2013 **Federal Register** (78 FR 12834), HHS published the ''Patient Protections and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation'' final rule, which included nondiscrimination protections.

Sections 2701, 2702, and 2703 of the PHS Act and Section 1312(c) of the ACA provide protections to individuals and employers in obtaining health insurance coverage. In the November 26, 2012 **Federal Register** (77 FR 70584), HHS published the ''Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review'' proposed rule to implement sections 2701, 2702, and 2703 of the PHS Act and section 1312(c) of the ACA. In the February 27, 2013 **Federal Register** (78 FR 13406), HHS published the ''Patient Protections and Affordable Care Act; Health Insurance Market Rules; Rate Review'' final rule, which included nondiscrimination protections.

In the HHS Notice of Benefit and Payment Parameters for 2017 proposed rule, published in the December 2, 2015 **Federal Register** (80 FR 75488), HHS proposed policies for nondiscrimination protections into the relevant notice of benefit and payment parameters. In the March 8, 2016 **Federal Register** (81 FR 12204), HHS published the HHS Notice of Benefit and Payment Parameters for 2017 final rule, which included nondiscrimination protections.

In the Nondiscrimination in Health and Human Education Programs or Activities final rule on section 1557 of the ACA, published in the June 19, 2020 **Federal Register** (85 FR 37160), HHS removed nondiscrimination protections on the basis of gender identity and sexual orientation from various CMS nondiscrimination regulations. In the HHS Notice of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, published in the May 25, 2021 **Federal Register** (86 FR 27984), HHS informed the public that HHS will interpret and enforce section 1557's and Title IX's prohibition on discrimination on the basis of sex to include discrimination based on sexual orientation and gender identity.

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the PHS Act federal market reform requirements, the operation of Exchanges and the risk adjustment (including HHS–RADV) program. We have held a number of meetings with consumers, providers, employers, health plans, advocacy groups and the actuarial community to gather public input. We have solicited input from state representatives on numerous topics, particularly EHBs, state mandates, and risk adjustment. We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states through the Exchange Blueprint approval and general Exchange oversight processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all public input we received as we developed the policies in this proposed rule.

C. Structure of Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 144, 147, 153, 155, 156 and 158.

The proposed changes to 45 CFR part 144 would remove superfluous language from the definition of large group market.

The proposed changes to 45 CFR part 147 would prohibit issuers from discriminating against individuals in issuer marketing practices and benefit designs based on sexual orientation and gender identity. We also propose to reinterpret the guaranteed availability requirements in § 147.104 such that issuers could not refuse to effectuate new coverage based on failure of an individual or employer to pay premiums owed for prior coverage.

The proposed changes to 45 CFR part 153 would recalibrate the 2023 benefit year risk adjustment models using the 2017, 2018, and 2019 enrollee-level External Data Gathering Environment (EDGE) data. We also propose to update the adult and child risk adjustment models for 2023 and beyond to better predict plan liability for certain subpopulations. We propose to update the adult risk adjustment models by removing the current severity illness factors and replacing the current enrollment duration factors with enrollment duration factors contingent on the enrollee having at least one HCC. In addition, we propose to update the adult and child risk adjustment models by adding a two-stage weighted approach to model recalibrations and an interacted HCC count model specification for 2023 and beyond. We propose to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models, consistent with the approach adopted beginning with the 2020 models. We discuss removing the mapping of hydroxychloroquine sulfate to RXC 09 (Immune Suppressants and Immunomodulators) in the 2018 and 2019 benefit year enrollee-level EDGE data used for the annual recalibration of the HHS risk adjustment models. We also propose for the 2024 benefit year and beyond to recalibrate the models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the current year's model recalibration. We propose using this approach for recalibration of the 2023 adult risk adjustment models with the exception of the 2017 enrollee-level EDGE data year, for which we propose to use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018).We also propose to collect and extract five new data elements including ZIP code, race, ethnicity, ICHRA indicator, and a subsidy indicator as part of the required risk adjustment data that issuers must make accessible to HHS in states where HHS is operating the risk adjustment program. We also propose to extract three new data elements issuers already

provide to HHS as part of the required risk adjustment data submissions (plan ID, rating area, and subscriber indicator) and to expand the permitted uses of the risk adjustment data and reports. Additionally, we propose an amendment to § 153.730 to address situations when April 30 does not fall on a business day and to provide that when this occurs, the deadline for issuers to submit the required risk adjustment data in states where HHS operates the program would be the next applicable business day.

The proposals in part 153 also relate to risk adjustment state flexibility requests. We propose to repeal the ability of states to request a reduction in risk adjustment transfers calculated by HHS under the state payment transfer formula starting with the 2024 benefit year, while proposing to create an exception for any state that has requested a reduction in prior benefit years. In addition, we solicit comments on the requests from Alabama to reduce risk adjustment state transfers for the 2023 benefit year in the individual (including the catastrophic and non-catastrophic risk pools) and small group markets.

In part 153 we also propose the risk adjustment user fee for the 2023 benefit year and modifications to the error estimation methodology applied in HHS–RADV. We propose updating the HHS–RADV error estimation process to extend the application of Super HCCs beyond the sorting step that assigns HCCs to failure rate groups to also apply throughout the HHS–RADV error rate calculation processes and to specify that Super HCCs will be defined separately according to the model (infant, child, adult) to which an enrollee is subject. We also propose to constrain to zero any failure rate group outlier negative failure rate, regardless of whether the outlier issuer has a negative or positive error rate. Finally, we propose that whenever HHS recoups high-cost risk pool funds as a result of audits of risk adjustment covered plans, an actionable discrepancy, or a successful administrative appeal, the recouped high-cost risk pool funds will be used to reduce high-cost risk pool charges for that national high-cost risk pool beginning for the next benefit year for which a high cost risk pool payment has not already been calculated.

In addition, the proposals regarding part 153 also relate to MLR reporting requirements and clarify how issuers should report certain ACA program amounts that could be subject to reconsideration for MLR reporting purposes. We propose to separately address and reference HHS–RADV adjustments to make clear that HHS expects issuers to report HHS–RADV adjustments as part of their MLR reports in the same manner as they report risk adjustment payment and charge amounts.

The proposed changes to 45 CFR part 155 would allow Exchanges to implement a verification process for enrollment in or eligibility for an eligible employer sponsored plan based on the Exchange's assessment of risk for inappropriate payments of APTC/CSR. In part 155 we also propose to require all Exchanges to prorate when administering APTC for enrollees enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. We also propose new requirements in part 155 related to the QHP comparative information and standardized disclaimer required to be displayed on web-broker non-Exchange websites, a prohibition on displaying QHP advertisements or otherwise providing favored or preferred placement in the display of QHPs on web-broker non-Exchange websites based on compensation agents, brokers, or web-brokers receive from QHP issuers, and a requirement regarding the prominent display of a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on web-broker non-Exchange websites to better inform and protect consumers using such websites. We also propose changes to part 155, to clarify the FFE standards of conduct and what it means for agents, brokers, and web-brokers to provide the Exchange with correct information under section 1411(b) of the ACA, including ensuring that accurate consumer information is being entered on Exchange applications. Finally, we propose changes to part 155 to set forth prohibited agent, broker, and web-broker business practices commonly observed by HHS and to create enforceable standards under which HHS may take enforcement action against agents, brokers, and web-brokers when these prohibited business practices are discovered.

In 45 CFR part 156, as we do every year in the HHS notice of benefit and payment parameters, we propose to update the user fee rates for the 2023 benefit year for all issuers participating on the Exchanges using the Federal platform. We note that we intend to publish the 2023 premium adjustment percentage index and related payment parameters in guidance as finalized in part 2 of the 2022 Payment Notice. The proposed changes to part 156 also include technical amendments to § 156.50 to conform the user fee regulations with the repeal of Exchange Direct Enrollment (DE) option finalized in part 3 of the 2022 Payment Notice.[15] We are proposing changes to § 156.430 to clarify that the CSR data submission process is mandatory only for those issuers that receive CSR payments from HHS for any part of the benefit year as a result of HHS possessing a valid appropriation to make CSR payments, and voluntary for other issuers.

In part 156, we also propose an evergreen deadline for EHB-benchmark plan applications by states, as well as proposing to remove the ability for states to permit issuers to substitute benefits between EHB categories, proposing to change de minimis thresholds for the AV of plans subject to the AV requirements, as well as narrower de minimis thresholds for individual market silver QHPs and income-based CSR plan variations; and proposing to remove the annual reporting requirement on states to report state-required benefits in addition to the EHB to HHS.

In part 156, we also propose to require issuers of QHPs in FFEs and SBE–FPs to offer through the Exchange standardized QHP options beginning in PY 2023. We also propose to update the QIS standards in part 156 to require QHP issuers to address health and health care disparities as a specific topic area within their QIS beginning with PY 2023.

The proposed changes to part 158 would clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. The proposed changes to part 158 would also specify that only expenses directly related to activities that improve health care quality may be included as QIA expenses for MLR reporting and rebate calculation purposes. In addition, the proposed changes to part 158 would make a technical amendment to § 158.170(b) to correct an oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8), a provision that was vacated by the United States District Court for the District of Maryland in *City of Columbus, et al.* v.

[15] 86 FR 53412.

Cochran,[16] and thus deleted in part 2 of the 2022 Payment Notice final rule.

III. Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2023

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Definitions (§ 144.103)

We propose to remove superfluous language from the definition of large group market. The definition currently provides that ''Large group market'' means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a large employer, unless otherwise provided under State law. We propose to amend the definition by deleting the phrase ''unless otherwise provided under State law.'' The phrase has no meaning or application, and does not appear in the statutory definition of the term in section 2791(e)(3) of the PHS Act. That phrase was initially included in the PHS Act regulatory definitions of large group market, large employer, and small employer adopted by HHS under HIPAA.[17] However, in final rules published on October 30, 2013 (78 FR 65045), we amended the definitions of large employer and small employer to make them consistent with PHS Act section 2791(e), as amended by the ACA, and in so doing, removed that phrase from the definitions. At that time, we inadvertently neglected to delete the phrase from the regulatory definition of large group market, and we now propose to do so, in order to align these definitions and make the regulatory definition for large group market consistent with the definition under the ACA.

B. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Guaranteed Availability of Coverage (§ 147.104)

a. Past-Due Premiums

We propose to re-interpret the guaranteed availability requirement at section 2702 of the PHS Act and its implementing regulation at § 147.104 to require issuers to accept individuals and employers who apply for coverage, even where the individual or employer owes past-due premiums for coverage from the same issuer or another issuer in the same controlled group. On January 28, 2021, President Biden issued Executive Order 14009, ''Strengthening Medicaid and the Affordable Care Act'' (E.O. 14009).[18] Section 3 of E.O. 14009 directs HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related to Medicaid and the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether they are inconsistent with policy priorities described in Section 1 of E.O. 14009, to include protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals. Consistent with E.O. 14009, specifically section 3(iv), this proposal intends to remove an unnecessary barrier to individuals and families attempting to enroll into health coverage in the individual market.

Specifically, we propose to redesignate § 147.104(i) as § 147.104(j) and add a new § 147.104(i) to specify that a health insurance issuer that denies coverage to an individual or employer due to the individual's or employer's failure to pay premium owed under a prior policy, certificate, or contract of insurance, including by attributing payment of premium for a new policy, certificate, or contract of insurance to the prior policy, certificate, or contract of insurance, violates § 147.104(a). The guaranteed availability provisions require health insurance issuers offering non-grandfathered coverage in the individual or group market to accept every individual and employer in the state that applies for such coverage unless an exception applies. Individuals and employers typically are required to pay the first month's premium to effectuate coverage. Under the current interpretation of the guaranteed availability requirement stated in the Market Stabilization final rule, to the extent permitted by applicable state law, an issuer does not violate the guaranteed availability requirements under § 147.104 where the issuer attributes a premium payment made for new coverage to any past-due premiums owed for coverage from the same issuer or another issuer in the same controlled group within the prior 12-month period before effectuating enrollment in the new coverage. This policy addressed concerns that individuals might take unfair advantage of the rules regarding grace periods.[19] However, in part 3 of the 2022 Payment Notice proposed rule, we stated our intention to reassess this interpretation to analyze whether this policy presents unnecessary barriers to accessing health coverage.[20]

After reevaluating our interpretation of the guaranteed availability requirement, we propose reinstating our previous interpretation of the guaranteed availability rules with respect to non-payment of premiums.[21] Under this interpretation, an issuer may not apply any premium payment made for new coverage in the same or a different plan or product to any outstanding debt owed from any previous coverage and then refuse to effectuate the new enrollment based on failure to pay premiums. Thus, the guaranteed availability requirement would prohibit issuers from refusing to effectuate new coverage due to failure to pay outstanding premium debt from the previous year.

Based on HHS' experience since we codified the currently-effective interpretation of guaranteed availability, we believe the current policy, has the unintended consequence of creating barriers to health coverage that disproportionately affect low-income individuals, and is therefore inconsistent with the intent of the guaranteed availability statutory requirements. The current policy heightens the risk of economic hardships for low-income individuals enrolled in health insurance coverage with APTC. Individuals stop paying premiums (and lose coverage due to nonpayment of premiums) for a variety of reasons throughout the year. For example, commenters to the Market Stabilization proposed rule stated that individuals who are victims of crime, or those grappling with domestic violence,

[16] 523 F. Supp. 3d 731 (D. Md. 2021).

[17] 62 FR 16894 (April 8, 1997) and 69 FR 78720 (Dec. 30, 2004).

[18] E.O. 14009; 86 FR 7793 (Feb. 2, 2021).

[19] QHP issuers are required, under § 156.270, to provide a grace period of 3 consecutive months for an enrollee, who, when failing to timely pay premiums, is receiving APTC. If the enrollee exhausts the grace period without paying all outstanding premiums, subject to a premium payment threshold implemented under § 155.400(g), then the QHP issuer must terminate the enrollee's enrollment back to the last day of the first month of the 3-month grace period. As a result, an individual receiving APTC whose coverage is terminated after the exhaustion of a grace period would owe at most 1 month of premiums, net of any APTC paid on their behalf to the issuer; however, an individual who attempts to enroll in new coverage while in a grace period, and whose coverage has not yet been terminated, could owe up to 3 months of premium, net of any APTC paid on their behalf to the issuer.

[20] 86 FR 35156, 36071.

[21] Federally-facilitated Marketplace (FFM) and Federally-facilitated Small Business Health Options Program Enrollment Manual, Section 6.3 Terminations for Non-Payment of Premiums, *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/ENR_FFMSHOP_Manual_080916.pdf* (describing operational requirements effective as of July 19, 2016, which were superseded by subsequent publications).

medical emergencies, incarceration, or other urgent circumstances are often forced to make difficult financial decisions that may lead to failure to pay their health insurance premiums. Even for some middle-income families, the high cost of health care for multiple family members with chronic health conditions may result in non-payment of premiums.[22] Requiring such individuals to pay back past-due premium plus a binder payment prior to enrollment may present an insurmountable barrier leading to gaps in coverage. For this reason, HHS is of the view that the current interpretation of the guaranteed availability requirement creates unnecessary barriers to accessing health coverage.

HHS is also concerned that the barriers created by the current interpretation of guaranteed availability disproportionately affect low-income enrollees for whom APTC is paid. Under federal law governing grace periods for enrollees for whom APTC is paid, QHP issuers must provide a 3-month grace period before they are allowed to terminate an enrollee's coverage for non-payment of premiums and must continue to provide coverage during the first month of the grace period. As a result, those enrollees who are unable to satisfy outstanding premium payments by the end of the 3-month grace period generally may owe at least one month of past due premium after their coverage is terminated. In contrast, grace period rules for individuals who are not eligible for APTC are governed by state law. Many state laws allow for termination back to the end of the period for which an enrollee paid premium, in which case an enrollee without APTC whose coverage is terminated for nonpayment would not owe past-due premium when they attempt to enroll in coverage during a subsequent open enrollment or special enrollment period. Enrollees for whom APTC is paid generally may have household incomes as low as 100 percent of the federal poverty level (FPL) (which, for the 2021 benefit year, is $12,760 for a single person household).[23] Thus, premium payment policies that require payment of past-due premiums prior to effectuation of new coverage are likely to disproportionately affect low-income enrollees with APTC, the individuals who may be least able to pay all outstanding premium debt among those seeking coverage in the individual market.

Conditioning health insurance enrollment on the payment of past-due premiums could disincentivize health insurance enrollment altogether, reducing the rate of enrollment for low-income individuals. The economic burden associated with being required to pay past-due premiums prior to enrolling in new coverage may prevent low-income individuals from enrolling in coverage and affect the demographics of the risk pool. Various studies have found that low-income families often struggle to balance out-of-pocket health care costs alongside rent or mortgage payments, and other necessary living expenses.[24] Maintaining the current interpretation of the guaranteed availability rules would uphold barriers to health insurance coverage for low-income individuals, who face a greater risk of poorer health outcomes.[25] Reverting to the previous interpretation of the guaranteed availability rules would ensure individuals who stand to benefit the most from health insurance coverage can enroll in coverage, and would promote more equitable access to health insurance coverage. In addition, the public health and economic crises caused by the COVID–19 pandemic exacerbated the hardships facing low-income individuals and families. The resulting financial and health insecurity caused by the pandemic underscores the critical role that access to continuous health coverage will continue to play during the ongoing and often unpredictable challenges of the pandemic and beyond. Returning to the previous interpretation of the guaranteed availability rule would remove a barrier to accessing health coverage that compounds the economic challenges from the COVID–19 crisis.

In the Market Stabilization rule, we noted concern that enrollees with APTC may take advantage of guaranteed availability by declining to make premium payments for coverage at the end of a benefit year without losing coverage. Although this remains possible, we are of the view that the disparate negative impact on low-income populations outweighs the possible deterrent effect on individuals who may try taking advantage of the guaranteed availability rules. We seek comment regarding the frequency of any potential gaming behavior, as well as information on the primary diagnoses and services that may be involved in suspected gaming situations so that we may better assess any contributing causes of such non-payment. For example, non-payment may not be the result of gaming, but could be indicative of contextual challenges individuals face in satisfying payment obligations. We are particularly interested in comments from issuers that have not adopted a premium payment policy that requires payment of past-due premiums prior to effectuating enrollment. In addition, we note that issuers are generally not permitted to forgive past-due premium debt, and can pursue other mechanisms to collect past-due premiums. We believe this mitigates the risk that some enrollees may take advantage of the guaranteed availability rules.

We seek comment on this proposal.

b. Nondiscrimination Based on Sexual Orientation and Gender Identity

We propose to amend 45 CFR 147.104(e) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 147.104(e), but amendments made in 2020 to § 147.104(e) removed any reference to sexual orientation and gender identity. If finalized, this proposal would revert § 147.104(e) to the pre-2020 nondiscrimination protections.

Section 147.104(e) states that a health insurance issuer and its officials, employees, agents, and representatives must not employ marketing practices or benefit designs that would have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions. Previously, in the 2014 Market Rules, we finalized § 147.104(e) to also prohibit discrimination based on sexual orientation and gender

[22] John Tozzi. (March 2018). ''Why Some Americans Are Risking It and Skipping Health Insurance.'' *Bloomberg News.* Retrieved from *https://www.bloomberg.com/news/features/2018-03-26/why-some-americans-are-risking-it-and-skipping-health-insurance.*

[23] See 2021 Poverty Guidelines for the 48 Contiguous States and the District of Columbia, available at *https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines/prior-hhs-poverty-guidelines-federal-register-references/2020-poverty-guidelines.*

[24] Tim Thomas, Ph.D.; Jose Hernandez, Ph.D.; et al. (2019). The Evictions Study. *The University of California Berkeley and the University of Washington.* Retrieved from *https://evictions.study/index.html.*

[25] P.J. Cunningham; T.L. Green; R.T. Braun. (February 2018). Income Disparities in the Prevalence, Severity, and Costs of Co-Occurring Chronic and Behavioral Health Conditions. *Medical Care.* Retrieved from *https://www.commonwealthfund.org/publications/journal-article/2018/feb/income-disparities-prevalence-severity-and-costs-co-occurring.*

identity.[26] However, in the 2020 final rule that revised regulations implementing section 1557 of the ACA, HHS also revised certain CMS regulations, including those at § 147.104(e), by removing sexual orientation and gender identity as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[27] The 2020 section 1557 final rule is the subject of ongoing litigation.[28]

Pursuant to section 1311(c)(1)(A) of the ACA, the HHS Secretary was required to establish by regulation criteria for certification that require QHP issuers to meet marketing requirements and not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs. Under the authority of section 1321(a) of the ACA, which provides the HHS Secretary broad rulemaking authority with respect to the establishment and operation of Exchanges and the offering of QHPs through such Exchanges, in the 2012 Exchange Standards final rule, CMS codified a regulation implementing this requirement at § 156.225. Under the general rulemaking authority in section 2792 of the PHS Act, which provides the HHS Secretary broad rulemaking authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act, the 2014 Market Rules adopted a similar standard in § 147.104(e), applying this requirement to the group and individual health insurance markets. Furthermore, in order to ensure consistency against employing discriminatory marketing practices and benefit designs, HHS finalized § 147.104(e) to align with other prohibitions on discrimination that HHS had already codified at that time with respect to EHB in § 156.125, with respect to standards applicable to QHPs under § 156.200(e) that included protections against discrimination on the basis of sexual orientation and gender identity, and with respect to marketing standards in § 156.225. The 2014 Market Rules further clarified that discriminatory marketing practices or benefit designs represent a failure by issuers to comply with the guaranteed availability requirements in PHS Act section 2702, as such practices or designs can have the effect of discouraging or preventing the enrollment of individuals in health insurance coverage.

In the 2020 section 1557 final rule, HHS revised the section 1557 implementing regulation. Among other things, the rule removed the definition of ''on the basis of sex,'' which included gender identity, and instead purported to rely upon the ''plain meaning'' of the word ''sex'' in the underlying Title IX regulation.[29] However, as HHS noted in the 2020 section 1557 final rule, CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination in the group and individual markets.[30]

Following public posting of the 2020 section 1557 final rule on the agency's website, the Supreme Court held in Bostock v. Clayton County, 140 S. Ct. 1731 (2020), that discrimination on the basis of sex under Title VII of the Civil Rights Act of 1964 includes discrimination on the basis of sexual orientation and gender identity. On January 20, 2021, the President signed Executive Order 13988 stating that it is the Administration's policy to prevent and combat discrimination on the basis of gender identity and sexual orientation, and that under Bostock's reasoning, laws that prohibit sex discrimination also prohibit discrimination on the basis of gender identity and sexual orientation, so long as the laws do not contain sufficient indications to the contrary.[31] The Executive Order (E.O.) also instructed all agency heads, including the HHS Secretary, to review all existing regulations, guidance documents, and other agency actions to determine whether they are consistent with the aforementioned policy, and to consider whether to suspend, revise, or rescind any agency actions that are inconsistent with it. The Department of Justice (DOJ) issued a memorandum on March 26, 2021 that determined the court's reasoning in Bostock applies to Title IX and thus that Title IX's prohibition on discrimination on the basis of sex includes discrimination on the basis of gender identity and sexual orientation.[32] Following the E.O. and DOJ's memorandum, HHS released on May 10, 2021 a Notice that HHS will interpret and enforce section 1557's and Title IX's prohibition on discrimination on the basis of sex to include: (1) Discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity.[33]

Likewise, CMS is not relying on authority from section 1557 of the ACA for the proposal at § 147.104(e) or the parallel proposals to nondiscrimination regulations at §§ 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b). We will further elaborate in the respective preambles to §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) the specific ACA authority CMS is relying on to prohibit discrimination in the group and individual markets. CMS proposes to exercise the same authority as it exercised in the 2014 Market Rules to amend § 147.104(e) to again prohibit a health insurance issuer and its officials, employees, agents, and representatives from discriminating in its marketing practices or benefit designs on the basis of sexual orientation and gender identity. Specifically, CMS proposes to again rely on section 2702 of the PHS Act, as well as section 2792 of the PHS Act, which provides the HHS Secretary broad rulemaking authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act. These are the same authorities CMS relies upon for implementation of existing nondiscrimination protections at § 147.104(e). Utilizing these same authorities to again prohibit discrimination based on sexual orientation and gender identity would be consistent with the authority CMS relies upon for those existing protections at § 147.104(e) that currently prohibit discrimination on the basis of race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions.

People who identify as part of the lesbian, gay, bisexual, transgender, and

[26] 78 FR 13406 (February 27, 2013).

[27] 85 FR 37160 (June 19, 2020); *See id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

[28] The 2020 section 1557 final rule is the subject of several lawsuits and court orders. For more information, *see https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html.*

[29] 85 FR 37160, 37166 (June 19, 2020). The 2016 and 2020 section 1557 final rules are the subject of several lawsuits and court orders. For more information, *see https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html, https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html.*

[30] 85 FR 37160, 37219, 37218–21 (June 19, 2020).

[31] Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, 86 FR 7023 (Jan. 20, 2021).

[32] U.S. Dep't of Justice, Memorandum on Application of Bostock v. Clayton County to Title IX of the Education Amendments of 1972 (Mar. 26, 2021), *https://www.justice.gov/crt/page/file/1383026/download.* On June 16, 2021, the Department of Education's Office for Civil Rights issued a similar Notice explaining that it too will enforce Title IX's prohibition on discrimination on the basis of sex to include: (1) Discrimination based on sexual orientation; and (2) discrimination based on gender identity (*available at https://www2.ed.gov/about/offices/list/ocr/docs/202106-titleix-noi.pdf*).

[33] 86 FR 27984.

queer (LGBTQI+) community face pervasive health and health care disparities, and are at higher risk for many concomitant conditions, including substance use and [34] mental health disorders, sexually transmitted infections,[35] HIV,[36] cancer, cardiovascular disease, and obesity.[37] Overall, LGBTQI+ people report being in poorer health than non-LGBTQI+ individuals. LGBTQI+ people of all genders are more likely to become disabled at a younger age than heterosexual individuals.[38] In addition to disparities in health outcomes, LGBTQI+ people face barriers to obtaining appropriate health care and transgender people who can access insurance may nonetheless be denied coverage for needed services. For example, nearly half of transgender respondents in one survey said their health insurance company denied them gender affirming surgery,[39] and a similar proportion reported that they were denied coverage for hormone therapy.[40] Beyond health coverage issues, LGBTQI+ people may struggle to access care because of cost barriers. LGBTQI+ people are also more likely than others to report postponing or forgoing health care due to costs, and costs were an even greater obstacle for younger LGBTQI+ people and those who are transgender—especially transgender people of color.[41]

We believe that prohibiting discrimination based on sexual orientation or gender identity can lead to improved health outcomes for this community [42] and that the removal of such protections in the 2020 section 1557 final rule frustrated not only guaranteed availability requirements, but also the broader aim of improving health equity. Without protection from discrimination, individuals may continue to face barriers to accessing medically necessary health care. For example, without protection from discrimination, transgender individuals may face barriers or be denied medically necessary gender-affirming care. We believe amending the nondiscrimination protections as proposed at § 147.104(e) to again explicitly prohibit discrimination based on sexual orientation and gender identity is warranted in light of the existing trends in health care discrimination and to better address barriers to health equity for LGBTQI+ individuals.[43] As proposed, such revisions to § 147.104(e) would also support the original objective of ensuring consistency against employing discriminatory marketing practices and benefit designs, as we are proposing parallel changes to nondiscrimination regulations at §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b).

If any of the provisions at §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) are held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances. In enforcing the nondiscrimination provisions in the corresponding CMS regulations, HHS will comply with laws protecting the exercise of conscience and religion, including the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb–4) and all other applicable legal requirements.

We seek comment on this proposal.

C. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

In subparts A, D, G, and H of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the ACA that transfers funds from lower-than-average risk, risk adjustment covered plans to higher-than-average risk, risk adjustment covered plans in the individual, small group markets, or merged markets, inside and outside the Exchanges. In accordance with § 153.310(a), a state that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf.[44] HHS did not receive any requests from states to operate risk adjustment for the 2023 benefit year. Therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2023 benefit year.

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2022, the permanent risk adjustment program is subject to the fiscal year 2022 sequestration.[45] The federal government's 2022 fiscal year begins October 1, 2021. Therefore, the risk adjustment program will be sequestered at a rate of 5.7 percent for payments made from fiscal year 2022 resources (that is, funds collected during the 2022 fiscal year).

HHS, in coordination with OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (Pub. L. 99–177, enacted December 12, 1985), as

[34] Hilary Daniel et al, Annals of Internal Med. Position Papers, *Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive Summary of a Policy Position Paper From the American College of Physicians* (July 21, 2105), *https://www.acpjournals.org/doi/full/10.7326/M14-2482?journalCode=aim.*

[35] Hilary Daniel et al, Annals of Internal Med. Position Papers, *Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive Summary of a Policy Position Paper From the American College of Physicians* (July 21, 2105), *https://www.acpjournals.org/doi/full/10.7326/M14-2482?journalCode=aim.*

[36] U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control and Prevention, *HIV Surveillance Report, 2019; Vol. 32* (May 2021), *https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2018-updated-vol-32.pdf.*

[37] *See, for example,* Lesbian, Gay, Bisexual, and Transgender Health, Healthy People 2020, *https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health#:~:text=Research%20suggests%20that%20LGBT%20individuals,%2C%2C%203%20and%20suicide;* Hafeez, Hudaisa et al. ''Healthcare Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review.'' *Cureus* vol. 9,4 e1184. 20 Apr. 2017, doi:10.7759/cureus.1184 (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478215/*); Fredriksen-Goldsen KI, Kim H–J, Barkan SE, Muraco A and Hoy-Ellis CP (2013) Health disparities among lesbian, gay, and bisexual older adults: Results from a population-based study. *American Journal of Public Health* 103, 1802–1809; Billy A. Caceres et al. ''A Systematic Review of Cardiovascular Disease in Sexual Minorities'', American Journal of Public Health 107, no. 4 (April 1, 2017): pp. e13–e21.

[38] Hilary Daniel et al, Annals of Internal Med. Position Papers, *Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive Summary of a Policy Position Paper From the American College of Physicians* (July 21, 2105), *https://www.acpjournals.org/doi/full/10.7326/M14-2482?journalCode=aim.*

[39] For purposes of this preamble, the term ''gender affirming care'' means gender affirming care for transgender individuals. This may also be referred to as ''transition related care.''

[40] Sharita Gruberg et al, Center for American Progress, *The State of the LGBTQ Community in 2020* (Oct. 6, 2020), *https://www.americanprogress.org/issues/lgbtq-rights/reports/2020/10/06/491052/state-lgbtq-community-2020/.*

[41] Sharita Gruberg et al, Center for American Progress, *The State of the LGBTQ Community in 2020* (Oct. 6, 2020), *https://www.americanprogress.org/issues/lgbtq-rights/reports/2020/10/06/491052/state-lgbtq-community-2020/.*

[42] Ward, BW, Dahlhamer, JM, Galinsky, AM, and Joestl, SS. Sexual Orientation & Health Among U.S. Adults: National Health Interview Survey, CDC National Health Statistics Report 77, 2014.

[43] Nguyen, T.T., Vable, A.M., Glymour, M.M. et al. Trends for Reported Discrimination in Health Care in a National Sample of Older Adults with Chronic Conditions. J GEN INTERN MED 33, 291–297 (2018). *https://doi.org/10.1007/s11606-017-4209-5.*

[44] Also see 42 U.S.C. 18041(c)(1).

[45] *https://www.whitehouse.gov/wp-content/uploads/2021/05/BBEDCA_251A_Sequestration_Report_FY2022.pdf.*

amended, and the underlying authority for the risk adjustment program, the funds that are sequestered in fiscal year 2022 from the risk adjustment program will become available for payment to issuers in fiscal year 2023 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, the program would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

Additionally, we note that the Coronavirus Aid, Relief, and Economic Security (CARES) Act amended section 251A(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 and extended sequestration for the risk adjustment program through fiscal year 2030 at a rate of 5.7 percent per fiscal year.[46]

2. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on that person's age, sex, and diagnoses (also referred to as hierarchical condition categories (HCCs)), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for clinical and cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXCs) beginning with the 2018 benefit year.[47] Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a CSR factor. The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score) within a geographic rating area is one of the inputs into the risk adjustment state payment transfer formula, which determines the state transfer payment or charge that an issuer will receive or be required to pay for that plan for the applicable state market risk pool. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

a. Data for Risk Adjustment Model Recalibration for 2023 Benefit Year and Beyond

We are proposing to recalibrate the 2023 benefit year risk adjustment models with the 2017, 2018, and 2019 enrollee-level EDGE data. Consistent with the approach outlined in the 2020 Payment Notice to no longer rely upon MarketScan® data for recalibrating the risk adjustment models, we will recalibrate the risk adjustment models for the 2023 benefit year using only enrollee-level EDGE data, and we will continue to use blended, or averaged, coefficients from the 3 years of separately solved models for the 2023 benefit year model recalibration.[48] Additionally, as outlined in the 2022 Payment Notice, we will use the 3 most recent consecutive years of enrollee-level EDGE data that are available at the time we incorporate the data in the draft recalibrated coefficients published in the proposed rule for the applicable benefit year,[49] and will not update the coefficients between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available for incorporation.[50] We believe this promotes stability, better meets the goal of the risk adjustment program, and allows issuers more time to incorporate this information when pricing their plans for the upcoming benefit year.

As such, we propose to determine coefficients for the 2023 benefit year based on a blend of separately solved coefficients from the 2017, 2018, and 2019 benefit years' enrollee-level EDGE data.[51] The draft coefficients listed in Tables 1 through 6 reflect the use of 2017, 2018, and 2019 benefit year enrollee-level EDGE data, as well as other risk adjustment model updates proposed in this proposed rule (including changes to the model specifications, the pricing adjustment to Hepatitis C drugs, and the removal of the mapping of hydroxychloroquine sulfate to an RXC). However, we note that the coefficients could change if we identify an error or if some or all of the proposed model changes are not finalized or are modified in response to comments. In addition, consistent with § 153.320(b)(1)(i), if we are unable to finalize the final coefficients in time for publication in the final rule, we would publish the final coefficients for the 2023 benefit year in guidance soon after the publication of the final rule. We seek comment on the proposal to determine 2023 benefit year coefficients based on a blend of separately solved coefficients from the 2017, 2018, and 2019 enrollee-level EDGE data.

We also solicit comments on the future use of the 2020 enrollee-level EDGE data due to the COVID–19 PHE. Under current policy, 2020 enrollee-level EDGE data would be used in recalibration of the HHS risk adjustment models for the 2024 benefit year and that data would continue to be used for the 2025 and 2026 benefit year models.[52] Although HHS has not analyzed the 2020 enrollee-level EDGE data yet, we solicit comment on the future use of the 2020 enrollee-level EDGE data for the annual recalibration of the HHS risk adjustment models.

b. Risk Adjustment Model Updates

Beginning with the 2023 benefit year, we are proposing three modeling updates to the risk adjustment models. Consistent with the potential model updates discussed in the 2021 RA Technical Paper, we propose the following model updates, which are the same as those proposed but not finalized in the 2022 Payment Notice:[53] (1) Adding a two-stage weighted model specification to the adult and child models; (2) removing the severity illness factors in the adult models and

[46] *https://www.congress.gov/116/bills/s3548/BILLS-116s3548is.pdf.*

[47] For the 2018 benefit year, there were 12 RXCs, but starting with the 2019 benefit year, the two severity-only RXCs were removed from the adult risk adjustment models. See, for example, 83 FR 16941.

[48] 84 FR 17463 through 17466.

[49] While we do receive the next year of enrollee-level EDGE data prior to the proposed rule, that data must go through several quality and analysis checks before it is useable for risk adjustment model recalibration.

[50] 86 FR 24140 at 24152.

[51] As discussed later in this proposed rule, we propose to remove the mapping of hydroxychloroquine to RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions.

[52] Consistent with the approach finalized in the 2022 Payment Notice, use of the 3 most recent consecutive years of enrollee-level EDGE data would result in the use of 2018, 2019, and 2020 enrollee-level EDGE data for the recalibration of the 2024 benefit year models; the use of 2019, 2020, and 2021 enrollee-level EDGE data for recalibration of the 2025 benefit year models; and the use of 2020, 2021, and 2022 enrollee-level EDGE data for recalibration of the 2026 benefit year models.

[53] See 85 FR 78572 at 78583–78586. In the 2022 Payment Notice Final Rule, in response to comments, we did not finalize the proposed updates and announced that we would publish a technical paper on the proposed model changes; see 86 FR 24140 at 24151–24162. See also the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.*

replacing them with new severity and transplant indicators interacted with HCC count factors in the adult and child models; and (3) replacing the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors in the adult models.

As described in prior rulemakings and in the 2021 RA Technical Paper, the current HHS–HCC models, which are linear models, underpredict plan liability for enrollees without HCCs and the lowest expected expenditures, underpredict plan liability for enrollees with the highest HCC counts and the highest expected expenditures, and underpredict plan liability for partial-year enrollees with HCCs.[54] The proposals in this proposed rule are intended to improve the risk adjustment adult and child models' prediction for these subpopulations. We released the 2021 RA Technical Paper in response to stakeholder requests for more information on the impacts of these proposals before they were adopted and released simulated transfer estimates reflecting the combination of these proposed changes in December 2021.[55] We continue to believe the combination of these proposed model changes will improve the current models' predictive accuracy for the lowest-risk enrollees, certain partial-year adult enrollees, and the very highest-risk enrollees, while limiting trade-offs in other areas of model performance and complexity. As such, we are re-proposing these combined model specification changes in this rule, and the following sections describe these proposed model specification changes in detail.

i. Two-Stage Weighted Model Specification

We propose to use a two-stage weighted model specification to recalibrate the adult and child risk adjustment models starting with the 2023 benefit year to improve the underprediction of plan liability for the lowest-risk enrollees (that is, enrollees in low risk deciles and enrollees without HCCs).[56] Since approximately 80 percent of enrollees in the individual and small group (or merged) markets do not have HCCs, this underprediction, while small in magnitude, represents a large number of enrollees.[57]

To improve prediction for the lowest-risk enrollees, we explored calibrating the adult and child models in two stages to reweight the healthier enrollees more heavily. In the first-stage estimation, the model coefficients would be estimated using the current model specifications; and in the second stage, we would re-estimate the model weighting enrollees in the recalibration sample by the capped reciprocal of the predicted values of relative expenditures from the first step estimation with the same model specification. More specifically, the first stage of this proposed weighted estimation method for the adult models involves a linear regression (weighted by the person-specific eligibility fraction of the number of months enrolled divided by 12) of simulated plan liability[58] on age-sex factors, payment HCC factors, severity illness factors,[59] the enrollment duration factors,[60] and RXCs. For the child models, the first stage of the proposed weighted estimation method involves a linear regression of simulated plan liability on age-sex factors and payment HCC factors.[61] The methodology for conducting the proposed first stage regression would be essentially identical to the current adult and child risk adjustment recalibrations. The second stage of the proposed two-stage weighted model specification involves using recalibration sample enrollees' inverse (also referred to as reciprocal) capped predictions from the first stage as weights for a second linear regression. As such, this step has the material effect of weighting healthier enrollees more heavily so that the statistical model predicts their expenditures more accurately. It also systematically reduces the influence of very expensive enrollees on the final model factors.

To help provide stability to the proposed two-stage weighted model specification, we imposed lower and upper bound caps on the first-stage predictions at the 2.5th and 97.5th percentiles in the adult models, and the 2.5th and 99.5th percentiles in the child models. This capped weighted approach avoids excessively large or small weights for any observations for the second stage estimation, and therefore mitigates the potential to underpredict at the high end for expensive enrollees, as well as any possible low-end overprediction of healthier enrollees. We tested various caps for the weights based on the distribution of costs and found these lower and upper bound caps achieved better prediction on average.[62]

Additionally, in our consideration of the two-stage weighted model specification, we tested various methods of determining weights for the second stage, including reciprocals of the square root of predictions, log of predictions, and residuals from the first stage estimation, but the reciprocal of the capped predictions from the first stage resulted in better predictive ratios for low-cost enrollees compared to any of these alternative weighting functions.[63]

Our conceptual reasoning for pursuing the two-stage weighted model specification is to retain the simple linear, additive structure of the current models while forcing the model to better predict lowest-risk enrollees, who our analyses identified as underpredicted in the current adult and child models. Based on analyses using 2018 enrollee-level EDGE data, the two-stage weighted approach significantly improves the predictive ratios (PRs) of the lower deciles and the PRs for enrollees without HCCs compared to the current models.[64] Similar results were also seen when using 2016 and 2017 enrollee-

[54] See, for example, 85 FR 29164 at 29188–29190; 85 FR 78572 at 78583–78586; and 86 FR 24140 at 24151–24162. See also the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[55] See the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.* Issuers that participated in the simulation also received issuer-specific data, including risk score and transfer estimates for the simulated results.

[56] When we refer to the enrollees without HCCs, we are referring to enrollees without payment HCCs.

[57] See Chapter 2 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf,* and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.*

[58] We simulate plan liability expenditures for each metal level for each enrollee in the recalibration dataset (that is, we apply different standardized benefit design parameters to the same sample for each metal level). See *https://www.cms.gov/mmrr/Downloads/MMRR2014_004_03_a03.pdf.*

[59] We are also proposing to remove the current severity illness indicators in the adult models and add new severity and transplant indicators interacted with HCC count factors in the adult and child models, as described elsewhere in this proposed rule.

[60] We are also proposing to modify the enrollment duration factors in the adult models, as described elsewhere in this proposed rule.

[61] See supra note 58.

[62] See Section 2.2 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* Also see 85 FR at 78667 and 86 FR at 24283.

[63] Ibid.

[64] See Figure 2.2 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

level EDGE data.[65] In addition, the two-stage weighted approach eliminated the overprediction observed in risk decile 8.[66] We also found that the two-stage weighted approach did not meaningfully change factor coefficients for most HCCs, providing stability to the risk adjustment model factors.

At the same time, we also considered whether the two-stage weighted approach worsens the fit of the models along other dimensions, identifying three areas that had minor, negative impacts on the model fit. First, the two-stage weighted approach predicts plan liability by age-sex factor less accurately than the current models, especially for younger and older women. Overall, we considered this to be an acceptable trade-off, because across all age and sex factors, most PRs were within a tolerable threshold of +/−5 percent (for example, 0.95 to 1.05), and the two-stage weighted approach has the major benefit of more accurately predicting the age-sex factors for the enrollees without HCCs, which is a much larger population than enrollees with HCCs. Second, the two-stage weighted approach is somewhat less accurate at predicting certain HCCs, with the two-stage weighted approach worsening adult model silver plan PRs by at least 5 percentage points for 14 (out of 91) ungrouped HCCs and 3 (out of 18) grouped HCCs. For the vast majority of HCCs, the impact is very small and most affected HCCs or HCC groups have small sample sizes.[67] Again, we considered this reduced accuracy to be an acceptable trade-off because most of the PRs for the two-stage weighted approach were within a tolerable threshold of +/−5 percent (for example, 0.95 to 1.05), most enrollees do not have HCCs, and the two-stage weighted approach predicts plan liability better for those no HCC enrollees. Third, the two-stage weighted approach had lower R-squared values compared to the current models. However, the decrease in R-squared is at most 0.1 percentage points for all metal levels, which is a minor reduction in fit across models.[68] Similar to the worsening of the age-sex cell and the HCC PRs, we were not concerned about the lower R-squared as the reduction in fit was minor at all metal levels, the values remained within the range of R-squared statistics of other concurrent models predicting expenditures for commercial insurance enrollees,[69] and the proposed two-stage weighted model specification better predicts plan liability for enrollees with no HCCs, which is the majority of enrollees. After considering the impact of the approach on model performance, we determined that the proposed two-stage weighted model specification does not have material unintended consequences in model performance and achieves the aim of improving the predictive accuracy of the current adult and child models for enrollees in the lowest risk deciles and for enrollees without HCCs. For these reasons, we believe that the two-stage weighted approach can improve prediction for lowest-risk enrollees with limited trade-offs in other parts of the models' performance. Therefore, we are proposing to add the two-stage weighted model specification to the adult and child models beginning with the 2023 benefit year in combination with the proposed interacted HCC counts model specification and the updated adult model enrollment duration factors described later in this proposed rule.

In the 2021 RA Technical Paper, we explained that we believe that by addressing the underprediction of costs associated with lowest-risk enrollees in the adult and child models, we could further encourage the retention and offering of plans that enroll a higher proportion of this subpopulation of enrollees. We believe issuers offering these types of plans are at greater risk of exiting the market if transfers calculated under the state payment transfer formula undercompensate for the true plan liability of the lowest-risk enrollees. We received stakeholder comments in this regard, noting that the underprediction of the lowest-risk enrollees could disincentivize issuers from attracting healthy enrollees to their plans, thereby undermining the goals of developing a healthy and stable market and encouraging competition on the basis of high quality rather than risk selection. However, other stakeholders have questioned if we should focus model changes on improving prediction for the lowest-risk enrollees when the risk adjustment program is intended to reduce incentives for issuers to avoid enrolling individuals with higher risk.

We also received comments concerned that the two-stage weighted model would be redundant of other elements in the state payment transfer formula, which stated that the administrative cost adjustment to statewide average premium[70] already addresses some of the underprediction of the lowest-risk enrollees in the risk adjustment models. We clarify that the proposed two-stage weighted model specification and existing administrative cost adjustment to statewide average premium are not redundant and address separate considerations. As detailed in the 2018 Payment Notice, the purpose of the administrative cost adjustment to statewide average premium is to exclude fixed administrative costs that are not dependent on enrollee risk, such as taxes.[71] In contrast, and as previously described elsewhere,[72] the purpose of the proposed two-stage weighed model specification is to improve the current adult and child models' prediction for the lowest risk enrollees.

We seek comment on the two-stage weighted model specification proposal, specifically regarding whether we should implement the proposed two-stage weighted model specification alone, independent of the other proposed model specification changes outlined in this rule, beginning with the 2023 benefit year; whether we should implement the proposed two-stage weighted model specification in conjunction with these other proposals; or whether we should not implement the two-stage weighted model specification at all. Additionally, given the stakeholder comments we received

[65] The PRs calculated in the 2021 RA Technical Paper are calculated using the same samples on which the models were calibrated. However, as is common practice in evaluating model fit, we also tested splitting the sample for calibration and validation purposes and the results were unchanged. Further, for purposes of the analysis in the 2021 RA Technical Paper, we calculated PRs for at least three data years and the results always appear the same. We therefore generally only reported results in the 2021 RA Technical Paper from the 2018 data year, which was the most recently available dataset at the time that we ran these analyses in preparation for announcing the proposed model changes in the proposed 2022 Payment Notice.

[66] See Figure 2.2 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[67] For example, only one HCC or HCC group whose PR was identified in our analysis as worsening by at least 5 percentage points was present in greater than 1 percent of the adult silver plan enrollees in the 2018 enrollee-level EDGE dataset (HCC 142 *Specified Heart Arrhythmias*). Our analysis found that all other HCCs had recalibration dataset frequencies of less than 0.5 percent of enrollees. See Chapter 2.3 and Table 2.1 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[68] See Figure 2.6 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[69] See Winkelman, R., & Mehmud, S. (2007). A Comparative Analysis of Claims-Based Tools for Health Risk Assessment. Schaumberg, IL: Society of Actuaries.

[70] 81 FR at 94099–94100.

[71] See 81 FR at 61488–61489. Also see 81 FR at 94099–94100.

[72] See Section 2.2 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* Also see 85 FR at 78667 and 86 FR at 24283.

questioning the need for this type of model update, we also generally solicit comments on whether we should seek to improve the current models' prediction for the lowest-risk enrollees.

ii. Interacted HCC Counts Model Specification

In addition to the two-stage weighted approach, we are proposing to add an interacted HCC counts model specification to the adult and child risk adjustment models starting with the 2023 benefit year to address the current models' underprediction of plan liability for the very highest-risk enrollees (that is, those in the top risk percentile and those enrollees with the most HCCs). While this highest-risk subpopulation represents a small number of enrollees, it represents a large portion of expenditures. As described in the 2021 RA Technical Paper, enrollees in risk decile 10 represent roughly 74.29 percent of actual plan liability, compared to only 1.36 percent for enrollees in risk decile 1.[73] We found that for enrollees with a high HCC count, there is an increasing, non-linear effect that leads to higher costs than are currently predicted by adding up the incremental effects of each HCC.

Therefore, to address the underprediction of the highest-cost enrollees, we explored the addition of severity and transplant factors interacted with HCC counts in the adult and child models, wherein a factor flagging the presence of at least one severe or transplant payment HCC is interacted with counts of the enrollee's payment HCCs.[74] The purpose of adding severity and transplant factors interacted with HCC count factors to the adult and child models is to address the underprediction of the highest risk enrollees (as the proposed two-stage-weighted model specification addresses the underprediction of the healthiest enrollees) by accounting for the fact that costs of certain HCCs rise significantly when they occur with multiple other HCCs. Specifically, the goals of this approach were to:

1. Address the non-linearity in costs between enrollees without HCCs or with very low costs and enrollees with multiple HCCs or with high costs;

2. Empirically incorporate the cost impact of multiple complex diseases; and

3. Reduce incentives for coding proliferation to mitigate the gaming concerns with HCC counts models.

In developing this interacted HCC counts approach, we identified common HCCs for enrollees with extremely high costs, as well as HCCs that were being underpredicted in the current risk adjustment adult and child models. We found that many of the HCCs that were flagged as being underpredicted were the current severe illness HCCs, the transplant HCCs, and other HCCs related to the severity of disease. Therefore, we considered dropping the current severity illness factors in the adult models and replacing them with severity and transplant factors interacted with HCC count factors in the adult models, as well as adding the severity and transplant factors interacted with HCC count factors to the child models.

We propose the inclusion of the factors in Tables 1 and 2 as the interacted severity and transplant factors in the adult and child models starting with the 2023 benefit year. We separated out transplant HCCs and severity HCCs into their own separate set of interacted factors, as expressed in Tables 1 and 2, because we found that this approach improved prediction for high-cost enrollees better than an approach that combined severity and transplant HCCs into a single set of factors. Furthermore, under the current risk adjustment models, adult severity illness interaction factors are collapsed into a single binary variable indicating the presence of any severity illness interaction. In contrast, the proposed severity factors would not be collapsed and would instead be separated out by the HCC count with which the severity or transplant illness indicator was interacted.

We defined the new proposed interaction factors such that an enrollee would receive one or more of these factors if they had any HCCs in the severity or transplant indicator groups in Table 3 and according to how many HCCs were recorded in the enrollee's data in total. As such, the proposed severity and transplant interaction factors would express the presence of one or more of the selected severity or transplant HCCs in Table 3. That is, an enrollee must have at least one HCC in the ''severity'' or ''transplant'' indicator groups in Table 3 to receive the interacted HCC count factor toward their risk score, but would not receive any additional flags for having more than one of the ''severity'' or ''transplant'' HCCs in an indicator group beyond the total HCC count.

The proposed severity-HCC-count-interaction factors were calculated as 10 separate factors for the adult models, and seven separate factors for the child models. In the adult models, the first nine factors specified the presence of (1) an HCC in the severity list in Table 3 and (2) exactly one payment HCC in the enrollee's data, exactly two, exactly three, and so on, up to exactly nine payment HCCs. The tenth factor specified the presence of (1) an HCC in the severity list in Table 3 and (2) ten or more payment HCCs in the enrollee's data. For the child models, the first five factors represented the presence of (1) an HCC in the severity list in Table 3 and (2) exactly one payment HCC in the enrollee's data, exactly two, exactly three, and so on, but the sixth factor represents the presence of (1) an HCC in the severity list in Table 3 and (2) six to seven payment HCCs, and the seventh factor represents the presence of (1) an HCC in the severity list in Table 3 and (2) eight or more payment HCCs in the enrollee's data.

The proposed transplant-HCC-count-interaction factors were calculated similarly. However, the transplant factors were calculated using a different range of HCC counts. In the adult models, five separate transplant interaction factors were created, representing the presence of (1) an HCC in the transplant list in Table 3 and (2) payment HCC counts of exactly four, exactly five, exactly six, exactly seven, and eight or more payment HCCs in the enrollee's data. For the child models, we created only one transplant interaction factor indicating the presence of (1) an HCC in the transplant list in Table 3 and (2) a total of four or more payment HCCs in the enrollee's data. As detailed later in this section, this treatment of transplant-HCC-count-interaction factors stabilized the child model estimates by increasing the sample size used to estimate the factor coefficients.

To illustrate how the proposed severity- (or transplant-) HCC-count-interaction factors would be assigned to an enrollee, consider an adult enrollee with four payment HCCs, one of which is HCC 34 ''Liver Transplant Status/Complications''. Because HCC 34 appears in both the severity and transplant indicator groups in Table 3, this enrollee would receive the following factor coefficients toward their risk score in the adult models: (1) The four factor coefficients for their individual HCCs (the three non-transplant HCC factors and the HCC 34

[73] See Table 4.1 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[74] For HCCs in a coefficient estimation group, the group is counted at most once. These groups of HCCs in the HHS risk adjustment adult and child models are detailed in the HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software ''Additional Adult Variables'' and ''Additional Child Variables'' table logic (Tables 6 and 7 in the 2021 Benefit Year DIY Software). The August 3, 2021 version of the DIY software is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.*

transplant HCC factor), (2) the factor coefficient for the severity-HCC-count-interaction indicating four payment HCCs, and (3) the factor coefficient for the transplant-HCC-count-interaction indicating four payment HCCs.[75] The child model would operate similarly. For a child enrollee with a transplant HCC in the transplant factor group and three other payment HCCs, the following would be used to calculate the enrollee's risk score: (1) The factor coefficients for all four HCCs (that is, the three non-transplant HCCs and the transplant HCC), (2) the factor coefficient for the severity-HCC-count-interaction indicating four payment HCCs, and (3) the factor coefficient for the transplant-HCC-count-interaction indicating four or more payment HCCs.

To implement the severity- and transplant-HCC-count-interaction factors in the regression model and estimate the value of their factor coefficients, we are proposing to remove the current severity illness factors in the adult models, and add severity- and transplant-HCC-count-interaction factors for the adult and child models beginning with the 2023 benefit year. Although the severity (or transplant) HCC-count-interaction factor coefficients may be estimated as having negative values, the combination of these interaction factor coefficients with the factor coefficient of the HCC that triggered the severity factor will always be positive. For example, the proposed adult silver metal level model factor coefficient for Viral or Unspecified Meningitis (HCC 04), which is proposed as a severe illness HCC, is 6.914, when combined with the proposed severity-HCC-count-interaction factor coefficient for one HCC of −4.603 (indicating that the enrollee only has HCC 04 present in their data), would increase the enrollee's risk score by 2.311. Moreover, an increase in the count of HCCs would lead to a monotonic increase in the enrollee risk score, because the severity-HCC-count-interaction factor coefficients are less negative (and sometimes positive) with a larger number of payment HCCs.

One potential concern with this proposed model specification change is that the severity- and transplant-HCC-count-interaction factor coefficients might be based on small sample sizes. In recognition of this issue, we considered sample sizes of the various interacted HCC count factors when developing this proposal and the proposed factor coefficients. We explored alternative methods of interacting HCC counts with severity and transplant HCCs, including interacting the HCC counts with individual selected severity and transplant HCCs, but found that interacting the HCC counts with a factor indicating the presence of at least one of the selected HCCs in each group produced PR improvements and sufficient sample sizes for reasonably stable factor coefficient estimates. To that end, we analyzed 2016, 2017, and 2018 enrollee-level EDGE data and chose the model specifications that grouped the HCC counts interacted with individual severity and transplant HCCs into two sets of aggregated factors to maximize sample size, reduce concerns of overfitting the model, and reduce the number of factors being added to the models. More specifically, in the adult models, we found that starting with 4+ HCCs for the transplant interacted factors improved predictions of enrollees at the very high end in terms of risk and cost and ending at 8+ HCCs for the transplant interacted factors, instead of 10+ HCCs, addressed the small sample sizes of enrollees with a transplant and 9 or more HCCs. For the child models, we found having one transplant interacted factor for 4+ HCCs provided more stable estimates given the smaller sample sizes for children than those for adults. With the proposed structure for transplant and severity interacted factors in place, the resulting sample sizes for both proposed sets of factors in the child and adult models in the proposed 2022 Payment Notice and in this rule are consistent with the sample sizes used for individual HCCs in the adult and child risk adjustment models.

We also considered potential gaming concerns in developing the proposed interacted HCC counts factors. We believe that the proposal to restrict the incremental risk score adjustment to enrollees with at least one severe illness HCC, which accounts for less than 2 percent of the adult enrollee-level EDGE data population across the 2016, 2017, and 2018 benefit years, helps mitigate the concern that issuers may attempt to inflate HCC counts to influence their transfers under the state payment transfer formula. In other words, the scope for potentially inflating HCC coding frequency under this proposal would be limited to a small fraction of total enrollees, in contrast to an approach that would interact HCC counts for any payment HCC, where a payment HCC is present in approximately 20 percent of the adult enrollee population across the same three benefit years of enrollee-level EDGE data.[76] We also note that enrollees with interacted HCCs are likely to have more HCCs and higher risk scores and therefore are more likely to be sampled and have their risk scores reviewed in the HHS-operated risk adjustment data validation (HHS–RADV) process due to our use of stratified sampling and application of the Neyman allocation.[77]

Our analysis of the proposed interacted HCC counts factors combined with the proposed HCC-contingent enrollment duration factors in the adult models (discussed in the following section) significantly improves predictions across most deciles and HCC counts for the very highest-risk enrollees, as well as the lowest-risk enrollees without HCCs. Specifically, as described in the 2021 RA Technical Paper, the proposed interacted HCC counts approach improves the PRs for enrollees across most HCC counts, with significant improvements for enrollees with high numbers of HCCs (greater than 6).[78] The proposed interacted HCC counts approach also demonstrated improved R-squared statistics across all metal levels in the adult and child models using 2016, 2017, and 2018 enrollee-level EDGE data.[79]

Some commenters on the 2021 RA Technical Paper were concerned about potential data bias because of the exclusion of enrollees with capitated claims from the analytic sample used to test the model specification changes. As previously stated in the 2016 RA White Paper,[80] we have historically excluded enrollees with capitated claims from the recalibration sample due to concerns that methods for computing and reporting derived amounts from capitated claims would not result in

[75] This is in addition to other factors that the adult enrollee has that are used to calculate their risk score (such as the applicable demographic factors, RXCs (if any), and the applicable enrollment duration factors).

[76] This analysis was based on 2016, 2017, and 2018 enrollee-level EDGE data. See Chapter 4.2 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[77] For a discussion of our use of stratified sampling and application of the Neyman allocation, see 79 FR at 13756–13758; and 84 FR at 17494–17495.

[78] See Figure 4.3 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[79] See Figure 4.4 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[80] See the March 2016 Risk Adjustment Methodology White Paper (March 24, 2016), available at *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.*

reliable data for recalibration or analysis.[81]

Beyond the predictive improvements, an additional benefit of the proposed interacted HCC count model specification is that it would not overhaul the existing risk adjustment factors and would instead build upon the current models. Additionally, the factors would remain fairly stable, could be used in combination with other refinements and model updates, and could be easily modified, adjusted, expanded, or constrained in the future to include additional HCCs or to remove HCCs. For all of these reasons, we are proposing to add the proposed interacted HCC counts model specification as outlined above to the adult and child risk adjustment models beginning with the 2023 benefit year.

We seek comment on this proposal, specifically regarding whether we should implement the proposed interacted HCC counts model specification alone, independent of the other proposed model specification changes outlined in this rule, beginning with the 2023 benefit year; whether we should implement the proposed interacted HCC counts model specification in conjunction with these other proposals; or whether we should not implement the proposed interacted HCC counts model specification at all. We also seek comment on the variations on the HCC counts model specification discussed in this section, including whether we should interact severity or transplant factors with individual HCCs, or should interact HCC counts with individual selected severity and transplant HCCs, rather than interacting HCC counts with only an indicator of the presence of severity or transplant HCCs, as proposed. Finally, we seek comment on the proposed list of severity and transplant HCCs in Table 3 that would be used to calculate the proposed interacted HCC count factor coefficients and whether other HCCs should be to added to the proposed list that trigger the interacted HCC count factor coefficients or whether any of the HCCs on the proposed list should be removed.

iii. Changes to the Adult Model Enrollment Duration Factors [82]

In addition to the proposed two-stage weighted model specification and the interacted HCC counts model specification, we are also proposing to change the enrollment duration factors in the adult risk adjustment models to improve the prediction for partial-year adult enrollees with and without HCCs. Although the value for the factors change from year to year as part of the annual recalibration of the adult models, we have not made changes to the structure of the enrollment duration factors since they were first adopted for the 2017 benefit year. To develop the current enrollment duration factors for the adult models, we reviewed the annualized predicted expenditures, actual expenditures, and PRs by enrollment duration groups (for each: 1 month, 2 months, and so on up to 12 months) for our risk adjustment concurrent modeling sample, which was made up of adults in the 2014 MarketScan® data.[83] This analysis found that actuarial risk for adult enrollees with short enrollment periods tended to be underpredicted in our methodology, and actuarial risk for adult enrollees with full enrollment periods (12 months) tended to be overpredicted. We therefore proposed and finalized in the 2018 Payment Notice that, beginning for the 2017 benefit year, the adult models would include enrollment duration factors that apply to all adults with partial-year enrollment.[84] The value for the enrollment duration factors have generally decreased since they were first introduced in the adult models for the 2017 benefit year, reflecting a reduced impact of enrollment duration on risk scores of partial year enrollees. After a slight increase between 2017 and 2018, the factors have decreased significantly from 2018 to 2021, and in some cases (the 10- and 11-month factors) the factors are now 0.000, relative to a 12-month enrollment baseline.[85]

As described in prior rulemakings and the 2021 RA Technical Paper, we have been considering potential adjustments to the enrollment duration factors and our more recent analysis of enrollee-level EDGE data found that the current adult model enrollment duration factors underpredicted plan liability for partial-year adult enrollees with HCCs and overpredicted plan liability for partial-year adult enrollees without HCCs.[86] [87] More specifically, our analysis of 2017 and 2018 enrollee-level EDGE data found that the current enrollment duration factors are driven by enrollees with HCCs.[88] That is, partial-year enrollees with HCCs had higher per member, per month (PMPM) expenditures on average as compared to full-year enrollees with HCCs, and partial-year enrollees without HCCs were not significantly different in PMPM expenditures compared to full-year enrollees without HCCs.[89]

Therefore, beginning with the 2023 benefit year, we are proposing to eliminate the current monthly enrollment duration factors of up to 11 months for all enrollees in the adult models, and replace them with new monthly enrollment duration factors of up to 6 months that would apply only to adult enrollees with HCCs. If finalized as proposed, this would mean there would be no enrollment duration factors for adult enrollees without HCCs starting with the 2023 benefit year nor would there be enrollment duration factors for adult enrollees with HCCs and more than 6 months of enrollment.

While we considered other enrollment duration factor structures, we are proposing to limit the enrollment duration factors to 6 months because we found that the monthly average cost variation by number of months enrolled is meaningfully reduced after 6 months for adult enrollees with HCCs, and enrollment duration factors beyond 6 months did not meaningfully improve

[81] See Chapter 1.4 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[82] As explained in the 2021 Payment Notice proposed rule, we found that partial year enrollees in the child models did not have the same risk differences as partial year enrollees in the adult models and they tended to have similar risk to full year enrollees in the child models. See 85 FR 7103–7104. In the infant models, we found that partial year infants had higher expenditures on average compared to their full year counterparts; however, the incorporation of enrollment duration factors created interaction issues with the current severity and maturity factors and did not have a meaningful impact on the general predictive accuracy of the infant models. Ibid. We therefore propose to continue to apply enrollment duration factors to the adult models only.

[83] See pages 35–39 of the March 2016 Risk Adjustment Methodology White Paper (March 24, 2016), available at *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.*

[84] 81 FR 94058 at 94071–94074.

[85] In unconstrained models, these factors are negative; therefore, we constrained them to zero because we do not believe negative enrollment duration factors are appropriate, as this would create inappropriate incentives. See Figure 3.1 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[86] See 85 FR 29164 at 29188–29190.; 86 FR 24140 at 24151–24162.; and the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[87] When we refer to the enrollees with and without HCCs, we are referring to enrollees without payment HCCs.

[88] See, for example, Chapters 1.4 and 3.2 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* Also see 85 FR at 7103–7104 and 85 FR at 78585–78586.

[89] See Chapter 1.4 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

prediction for the adult models. As part of our analysis of enrollment duration factor options, we also considered adoption of enrollment duration factors by market, but we did not find a meaningful distinction in relative costs between markets on average once we implemented the proposed enrollment duration factors of up to 6 months for adult enrollees with HCCs.[90] We also considered HCC-type contingent enrollment duration factors. Specifically, we found that the distribution of enrollment duration and PMPM allowed charges by enrollment duration is similar for adults with any acute HCCs versus adults with only chronic HCCs.[91] We therefore determined that, on balance, it would add unnecessary complexity to introduce enrollment duration factors by market type or that are contingent on types of HCCs with little benefit. Therefore, we are not proposing enrollment duration factors for the adult models by market type or that are contingent on types of HCCs at this time.

We also considered previous comments we received that expressed concerns that certain issuers—particularly small group market issuers, small issuers, or Medicaid issuers—may have partial-year enrollees with HCCs that are not coded. These commenters expressed concerns that these issuers may have difficulty obtaining diagnoses for these enrollees, creating cases where the issuer may pay claims, and incur costs, for services associated with a condition for the partial-year enrollee, but the issuer's limited time with the partial-year enrollee may not be adequate to capture the diagnosis code associated with the HCC.[92] [93] In response to the 2021 RA Technical Paper, we got further comment from stakeholders who questioned whether the HCC-contingent enrollment duration factors would have negative impacts on small group market issuers that offer non-calendar year coverage and take on new business later in the year. As we noted in the 2021 RA Technical Paper, our analysis did not find evidence that issuers are unable to capture cost-meaningful HCCs for partial-year enrollees in the individual or small group (including merged) market.[94]

We solicit comments on the proposed changes to the enrollment duration factors for the adult models. We also solicit comments regarding whether we should implement the proposed changes to enrollment duration factors alone, independent of the other proposed model specification changes outlined in this rule, beginning with the 2023 benefit year; whether we should implement the proposed changes to enrollment duration factors in conjunction with these other proposals; or whether we should not implement the proposed changes to enrollment duration factors at all and maintain the current structure for these factors.

iv. Combined Impact of the Proposed Model Changes

In sum, we are proposing to modify the HHS risk adjustment model specifications for the adult and child models beginning with the 2023 benefit year by combining a two-stage weighted approach with the removal of the current adult model severe illness interaction factors and the addition of new severe illness and transplant interacted HCC count factors to the adult and child models. We are also proposing to replace the current enrollment duration factors in the adult models. For the two-stage weighted approach, we propose calibrating the adult and child models in two stages. The first stage of the weighted estimation method would involve a linear regression of simulated plan liability on age-sex factors and payment HCC factors for the adult and child models, with the addition of RXCs and the new proposed enrollment duration factors for the adult models. The second stage would use the reciprocal of prediction from the first step to weight a second stage linear regression. To stabilize the weights from the first stage predictions, we propose lower and upper bound caps on the predictions used as weights at the 2.5th and 97.5th percentiles in the adult models and the 2.5th and 99.5th percentiles in the child models. This two-stage weighted approach would be combined with the new severity and transplant indicators from the interacted HCC count factors. For the severity indicator group, we propose to add separate count factors for one to 10+ payment HCCs (1, 2, . . . , 10+) for the adult models and one to 5, 6 or 7, and 8+ payment HCCs (1, 2, . . . 5, 6 or 7, 8+) for the child models. The proposed HCCs that would flag the severity indicator are listed in Table 3. For the transplant HCCs, we propose to incorporate factors for 4 to 8+ payment HCCs (4, 5, 6, 7, 8+) for the adult models and one factor for 4+ payment HCCs for the child models. The proposed HCCs that would flag the transplant indicator are listed in Table 3. The severity- (and transplant-) HCC-count-interaction factors would be included in both stages of the regressions. We propose to incorporate the two-stage weighted approach and the interacted HCC count specification updates beginning with the 2023 benefit year HHS risk adjustment adult and child models. We also propose to remove the current severity illness factors in the adult models beginning with the 2023 benefit year. Lastly, we propose to remove the current 11 enrollment duration factors for all enrollees in the adult models and replace them with new monthly enrollment duration factors of up to 6 months that only apply to enrollees with HCCs. We propose to incorporate the new HCC-contingent enrollment duration factors beginning with the 2023 benefit year adult models.

We tested combining these model specifications into an approach that incorporated the two-stage weighted approach, the severity and transplant factors interacted with HCC count factors, and the HCC-contingent enrollment duration factors. We found that, together, these changes are expected to improve model performance in comparison to the current models. Our analysis found this combined approach generally improved prediction for enrollees at both the low and high ends of expected expenditures and had higher R-squared statistics across metal levels than the current models, indicating a better individual-level fit.[95] Our analysis also found general improvement in PRs for the models with the combined proposed model specification changes across each decile of predicted plan liability, by age-sex factor for adult enrollees with and without HCCs, and by enrollment

[90] See Chapter 3.3.2 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[91] See Chapter 3.3.3 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[92] See Chapter 3.4 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[93] This issue differs from situations where issuers may not have a complete diagnostic profile for a partial-year enrollee because the services received were not related to the diagnoses that were not captured. For example, if an enrollee received services due to a condition while enrolled with a different issuer, then the current issuer may not have all diagnosis codes for a partial-year enrollee. However, such cases do not have cost implications for the current issuer since the partial-year enrollee received no services associated with that diagnosis.

[94] See Chapter 3.4 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[95] See Chapter 5.1 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

length.[96] We also found that the mean absolute error did not materially differ between the current adult and child models and the proposed adult and child models with the combined proposed model specification changes incorporated.[97] These observations support our belief that the best way to comprehensively improve the predictive accuracy of the current models across the risk spectrum is to implement all three proposed model specification changes together. To further assist issuers and other stakeholders with analyzing the impact of the combination of these proposed model specification changes, HHS also conducted a transfer simulation and provided summary-level and issuer-specific risk score and transfer estimates.[98] [99]

As detailed in the 2021 RA Technical Paper, this transfer simulation applied the proposed model specification changes to 2020 benefit year EDGE data to illustrate and estimate what 2020 benefit year risk adjustment transfers would have been if the combined model specification changes were applied.[100] The transfer simulation provided issuers with detailed, plan-level simulated results.[101] The coefficients values presented in Tables 1 and 2 incorporate the combination of these proposed model specification changes and Table 3 provides the list of the proposed severity and transplant HCCs that would apply for the proposed interacted HCC counts factors. We seek comment on the combination of these proposed model changes and the adoption of these changes beginning with the 2023 benefit year.

We seek comment on finalizing each of these proposed model specification changes as a whole, in part, or in combination or for example, whether we should finalize the proposed interaction HCC counts model specification and the proposed changes to the adult model enrollment duration factors without the proposed two stage weighted model specification. Finally, we seek comment on finalizing the 2023 models without the proposed model specification changes, but with updates to the data years used for recalibration, (that is, to use 2017, 2018, and 2019 enrollee-level EDGE data, as detailed elsewhere in this proposed rule); or, alternatively, using the updated final 2022 risk adjustment model coefficients [102] for the 2023 benefit year risk adjustment models, trended forward to project 2023 costs or not trended forward to project 2023 costs.

c. Pricing Adjustment for the Hepatitis C Drugs

For the 2023 benefit year, we propose to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models.[103] Since the 2020 benefit year risk adjustment models, we have been making a market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the models.[104] This market pricing adjustment has been necessary to account for the significant pricing changes associated with the introduction of new and generic Hepatitis C drugs between the data years used for recalibrating the models and the applicable recalibration benefit year. We also continue to be cognizant that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim, and therefore, make the transfer results more favorable for the issuer. We have committed to reassessing this pricing adjustment with additional years of enrollee-level EDGE data, as data become available. As part of the 2023 benefit year model recalibration, we reassessed the Hepatitis C RXC using available enrollee-level EDGE data (including 2019 benefit year data) to consider whether the adjustment was still needed and if it is still needed, whether it should be modified. We found that the data for the Hepatitis C RXC that would be used for the 2023 benefit year recalibration (that is, the 2017, 2018, and 2019 enrollee-level EDGE data) still do not account for the significant pricing changes due to the introduction of new Hepatitis C drugs and, therefore, do not precisely reflect the average cost of Hepatitis C treatments applicable to the benefit year in question.

Specifically, we are proposing to recalibrate the 2023 benefit year risk adjustment models with the 2017, 2018, and 2019 enrollee-level EDGE data. Generic Hepatitis C drugs did not become available on the market until 2019.[105] Due to the lag between the data years used to recalibrate the risk adjustment models and the applicable benefit year of risk adjustment, we do not believe that the data used for recalibrating the models precisely reflect the average cost of Hepatitis C treatments expected in the 2023 benefit year. Therefore, we continue to believe a market pricing adjustment for the 2023 benefit year is necessary to account for the significant pricing changes associated with the introduction of new and generic Hepatitis C drugs between the data years used for recalibrating the models and the applicable recalibration benefit year. We intend to continue to assess this pricing adjustment in future benefit year recalibrations using additional years of enrollee-level EDGE data. We seek comment on our proposal to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs for the 2023 benefit year.

d. Risk Adjustment RXC Mapping for Recalibration

i. Inclusion and Exclusion Criteria for Drugs in RXC Mapping and Recalibration

This section provides an overview of the inclusion and exclusion criteria HHS uses to identify drugs for mapping to RXCs in the adult risk adjustment models, reviews what version of the RXC mapping document HHS uses when processing the enrollee-level EDGE data for a benefit year for recalibration of the adult risk adjustment models, and outlines the criteria that warrant consideration for changes to the incorporation (or

[96] Ibid.

[97] Ibid.

[98] See the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* See also the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.* Issuers that participated in the simulation also received detailed issuer-specific data, including risk score and transfer estimates for the simulated results.

[99] If an issuer wishes to use the simulation results to assist in assessing the impact of these model specification changes on future benefit year transfer amounts, it should do so with caution and in combination with other significant data.

[100] See Chapter 5.2 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[101] See the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.*

[102] See ''Final 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients.'' May 12, 2020. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.*

[103] See, for example, 84 FR 17463 through 17466.

[104] The Hepatitis C drugs market pricing adjustment to plan liability is applied for all enrollees taking Hepatitis C drugs in the data used for recalibration.

[105] See *https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv.* See also *https://news.abbvie.com/news/abbvie-receives-us-fda-approval-mavyret-glecaprevirpibrentasvir-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm.*

exclusion) of particular drugs from the RXC mappings in future benefit year recalibrations. We also propose a change to the approach for identifying the version of the RXC mapping document HHS would use to process a given benefit year's enrollee-level EDGE data for recalibration of the adult risk adjustment models.

In accordance with § 153.320, HHS develops and publishes the risk adjustment methodology applicable in states where HHS operates the program, including the draft factors to be employed in the models for the benefit year. This includes the annual recalibration of the adult risk adjustment models' RXC coefficients using data from the applicable prior benefit years trended forwarded to reflect the applicable benefit year of risk adjustment. Drugs that appear on claims data, either through National Drug Codes (NDCs) or Healthcare Common Procedural Coding System (HCPCS), are cross walked to RxNorm Concept Unique Identifiers (RXCUIs).[106] RXCUI mappings are always matched to the NDCs and HCPCS applicable to the particular EDGE data year as the NDC and HCPCS reflect the drugs that were available in the market during the benefit year.[107] Currently, we use the most recent RXC mappings (RXCUIs that map to RXCs) that are available when we first process the enrollee-level EDGE data for a benefit year for recalibration of the adult risk adjustment models. For example, for the 2022 benefit year, we recalibrated the adult risk adjustment models using 2016, 2017, and 2018 enrollee-level EDGE data and applied the second quarter (Q2) 2018 RXC mapping document for both 2016 and 2017,[108] and applied the Q2 2019 mapping document for 2018 for recalibration of the adult risk adjustment models RXC factors.[109]

As noted in the 2022 Payment Notice, we also continuously assess the availability of drugs in the market and the associated mapping of those drugs to RXCs in the adult risk adjustment models.[110] More specifically, during a benefit year, HHS conducts quarterly reviews of RXCUIs that map to RXCs in the adult risk adjustment models for that benefit year. During our annual review of enrollee-level EDGE data for recalibration purposes, and to a certain extent during quarterly reviews of RXCUIs that map to RXCs in the adult risk adjustment models, HHS evaluates the inclusion and exclusion of RXCUIs based on criteria such as: (1) Whether costs for an individual drug are comparable to the costs of other drugs in the same class, (2) whether a drug is a good predictor of the presence of the diseases that map to the HCCs that an RXC indicates (which can be evaluated through clinical expert review in the absence of data), (3) whether clinical expert reviews of the pharmacological properties and prescribing patterns are consistent with treatment of a particular condition, and (4) stakeholder feedback.[111] As a result of this on-going assessment, we may make quarterly updates to the RXC Crosswalk, which identifies the list of NDCs and HCPCS indicating the presence of an RXC in the current benefit year DIY and EDGE reference data, to ensure drugs are mapped to RXCs, where appropriate. This can include the addition or removal of drugs based on market availability and the other criteria identified above. As such, the risk adjustment mapping of RXCUIs to RXCs, along with the list of NDCs and HCPCS that crosswalk to each RXCUI, may be updated throughout a particular benefit year of risk adjustment. HHS provides information to issuers on these updates through the DIY software, which is published on the CCIIO website,[112] as well as through the EDGE global reference updates, which are published on the Distributed Data Collection program page on the Registration for Technical Assistance Portal (REGTAP).[113]

This ongoing updating process occurs on a different timeline than the annual model recalibration activities for a given benefit year.

In this rule, we propose to change the approach for identifying the version of the RXC mapping document HHS would use to process a given benefit year's enrollee-level EDGE data for the annual recalibration of the adult risk adjustment models. More specifically, we propose to recalibrate the adult risk adjustment models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the applicable benefit year's model recalibration, while continuing to engage in annual and quarterly review processes using the inclusion and exclusion criteria described above. For example, if we recalibrate the 2024 benefit year adult risk adjustment models using 2018, 2019, and 2020 benefit years of enrollee-level EDGE data, we would use the Q4 RXC mapping document for each of those benefit years (that is, Q4 2018, Q4 2019, and Q4 2020, respectively) for recalibration purposes. We would also use the criteria described above to evaluate the inclusion and exclusion of RXCUIs and may make other updates to the 2024 benefit year RXC Crosswalk to ensure drugs are mapped to RXCs, where appropriate.

We propose to begin to use this approach for recalibration of the 2023 adult risk adjustment models with the exception of the 2017 enrollee-level EDGE data year, for which we propose to use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018). We propose to use the applicable benefit year's Q4 RXC mapping documents for both the 2018 and 2019 benefit years of enrollee-level EDGE data for the recalibration of the adult risk adjustment models for the 2023 benefit year. Under this proposal, we would hold those mappings constant when using the 2018 and 2019 enrollee level EDGE data years in future benefit year model recalibrations—meaning that we would use the applicable benefit year's Q4 RXC mapping documents when the 2018 or 2019 benefit year of enrollee-level EDGE data is used for future benefit year model recalibrations.[114]

[106] See, for example, 81 FR at 94074–94080.

[107] See, for example, Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk Memorandum at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf*.

[108] RXCs were not added to the risk adjustment models until 2018 benefit year; therefore, we used 2018 RXC mappings for both 2016 and 2017 enrollee-level EDGE data as there were no 2016 and 2017 RXC mapping documents. Note that, even though 2018 RXC mappings were applied to these earlier years, they were cross walked to the NDCs and HCPCS that describe the applicable drugs during those earlier years.

[109] Although the recalibration proposals are typically released towards the end of the calendar year, we generally receive the prior benefit year enrollee-level EDGE data in the summer or fall, at which point we apply the most recently available mapping document as we begin to prepare the data to recalibrate the models for the applicable benefit year. This is why, for example, we used the 2019 Q2 mapping document when processing the 2018 enrollee-level EDGE data for recalibration of the 2022 benefit year adult models.

[110] See 86 FR at 26164.

[111] See, for example, the Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk (September 17, 2017), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf*.

[112] The August 3, 2021 version of the DIY software is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance*.

[113] Available at *https://www.regtap.info/reg_library.php?libfilter_topic=3*.

[114] Consistent with the approach finalized in the 2022 Payment Notice, the 2018 and 2019 enrollee-level EDGE data would be used for the recalibration

The purpose of maintaining a specific version of the same RXC mapping document for future recalibrations under this proposal is to limit the volatility of some coefficients from year-to-year and to ensure that we are capturing the utilization and costs observed for the underlying drugs in use in that year for the condition. Because the final DIY software update contains the Q4 list, this approach would also have the added benefit of providing issuers the opportunity to see the mappings/crosswalk that will be applied to that data year in the final DIY software release before it is used for recalibration.

For purposes of the 2023 benefit year recalibration, we are proposing an exception for the 2017 benefit year enrollee-level EDGE data and would instead use the most recent RXC mapping document that was available when we first processed the benefit year's enrollee-level EDGE data for recalibration purposes (that is, Q2 2018). We are proposing this approach for the 2017 benefit year enrollee-level EDGE data because we did not include RXCs in the adult risk adjustment models until 2018 [115] and therefore, we do not have a Q4 RXC mapping for the 2017 benefit year. Thus, we propose to use the Q2 2018 RXC mapping document for the 2017 benefit year enrollee-level EDGE data year for 2023 model recalibration, consistent with the mapping used for processing the 2017 data for recalibration of the 2021 and 2022 adult models. We seek comment on this proposal to change the approach for identifying the version of the RXC mapping document that would be used to process a given benefit year's data for the annual recalibration of the adult models, as well as the proposed applicability beginning with the 2023 benefit year model recalibration and the proposed exception for the mapping document for the 2017 benefit year enrollee-level EDGE data.

Alternatively, we seek comment on whether we should take a different approach to recalibration of the RXC mappings for the adult risk adjustment models. Under this alternative, we would use the latest RXC mapping document available at the time that we recalibrate the adult risk adjustment models and apply it to all three underlying EDGE data years used to recalibrate the models for the benefit year. This alternative is in contrast to the current approach of using the most recent RXC mappings (RXCUIs that map to RXCs) that are available when we *first process* the enrollee-level EDGE data for recalibration of the applicable benefit year's adult models and the above proposed approach to use the final Q4 RXC mappings that was applicable for each benefit year of data included in the applicable benefit year's model recalibration. More specifically, under this alternative approach, we would instead use the most recent RXCUI to RXC mapping document available at the time of developing a benefit year's proposed model factors for publication in the applicable benefit year's Payment Notice. As the recalibration process typically begins several months prior to the proposed Payment Notice being released, the most recently available RXCUI to RXC mapping document available at the time of developing a benefit year's proposed model factors would generally be either the Q4 mapping from the prior benefit year (for 2023 benefit year (BY) model recalibration that would have been the Q4 mapping for BY 2020), or the Q1 or Q2 mapping document from the year in which recalibration is occurring (for 2023 benefit year model recalibration that would have been the Q1 or Q2 mapping for BY 2021). Under this approach, the RXCUI to RXC mappings applied to the underlying data years used in model recalibration would be updated each year of model recalibration to reflect the most recently available decisions in the quarterly mapping document about which RXCUIs map to RXCs in the adult models. While this approach would represent what is most likely to map to the RXCs in the upcoming benefit year of risk adjustment, the RXC mapping document used would still lag behind what the RXC mapping document will be in the applicable benefit year due to the inherent time lag between when recalibration occurs for a benefit year and the actual benefit year.[116] Also, while we believe that the impact will likely be minimal, this approach to remapping the RXCs every year may contribute to volatility of some coefficients, as the RXC mappings for the underlying data years would be updated each year during the annual model recalibration. Another drawback of this approach is that the most recent RXC mappings will be reflective of similarly recent costs, clinical relevancies, and prescribing patterns. If changes to any of these have occurred between an earlier data year and the most recent year, RXC mappings reflecting the latter will generally be applied to the former.[117] We seek comment on all aspects of this alternative approach.

ii. Targeted Changes to RXC Mappings for Recalibration

Regardless of the version of the RXC mapping document we use during the annual adult risk adjustment model recalibration, there may be a relatively small number of drugs that still require additional analysis and consideration given the changes that can occur in the market between the data year and the applicable benefit year of risk adjustment. The targeted changes to particular drugs' mappings would typically occur when performing recalibration for future benefit years. Based on our experience since the incorporation of RXCs into risk adjustment models in the 2018 benefit year, we do not believe that the removal or addition of an RXCUI from the RXC mappings (and the associated removal of the NDCs and HCPCS associated with that RXCUI) are typically material to recalibration because most drug removals are not associated with utilization and cost levels that would have a meaningful impact on model coefficients.[118] However, in extenuating circumstances where HHS believes there will be a significant impact from a change in an RXCUI to RXC mapping, such as: (1) Evidence of significant off-label prescribing (as was the case with hydroxychloroquine sulfate [119]); (2) abnormally large changes in clinical indications or practice patterns associated with drug usage; or (3) certain situations in which the cost of a drug (or biosimilars) become much higher or lower than the typical cost of drugs in the same prescription drug category, HHS will consider whether changes to the RXCUI to RXC mapping from the applicable data year crosswalk are needed for future benefit year recalibrations. In the following sections of this proposed rule, we illustrate cases where we believe extenuating

of the 2024 benefit year models and the 2019 enrollee-level EDGE data would be used for the recalibration of the 2025 benefit year models. See, supra, note 47.

[115] See 81 FR at 94075.

[116] For example, the current recalibration activities (in calendar year 2021) relate to the 2023 benefit year risk adjustment models.

[117] As noted elsewhere in this rule, in certain circumstances, HHS may consider changes to the RXCUIs from the applicable data year crosswalk as part of future benefit year model recalibration and quarterly review processes.

[118] For example, the average effect of the removal of a single therapeutic drug ingredient in the 2019 Drug Removal Review on 2020 Q1 was an approximate decrease of 0.14% percent in total pharmacy claims spending among RXC drugs, and the average effect of the removal of a single non-hydroxychloroquine therapeutic drug ingredient in the 2020 Drug Removal Review on 2021 Q1 was an approximate decrease of 0.68 percent in total pharmacy claims spending among RXC drugs.

[119] See, for example, 86 FR at 24180.

circumstances existed and our evaluation of whether to make targeted changes to the mapping of select RXCUIs to RXCs due to those extenuating circumstances as part of the annual recalibration process for the 2023 benefit year adult models. In particular, we consider the cases of RXCUI to RXC mapping of Descovy® and hydroxychloroquine sulfate. We also note that, as discussed above, HHS may make other exception-based adjustments during the recalibration process to reflect changes in clinical practice and prescribing between recalibration and the benefit year, such as the adjustment for Hepatitis C drugs, where HHS determines it is necessary and appropriate to do so. We are not proposing changes to this approach or the criteria used for these reviews, but are sharing these examples to further promote transparency about the process for targeted changes to mapping of select RXCUI to RXCs.[120]

(a) Descovy®

Descovy® has been included in RXC 01 (Anti-HIV Agents) since RXCs were initially added to the adult risk adjustment models for the 2018 benefit year because it met the inclusion criteria of being a reliable predictor of the presence of HIV and being representative of the costs of other drugs associated with the treatment of HIV. However, in October 2019, Descovy® was approved by the Food and Drug Administration (FDA) for pre-exposure prophylaxis (PrEP).[121] As noted in the 2022 Payment Notice, HHS removed Descovy® from the Q4 2020 RXCUI to RXC mappings for consistency with the treatment of other PrEP drugs.[122] [123] The 2023 benefit year model recalibration, however, is the first benefit year recalibration that will use the 2019 benefit year enrollee-level EDGE data. HHS therefore considered removal of Descovy® from the RXC mappings applied to the 2019 benefit year enrollee-level EDGE data year. The reason for this consideration was that some enrollees in 2019 would have used Descovy® for PrEP, which would have an impact on the recalibration of the coefficients for RXC 01 (Anti-HIV Agents) and was in keeping with the previously mentioned criteria of changes in clinical indications or practice patterns associated with drug usage for further evaluation for potential exception. However, our internal analysis of available enrollee-level EDGE data indicated that most Descovy® users in 2019 were using the drug as part of active HIV treatment, rather than PrEP.[124] This, supported by the fact that Descovy® was approved for PrEP late in the calendar year of 2019, suggested that the benefits of keeping Descovy® mapped to RXC 01 (Anti-HIV Agents) outweighed the tradeoffs of removing it.[125] Similarly, the 2019 approval and subsequent change in Descovy® use that triggered its removal from the crosswalk in Q4 BY 2020 was not applicable to its use in 2017 or 2018 when it was not approved PrEP. Therefore, we are not proposing to make an exception to the RXCUI to RXC mappings to remove Descovy® from mapping to RXC 01 in 2017, 2018 and 2019 benefit year enrollee-level EDGE datasets used for the 2023 benefit year recalibration of the adult models. We further note that, regardless of the mapping approach adopted for Descovy®, enrollees in risk adjustment covered plans that use Descovy® (or other PrEP drugs) in combination with another HIV treatment drug that maps to RXC 01 would still receive credit for RXC 01 in the 2023 benefit year of risk adjustment. If we adopt the alternative mapping approach of using the latest RXC mapping document available at the time that we recalibrate adult risk adjustment models and apply it to all three underlying EDGE data years used to recalibrate the models for the benefit year, Descovy® would not map to RXC 01 and we would have to make an exception to include it in the mapping. We seek comment on whether we should make such an exception to include and map Descovy® to RXC 01 in the datasets used to recalibrate the 2023 benefit year adult models, should the alternative approach be finalized.

(b) Hydroxychloroquine Sulfate

Hydroxychloroquine sulfate was initially mapped to RXC 09 (Immune Suppressants and Immunomodulators) in the Q3 BY 2018 review because it was believed to be a reliable predictor of the presence of conditions associated with RXC 09. However, HHS removed the RXCU for hydroxychloroquine sulfate from mapping to RXC 09 (Immune Suppressants and Immunomodulators) in the Q4 BY 2020 RXC mappings because of concerns regarding unrepresentative expenditures and off-label prescribing during the COVID–19 PHE.[126] This meant that beginning with the 2020 benefit year of risk adjustment, hydroxychloroquine sulfate no longer mapped to RXC 09.

Then, in part 2 of the 2022 Payment Notice final rule, we finalized proposals for the 2022 benefit year model recalibration, including the targeted removal of hydroxychloroquine sulfate for recalibration of the adult models.[127] As we explained, our analysis of pre-2020 data showed that the cost of hydroxychloroquine sulfate drugs were much lower than the costs of other drugs taken by enrollees assigned RXC 09.[128] However, even though hydroxychloroquine sulfate was no longer mapping to the RXC 09 in the Q4 2020 DIY software, hydroxychloroquine sulfate was still mapping to RXC 09 in the 2018 enrollee-level EDGE data that would be used for the 2022 benefit year model recalibration.[129] Additionally, after hydroxychloroquine sulfate was removed from mapping to RXC 09 in the

[120] As noted above, HHS also conducts quarterly reviews of RXCUIs that map to RXCs in the adult models and may make targeted changes to RXC mappings during a benefit year as a result of these reviews. We are not proposing any changes to the quarterly update process or the criteria used for such reviews.

[121] See *https://www.fda.gov/news-events/press-announcements/fda-approves-second-drug-prevent-hiv-infection-part-ongoing-efforts-end-hiv-epidemic*.

[122] See 86 FR at 24164. Also see HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software Instructions for the 2020 Benefit Year (April 15, 2021 Update), available at *https://www.cms.gov/files/document/cy2020-diy-instructions04132021.pdf*.

[123] We further explained that enrollees that use Descovy® (or other PrEP drugs) in combination with other HIV treatment drugs would still receive credit for RXC 01. See 86 FR at 24164.

[124] Assessing the use of Descovy® for PrEP involved identifying instances of the use of Descovy® without an accompanying HIV diagnosis (as defined by the presence of HCC01) or use of any other anti-HIV agent (as defined by the use of any drug in RXC01 other than Descovy®). The reason the latter helps to identify non-PrEP Descovy® use is because Descovy® for active HIV–1 treatment is required to be co-administered with other anti-HIV agents.

[125] Consistent with the approach outlined in this rule, Descovy® was mapped to RXC 01 in the Q4 2019 RXC mapping applied to enrollee-level EDGE data that was used to develop the proposed 2023 benefit year factors for the adult models in this rule. If the alternative approach to RXC mapping is adopted, such that the Q4 2020 RXC mapping is applied for the 2023 benefit year recalibration of the adult models, Descovy® would not map to RXC 01 unless an exception is made.

[126] 85 FR at 24180. Also see the HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software Instructions for the 2020 Benefit Year, April 15, 2021 Update, available at *https://www.cms.gov/files/document/cy2020-diy-instructions04132021.pdf*.

[127] 86 FR at 24180.

[128] 86 FR at 24180.

[129] The same concern was not present for the 2016 or 2017 enrollee-level EDGE datasets used for the 2022 benefit year model recalibration because hydroxychloroquine sulfate was not mapped to RXC 09 until the Q3 2018 crosswalk.

Q4 2020 RXC mapping, stakeholders expressed concern about the impact on the coefficients for RXC 09, and associated interaction terms, of including hydroxychloroquine sulfate in RXC mapping for recalibration given that these drugs were such low-cost. After consideration of these issues, HHS determined that hydroxychloroquine sulfate met the criteria of significant off-label prescribing, changes in clinical practice patterns associated with drug usage, and the cost of the drug being much lower than the typical cost of drugs in the same prescription drug category that warrants further consideration of whether an exception is appropriate. After determining that hydroxychloroquine sulfate met those criteria and considering the feedback from stakeholders, HHS made the determination that it should be removed. Therefore, to effectuate the targeted removal of hydroxychloroquine sulfate for the recalibration of the 2022 benefit year adult risk adjustment models, we only used 2016 and 2017 enrollee-level EDGE data, where hydroxychloroquine sulfate was not mapped to RXC 09, for the limited purpose of developing the coefficients for RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions (RXC 09 × HCC056 or 057 and 048 or 041; RXC 09 × HCC056; RXC 09 × HCC057; RXC 09 × HCC048, 041).[130]

Our consideration of the targeted removal of select drugs from RXC mappings for purposes of the 2023 benefit year model recalibration similarly identified hydroxychloroquine sulfate as a drug for further consideration. It continues to meet the criteria of significant off-label prescribing, changes in clinical practice patterns associated with drug usage, and the cost of the drug being much lower than the typical cost of drugs in the same prescription drug category. However, unlike the 2022 benefit year model recalibration, the 2023 benefit year updates involve two years of enrollee-level EDGE data (2018 and 2019 data years) where the inclusion of hydroxychloroquine sulfate could impact the annual model recalibration updates to the coefficients and associated interaction terms for RXC 09. Therefore, we determined that the targeted removal of this drug from mapping to RXC 09 was again appropriate, but to effectuate the targeted removal of this drug for purposes of the 2023 benefit year recalibration of the adult models, we would adopt a different approach than 2022 risk adjustment model recalibration and would remove the RXCUI to RXC mapping in the 2018 and 2019 enrollee-level EDGE data for hydroxychloroquine sulfate to RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions (RXC 09 x HCC056 or 057 and 048 or 041; RXC 09 x HCC056; RXC 09 x HCC 057; RXC 09 x HCC048, 041). We would adopt a similar approach for any future year that uses the enrollee-level EDGE data for the 2018 and 2019 benefit years for purposes of the annual model recalibration.[131] We note that the same concern was not present for the 2017 benefit year enrollee-level EDGE data—the other benefit year of data that will be used for the 2023 benefit year model recalibration—because hydroxychloroquine was not included in the RXC crosswalk until the 2018 benefit year.

We seek comment on these proposals.

e. List of Factors To Be Employed in the Risk Adjustment Models

The proposed 2023 benefit year risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using the 2017, 2018, and 2019 enrollee-level EDGE data, including all of the model specification changes and recalibration proposals detailed above, are shown in Tables 1 through 6. The adult, child, and infant models have been truncated to account for the high-cost risk pool payment parameters by removing 60 percent of costs above the $1 million threshold.[132] Table 1 contains factor coefficients for each adult model, including the age-sex, HCCs, RXCs, RXC–HCC interactions, interacted HCC counts, and enrollment duration coefficients. Table 2 contains the factor coefficients for each child model, including the age-sex, HCCs, and interacted HCC counts coefficients. Table 3 lists the proposed HHS–HCCs that have been selected for the proposed interacted HCC counts factors that would apply to the adult and child models. Table 4 contains the factors for each infant model. Tables 5 and 6 contain the HCCs included in the infant models' maturity and severity categories, respectively.

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[130] 86 FR at 24180.

[131] Consistent with the approach finalized in the 2022 Payment Notice, the 2018 and 2019 benefit year enrollee-level EDGE datasets would continue to be used for recalibration of the 2024 benefit year models; and the 2019 benefit year enrollee-level EDGE dataset would also be used for recalibration of the 2025 benefit year models.

[132] We are not proposing changes to the high-cost risk pool parameters for the 2023 benefit year. Therefore, we would maintain the $1 million threshold and 60 percent coinsurance rate.

TABLE 1: Proposed Adult Risk Adjustment Model Factors for 2023 Benefit Year

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors						
	Age 21-24, Male	0.178	0.131	0.096	0.070	0.070
	Age 25-29, Male	0.184	0.137	0.101	0.076	0.075
	Age 30-34, Male	0.212	0.158	0.117	0.087	0.086
	Age 35-39, Male	0.242	0.181	0.134	0.098	0.097
	Age 40-44, Male	0.271	0.205	0.153	0.111	0.110
	Age 45-49, Male	0.301	0.229	0.172	0.126	0.125
	Age 50-54, Male	0.381	0.301	0.236	0.184	0.182
	Age 55-59, Male	0.433	0.344	0.272	0.214	0.212
	Age 60-64, Male	0.509	0.409	0.328	0.262	0.260
	Age 21-24, Female	0.291	0.219	0.164	0.125	0.123
	Age 25-29, Female	0.315	0.236	0.178	0.135	0.134
	Age 30-34, Female	0.367	0.280	0.212	0.161	0.159
	Age 35-39, Female	0.418	0.324	0.248	0.189	0.187
	Age 40-44, Female	0.476	0.374	0.291	0.223	0.221
	Age 45-49, Female	0.498	0.391	0.302	0.229	0.227
	Age 50-54, Female	0.554	0.445	0.351	0.275	0.272
	Age 55-59, Female	0.557	0.447	0.353	0.276	0.274
	Age 60-64, Female	0.602	0.487	0.390	0.311	0.309
Diagnosis Factors						
HCC001	HIV/AIDS	1.171	1.037	0.949	0.888	0.886
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	8.763	8.379	8.064	7.677	7.660
HCC003	Central Nervous System Infections, Except Viral Meningitis	7.668	7.366	7.042	6.580	6.558
HCC004	Viral or Unspecified Meningitis	7.586	7.267	6.914	6.411	6.388
HCC006	Opportunistic Infections	6.894	6.657	6.346	5.847	5.823
HCC008	Metastatic Cancer	23.803	23.352	23.257	23.273	23.274
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	14.250	13.933	13.836	13.798	13.797
HCC010	Non-Hodgkin Lymphomas and Other Cancers and Tumors	5.798	5.612	5.525	5.459	5.457
HCC011	Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.679	3.472	3.351	3.255	3.252
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.444	2.287	2.185	2.099	2.096
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.077	0.961	0.838	0.715	0.711
HCC018	Pancreas Transplant Status	4.972	4.824	4.603	4.209	4.187
HCC019	Diabetes with Acute Complications	0.357	0.294	0.237	0.185	0.184
HCC020	Diabetes with Chronic Complications	0.357	0.294	0.237	0.185	0.184
HCC021	Diabetes without Complication	0.357	0.294	0.237	0.185	0.184
HCC022	Type 1 Diabetes Mellitus, add-on to Diabetes HCCs 19-21	0.278	0.247	0.203	0.138	0.136
HCC023	Protein-Calorie Malnutrition	10.190	9.956	9.733	9.422	9.407
HCC026	Mucopolysaccharidosis	27.310	27.073	27.002	26.980	26.979
HCC027	Lipidoses and Glycogenosis	27.310	27.073	27.002	26.980	26.979
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	7.525	7.375	7.287	7.213	7.210

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	1.260	1.153	1.052	0.951	0.948
HCC034	Liver Transplant Status/Complications	6.981	6.706	6.358	5.888	5.861
HCC035_1 [133]	Acute Liver Failure/Disease, Including Neonatal Hepatitis	7.175	7.010	6.973	6.985	6.985
HCC035_2	Chronic Liver Failure/End-Stage Liver Disorders	2.731	2.530	2.426	2.345	2.342
HCC036	Cirrhosis of Liver	1.231	1.124	1.026	0.919	0.915
HCC037_1	Chronic Viral Hepatitis C	0.680	0.585	0.492	0.402	0.399
HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.680	0.585	0.492	0.402	0.399
HCC041	Intestine Transplant Status/Complications	19.349	19.028	18.825	18.506	18.490
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	10.418	10.050	9.776	9.429	9.413
HCC045	Intestinal Obstruction	4.639	4.411	4.317	4.249	4.248
HCC046	Chronic Pancreatitis	2.993	2.854	2.895	3.033	3.043
HCC047	Acute Pancreatitis	2.748	2.521	2.388	2.305	2.304
HCC048	Inflammatory Bowel Disease	0.778	0.677	0.568	0.445	0.440
HCC054	Necrotizing Fasciitis	9.043	8.839	8.772	8.734	8.732
HCC055	Bone/Joint/Muscle Infections/Necrosis	4.470	4.264	4.204	4.194	4.194
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	1.266	1.152	1.046	0.947	0.944
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.823	0.728	0.609	0.479	0.474
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	2.288	2.119	2.006	1.907	1.903
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	2.288	2.119	2.006	1.907	1.903
HCC063	Cleft Lip/Cleft Palate	1.555	1.416	1.311	1.217	1.215
HCC066	Hemophilia	71.880	71.564	71.483	71.476	71.476
HCC067	Myelodysplastic Syndromes and Myelofibrosis	12.239	12.101	12.041	11.997	11.994
HCC068	Aplastic Anemia	12.239	12.101	12.041	11.997	11.994
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	12.239	12.101	12.041	11.997	11.994
HCC070	Sickle Cell Anemia (Hb-SS)	2.192	2.074	1.979	1.889	1.886
HCC071	Beta Thalassemia Major	2.192	2.074	1.979	1.889	1.886
HCC073	Combined and Other Severe Immunodeficiencies	3.744	3.636	3.600	3.611	3.613
HCC074	Disorders of the Immune Mechanism	3.744	3.636	3.600	3.611	3.613
HCC075	Coagulation Defects and Other Specified Hematological Disorders	1.692	1.596	1.516	1.436	1.433
HCC081	Drug Use with Psychotic Complications	1.946	1.774	1.620	1.450	1.444
HCC082	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	1.946	1.774	1.620	1.450	1.444
HCC083	Alcohol Use with Psychotic Complications	1.151	1.023	0.908	0.796	0.792

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC084	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.151	1.023	0.908	0.796	0.792
HCC087_1	Schizophrenia	2.331	2.130	1.995	1.886	1.883
HCC087_2	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	2.223	2.035	1.898	1.771	1.768
HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	1.167	1.036	0.904	0.767	0.762
HCC090	Personality Disorders	0.771	0.658	0.524	0.382	0.377
HCC094	Anorexia/Bulimia Nervosa	1.957	1.821	1.716	1.614	1.610
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	7.189	6.981	6.684	6.181	6.153
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.071	0.981	0.892	0.785	0.778
HCC102	Autistic Disorder	0.895	0.786	0.667	0.548	0.544
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	0.771	0.658	0.524	0.382	0.377
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	9.152	8.994	8.931	8.905	8.905
HCC107	Quadriplegia	9.152	8.994	8.931	8.905	8.905
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	6.565	6.448	6.400	6.356	6.355
HCC109	Paraplegia	6.565	6.448	6.400	6.356	6.355
HCC110	Spinal Cord Disorders/Injuries	4.872	4.668	4.585	4.534	4.533
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	5.292	5.066	4.914	4.779	4.774
HCC112	Quadriplegic Cerebral Palsy	2.348	2.184	2.084	1.996	1.992
HCC113	Cerebral Palsy, Except Quadriplegic	0.826	0.739	0.656	0.570	0.567
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.471	1.347	1.236	1.129	1.125
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	4.849	4.761	4.732	4.703	4.700
HCC117	Muscular Dystrophy	1.659	1.531	1.411	1.280	1.275
HCC118	Multiple Sclerosis	2.305	2.156	2.045	1.937	1.933
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	1.659	1.531	1.411	1.280	1.275
HCC120	Seizure Disorders and Convulsions	1.207	1.083	0.971	0.860	0.856
HCC121	Hydrocephalus	8.794	8.572	8.329	7.970	7.954
HCC122	Coma, Brain Compression/Anoxic Damage	9.137	8.866	8.603	8.235	8.218
HCC123	Narcolepsy and Cataplexy	5.885	5.703	5.583	5.478	5.474
HCC125	Respirator Dependence/Tracheostomy Status	19.391	19.095	18.890	18.665	18.655
HCC126	Respiratory Arrest	8.094	7.750	7.451	7.070	7.053
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	8.094	7.750	7.451	7.070	7.053
HCC128	Heart Assistive Device/Artificial Heart	18.956	18.635	18.352	17.977	17.961

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC129	Heart Transplant Status/Complications	18.956	18.635	18.352	17.977	17.961
HCC130	Heart Failure	1.946	1.836	1.762	1.694	1.693
HCC131	Acute Myocardial Infarction	5.518	5.227	5.150	5.147	5.147
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	4.282	4.015	3.907	3.849	3.849
HCC135	Heart Infection/Inflammation, Except Rheumatic	7.915	7.652	7.325	6.837	6.815
HCC137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	1.730	1.625	1.530	1.440	1.438
HCC138	Major Congenital Heart/Circulatory Disorders	1.730	1.625	1.530	1.440	1.438
HCC139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	1.730	1.625	1.530	1.440	1.438
HCC142	Specified Heart Arrhythmias	1.721	1.591	1.481	1.365	1.368
HCC145	Intracranial Hemorrhage	10.077	9.762	9.496	9.152	9.136
HCC146	Ischemic or Unspecified Stroke	1.547	1.406	1.307	1.214	1.212
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	2.342	2.190	2.084	1.982	1.979
HCC150	Hemiplegia/Hemiparesis	3.111	2.980	2.948	2.949	2.949
HCC151	Monoplegia, Other Paralytic Syndromes	2.198	2.068	1.979	1.888	1.885
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	7.661	7.504	7.481	7.487	7.487
HCC154	Vascular Disease with Complications	5.122	4.991	4.954	4.937	4.938
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	6.904	6.608	6.237	5.677	5.650
HCC158	Lung Transplant Status/Complications	11.241	10.954	10.742	10.479	10.464
HCC159	Cystic Fibrosis	4.913	4.768	4.705	4.655	4.654
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.779	0.680	0.571	0.459	0.455
HCC161_1	Severe Asthma	0.779	0.680	0.571	0.459	0.455
HCC161_2	Asthma, Except Severe	0.779	0.680	0.571	0.459	0.455
HCC162	Fibrosis of Lung and Other Lung Disorders	1.692	1.571	1.469	1.364	1.361
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	6.292	6.048	5.729	5.238	5.213
HCC174	Exudative Macular Degeneration	1.386	1.237	1.096	0.948	0.944
HCC183	Kidney Transplant Status/Complications	6.706	6.492	6.310	5.891	5.861
HCC184	End Stage Renal Disease	21.049	20.604	20.584	20.575	20.577
HCC187	Chronic Kidney Disease, Stage 5	0.988	0.901	0.842	0.783	0.780
HCC188	Chronic Kidney Disease, Severe (Stage 4)	0.988	0.901	0.842	0.783	0.780
HCC203	Ectopic and Molar Pregnancy	2.154	1.940	1.722	1.472	1.464
HCC204	Miscarriage with Complications	0.908	0.798	0.641	0.433	0.424
HCC205	Miscarriage with No or Minor Complications	0.908	0.798	0.641	0.433	0.424
HCC207	Pregnancy with Delivery with Major Complications	3.918	3.614	3.339	3.041	3.036
HCC208	Pregnancy with Delivery with Complications	3.918	3.614	3.339	3.041	3.036

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC209	Pregnancy with Delivery with No or Minor Complications	2.796	2.577	2.305	1.925	1.913
HCC210	(Ongoing) Pregnancy without Delivery with Major Complications	1.221	1.081	0.900	0.691	0.683
HCC211	(Ongoing) Pregnancy without Delivery with Complications	0.893	0.779	0.623	0.462	0.456
HCC212	(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.334	0.265	0.179	0.113	0.111
HCC217	Chronic Ulcer of Skin, Except Pressure	1.471	1.348	1.257	1.172	1.169
HCC218	Extensive Third -Degree Burns	21.774	21.387	21.092	20.726	20.709
HCC219	Major Skin Burn or Condition	2.417	2.278	2.184	2.106	2.103
HCC223	Severe Head Injury	16.806	16.566	16.369	16.139	16.129
HCC226	Hip and Pelvic Fractures	7.986	7.739	7.691	7.688	7.689
HCC228	Vertebral Fractures without Spinal Cord Injury	4.055	3.873	3.763	3.662	3.659
HCC234	Traumatic Amputations and Amputation Complications	4.788	4.611	4.554	4.529	4.528
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	20.991	20.797	20.488	20.005	19.981
HCC253	Artificial Openings for Feeding or Elimination	5.803	5.684	5.657	5.654	5.654
HCC254	Amputation Status, Upper Limb or Lower Limb	1.685	1.522	1.403	1.302	1.299
Interacted HCC Counts Factors						
	Severe illness, 1 payment HCC	-4.972	-4.824	-4.603	-4.209	-4.187
	Severe illness, 2 payment HCCs	-4.958	-4.824	-4.594	-4.209	-4.187
	Severe illness, 3 payment HCCs	-3.796	-3.665	-3.329	-2.788	-2.763
	Severe illness, 4 payment HCCs	-2.837	-2.627	-2.160	-1.445	-1.413
	Severe illness, 5 payment HCCs	-2.036	-1.708	-1.094	-0.196	-0.157
	Severe illness, 6 payment HCCs	-1.576	-1.091	-0.319	0.768	0.814
	Severe illness, 7 payment HCCs	-0.606	0.108	1.082	2.407	2.463
	Severe illness, 8 payment HCCs	-0.399	0.377	1.415	2.829	2.889
	Severe illness, 9 payment HCCs	1.675	2.727	3.986	5.656	5.726
	Severe illness, 10 or more payment HCCs	10.392	12.008	13.694	15.874	15.966
	Transplant severe illness, 4 payment HCCs	3.563	3.539	3.534	3.560	3.567
	Transplant severe illness, 5 payment HCCs	6.997	6.977	6.968	7.011	7.018
	Transplant severe illness, 6 payment HCCs	13.244	13.242	13.276	13.385	13.396
	Transplant severe illness, 7 payment HCCs	18.237	18.225	18.266	18.387	18.397
	Transplant severe illness, 8 or more payment HCCs	33.690	33.890	34.117	34.474	34.495
Enrollment Duration Factors						
	Enrolled for 1 month, at least one payment HCC	9.276	7.861	6.698	5.524	5.483
	Enrolled for 2 months, at least one payment HCC	3.425	2.687	2.120	1.647	1.631
	Enrolled for 3 months, at least one payment HCC	1.925	1.475	1.118	0.838	0.829
	Enrolled for 4 months, at least one payment HCC	1.039	0.747	0.506	0.327	0.321

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Enrolled for 5 months, at least one payment HCC	0.693	0.485	0.310	0.173	0.169
	Enrolled for 6 months, at least one payment HCC	0.454	0.304	0.172	0.075	0.071
Prescription Drug Factors						
RXC 01	Anti-HIV Agents	8.084	7.444	7.084	6.752	6.745
RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	7.280	6.771	6.640	6.685	6.689
RXC 03[134]	Antiarrhythmics	0.103	0.094	0.086	0.063	0.039
RXC 04	Phosphate Binders	1.491	1.608	1.568	1.643	1.631
RXC 05	Inflammatory Bowel Disease Agents	1.553	1.314	1.127	0.879	0.870
RXC 06	Insulin	1.196	0.976	0.736	0.496	0.487
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.725	0.618	0.502	0.384	0.380
RXC 08	Multiple Sclerosis Agents	22.757	21.749	21.373	21.176	21.176
RXC 09[135]	Immune Suppressants and Immunomodulators	16.519	15.829	15.703	15.737	15.740
RXC 10	Cystic Fibrosis Agents	16.556	16.178	16.118	16.167	16.171
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 and HCC 001	2.676	2.811	3.123	3.539	3.550
RXC 02 x HCC037_1 , 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.680	-0.585	-0.492	-0.402	-0.399
RXC03xHCC142	Additional effect for enrollees with RXC 03 and HCC 142	0.000	0.000	0.000	0.000	0.000
RXC04xHCC184, 183, 187, 188	Additional effect for enrollees with RXC 04 and (HCC 184 or 183 or 187 or 188)	0.000	0.000	0.000	0.000	0.000
RXC05xHCC048, 041	Additional effect for enrollees with RXC 05 and (HCC 048 or 041)	-0.644	-0.458	-0.379	-0.300	-0.297
RXC06xHCC018, 019, 020, 021	Additional effect for enrollees with RXC 06 and (HCC 018 or 019 or 020 or 021)	0.647	0.718	0.814	0.878	0.881
RXC07xHCC018, 019, 020, 021	Additional effect for enrollees with RXC 07 and (HCC 018 or 019 or 020 or 021)	-0.180	-0.128	-0.096	-0.106	-0.106
RXC08xHCC118	Additional effect for enrollees with RXC 08 and HCC 118	0.015	0.510	0.888	1.249	1.257

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC09xHCC056 or 057and048 or 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041) and (HCC 056 or 057)	0.884	0.776	0.832	0.877	0.878
RXC09xHCC056	Additional effect for enrollees with RXC 09 and HCC 056	-1.266	-1.152	-1.046	-0.947	-0.944
RXC09xHCC057	Additional effect for enrollees with RXC 09 and HCC 057	-0.823	-0.728	-0.609	-0.479	-0.474
RXC09xHCC048, 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041)	0.431	0.774	0.884	1.018	1.023
RXC10xHCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	49.790	49.773	49.829	49.924	49.926

TABLE 2: Proposed Child Risk Adjustment Model Factors for 2023 Benefit Year

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2-4, Male	0.273	0.202	0.153	0.116	0.115
Age 5-9, Male	0.192	0.133	0.095	0.068	0.067
Age 10-14, Male	0.224	0.163	0.120	0.094	0.093
Age 15-20, Male	0.267	0.202	0.152	0.118	0.117
Age 2-4, Female	0.225	0.163	0.126	0.100	0.099
Age 5-9, Female	0.166	0.111	0.081	0.060	0.059
Age 10-14, Female	0.212	0.154	0.116	0.091	0.091
Age 15-20, Female	0.337	0.257	0.195	0.149	0.148
Diagnosis Factors					
HIV/AIDS	6.429	5.960	5.765	5.649	5.647
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	14.096	13.866	13.726	13.622	13.621
Central Nervous System Infections, Except Viral Meningitis	13.094	12.934	12.866	12.837	12.837
Viral or Unspecified Meningitis	11.331	11.241	11.109	10.995	10.994
Opportunistic Infections	15.156	15.121	15.054	14.969	14.965
Metastatic Cancer	31.899	31.609	31.506	31.464	31.463
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	8.432	8.188	8.073	7.991	7.988
Non-Hodgkin Lymphomas and Other Cancers and Tumors	6.783	6.561	6.434	6.329	6.326
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.961	3.790	3.658	3.530	3.525
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.961	3.790	3.658	3.530	3.525
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.014	0.878	0.759	0.617	0.613
Pancreas Transplant Status	14.250	14.144	14.055	13.989	13.985
Diabetes with Acute Complications	2.502	2.226	1.938	1.636	1.628
Diabetes with Chronic Complications	2.502	2.226	1.938	1.636	1.628
Diabetes without Complication	2.502	2.226	1.938	1.636	1.628
Protein-Calorie Malnutrition	17.721	17.613	17.580	17.574	17.573
Mucopolysaccharidosis	38.371	38.095	38.005	37.967	37.966

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Lipidoses and Glycogenosis	38.371	38.095	38.005	37.967	37.966
Congenital Metabolic Disorders, Not Elsewhere Classified	5.598	5.463	5.374	5.298	5.295
Amyloidosis, Porphyria, and Other Metabolic Disorders	5.598	5.463	5.374	5.298	5.295
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.772	6.502	6.396	6.346	6.345
Liver Transplant Status/Complications	14.250	14.144	14.055	13.989	13.985
Acute Liver Failure/Disease, Including Neonatal Hepatitis	10.018	9.833	9.778	9.776	9.775
Chronic Liver Failure/End-Stage Liver Disorders	9.546	9.360	9.278	9.240	9.239
Cirrhosis of Liver	2.657	2.549	2.455	2.373	2.374
Chronic Viral Hepatitis C	1.774	1.629	1.541	1.506	1.506
Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.693	0.589	0.484	0.385	0.383
Intestine Transplant Status/Complications	13.918	13.773	13.667	13.578	13.576
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	17.163	16.863	16.788	16.799	16.801
Intestinal Obstruction	3.430	3.214	3.061	2.912	2.907
Chronic Pancreatitis	11.310	11.100	11.034	11.016	11.017
Acute Pancreatitis	4.408	4.138	3.969	3.820	3.816
Inflammatory Bowel Disease	10.270	9.855	9.687	9.584	9.581
Necrotizing Fasciitis	3.164	2.937	2.798	2.693	2.690
Bone/Joint/Muscle Infections/Necrosis	3.164	2.937	2.798	2.693	2.690
Rheumatoid Arthritis and Specified Autoimmune Disorders	5.297	5.022	4.885	4.795	4.793
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.300	1.170	1.038	0.911	0.906
Osteogenesis Imperfecta and Other Osteodystrophies	1.188	1.076	0.989	0.952	0.950
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.188	1.076	0.989	0.952	0.950
Cleft Lip/Cleft Palate	1.348	1.157	0.959	0.771	0.765
Hemophilia	72.572	72.060	71.904	71.853	71.853
Myelodysplastic Syndromes and Myelofibrosis	12.112	11.943	11.864	11.812	11.811
Aplastic Anemia	12.112	11.943	11.864	11.812	11.811
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	12.112	11.943	11.864	11.812	11.811
Sickle Cell Anemia (Hb-SS)	4.650	4.438	4.306	4.201	4.197
Beta Thalassemia Major	4.650	4.438	4.306	4.201	4.197
Combined and Other Severe Immunodeficiencies	4.084	3.920	3.820	3.728	3.724
Disorders of the Immune Mechanism	4.084	3.920	3.820	3.728	3.724
Coagulation Defects and Other Specified Hematological Disorders	3.254	3.117	3.002	2.895	2.892
Drug Use with Psychotic Complications	2.069	1.882	1.730	1.578	1.573
Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	2.069	1.882	1.730	1.578	1.573
Alcohol Use with Psychotic Complications	1.256	1.112	0.971	0.815	0.810
Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.256	1.112	0.971	0.815	0.810
Schizophrenia	4.160	3.861	3.673	3.518	3.514
Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	3.217	2.957	2.762	2.574	2.569

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Major Depressive Disorder, Severe, and Bipolar Disorders	2.404	2.188	1.999	1.813	1.807
Personality Disorders	0.506	0.411	0.304	0.219	0.218
Anorexia/Bulimia Nervosa	2.260	2.088	1.960	1.844	1.840
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	11.538	11.458	11.385	11.331	11.329
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.541	1.388	1.245	1.096	1.089
Autistic Disorder	2.404	2.188	1.999	1.813	1.807
Pervasive Developmental Disorders, Except Autistic Disorder	0.506	0.411	0.304	0.219	0.218
Traumatic Complete Lesion Cervical Spinal Cord	9.534	9.288	9.170	9.099	9.098
Quadriplegia	9.534	9.288	9.170	9.099	9.098
Traumatic Complete Lesion Dorsal Spinal Cord	8.988	8.747	8.655	8.602	8.601
Paraplegia	8.988	8.747	8.655	8.602	8.601
Spinal Cord Disorders/Injuries	3.486	3.281	3.131	2.982	2.975
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	48.007	47.749	47.629	47.534	47.531
Quadriplegic Cerebral Palsy	3.118	2.961	2.881	2.822	2.821
Cerebral Palsy, Except Quadriplegic	1.411	1.269	1.123	0.968	0.962
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.616	1.469	1.357	1.248	1.244
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	9.977	9.787	9.721	9.697	9.697
Muscular Dystrophy	5.687	5.505	5.380	5.258	5.254
Multiple Sclerosis	12.134	11.693	11.573	11.551	11.552
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	5.687	5.505	5.380	5.258	5.254
Seizure Disorders and Convulsions	1.551	1.413	1.266	1.129	1.124
Hydrocephalus	11.308	11.280	11.259	11.254	11.254
Coma, Brain Compression/Anoxic Damage	11.213	11.150	11.071	11.028	11.026
Narcolepsy and Cataplexy	5.298	5.103	4.953	4.799	4.793
Respirator Dependence/Tracheostomy Status	27.709	27.451	27.357	27.326	27.325
Respiratory Arrest	14.691	14.404	14.285	14.230	14.230
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	14.691	14.404	14.285	14.230	14.230
Heart Assistive Device/Artificial Heart	13.918	13.773	13.667	13.578	13.576
Heart Transplant Status/Complications	13.918	13.773	13.667	13.578	13.576
Heart Failure	4.805	4.702	4.634	4.582	4.580
Acute Myocardial Infarction	1.458	1.316	1.201	1.094	1.091
Unstable Angina and Other Acute Ischemic Heart Disease	1.458	1.316	1.201	1.094	1.091
Heart Infection/Inflammation, Except Rheumatic	15.257	15.116	15.014	14.897	14.892
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	2.816	2.592	2.403	2.194	2.181
Major Congenital Heart/Circulatory Disorders	0.974	0.842	0.703	0.571	0.568
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.698	0.593	0.496	0.430	0.428
Specified Heart Arrhythmias	2.605	2.419	2.291	2.169	2.165
Intracranial Hemorrhage	12.911	12.812	12.746	12.660	12.654

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Ischemic or Unspecified Stroke	1.877	1.766	1.705	1.648	1.647
Cerebral Aneurysm and Arteriovenous Malformation	2.557	2.380	2.267	2.129	2.119
Hemiplegia/Hemiparesis	4.097	3.963	3.877	3.782	3.777
Monoplegia, Other Paralytic Syndromes	2.562	2.401	2.266	2.127	2.122
Atherosclerosis of the Extremities with Ulceration or Gangrene	12.054	11.811	11.700	11.637	11.635
Vascular Disease with Complications	7.002	6.852	6.796	6.764	6.763
Pulmonary Embolism and Deep Vein Thrombosis	19.955	19.813	19.737	19.693	19.692
Lung Transplant Status/Complications	13.918	13.773	13.667	13.578	13.576
Cystic Fibrosis	54.075	53.528	53.389	53.377	53.377
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	1.973	1.798	1.651	1.502	1.497
Severe Asthma	1.310	1.149	0.982	0.800	0.794
Asthma, Except Severe	0.371	0.288	0.198	0.124	0.121
Fibrosis of Lung and Other Lung Disorders	1.310	1.149	0.982	0.800	0.794
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	10.858	10.819	10.800	10.793	10.793
Kidney Transplant Status/Complications	14.250	14.144	14.055	13.989	13.985
End Stage Renal Disease	35.540	35.287	35.230	35.234	35.234
Chronic Kidney Disease, Stage 5	3.500	3.273	3.093	2.995	2.987
Chronic Kidney Disease, Severe (Stage 4)	3.500	3.273	3.093	2.995	2.987
Ectopic and Molar Pregnancy	2.005	1.788	1.554	1.287	1.276
Miscarriage with Complications	0.867	0.737	0.556	0.329	0.319
Miscarriage with No or Minor Complications	0.867	0.737	0.556	0.329	0.319
Pregnancy with Delivery with Major Complications	3.599	3.289	2.974	2.581	2.568
Pregnancy with Delivery with Complications	3.599	3.289	2.974	2.581	2.568
Pregnancy with Delivery with No or Minor Complications	2.570	2.339	2.035	1.585	1.567
(Ongoing) Pregnancy without Delivery with Major Complications	0.942	0.797	0.594	0.378	0.371
(Ongoing) Pregnancy without Delivery with Complications	0.942	0.797	0.594	0.378	0.371
(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.447	0.344	0.227	0.135	0.134
Chronic Ulcer of Skin, Except Pressure	1.312	1.190	1.080	0.988	0.986
Extensive Third -Degree Burns	19.825	19.594	19.501	19.461	19.461
Major Skin Burn or Condition	1.901	1.739	1.609	1.491	1.488
Severe Head Injury	19.825	19.594	19.501	19.461	19.461
Hip and Pelvic Fractures	3.488	3.241	3.079	2.963	2.959
Vertebral Fractures without Spinal Cord Injury	3.451	3.235	3.067	2.894	2.888
Traumatic Amputations and Amputation Complications	3.540	3.302	3.128	2.950	2.943
Stem Cell, Including Bone Marrow, Transplant Status/Complications	13.918	13.773	13.667	13.578	13.576
Artificial Openings for Feeding or Elimination	6.793	6.599	6.560	6.565	6.566
Amputation Status, Upper Limb or Lower Limb	3.540	3.302	3.128	2.950	2.943
Interacted HCC Counts Factors					
Severe illness, 1 payment HCC	-9.888	-9.970	-10.057	-10.158	-10.162
Severe illness, 2 payment HCCs	-9.814	-9.827	-9.906	-10.003	-10.006
Severe illness, 3 payment HCCs	-8.266	-8.306	-8.198	-8.090	-8.086
Severe illness, 4 payment HCCs	-7.829	-7.855	-7.707	-7.515	-7.506
Severe illness, 5 payment HCCs	-5.539	-5.425	-5.125	-4.779	-4.766

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Severe illness, 6 or 7 payment HCCs	-0.942	-0.645	-0.200	0.273	0.290
Severe illness, 8 or more payment HCCs	15.918	16.769	17.562	18.301	18.326
Transplant severe illness, 4 or more payment HCCs	16.762	16.867	16.917	16.950	16.952

TABLE 3: HCCs Selected for the Proposed HCC Interacted Counts Variables for the Adult and Child Models Beginning with the 2023 Benefit Year

Payment HCC	Severity Illness Indicator	Transplant Indicator
HCC 2 Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	X	
HCC 3 Central Nervous System Infections, Except Viral Meningitis	X	
HCC 4 Viral or Unspecified Meningitis	X	
HCC 6 Opportunistic Infections	X	
HCC 18 Pancreas Transplant	X	X
HCC 23 Protein-Calorie Malnutrition	X	
HCC 34 Liver Transplant Status/Complications	X	X
HCC 41 Intestine Transplant Status/Complications	X	X
HCC 42 Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	X	
HCC 96 Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	X	
HCC 121 Hydrocephalus	X	
HCC 122 Coma, Brain Compression/Anoxic Damage	X	
HCC 125 Respirator Dependence/Tracheostomy Status	X	
HCC 135 Heart Infection/Inflammation, Except Rheumatic	X	
HCC 145 Intracranial Hemorrhage	X	
HCC 156 Pulmonary Embolism and Deep Vein Thrombosis	X	
HCC 158 Lung Transplant Status/Complications	X	X
HCC 163 Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	X	
HCC 183 Kidney Transplant Status/Complications	X	X
HCC 218 Extensive Third -Degree Burns	X	
HCC 223 Severe Head Injury	X	
HCC 251 Stem Cell, Including Bone Marrow, Transplant Status/Complications	X	X
G13 (Includes HCC 126 Respiratory Arrest and HCC 127 Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes)	X	
G14 (Includes HCC 128 Heart Assistive Device/Artificial Heart and HCC 129 Heart Transplant Status/Complications)	X	X

TABLE 4: Proposed Infant Risk Adjustment Model Factors for 2023 Benefit Year

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	211.839	210.253	209.766	209.650	209.649
Extremely Immature * Severity Level 4	148.689	146.914	146.263	145.989	145.984
Extremely Immature * Severity Level 3	33.465	32.024	31.445	31.172	31.166
Extremely Immature * Severity Level 2	33.465	32.024	31.445	31.172	31.166
Extremely Immature * Severity Level 1 (Lowest)	33.465	32.024	31.445	31.172	31.166
Immature * Severity Level 5 (Highest)	114.339	112.648	112.101	111.930	111.927
Immature * Severity Level 4	68.723	67.058	66.498	66.297	66.293
Immature * Severity Level 3	33.465	32.024	31.445	31.172	31.166
Immature * Severity Level 2	30.547	29.122	28.535	28.241	28.233

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Immature * Severity Level 1 (Lowest)	25.485	24.145	23.552	23.233	23.224
Premature/Multiples * Severity Level 5 (Highest)	101.847	100.436	99.969	99.809	99.806
Premature/Multiples * Severity Level 4	28.534	27.101	26.508	26.227	26.221
Premature/Multiples * Severity Level 3	13.748	12.735	12.108	11.610	11.594
Premature/Multiples * Severity Level 2	7.676	6.953	6.336	5.695	5.672
Premature/Multiples * Severity Level 1 (Lowest)	5.767	5.141	4.569	4.022	4.004
Term * Severity Level 5 (Highest)	78.537	77.271	76.765	76.525	76.520
Term * Severity Level 4	15.369	14.386	13.769	13.290	13.278
Term * Severity Level 3	5.921	5.324	4.752	4.173	4.153
Term * Severity Level 2	3.667	3.171	2.610	2.020	1.999
Term * Severity Level 1 (Lowest)	1.898	1.532	1.094	0.778	0.769
Age1 * Severity Level 5 (Highest)	63.541	62.812	62.524	62.386	62.383
Age1 * Severity Level 4	12.611	12.090	11.787	11.574	11.567
Age1 * Severity Level 3	2.978	2.695	2.472	2.291	2.285
Age1 * Severity Level 2	1.969	1.732	1.508	1.303	1.296
Age1 * Severity Level 1 (Lowest)	0.573	0.489	0.433	0.392	0.391
Age 0 Male	0.534	0.491	0.451	0.386	0.384
Age 1 Male	0.112	0.096	0.077	0.058	0.058

TABLE 5: HHS HCCs Included in Infant Model Maturity Categories

Maturity Category	HCC/Description
Extremely Immature	Extremely Immature Newborns, Birth weight < 500 Grams
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500-749 Grams
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750-999 Grams
Immature	Premature Newborns, Including Birth weight 1000-1499 Grams
Immature	Premature Newborns, Including Birth weight 1500-1999 Grams
Premature/Multiples	Premature Newborns, Including Birth weight 2000-2499 Grams
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight
Age 1	All age 1 infants

TABLE 6: HHS HCCs Included in Infant Model Severity Categories

Severity Category	HCC/Description
Severity Level 5 (Highest)	Metastatic Cancer
Severity Level 5	Pancreas Transplant Status
Severity Level 5	Liver Transplant Status/Complications
Severity Level 5	Intestine Transplant Status/Complications
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
Severity Level 5	Respirator Dependence/Tracheostomy Status
Severity Level 5	Heart Assistive Device/Artificial Heart
Severity Level 5	Heart Transplant Status/Complications
Severity Level 5	Heart Failure
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders
Severity Level 5	Lung Transplant Status/Complications
Severity Level 5	Kidney Transplant Status/Complications
Severity Level 5	End Stage Renal Disease
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia
Severity Level 4	Mucopolysaccharidosis
Severity Level 4	Adrenal, Pituitary, and Other Significant Endocrine Disorders
Severity Level 4	Acute Liver Failure/Disease, Including Neonatal Hepatitis
Severity Level 4	Chronic Liver Failure/End-Stage Liver Disorders
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age < 2

Severity Category	HCC/Description
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis
Severity Level 4	Aplastic Anemia
Severity Level 4	Combined and Other Severe Immunodeficiencies
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord
Severity Level 4	Quadriplegia
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease
Severity Level 4	Quadriplegic Cerebral Palsy
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy
Severity Level 4	Coma, Brain Compression/Anoxic Damage
Severity Level 4	Respiratory Arrest
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
Severity Level 4	Acute Myocardial Infarction
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic
Severity Level 4	Major Congenital Heart/Circulatory Disorders
Severity Level 4	Intracranial Hemorrhage
Severity Level 4	Ischemic or Unspecified Stroke
Severity Level 4	Vascular Disease with Complications
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections
Severity Level 4	Chronic Kidney Disease, Stage 5
Severity Level 4	Artificial Openings for Feeding or Elimination
Severity Level 3	HIV/AIDS
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis
Severity Level 3	Opportunistic Infections
Severity Level 3	Non-Hodgkin Lymphomas and Other Cancers and Tumors
Severity Level 3	Colorectal, Breast (Age < 50), Kidney and Other Cancers
Severity Level 3	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors
Severity Level 3	Lipidoses and Glycogenosis
Severity Level 3	Intestinal Obstruction
Severity Level 3	Necrotizing Fasciitis
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies
Severity Level 3	Cleft Lip/Cleft Palate
Severity Level 3	Hemophilia
Severity Level 3	Disorders of the Immune Mechanism
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders
Severity Level 3	Drug Use with Psychotic Complications
Severity Level 3	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications
Severity Level 3	Alcohol Use with Psychotic Complications
Severity Level 3	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord
Severity Level 3	Paraplegia
Severity Level 3	Spinal Cord Disorders/Injuries
Severity Level 3	Cerebral Palsy, Except Quadriplegic
Severity Level 3	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies
Severity Level 3	Muscular Dystrophy
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders
Severity Level 3	Hydrocephalus
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders
Severity Level 3	Specified Heart Arrhythmias
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation

Severity Category	HCC/Description
Severity Level 3	Hemiplegia/Hemiparesis
Severity Level 3	Cystic Fibrosis
Severity Level 3	Extensive Third -Degree Burns
Severity Level 3	Severe Head Injury
Severity Level 3	Hip and Pelvic Fractures
Severity Level 3	Vertebral Fractures without Spinal Cord Injury
Severity Level 2	Viral or Unspecified Meningitis
Severity Level 2	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors
Severity Level 2	Diabetes with Acute Complications
Severity Level 2	Diabetes with Chronic Complications
Severity Level 2	Diabetes without Complication
Severity Level 2	Protein-Calorie Malnutrition
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders
Severity Level 2	Cirrhosis of Liver
Severity Level 2	Chronic Pancreatitis
Severity Level 2	Acute Pancreatitis
Severity Level 2	Inflammatory Bowel Disease
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn
Severity Level 2	Sickle Cell Anemia (Hb-SS)
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes
Severity Level 2	Seizure Disorders and Convulsions
Severity Level 2	Monoplegia, Other Paralytic Syndromes
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis
Severity Level 2	Severe Asthma
Severity Level 2	Fibrosis of Lung and Other Lung Disorders
Severity Level 2	Chronic Kidney Disease, Severe (Stage 4)
Severity Level 2	Chronic Ulcer of Skin, Except Pressure
Severity Level 2	Major Skin Burn or Condition
Severity Level 1 (Lowest)	Chronic Viral Hepatitis C
Severity Level 1	Chronic Hepatitis, Except Chronic Viral Hepatitis C
Severity Level 1	Beta Thalassemia Major
Severity Level 1	Autistic Disorder
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder
Severity Level 1	Multiple Sclerosis
Severity Level 1	Asthma, Except Severe
Severity Level 1	Traumatic Amputations and Amputation Complications
Severity Level 1	Amputation Status, Upper Limb or Lower Limb

f. Cost-Sharing Reduction Adjustments

We propose to continue including an adjustment for the receipt of CSRs in the risk adjustment models in all 50 states and the District of Columbia. While we continue to study and explore ways to update the CSR adjustments to improve prediction for CSR enrollees,[136] for the 2023 benefit year, to maintain stability and certainty for issuers, we are proposing to maintain the CSR adjustment factors finalized in the 2019, 2020, 2021, and 2022 Payment Notices.[137] See Table 7. We also propose to continue to use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent.[138] We seek comment on these proposals.

[136] See Appendix A of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[137] See 83 FR 16930 at 16953; 84 FR 17454 at 17478 through 17479; 85 FR 29164 at 29190; and 86 FR 24140 at 24181.

[138] See 81 FR 12203 at 12228.

TABLE 7: Cost-Sharing Reduction Adjustment Factors

Household Income	Plan AV	Adjustment Factor
Silver Plan Variation Recipients		
100-150% of Federal Poverty Level (FPL)	Plan Variation 94%	1.12
150-200% of FPL	Plan Variation 87%	1.12
200-250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12
<300% of FPL	Bronze (60%)	1.15
Limited Cost Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

g. Model Performance Statistics

Each benefit year, to evaluate risk adjustment model performance, we examine each model's R-squared statistic and PRs. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The PR for each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The PR represents how well the model does on average at predicting plan liability for that subpopulation.

A subpopulation that is predicted perfectly would have a PR of 1.0. For each of the current and proposed HHS risk adjustment models, the R-squared statistic and the PRs are in the range of published estimates for concurrent risk adjustment models.[139] As detailed in the 2021 RA Technical Paper, the proposed model specification updates, when taken together, generally demonstrate improvements in R-squared as well as PRs.[140] Because we propose to blend the coefficients from separately solved models based on the 2017, 2018, and 2019 benefit years' enrollee-level EDGE data, we are publishing the R-squared statistic for each model separately to verify their statistical validity. The R-squared statistics for the proposed 2023 benefit models are shown in Table 8.

TABLE 8: R-Squared Statistic for Proposed HHS Risk Adjustment Models

R-Squared Statistic			
Models	2017 Enrollee level EDGE Data	2018 Enrollee-level EDGE Data	2019 Enrollee-level EDGE Data
Platinum Adult	0.4501	0.4467	0.4475
Gold Adult	0.4438	0.4400	0.4407
Silver Adult	0.4405	0.4366	0.4371
Bronze Adult	0.4376	0.4337	0.4340
Catastrophic Adult	0.4374	0.4336	0.4339
Platinum Child	0.3487	0.3527	0.3535
Gold Child	0.3453	0.3494	0.3501
Silver Child	0.3430	0.3470	0.3476
Bronze Child	0.3405	0.3444	0.3451
Catastrophic Child	0.3404	0.3443	0.3450
Platinum Infant	0.3311	0.3112	0.3146
Gold Infant	0.3272	0.3073	0.3107
Silver Infant	0.3252	0.3053	0.3087
Bronze Infant	0.3237	0.3037	0.3073
Catastrophic Infant	0.3236	0.3037	0.3072

[139] Hileman, Geof and Spenser Steele. ''Accuracy of Claims-Based Risk Scoring Models.'' Society of Actuaries. October 2016.

[140] See, for example, Chapter 5.1 in the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

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3. Overview of the HHS Risk Adjustment Methodology (§ 153.320)

In part 2 of the 2022 Payment Notice final rule, we finalized the proposal to continue to use the state payment transfer formula finalized in the 2021 Payment Notice for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking.[141] We explained that under this approach, we will no longer republish these formulas in future annual HHS notice of benefit and payment parameter rules unless changes are being proposed. We are not proposing any changes to the formula in this rule and therefore are not republishing the formulas in this rule. We would continue to apply the formula as finalized in the 2021 Payment Notice in the states where HHS operates the risk adjustment program in the 2023 benefit year.[142] Additionally, as finalized in the 2020 Payment Notice, we will maintain the high-cost risk pool parameters for the 2020 benefit year and beyond, unless amended through notice-and-comment rulemaking.[143] We are not proposing any changes to the high-cost risk pool parameters for the 2023 benefit year; therefore, we would maintain the $1 million threshold and 60 percent coinsurance rate.

4. Risk Adjustment State Flexibility Requests (§ 153.320(d))

We propose to repeal the ability of states to request a reduction in risk adjustment state transfers starting with the 2024 benefit year, with an exception for states that have requested such reductions in prior benefit years. We also solicit comments on requests from Alabama to reduce risk adjustment state transfers for the 2023 benefit year in the individual (including the catastrophic and non-catastrophic risk pools) and small group markets. In the 2019 Payment Notice, we provided states the flexibility to request a reduction to the applicable risk adjustment state transfers calculated by HHS using the state payment transfer formula for the state's individual (catastrophic or non-catastrophic risk pools), small group, or merged markets by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's markets.[144] We finalized that any requests we received would be published in the applicable benefit year's proposed HHS notice of benefit and payment parameters, and the supporting evidence provided by the state in support of its request would be made available for public comment.[145]

In accordance with § 153.320(d)(2), beginning with the 2020 benefit year, states must submit such requests with the supporting evidence and analysis outlined under § 153.320(d)(1) by August 1st of the calendar year that is 2 calendar years prior to the beginning of the applicable benefit year. If approved by HHS, state reduction requests will be applied to the plan PMPM payment or charge state payment transfer amount (Ti in the state payment transfer formula).[146] For the 2020 and 2021 benefit years, the state of Alabama submitted a 50 percent risk adjustment transfer reduction request for its small group market and HHS approved both requests.[147] For the 2022 benefit year, the state of Alabama submitted 50 percent risk adjustment transfer reduction requests for its individual (including catastrophic and non-catastrophic risk pools) and small group markets, and HHS approved both requests.[148]

a. Requests To Reduce Risk Adjustment Transfers for the 2023 Benefit Year

For the 2023 benefit year, HHS received requests from Alabama to reduce risk adjustment state transfers for its individual and small group markets by 50 percent.[149] Alabama asserts that the state payment transfer formula produces imprecise results in Alabama because of the extremely unbalanced market share in the individual and small group markets. Specifically, Alabama asserts that the presence of a dominant issuer in the individual and small group markets precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share, which Alabama believes precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share. The state regulators stated that their review of the issuers' financial data suggested that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the individual market for the 2023 benefit year would not exceed 1 percent, the de minimis premium increase threshold set forth in § 153.320(d)(1)(iii) and (d)(4)(i)(B).

In the small group market request, Alabama states that its review of the issuers' financial data from the 2020 benefit year suggests that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the small group market for the 2023 benefit year would exceed the de minimis threshold. However, Alabama asserts that HHS should consider data for years prior to 2021 to analyze its small group market request for the 2023 benefit year because the COVID–19 PHE renders an analysis based on 2020 data unreliable. Alabama further notes that there is no regulatory requirement to analyze the request using the most recent available year of data. Alabama further states that the de minimis regulatory threshold does not work when a small issuer receives a risk adjustment payment, and that the test should instead be based on what percentage market share the large issuer in Alabama holds compared to the other issuers in the market.

We seek comment on the requests to reduce risk adjustment state transfers in the Alabama individual and small group markets by 50 percent for the 2023 benefit year. The requests and additional documentation submitted by Alabama are posted under the ''State Flexibility Requests'' heading at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html.*

b. Repeal of Risk Adjustment State Flexibility To Request a Reduction in Risk Adjustment State Transfers (§ 153.320(d))

We propose to generally repeal the flexibility for states to request reductions of transfers calculated by HHS under the state payment transfer formula in all state market risk pools starting with the 2024 benefit year, with an exception for states that previously requested a reduction in risk adjustment state transfers under § 153.320(d). Section 3 of E.O. 14009 directs HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related

[141] See 86 FR at 24183–24186.

[142] For an illustration and further details on the state payment transfer formula, see 86 FR at 24183–24186.

[143] See 84 FR at 17466–17468.

[144] 83 FR 16955–16960.

[145] If the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will only make available on the CMS website the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence. See 45 CFR 153.320(d)(3).

[146] For an illustration of the state payment transfer formula, see 86 FR at 24184.

[147] See 84 FR 17484–17485 and 85 FR 29193–29194.

[148] See 86 FR 24187–24189.

[149] Alabama's individual market request is for a 50 percent reduction to risk adjustment transfers for its individual market non-catastrophic and catastrophic risk pools.

to Medicaid and the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether they are inconsistent with policy priorities described in Section 1 of E.O. 14009, to include protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals.[150] Consistent with this directive, we have been considering whether the risk adjustment state flexibility under § 153.320(d) is inconsistent with policies described in Sections 1 and 3 of E.O. 14009.

In prior rulemakings, we received comments stating that this policy does not strengthen the ACA and requesting that HHS repeal this policy, as risk adjustment state flexibility may result in risk selection, market destabilization, increased premiums, smaller networks, and worse plan options. Specifically, these commenters stated that reducing transfers to plans with higher-risk enrollees could create incentives for issuers to avoid enrolling high-risk enrollees in the future through distorting plan offering and designs, including by avoiding broad network plans, not offering platinum plans at all, and only offering limited gold plans. Commenters further stated that issuers could also distort plan designs by excluding coverage or imposing high cost sharing for certain drugs or services. Some commenters stated that the risk adjustment state payment transfer formula already adjusts for differences in types of individuals enrolled in different states and aggregate differences in prices and utilization by using the statewide average premium as a scaling factor, so state flexibility to account for state-specific factors is unnecessary.[151] The commenters also generally noted that states that believe the HHS risk adjustment methodology does not work properly in their markets have the option, if they operate their Exchange, to operate a state-based risk adjustment program.

Moreover, since HHS finalized the risk adjustment state flexibility policy in the 2019 Payment Notice, there have been changes in Administration policy priorities. This Administration's stated priorities include protecting and strengthening the ACA, of which the risk adjustment program is an integral part, and supporting protections for people with pre-existing conditions;[152] in contrast, past Administration priorities included reducing economic burden on states and other entities and maximizing state flexibility.[153] Market participation has also stabilized in recent years, with new issuers entering the market and premiums remaining stable since 2019.[154]

Following our further consideration of this policy consistent with the instructions in the E.O., prior comments on this policy, and the earlier described changes, as well as the general low level of interest states have expressed in the policy, we propose, beginning for the 2024 benefit year, to repeal the ability for states to request a reduction in risk adjustment state transfers of up to 50 percent in any state market risk pool with an exception for states who previously requested this flexibility in prior benefit years. We propose to effectuate this change by amending the introductory text to § 153.320(d) to reflect that this flexibility was available from the 2020 through 2023 benefit years for all states and to add a new second sentence to the introductory text in § 153.320(d) to capture the proposal to permit states that previously participated to request these reductions beginning with the 2024 benefit year.

In addition, we propose to add new § 153.320(d)(5) to define prior participants as any state that previously submitted a risk adjustment state flexibility request for any market risk pool. We are proposing to create an exception for states that previously participated because there is one state, Alabama, that requested this flexibility since 2020 (the first benefit year these requests were permitted). Alabama has generally been able to demonstrate a de minimis impact on the market risk pool in which the reduction in transfers was requested, meaning any impacted issuer would not need to increase their premiums by more than 1 percent to account for the reduction to risk adjustment transfers. As explained in the state's requests, Alabama has unique state characteristics, in which there is an extremely unbalanced market share in both its individual and small group markets, with one very dominant issuer and a few very small competitors that produces imprecise results under the HHS risk adjustment methodology, which is calibrated on a national dataset.[155] We do not believe that continuing to permit a reduction in risk adjustment transfers in this state, given its unique characteristics, undermines the efficacy of risk adjustment. In addition, we believe that any minimal impact on transfers in this state is outweighed by the benefit of maintaining and taking steps to support the state's effort to maximize participation in its state market risk pools that have developed as a result of this flexibility in prior years, and that might otherwise only have a single issuer offering coverage in the absence of this flexibility.

We note that this proposal to retain this flexibility for prior participants is only intended to permit such states to continue to request risk adjustment state flexibility in benefit year 2024 and beyond, not to automatically apply previously approved transfer reductions to future benefit years. Under this proposal, a prior participant will still be required to submit its request(s) to reduce risk adjustment state transfers each year in the timeframe, form, and manner set forth in § 153.320(d)(1) and (2), and HHS will continue to evaluate risk adjustment state flexibility requests for approval as set forth in § 153.320(d)(4). If state requests do not meet the applicable approval criteria, HHS will not approve the requests. The flexibility for HHS to approve a reduction amount that is lower than the amount requested by the State in § 153.320(d)(4)(ii) would also be retained.

Finally, for reduction requests for the 2024 benefit year and beyond, we also propose to remove the option for the state to demonstrate the state-specific factors that warrant an adjustment to more precisely account for relative risk differences in the state individual catastrophic, individual non-catastrophic, small group, or merged

[150] E.O. 14009; 86 FR 7793 (Feb. 2, 2021).

[151] See *https://www.brookings.edu/wp-content/uploads/2020/12/FiedlerLaytonCommentLetterNBPP2022.pdf.*

[152] Executive Order 14009; 86 FR 7793 (Feb. 2, 2021).

[153] Executive Order 13765; 82 FR 8351 (Jan. 24, 2017).

[154] See, for example, the 2019, 2020, and 2021 Unified Rate Review Public Use Files, available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/ratereview.* See also the Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf.* See also the Summary Report on Permanent Risk Adjustment Transfers for the 2019 Benefit year, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2019.pdf.*

[155] See Alabama requests for 2020 through 2022 under the Risk Adjustment State Flexibility Requests heading at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.* Some of the information in these requests is redacted in accordance with 45 CFR 153.320(d)(3). If the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will only make available on the CMS website the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence.

market risk pool as one of the justifications for the state's request and one of the criteria for HHS approval. Instead, we propose to require prior participants to meet the other existing criterion that the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments, as the sole justification for the state's request and criterion for HHS approval beginning with 2024 benefit year requests. To effectuate this change, we propose to amend paragraph (d)(1)(iii) of § 153.320 to add the phrase ''For the 2020 through 2023 benefit years'' to reflect that state requests submitted for those benefit years must include a justification for the reduction requested demonstrating either of the existing criteria, that is, the state-specific factors that warrant an adjustment to more precisely account for relative risk differences in the state individual catastrophic, individual non-catastrophic, small group, or merged market risk pool, or that the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments. We also propose to add a new § 153.320(d)(1)(iv) to capture the requirement that prior participant requests beginning with the 2024 benefit year must include a justification demonstrating the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments. We similarly propose to amend the standards for HHS approval under § 153.320(d)(4)(i) to create a new paragraph (d)(4)(i)(A) to capture the existing options available for 2020 through 2023 benefit year requests and a new paragraph (d)(4)(i)(B) to capture the new proposed option that would apply to prior participants' requests beginning with the 2024 benefit year. Retaining the de minimis standard as the only option for prior participants to justify the reduction and for HHS to approve a request would help ensure that consumers would not experience an increase in premiums greater than 1 percent as the result of a state requested reduction in transfers, which aligns with the priorities under E.O. 14009 to ensure that health care remains affordable for consumers. HHS would continue to publish any requests submitted under this revised framework, make them available for public comment, and announce any approved or denied reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters, as set forth in § 153.320(d)(3).

We seek comment on this proposal to generally repeal the state flexibility to request reductions in the transfers calculated by HHS under the state payment transfer formula beginning with 2024 benefit year, with the exception of states that previously submitted a risk adjustment state flexibility request for any market risk pool. We also seek comment on whether we should limit this repeal to the individual market catastrophic and non-catastrophic risk pools (including merged market states whose issuers report risk adjustment data in the individual market) and continue to permit the submission of these requests in the small group market only (including merged market states whose issuers report risk adjustment data in the small group market). We further seek comment on the proposed prior participant exception, including the proposed definition for prior participants. We also seek comment on the proposal to retain as the only option for state justification and HHS approval of requested reductions beginning with the 2024 benefit year the demonstration that the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments, and to remove the criterion related to the state demonstrating the state-specific factors that warrant an adjustment to more precisely account for relative risk differences in the applicable state market risk pool. Finally, we seek comment on the health equity impacts of these proposals, especially for underserved and minority communities.

5. Risk Adjustment Issuer Data Requirements (§§ 153.610, 153.700, and 153.710)

In this section, we propose that issuers collect and make available for HHS' extraction from issuers' EDGE servers five new data elements—ZIP code,[156] race, ethnicity, an ICHRA indicator, and a subsidy indicator (APTC indicator at the policy-level)—as part of the required risk adjustment data that issuers must make accessible to HHS in states where HHS operates the risk adjustment program,[157] beginning with the 2023 benefit year. We also propose that beginning with the 2022 benefit year, HHS would extract from issuers' EDGE servers the following three data elements that issuers already are required to make accessible to HHS as part of the required risk adjustment data: Plan ID (which represents the HIOS ID, state, product ID, standard component number, and variant), rating area, and subscriber indicator. We also propose to exclude plan ID, ZIP code, and rating area from the limited data set HHS makes available to requestors for research purposes, but include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in that limited data set once available. Lastly, we propose to expand and clarify the scope of permissible HHS uses for the data and the reports extracted from issuer EDGE servers (including data reports and ad hoc query reports). Related to these proposals, we also consider the burden associated with the proposed collection and extraction of these data elements and whether there are any policies that HHS could pursue to encourage the consistent use and reporting of ICD–10–CM z codes. The following subsections provide further discussion of these proposals.

a. Background

Section 1343(b) of the ACA provides that the Secretary, in consultation with States, shall establish criteria and methods to be used in carrying out the risk adjustment activities under this section. Consistent with section 1321(c) of the ACA, the Secretary is responsible for operating the risk adjustment program in any state that fails to do so.[158] 45 CFR 153.610(a) requires that health insurance issuers of risk adjustment covered plans submit or make accessible all required risk adjustment data in accordance with the data collection approach established by HHS [159] in states where HHS operates the program on behalf of a state. In the 2014 Payment Notice, HHS established an approach for obtaining the necessary data for risk adjustment calculations in states where HHS operates the program through a distributed data collection model that prevented the transfer of individuals' personally identifiable information (PII).[160] Since the 2016 benefit year, HHS required issuers of risk adjustment covered plans to submit 95 data elements to their EDGE servers

[156] ZIP code™ is a trademark of the United States Postal Service.

[157] HHS has been operating the risk adjustment program in all 50 states and the District of Columbia since the 2017 benefit year.

[158] In the 2014 through 2016 benefit years, HHS operated the risk adjustment program in every state and the District of Columbia, except Massachusetts. Beginning with the 2017 benefit year, HHS has operated the risk adjustment program in all 50 states and the District of Columbia.

[159] Also see 45 CFR 153.700–153.740.

[160] See 78 FR at 15497–15500 and 45 CFR 153.720.

to support the HHS' calculation of risk adjustment transfers.[161]

Then, in the 2018 Payment Notice, we finalized policies for the extraction and use of enrollee-level EDGE data beginning with the 2016 benefit year.[162] The purpose of collecting and extracting enrollee-level EDGE data was to provide HHS with more granular data to use to recalibrate the HHS risk adjustment models and to use actual data from issuers' individual and small group (and merged) market populations, as opposed to the MarketScan® commercial database that approximates these populations, for model recalibration purposes. We also finalized the use of the extracted enrollee-level EDGE data to inform development of the AV Calculator and methodology and noted the data could be a valuable source for calibrating other HHS programs in the individual and small group markets. In the 2020 Payment Notice, we expanded the permitted uses of the extracted enrollee-level EDGE data to provide that HHS may use these data and the reports extracted from issuers' EDGE servers (including data reports and ad hoc query reports) to calibrate and operationalize our individual and small group (including merged) market programs, including to recalibrate the HHS risk adjustment models, to inform updates to the AV Calculator, and to conduct policy analysis for the individual and small group (including merged) markets.[163] These additional uses of the enrollee-level EDGE data and reports enhance HHS' ability to develop and set policy for the individual and small group (including merged) markets and avoid the need to pursue alternative burdensome data collections from issuers.[164]

b. Proposed Collection and Extraction of New Data Elements and Extraction of Current Data Elements

Based on our experience accessing EDGE server data for the risk adjustment model recalibration and analytics purposes, and as part of our ongoing efforts to continuously improve HHS programs, we propose to collect and extract new data elements from issuers' EDGE servers through issuers' EDGE Server Enrollment Submission (ESES) files and risk adjustment recalibration enrollment files, specifically: (1) ZIP code, (2) race, (3) ethnicity, (4) subsidy indicator, and (5) ICHRA indicator. For race and ethnicity data, we propose to require issuers to report race and ethnicity in accordance with the October 30, 2011 HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status (2011 HHS Data Standards),[165] which is collected at a granular level that would allow HHS to better analyze more subpopulations than our current data allows us to do, thereby allowing us to consider more areas of health equity, as well as to better address discrimination in health care and health disparities.[166] We propose to require issuers of risk adjustment covered plans to submit and make accessible these new data elements to HHS in states where HHS operates the risk adjustment program beginning with the 2023 benefit year. Extraction of these new five data elements as part of the enrollee-level EDGE data and the reports extracted from issuers' EDGE servers (including data reports and ad hoc query reports) would begin with the 2023 benefit year.[167] In addition to collecting and extracting these new data elements, we also propose to extract plan ID, rating area, and subscriber indicator as part of the enrollee-level EDGE data beginning with the 2022 benefit year data and reports extracted from issuers' EDGE servers. For the plan ID, rating area, and subscriber indicator, we note that issuers are already required under current HHS program requirements to submit these data elements to their EDGE servers.[168]

Collecting and extracting these new and current data elements would allow HHS to further assess and analyze actuarial risk and risk patterns in the individual, small group, and merged markets, and determine if, based on future analysis, any refinements to the HHS risk adjustment methodology, the AV Calculator, or other HHS individual or small group (including merged) market programs should be proposed through notice-and-comment rulemaking. For example, we propose to collect and extract the ICHRA indicator to conduct analyses on whether there are any unique actuarial characteristics of the ICHRA population[169] and to examine if employers with sicker enrollees are more attracted to offering ICHRAs, and if ICHRA enrollment is impacting state individual (or merged) market risk pools. We similarly want to examine whether there are any risk patterns or impacts when analyzing risk adjustment data using ZIP codes, race, ethnicity, and the subsidy indicator. For example, we are interested in conducting analysis on whether there are any cost differentials for certain conditions based on race, ethnicity or subsidy indicator. For the three current data elements that we are proposing to newly extract, our purpose would be to similarly use these data to further assess risk patterns and the impact of risk adjustment policies. For example, the extraction of rating area data would provide HHS with more granular data to assess risk patterns and impacts based on geographic differences. In addition, the proposal to newly extract plan ID and subscriber indicator from issuers' EDGE servers would allow HHS to be able to simulate transfers using the enrollee-level data, which is currently not possible without the plan ID.[170]

We believe these proposed data collections and extractions would serve the compelling government interest of promoting equity in health coverage and care, as well as the ACA's goal of making high-quality health care accessible and affordable for all individuals. Specifically, we believe that the collection and extraction of these new data elements would allow HHS to analyze and assess health equity

[161] The full list of required data elements can be found in Appendix A of OMB control number 0938–1155 (Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS–10401)), which is currently being updated. The current Appendix A is available at *https://omb.report/icr/201712-0938-015/doc/79644301.pdf.* The previous version is available at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201712-0938-015.*

[162] 81 FR 94058 at 94101.

[163] 84 FR 17454, 17488.

[164] We also clarified that our policies regarding HHS uses of the enrollee-level EDGE data apply to the HHS components that currently receive and use such data for purposes of the HHS risk adjustment program. See *ibid* at 17488.

[165] *https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0.*

[166] As detailed further later in this preamble, issuers would have the option of selecting ''unknown'' for this data element if they do not have this information for a particular enrollee.

[167] The deadline for submission of 2023 benefit year risk adjustment data submissions is April 30, 2024. See 45 CFR 153.730.

[168] The full list of required data elements can be found in Appendix A of OMB control number 0938–1155 (Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS–10401)), which is currently being updated. The current Appendix A is available at *https://omb.report/icr/201712-0938-015/doc/79644301.pdf.* The previous version is available at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201712-0938-015.*

[169] Currently, HHS only collects information on an enrollee's ICHRA status in connection with a special enrollment period eligibility determination for Exchanges, which does not provide us with complete data.

[170] For the transfer simulation of the combined model specification changes, HHS was not able to use the available enrollee-level EDGE datasets. Instead, issuers needed to run multiple EDGE Ad Hoc commands on their respective EDGE servers for the simulation to be successful. See Section 5.2 of the 2021 RA Technical Paper, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.*

impacts more than current data allow. Consistent with Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [171] we believe this proposal would facilitate our ability to assess the extent to which specific communities experience barriers or challenges in accessing benefits and opportunities available related to our individual, small group, and merged market programs. This proposed data collection could also facilitate our ability to assess whether new policies, regulation, or guidance may be necessary or appropriate to further advance equity within our programs in the individual, small group and merged markets. We believe that the proposed collection and extraction of these data elements is narrowly tailored to serve this compelling government interest because this is the minimum data anticipated at this time that would allow HHS to further assess and analyze actuarial risk and risk patterns in the individual, small group, and merged markets. Consistent with the policy adopted in the 2020 Payment Notice regarding the use of data and reports extracted from issuer EGDE servers (including data reports and ad hoc query reports), and our proposal below to expand the permissible HHS uses of such data and reports, we would collect, extract and use these new and current data elements to conduct policy analysis for HHS programs in the individual and small group (including merged) markets and to inform policy analyses and improve the integrity of other HHS federal health-related programs to the extent such use is otherwise authorized by, required under, or not inconsistent with applicable federal law.

In the proposed 2020 Payment Notice, we sought comment on the advantages and disadvantages of extracting state and rating area data as part of the enrollee-level EDGE data for use to recalibrate the HHS-operated risk adjustment models, to inform updates to the AV Calculator and methodology, and to conduct policy analyses for other HHS individual and small group (including merged) market programs.[172] We explained that extracting these geographic details could enable HHS to assess the impact of differences in geographic factors in the HHS risk adjustment methodology and to better estimate the AV of plans based on cost differences across regions. We also noted that extraction of geographic details (state and rating area) could help support other HHS programs and policy priorities, as well as provide additional data elements for researchers. However, after consideration and review of the public comments received on the proposed 2020 Payment Notice, we did not finalize the proposed extraction of these data elements. We explained that, at that time, in response to stakeholder feedback, we did not believe that the benefits of these additional data element extractions would outweigh the potential increased risk to issuers' proprietary information and increased issuer burden.[173]

However, in light of E.O. 13985 and E.O. 14009, we have continued to consider whether extraction of these data elements would support and enhance HHS' policy analysis capabilities with regard to the HHS risk adjustment program, as well as other HHS individual and small group (including merged) market programs that seek to provide access to health care to consumers. Based on this further analysis and consideration, HHS has determined that the proposed extraction of rating area data, along with the proposed collection and extraction of the other data elements discussed in this proposal, align with the policy goals in E.O. 13985 and E.O. 14009 and would provide HHS with more granular data to help improve HHS' analytical capacity to assess equity impacts of programs impacted by this proposed rule, including our capacity to identify potential refinements to the HHS risk adjustment methodology, consider policy and operational changes to improve other HHS individual and small group (including merged) market programs, and identify ways to address health equity issues in these programs. For example, HHS believes that analysis of the additional data elements proposed for collection and extraction from issuers' EDGE servers would help HHS better monitor trends in the health insurance markets, inform HHS analyses of whether updates to the QHP certification review processes would be necessary or appropriate,[174] and inform QHP compliance reviews and subregulatory guidance. HHS also is of the view that the additional data elements proposed for collection and extraction from EDGE servers could be valuable in assessing policy and operational issues in connection with programs that are not centered around the individual or small group (including merged) commercial health insurance markets, such as the wrap-around QHP coverage offered to Medicaid expansion populations in some states [175] and coverage offered by non-federal governmental plans.[176]

Additionally, HHS continually considers methods and mechanisms to identify discriminatory practices in the commercial health insurance markets and HHS federal health-related programs. The additional data we propose to collect and extract from issuers' EDGE servers also would inform future policy to better address discrimination and other systemic barriers in health care and health disparities that may exist in connection with coverage offered in the commercial health insurance markets, as well as in other HHS federal health-related programs that do not focus on commercial health insurance.

For all of the reasons discussed in this section, HHS proposes to collect and extract the proposed five new data elements outlined above as part of the required risk adjustment data issuers must make accessible to HHS through their respective EDGE servers beginning with the 2023 benefit year. We also propose to extract plan ID, rating area, and subscriber indicator as part of the EDGE enrollee-level data set beginning with the 2022 benefit year.[177] We note that any changes to the risk adjustment methodology or other policies based on HHS's analysis of these data would be set forth in notice and comment rulemaking.

We seek comments on these proposals, including feedback specifically on whether we should extract only certain portions of the plan ID, such as the five-digit HIOS ID, two-character state ID, three-digit product number, four-digit standard component

[171] E.O. 13985 is 86 FR 7009 available at *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[172] 84 FR 227 at 251.

[173] 84 FR 17454 at 17488.

[174] Each year, HHS provides an overview of its QHP certification review processes in the annual Letter to Issuers in the FFEs. The 2022 Final Letter to Issuers in the FFEs is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2022-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces.pdf.*

[175] See, *e.g., https://www.medicaid.gov/medicaid/downloads/wraparound-benefits.pdf.*

[176] Non-federal governmental plans are subject to many PHS Act federal market reform requirements. See, *e.g.,* 42 U.S.C. 300gg–21(a)(1)(A). Also see 42 U.S.C. 300bb–1, *et seq.* HHS is generally responsible for enforcement of provisions of the PHS Act that apply to non-federal governmental plans. See, *e.g.,* 42 U.S.C. 300gg–22(b)(1)(B) and 45 CFR 150.301, *et seq.*

[177] We propose to extract plan ID, rating area, and subscriber indicator for the 2022 benefit year, which is one year earlier than we propose to extract the other five new data elements, because issuers already submit plan ID, rating area, and subscriber indicator to their EDGE servers.

number, two-digit variant ID, or any combination thereof.[178]

c. Limited Data Set

In conjunction with the proposed collection and extraction of the new and current data elements in this proposed rule, we propose to exclude plan ID, ZIP code, and rating area from the limited data set containing enrollee-level EDGE data that HHS makes available to qualified researchers.[179] However, we propose to include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in the limited data set once they are available.[180] In the 2020 Payment Notice, we finalized our proposal to create on an annual basis a limited data set file using masked enrollee-level data submitted to HHS from issuers' EDGE servers. The limited data set file is made available to requestors who seek the data for research purposes only.[181] We adopted this policy because we believed making the limited data set file available to qualified researchers upon request would increase understanding of these markets and contribute to greater transparency. HHS strictly adheres to all the requirements and CMS guidelines related to providing the limited data set to qualified researchers, including requiring the recipient of the limited data set to enter into a data use agreement that establishes the permitted uses or disclosures of the information and prohibits the recipient from identifying the information. We believe that including race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator would enhance the usefulness of the limited data set for research and would continue to protect enrollees' PII and issuers' proprietary information. Although we believe that including plan ID, ZIP code, and rating area in the limited data set similarly would enhance the usefulness of the limited data set, we believe this would raise significant concerns for issuers given previous comments noting the competitive and proprietary nature of these geographic identifiers. We therefore propose to not include these geographic identifiers as part of the limited data set that HHS makes available to qualified researchers upon request. We seek comments on the proposal to exclude plan ID, ZIP code, and rating area, and to include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator as part of the enrollee-level EDGE limited data set made available to qualified researchers upon request. We seek comment on this proposal, including about whether collecting race and ethnicity data in accordance with the 2011 HHS Data Standards would require systems changes and about any costs associated with such changes. If finalized as proposed, race, ethnicity, the ICHRA indicator, and the subsidy indicator would be included beginning with the 2023 benefit year enrollee-level EDGE limited data set. Subscriber indicator would be included beginning with the 2022 benefit year enrollee-level EDGE limited data set if the proposal to extract that data element is finalized as proposed. We appreciate the sensitivities related to enrollee-level EDGE data and the importance of ensuring that our policies continue to safeguard enrollees' privacy and security and issuers' proprietary information. Thus, we are particularly interested in feedback on any privacy or confidentiality concerns with including these elements in the limited data set made available to qualified researchers upon request.

d. Proposal To Expand Permissible Uses of EDGE Data

We also propose to expand the permitted uses of the data and reports (including data reports and ad hoc query reports) extracted from issuers' EDGE servers to include other HHS federal health-related programs outside of the commercial individual and small group (including merged) markets. This proposed expansion would apply to data that HHS already collects as well as the proposed collection and extraction of ZIP code, race, ethnicity, subsidy indicator, ICHRA indicator, plan ID, rating area, and subscriber indicator as outlined in this rule. The proposed expansion to the permitted uses of the EDGE data and reports would apply as of the effective date of the final rule. Specifically, HHS proposes to expand the uses of the data and reports HHS extracts from issuers' EDGE servers to include not only the specific uses for purposes we identified in the 2020 Payment Notice[182]—that is, to calibrate and operationalize our individual and small group (including merged) market programs (including assessing risk in the market for risk adjustment purposes and informing updates to the AV Calculator), and to conduct policy analysis for the individual and small group (including merged) markets—but also for the purposes of informing policy analyses and improving the integrity of other HHS federal health-related programs, to the extent such use of the data is otherwise authorized by, required under, or not inconsistent with applicable federal law. For example, certain states have wrap-around coverage that include enrolling their Medicaid expansion populations in QHPs and those enrollees are currently reflected in the enrollee-level EDGE data. Under this proposal to expand the permitted uses of EDGE data and reports, it would be clear that HHS could use this information to inform policy analyses and improve the integrity of these Medicaid expansion population approaches. Similarly, to the extent appropriate, this proposal would allow HHS to use the EDGE data and reports to inform policy analyses related to PHS Act requirements enforced by HHS that are applicable market-wide[183] and those that are applicable to non-federal governmental plans.[184] Consistent with our current policy, the proposals in this rule related to HHS use of the enrollee-level EDGE data and reports would apply to the HHS components that currently receive and use such data for purposes of the HHS risk adjustment program. Other government components would be able to request the enrollee-level EDGE limited data set file for research, as that term is defined under § 164.501. We also note that the enrollee-level EDGE data, including the data elements proposed for collection and extraction in this rule, may be subject to disclosure as otherwise required by law.[185]

[178] For additional explanation of the plan ID components, see pg. 42 of the CMS Standard Companion Guide Transaction Information: Instructions related to the ASC X12 Benefit Enrollment and Maintenance (834) transaction, based on the 005010X220 Implementation Guide and its associated 005010X220A1 addenda for the FFE, available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/companion-guide-for-ffe-enrollment-transaction-v15.pdf.*

[179] See 84 FR at 17487.

[180] As proposed, the subscriber indicator would be included in the enrollee-level data HHS extracts from issuer EDGE servers beginning with the 2022 benefit year; therefore, this new data field would be included beginning with the 2022 benefit year limited data set. As proposed, race, ethnicity, ICHRA indicator, and subsidy indicator would be included in the enrollee-level data HHS extracts from issuer EDGE servers beginning with the 2023 benefit year; therefore, these data fields would be included beginning with the 2023 benefit year limited data set.

[181] As explained in the 2020 Payment Notice, we do not currently make the limited data set available to requestors for public health or health care operation activities. See 84 FR at 17488.

[182] See 84 FR 17488.

[183] See, for example, 42 U.S.C. 300gg–300gg–28.

[184] Non-federal governmental plans are subject to many PHS Act federal market reform requirements. See, *e.g.,* 42 U.S.C. 300gg–21(a)(1)(A). Also see 42 U.S.C. 300bb–1, *et seq.* HHS is generally responsible for enforcement of provisions of the PHS Act that apply to non-federal governmental plans. See, *e.g.,* 42 U.S.C. 300gg–22(b)(1)(B) and 45 CFR 150.301, *et seq.*

[185] See, for example, 2 U.S.C. 601(d).

We note that any changes to our policies that result from analysis of these data, such as using the data to modify the state payment transfer formula, would be subject to notice and comment rulemaking. Furthermore, we would not use the additional data elements or any analysis of them to pursue changes to our policies until we conduct thorough data quality checks. For example, in submitting data on race and ethnicity, issuers would have the option of selecting ''unknown'' for these data elements and we would ensure an adequate response rate before conducting analyses that could inform policy decisions. We would similarly ensure an adequate response rate with respect to submission of the ICHRA indicator before conducting analyses that could inform policy decisions.[186] We solicit comment on this proposal to expand the permitted uses of the enrollee-level EDGE data.

e. Burden for Collecting and Extracting Additional Data Elements

As stated above, we propose to extract plan ID, rating area, and subscriber indicator from issuers' EDGE servers to consider for use in risk adjustment model recalibration and other potential refinements to the HHS-operated risk adjustment program, as well as to conduct policy analysis for HHS federal health-related programs, including those related to the individual and small group (including merged) health insurance markets and HHS non-commercial market programs, beginning with the 2022 benefit year. While collecting additional data elements may represent increased burden for issuers, there would be little to no additional issuer burden related to extracting these three proposed data elements because HHS extracts and stores the data, and issuers would only be required to execute a command provided by HHS to generate the EDGE report(s) containing all required data elements. Since issuers are already required to include these three data elements (plan ID, rating area, and subscriber indicator) as part of the required risk adjustment submissions to their respective EDGE servers, we believe there would be little to no additional burden associated with the proposed extraction of these three data elements beginning with the 2022 benefit year.

As stated above, we also propose to require issuers to include five new data elements—ZIP code, race, ethnicity, an ICHRA indicator, and a subsidy indicator—as part of their risk adjustment submissions to issuer EDGE servers beginning with the 2023 benefit year. We believe issuers currently collect ZIP codes; therefore, the burden associated with the proposed collection of this data element through issuer EDGE servers would only be the additional effort and expense for issuers to compile and submit this additional data element to their EDGE servers, as well as to retain this data element as part of their risk adjustment records as required under § 153.620(b). Because the subsidy indicator is derived from existing data,[187] we believe the burden would again only be the additional effort and expense for issuers to compile and submit this data element to their EDGE servers, as well as to retain this data element as part of their risk adjustment records as required under § 153.620(b). In contrast, we do not believe information to populate the ICHRA indicator is routinely collected by all issuers at this time; therefore, in recognition of the burden that collection of this new data element potentially would pose for some issuers, we propose to make submission of the ICHRA indicator on issuers' EDGE servers optional for the 2023 and 2024 benefit years. This transitional approach for the ICHRA indicator would be similar to how we have handled other new data collection requirements[188] and would allow issuers additional time to develop processes for collection, validation and submission of this new data field before it is required.

We believe that most issuers currently collect race and ethnicity data in some manner, and therefore the burden associated with the collection of this information through issuer EDGE servers would only be the additional effort and expense for issuers to compile and submit these additional data elements to their EDGE servers and retain these data elements as part of their risk adjustment records as required under § 153.620(b). However, we are interested in comments on the collection of these data elements, issuers' rate of collections of these data elements in accordance with the 2011 HHS Data Standards[189] and whether there are any considerations about the availability and current collection of these data elements that HHS should be aware of, given that these data fields are often an optional field on health insurance application and enrollment forms.[190] We also acknowledge that some of these new proposed data elements, such as race and ethnicity and the ICHRA indicator, may be collected by HHS from FFE or SBE–FP enrollees through the QHP application process and from State Exchange enrollees through the State Exchange enrollment and payment files and our intention would be to structure these data elements similar to current collections, where possible. However, this proposal would require all issuers of risk adjustment covered plans to make these data elements accessible to HHS through their EDGE servers as part of the required risk adjustment data submissions in states where HHS operates the risk adjustment program. The data that issuers submit to their EDGE servers would be more uniform and comprehensive than information submitted by FFE and SBE–FP enrollees on a QHP application and by State Exchange enrollees through enrollment and payment files, as it would represent all enrollees in risk adjustment covered plans, including coverage offered inside and outside of Exchanges. By collecting these data as part of the required risk adjustment data issuers submit to their respective EDGE servers, HHS would also have the ability to extract and aggregate these data elements with other claims and enrollment data accessible through issuer EDGE servers, which would not be possible with the data collected from consumers through other processes because the EDGE data is masked[191] and therefore cannot be linked with other sources. We considered the possibility of using data imputation methods with existing *HealthCare.gov* application data to construct a simulated dataset and conduct preliminary exploratory analysis, but once again determined that

[186] As detailed later, we propose to adopt a transition approach for the ICHRA indicator, which would make this data field optional for the 2023 and 2024 benefit years.

[187] Subsidy indicator is derived from the Marketplace enrollment data communicated to issuers where this data provides the APTC amount for an enrollee. Issuers would be able to use this information to derive the subsidy indicator for each enrollee.

[188] For example, HHS did not penalize issuers for temporarily submitting a default value for the in/out-of-network indicator for the 2018 benefit year in order to give issuers time to make the necessary changes to their operations and systems to comply with the new data collection requirement, but required issuers to provide full and accurate information for the in/out-of-network indicator beginning with the 2019 benefit year.

[189] HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status | ASPE *See* HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status | ASPE, available at *https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0.*

[190] Race and ethnicity questions, for example, are optional on the *HealthCare.gov* application. See *https://www.reginfo.gov/public/do/PRAICList?ref_nbr=201903-0938-016* (Attachment A, page 27–28).

[191] 45 CFR 153.720.

we would be unable to impute data from the applications due to the EDGE data being masked. We therefore do not view this as a duplicative data collection. Our proposal also would ensure HHS has access to the same information in the same format for on- and off-Exchange enrollments, as well as across all Exchange types—FFEs, SBE–FPs and State Exchanges—for the individual, small group and merged markets.

To fully assess the additional issuer burden resulting from this proposal, we seek comment on the relative value of the additional data elements we propose to require when compared to other data elements we could propose to collect. For instance, we seek comment on whether HHS should consider collecting county data in lieu of ZIP code, and also solicit comment on whether HHS should consider requiring issuers to report census tract data, instead of ZIP codes or county data. Specifically, we understand that five-digit ZIP codes can change on a regular basis, which could limit the usefulness of this data element when comparing data across benefit years. Census tract data or county data, therefore, may be more useful. We also clarify that, while race and ethnicity would be required data submission elements under these proposals, issuers would have the option of selecting ''unknown'' for this data element, which aligns with the approach taken for application and enrollment forms. In other words, issuers would not be penalized if they did not have the data for a particular enrollee. Instead, this proposal is designed to require the submission of race and ethnicity data if a particular enrollee provided it to their respective issuer. We also seek comment on how issuers may already be collecting data on race and ethnicity in order to identify alternatives that HHS could consider to further ease the burden of this collection while also meeting the stated goals of collecting data to analyze more subpopulations than the current data allows, consider more areas of health equity, and better address discrimination in health care and health disparities.

f. Encouraging the Use of Z Codes

We seek comment on the collection and extraction of z codes (particularly Z55–Z65), a subset of ICD–10–CM encounter reason codes used to identify, analyze, and document social determinants of health.[192] We are currently collecting z codes in the enrollee-level EDGE data and have started analyzing those codes.[193] However, we understand there have been reports of a lack of consistent use of z codes by providers [194] and we want to encourage consistent use of z codes to help further assess risk in the individual, small group and merged market risk pools. We solicit comment on whether there are policies that HHS should pursue that could encourage consistent use of z codes by providers to support collection and use of the data for the HHS-operated risk adjustment program. In light of E.O. 13985 and E.O. 14009, HHS is interested in analyzing z code data to learn about the relationship between risk and the social determinants of health. Finally, we seek comment on whether there are other data elements HHS should consider collecting and extracting to support the operation of the HHS-operated risk adjustment program.

6. Risk Adjustment User Fee for 2023 Benefit Year (§ 153.610(f))

HHS proposes a risk adjustment user fee for the 2023 benefit year of $0.22 per member per month (PMPM). Under § 153.310, if a state is not approved to operate, or chooses to forgo operating, its own risk adjustment program, HHS will operate risk adjustment on its behalf. As noted previously in this proposed rule, for the 2023 benefit year, HHS will be operating the risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS' operation of risk adjustment on behalf of states is funded through a risk adjustment user fee.[195] Section 153.610(f)(2) provides that, where HHS operates a risk adjustment program on behalf of a state, an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A–25 established federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. The HHS-operated risk adjustment program provides special benefits as defined in section 6(a)(1)(B) of Circular No. A–25 to issuers of risk adjustment covered plans because it mitigates the financial instability associated with potential adverse risk selection. The risk adjustment program also contributes to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual, merged, and small group markets.

In part 2 of the 2022 Payment Notice final rule, we calculated the federal administrative expenses of operating the risk adjustment program for the 2022 benefit year to result in a risk adjustment user fee rate of $0.25 PMPM based on our estimated costs for risk adjustment operations and estimated billable member months for individuals enrolled in risk adjustment covered plans.[196] For the 2023 benefit year, HHS proposes to use the same methodology to estimate our administrative expenses to operate the risk adjustment program. These costs cover development of the model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, operational support, and administrative and personnel costs dedicated to risk adjustment program activities. To calculate the user fee, we divided HHS' projected total costs for administering the risk adjustment program on behalf of states by the expected number of billable member months in risk adjustment covered plans in states where the HHS-operated risk adjustment program will apply in the 2023 benefit year.

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of states for the 2023 benefit year will be approximately $60 million, and therefore, the proposed risk adjustment user fee is $0.22 PMPM. The risk adjustment user fee costs for the 2023 benefit year are expected to remain steady from the prior 2022 benefit year estimates. However, we project a small increase in billable member months in the individual and small group (including merged) markets overall in the 2023 benefit year based on the enrollment increases observed in the 2020 benefit year prior to implementation of the ARP in 2021. The

[192] See CMS Infographic: *Using Z Codes: The Social Determinants of Health; Data Journey to Better Outcomes,* available at *https://www.cms.gov/files/document/zcodes-infographic.pdf,* last accessed Nov. 5, 2021. See also *Utilization of Z Codes for Social Determinants of Health Among Medicare Fee-for-Service Beneficiaries, 2019,* available at *https://www.cms.gov/files/document/zcodes-infographic.pdf.*

[193] Using the 2019 enrollee-level EDGE data, we found that only 0.49 percent of the population had a code within Z55–Z65 range. These enrollees had higher costs than enrollees without a Z55–Z65 code across all age/sex and market/metal/CSR categories.

[194] See *https://journals.lww.com/lww-medicalcare/Fulltext/2020/12000/Utilization_of_Social_Determinants_of_Health.2.aspx.*

[195] 78 FR 15409 at 15416–15417.

[196] 86 FR 24140 at 24195–24196.

assumption that the enhanced premium tax credit subsidies in section 9661 of the ARP will expire after the 2022 benefit year significantly influenced our development of the 2023 enrollment and premium projections used to develop the proposed risk adjustment user fee for the 2023 benefit year. We expect the expiration of this ARP provision to revert enrollment projections to the pre-ARP level observed in the 2020 benefit year. We seek comment on the proposed risk adjustment user fee for the 2023 benefit year.

7. Compliance With Risk Adjustment Standards; High-Cost Risk Pool Funds—Audits of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))

HHS proposes that whenever HHS recoups high-cost risk pool funds as a result of audits of risk adjustment covered plans under § 153.620(c)(5)(ii), the high-cost risk pool funds recouped from an issuer in an applicable national high-cost risk pool [197] would be used to reduce high-cost risk pool charges for that national high-cost risk pool beginning for the current benefit year, if high-cost risk pool payments have not already been calculated for that benefit year. If high-cost risk pool payments have already been calculated for the current benefit year, we propose to use the recouped high-cost risk pool funds to reduce the next applicable benefit year's high-cost risk pool charges for all issuers owing high-cost risk pool charges for that national high-cost risk pool.

In part 2 of the 2022 Payment Notice final rule, HHS codified several requirements related to the audits and compliance reviews of risk adjustment covered plans.[198] We did not finalize our disbursement proposal for high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan under § 153.620(c), but stated our intention to address this issue in future rulemaking.[199] As such, we are proposing here that any high-cost risk pool funds recouped through an audit under § 153.620(c)(5)(ii) would be disbursed in the next benefit year for which high-cost risk pool payments have not already been calculated, in the form of reduced charges for all issuers owing high-cost risk pool charges in the applicable national high-cost risk pool. If HHS recoups high-cost risk pool funds after the current benefit year's high-cost risk pool payments have been calculated, we propose to apply the high-cost risk pool funds recouped through an audit under § 153.620(c)(5)(ii) to reduce the next applicable benefit year's high-cost risk pool charges for all issuers owing high-cost risk pool charges for the applicable national high-cost risk pool. For example, if a 2018 high-cost risk pool audit results in funds being recouped for the national high-cost risk pool for the individual market in March 2022, then these recouped funds would be disbursed in the form of reduced 2021 benefit year high-cost risk pool charges for issuers in the national high-cost risk pool for the individual market because high-cost risk pool payments for the 2021 benefit year are not calculated until June 2022. Notwithstanding any reduction to a national high-cost risk pool's charges for a given benefit year, this proposed policy would not impact the amount of high-cost risk pool payments made to eligible issuers, because the reduction in charges is due to the recoupment of funds as the result of an audit of a prior benefit year rather than a change in payments for the given benefit year. In addition, the calculation of high-cost risk pool charges and payments will continue to be calculated in accordance with the established policies, terms and factors.[200] [201] We believe this proposal is consistent with our general policy that HHS would not rerun or otherwise recalculate high-cost risk pool charges and payments for the applicable benefit year if monies are recouped as a result of an audit under § 153.620(c).[202]

We also clarify that when HHS recoups high-cost risk pool funds as a result of an audit, the issuer subject to the audit would then be responsible for reporting that adjustment to its high-cost risk pool payments or charges in the next MLR reporting cycle consistent with the applicable instructions in § 153.710(h). Additionally, for any benefit year in which high-cost risk pool charges are reduced as a result of recouped audit funds, issuers whose charge amounts are reduced would report the high-cost risk pool charges paid for that benefit year net of recouped audit funds in the next MLR reporting cycle consistent with § 153.710(h).

We also propose that any high-cost risk pool funds recouped as a result of an actionable discrepancy or successful administrative appeal filed pursuant to §§ 153.710(d) and 156.1220, respectively, would be treated the same way, that is, any high-cost risk pool funds recouped based on an actionable discrepancy or successful appeal would be used to reduce high-cost risk pool charges for that national high-cost risk pool for the next benefit year for which high-cost risk pool payments have not already been calculated. Additionally, issuers would similarly be responsible for reporting any high-cost risk pool related adjustments that result from the recoupment of funds due to an actionable discrepancy or successful administrative appeal in the next MLR reporting cycle consistent with § 153.710(h).

We seek comment on these proposals.

8. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (HHS–RADV) (§§ 153.350 and 153.630)

To ensure the integrity of the HHS-operated risk adjustment program, HHS conducts risk adjustment data validation (HHS–RADV) under §§ 153.350 and 153.630 in any state where HHS is operating risk adjustment on a state's behalf. [203] The purpose of HHS–RADV is to ensure issuers are providing accurate and complete risk adjustment data to HHS, which is crucial to the purpose and proper functioning of the HHS-operated risk adjustment program. HHS–RADV also ensures that risk adjustment transfers reflect verifiable actuarial risk differences among issuers, rather than risk score calculations that are based on poor data quality, thereby helping to ensure that the HHS-operated risk adjustment program assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. HHS–RADV consists of an IVA and an SVA. Under § 153.630, each issuer of a risk

[197] The high-cost risk pool calculation under the HHS risk adjustment methodology involves two national risk pools—one for the individual market (including catastrophic and non-catastrophic plans, and merged market plans), and another for the small group market. See, for example, 81 FR at 94080–94082.

[198] See 86 FR 24140 at 24287.

[199] We proposed that any high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis to other issuers in the relevant national high-cost risk pool in the form of a reduced high-cost risk pool charge in the applicable benefit year. See 85 FR 78572 at 78604.

[200] See 81 FR 94058, 94081. Also see 84 FR 17454, 17467 (We are finalizing the $1 million threshold and 60 percent coinsurance rate for 2020 benefit year and beyond without requiring notice and comment on the high-cost risk pool thresholds each year.). We are not proposing changes to the high-cost risk pool parameters for the 2023 benefit year. Therefore, we would maintain the $1 million threshold and 60 percent coinsurance rate.

[201] For a visual illustration of the high-cost risk pool terms and factors, see 86 FR at 24184–24185.

[202] 86 FR 24140 at 24193.

[203] HHS has operated the risk adjustment program in all 50 states and the District of Columbia since the 2017 benefit year.

adjustment covered plan must engage an independent IVA entity. The issuer provides demographic, enrollment, prescription drug, and medical record documentation for a sample of enrollees selected by HHS to the issuer's IVA entity. Each issuer's IVA is followed by an SVA, which is conducted by an entity HHS retains to verify the accuracy of the findings of the IVA. Based on the findings from the IVA and SVA as applicable, HHS conducts error estimation to calculate an error rate.

In the 2020 HHS–RADV Amendments Rule,[204] we described and finalized the error rate calculation methodology for HHS–RADV applicable for benefit years 2019 and onward. In this rule, we propose further refinements to the HHS–RADV error rate calculation methodology beginning with the 2021 benefit year and beyond to: (1) Extend the application of Super HCCs to also apply to coefficient estimation groups throughout the HHS–RADV error rate calculation processes, (2) specify that the Super HCC will be defined separately according to the age group model to which an enrollee is subject, and (3) constrain to zero any outlier negative failure rate in a failure rate group, regardless of whether the outlier issuer has a negative or positive error rate.

HHS is committed to ensuring the integrity and reliability of HHS–RADV and continuously improving the error rate calculation methodology and program requirements. As part of our ongoing efforts to explore potential modifications to the HHS–RADV error rate calculation methodology, we have identified through our own analysis, and through feedback from stakeholders, these areas for further refinement. We believe these proposals will better align the calculation and application of error rates with the intent of the HHS–RADV program, thereby enhancing the integrity of HHS–RADV and the HHS-operated risk adjustment program.

a. Coefficient Estimation Groups in Error Estimation

First, we propose to modify our process for grouping coefficient estimation groups in error estimation. In the 2020 HHS–RADV Amendments Rule,[205] we finalized a policy to ensure that HCCs that share a coefficient estimation group used in the risk adjustment models are sorted into the same failure rate groups by first aggregating any HCCs that share a coefficient estimation group into Super HCCs before applying the HHS–RADV failure rate group sorting algorithm. Since implementing the Super HCC policy, we found there are rare occasions where there is a minor misalignment between the calculation of risk adjustment plan liability risk score (PLRS) values and HHS–RADV error estimation. To address these rare situations, in this rule we propose to modify the Super HCC policy to apply the coefficient estimation group logic as expressed in the applicable benefit year's DIY software throughout the HHS–RADV error rate calculation methodology, as they are in risk adjustment. We propose to adopt these changes beginning with the 2021 benefit year of HHS–RADV.

The majority of HCCs in a coefficient estimation group are in the same hierarchy, but in rare instances an individual enrollee may be recorded on an issuer's EDGE server as having multiple HCCs in an HCC coefficient estimation group that do not have a direct hierarchical relationship to one another. For example, based on the 2021 DIY software Tables 4 and 6,[206] HCC 61 Osteogenesis Imperfecta and Other Osteodystrophies shares coefficient estimation group G04 with HCC 62 Congenital/Developmental Skeletal and Connective Tissue Disorders in the adult risk adjustment models, but the two HCCs are not hierarchically related. However, even if an enrollee has both unrelated conditions, the enrollee only receives the coefficient for one of those conditions in the enrollee's risk adjustment risk score calculation because both conditions share the same coefficient estimation group.

To further explain, when such HCCs share a direct hierarchical relationship, the presence of the more severe condition nullifies the presence of the less severe condition; that is, the enrollee will receive credit in risk adjustment and HHS–RADV for only the most severe of the two conditions. Similarly, in risk adjustment, when HCCs that share a coefficient estimation group do not share a direct hierarchical relationship, an enrollee will have both HCCs nullified and replaced with a single instance of a variable indicating the presence of HCCs in that coefficient estimation group, as seen in DIY software Tables 6 and 7, leading to the enrollee only receiving one indicator of risk across both conditions. However, in this latter case, the process of nullifying and replacing the HCCs with the variable representing the coefficient estimation group is not currently replicated in the calculation of HHS–RADV failure rates, group adjustment factors, or enrollee adjustment factors, so it is possible for an enrollee to be recorded in their EDGE, IVA, or SVA data as having both conditions for the purposes of HHS–RADV.

The nullification and replication process in the risk adjustment risk score calculation de-duplicates conditions in coefficient estimation groups in the same way that multiple HCCs that share a hierarchical relationship are de-duplicated. However, there is no analogous de-duplication process for coefficient estimation groups in HHS–RADV.[207] As such, it is possible for an enrollee to be recorded as having multiple conditions in a coefficient estimation group for HHS–RADV, requiring the issuer to be able to validate both conditions to avoid receiving an HHS–RADV adjustment to the enrollee's risk score, even though the enrollee only received the coefficient for one of those conditions in the enrollee's risk adjustment risk score calculation. Therefore, beginning with the 2021 benefit year of HHS–RADV, we are proposing to extend the Super HCC policy finalized in the 2020 HHS–RADV Amendments Rule, such that HHS will apply the coefficient estimation group logic as expressed in the applicable benefit year's DIY software[208] throughout HHS–RADV error estimation, rather than just at the sorting step that assigns HCCs to failure rate groups. This change would mean that an issuer would only need to validate one HCC in a coefficient estimation group to avoid further impacting an adjustment to an enrollee's risk score in HHS–RADV, aligning with how an enrollee's risk score[209] would be calculated under the state payment transfer formula.

[204] 85 FR 76979.

[205] See 85 FR 76979 at 76984–76989.

[206] See, for example, the August 3, 2021 version of the DIY software is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.*

[207] It is rare for an enrollee to have two HCCs in the same coefficient estimation group that are not also in a hierarchical relationship. This situation occurred in no more than 0.1 percent of enrollees sampled for 2017 and 2018 HHS–RADV.

[208] In section III.C.8.b. of this proposed rule, we propose how the coefficient estimation group logic would be applied to adult, child, and infant enrollees and discuss alternative application methodologies.

[209] In the application of the coefficient estimation group logic to HHS–RADV, the definition of coefficient estimation groups for the infant models depends upon proposals in section III.C.8.b. of this proposed rule. If the approach in section III.C.8.b. is finalized as proposed, Super HCCs for the infant models would be based on the calculated model factors used for the infant models, as described in the applicable benefit year's DIY software ''Additional Infant Variables'' table logic (Table 8 of the 2021 Benefit Year DIY Software). In section III.C.8.b. of this rule, we also briefly describe alternative approaches wherein Super HCCs for infants would be identical to those for the child

If finalized as proposed, this update to the Super HCC policy would necessitate a change to the policy finalized in the 2021 Payment Notice [210] which amended the outlier identification process to not consider an issuer as an outlier in any failure rate group in which that issuer has fewer than 30 HCCs.[211] That policy was developed based on results of analysis that showed that if the number of EDGE HCCs per sample of enrollees was below 30 HCCs, the implied alpha of our statistical tests for outliers was higher than our 5 percent target, thereby failing to meet the threshold for statistical significance. Moreover, statistical practice often relies on a standard recommendation regarding the determination of sample size, which states that sample sizes below 30 observations are often insufficient to assume that the sampling distribution is normally distributed.[212]

The 2021 Payment Notice policy was developed when individual HCCs were the unit of analysis for calculating failure rates. However, the proposed policy in this rule to de-duplicate coefficient estimation groups in HHS–RADV would alter the unit of analysis of failure rates to be de-duplicated Super HCCs,[213] rather than individual HCCs. Although the unit of analysis would have changed, the underlying issue with sample size in the outlier identification process would remain the same. As such, as a part of this proposal, we propose to generally maintain the outlier identification approach adopted in the 2021 Payment Notice and propose to not consider an issuer as an outlier in any failure rate group in which that issuer has fewer than 30 de-duplicated EDGE Super HCCs (which would include, as proposed below, maturity-severity factors for infant enrollees) beginning with 2021 benefit year HHS–RADV. Consistent with the policies adopted in the 2021 Payment Notice,[214] we also propose to continue to include data from an issuer who has fewer than 30 de-duplicated EDGE Super HCCs in a failure rate group in the calculation of national metrics for that failure rate group, including the national mean failure rate, standard deviation, and upper and lower confidence interval bounds. However, the issuer would not have its risk score adjusted for that group, even if the magnitude of its failure rate appeared to otherwise be very large relative to other issuers. In addition, we clarify that under this proposal this issuer may be considered an outlier in other failure rate groups in which it has 30 or more de-duplicated EDGE Super HCCs.

We seek comment on this proposal and whether HCCs in coefficient estimation groups should be de-duplicated before they are sorted into failure rate groups and in all subsequent stages of HHS–RADV error estimation.

b. Defining Super HCCs Separately for Adults, Children, and Infants

In conjunction with our proposal to modify the application of coefficient estimation groups in section III.C.8.a. of this proposed rule, we also propose to modify the Super HCC policy to apply coefficient estimation groups to enrollees according to the risk adjustment model to which they are subject. Under the current Super HCC policy, coefficient estimation group logic from the adult models is applied to all enrollees, including those subject to the child and infant models.[215] As detailed in the 2020 HHS–RADV Amendments Rule, we adopted this approach because the adult models' HCC coefficient estimation groups will be applicable to the vast majority of enrollees [216] and our belief that the use of HCC coefficient estimation groups present in the adult risk adjustment models sufficiently balances the representativeness and accuracy of HCC failure rate estimates across the entire population in aggregate.[217]

However, there are some differences in the structure of the risk adjustment model coefficient estimation groups between the adult, child, and infant models that the current approach does not take into account. For example, the child and adult risk adjustment models' coefficient estimation groups for the 2021 benefit year and onward [218] are almost identical with the exception of two adult-only coefficient estimation groups and five child-only coefficient estimation groups (Table 9).

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models, or identical to those for the adult models, and would involve additional steps analogous to those described in Chapter 11.3.4 of the 2020 Benefit Year HHS–RADV Protocols, available at *https://www.regtap.info/uploads/library/2020_RADV_Protocols__042921_5CR_060421.pdf*. These additional steps would not be necessary if the Super HCCs proposals in this rule to define Super HCCs separately for adults, children, and infants are finalized as proposed.

[210] 85 FR at 29196 through 29198.

[211] Under the outlier identification policy finalized in the 2021 Payment Notice, data from an issuer who has fewer than 30 HCCs in a failure rate group is included in the calculation of national metrics for that failure rate group, including the national mean failure rate, standard deviation, and upper and lower confidence interval bounds. However, the issuer does not have its risk score adjusted for that group, even if the magnitude of its failure rate appeared to otherwise be very large relative to other issuers. In addition, we clarified that this issuer may be considered an outlier in other failure rate groups in which it has 30 or more HCCs.

[212] For example, David C. Howell, ''Hypothesis Tests Applied to Means'' In Statistical Methods for Psychology (8th Ed.), 177–228. Belmont, CA: Wadsworth, 2010.

[213] If the approach in section III.C.8.b. is finalized as proposed, Super HCCs for the infant models would be based on the calculated model factors used for the infant models, as described in the applicable benefit year's DIY software ''Additional Infant Variables'' table logic (Table 8 of the 2021 Benefit Year DIY Software). In section III.C.8.b. of this rule, we also briefly describe alternative approaches under which Super HCCs for infants would be identical to those for the child models, or identical to those for the adult models, and would involve additional steps analogous to those described in Chapter 11.3.4 of the 2020 Benefit Year HHS–RADV Protocols (available at). These additional steps would not be necessary if the Super HCCs proposals in this rule proposed to define Super HCCs separately for adults, children, and infants are finalized as proposed.

[214] 85 FR at 29196 through 29198.

[215] See 85 FR at 76984 through 76900.

[216] The majority of the population with HCCs in the HHS–RADV samples are subject to the adult models (88.3 percent for the 2017 benefit year; 88.7 percent for the 2018 benefit year). For 2017, this was calculated after removing issuers in Massachusetts and incorporating cases where issuers failed pairwise and the SVA subsample was used.

[217] See 85 FR at 76987.

[218] Starting in 2021 benefit year, the HHS risk adjustment models use Version 07 for the HHS–HCC classification. Prior to the 2021 benefit year, the HHS risk adjustment models used Version 05 for HHS–HCC classification.

TABLE 9: Comparison of V07 Coefficient Estimation Groups Used in the Adult and Child Models

Coefficient Estimation Group	Used in Model		HCC	Description
	Adult	Child		
G01	✔	✔	HCC 19	Diabetes with Acute Complications
			HCC 20	Diabetes with Chronic Complications
			HCC 21	Diabetes without Complication
G02B	✔	✔	HCC 26	Mucopolysaccharidosis
			HCC 27	Lipidoses and Glycogenosis
G02D		✔	HCC 28	Congenital Metabolic Disorders, Not Elsewhere Classified
			HCC 29	Amyloidosis, Porphyria, and Other Metabolic Disorders
G03		✔	HCC 54	Necrotizing Fasciitis
			HCC 55	Bone/Joint/Muscle Infections/Necrosis
G04	✔	✔	HCC 61	Osteogenesis Imperfecta and Other Osteodystrophies
			HCC 62	Congenital/Developmental Skeletal and Connective Tissue Disorders
G06A	✔	✔	HCC 67	Myelodysplastic Syndromes and Myelofibrosis
			HCC 68	Aplastic Anemia
			HCC 69	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn
G07A	✔	✔	HCC 70	Sickle Cell Anemia (Hb-SS)
			HCC 71	Beta Thalassemia Major
G08	✔	✔	HCC 73	Combined and Other Severe Immunodeficiencies
			HCC 74	Disorders of the Immune Mechanism
G09A	✔	✔	HCC 81	Drug Use with Psychotic Complications
			HCC 82	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications
G09C	✔	✔	HCC 83	Alcohol Use with Psychotic Complications
			HCC 84	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications
G10	✔	✔	HCC 106	Traumatic Complete Lesion Cervical Spinal Cord
			HCC 107	Quadriplegia
G11	✔	✔	HCC 108	Traumatic Complete Lesion Dorsal Spinal Cord
			HCC 109	Paraplegia
G12	✔	✔	HCC 117	Muscular Dystrophy
			HCC 119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders
G13	✔	✔	HCC 126	Respiratory Arrest
			HCC 127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
G14	✔	✔	HCC 128	Heart Assistive Device/Artificial Heart
			HCC 129	Heart Transplant Status/Complications
G15A	✔		HCC 160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis
			HCC 161_1	Severe Asthma
			HCC 161_2	Asthma, Except Severe
G16	✔	✔	HCC 187	Chronic Kidney Disease, Stage 5
			HCC 188	Chronic Kidney Disease, Severe (Stage 4)
G17A	✔	✔	HCC 204	Miscarriage with Complications
			HCC 205	Miscarriage with No or Minor Complications
G18A	✔	✔	HCC 207	Pregnancy with Delivery with Major Complications

			HCC 208	Pregnancy with Delivery with Complications
G19B		✔	HCC 210	(Ongoing) Pregnancy without Delivery with Major Complications
			HCC 211	(Ongoing) Pregnancy without Delivery with Complications
G21	✔		HCC 137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders
			HCC 138	Major Congenital Heart/Circulatory Disorders
			HCC 139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders
G22		✔	HCC 234	Traumatic Amputations and Amputation Complications
			HCC 254	Amputation Status, Upper Limb or Lower Limb
G23		✔	HCC 131	Acute Myocardial Infarction
			HCC 132	Unstable Angina and Other Acute Ischemic Heart Disease

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The infant models also are composed of variables that function analogously to coefficient estimation groups in that they can represent the presence of a large number of HCCs, or just a single HCC. However, these variables in the infant models, the severity-maturity interaction factors, are structured completely differently from the coefficient estimation groups in the adult and child models. We have continued to consider these issues as we gained more experience with operating HHS–RADV and had access to additional years of HHS–RADV data to analyze.

In recognition of the differences in each age group model's definitions, and based on the results of further analysis on the year-over-year stability of sorting Super HCCs into three failure rate groups, described below, we propose to define Super HCCs as:

- The HCC-derived adult model variables after the application of the relevant rows in the applicable benefit year's DIY software adult variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software,[219] the ''HCC group'' rows in Table 6: Additional Adult Variables),
- The HCC-derived child model variables after the application of the relevant rows in the applicable benefit year's DIY software child variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software, the ''HCC group'' rows in Table 7: Additional Child Variables), and
- The HCC-derived infant model variables after the application of the relevant rows in the applicable benefit year's DIY software infant variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software, the ''Severity level'', ''Maturity level'', ''Assign as IHCC AGE1 if needed'', ''Impose hierarchy'', and ''Maturity x severity level interactions'' rows in Table 8: Additional Infant Variables).

Under this approach, we would sort the adult and child coefficient estimation groups into failure rate groups together, when they are identical in definition between the adult and child models, and independently from one another when they are not identical. For infant enrollees, rather than have individual HCCs sorted into failure rate groups, or use the adult or child coefficient estimation group (Super HCC) definitions, we would sort the infant enrollees' maturity-severity level interaction factors themselves into failure rate groups as Super HCCs after they have been de-duplicated. In short, for the risk adjustment models for 2021 benefit year and onward, using each age group's model factors to define Super HCCs, and sorting adult and child Super HCCs together when they have identical definitions, would increase the number of factors used in sorting from 110 under the current Super HCC grouping policy established in the 2020 RADV Amendments Rule to 146 under this approach. We propose to adopt these changes to the Super HCC policy beginning with the 2021 benefit year of HHS–RADV.

When we established the current Super HCC grouping policy in the 2020 HHS–RADV Amendments Rule,[220] we acknowledged the possibility of defining Super HCCs based on each model separately. Nevertheless, we proposed and finalized Super HCCs based on only the adult models due to concerns that using the child and infant models separately would result in some infant model Super HCCs with very small sample sizes, leading to less stable failure rate group assignments year-over-year. We also finalized a policy to use the adult models to create Super HCCs because the adult models' HCC coefficient estimation groups will be applicable to the vast majority of enrollees (including most children, considering the strong overlap between the structure of the adult and child models) and our belief that the use of HCC coefficient estimation groups present in the adult risk adjustment models sufficiently balances the representativeness and accuracy of HCC failure rate estimates across the entire population in aggregate. However, simulations run using 2018 HHS–RADV data[221] have shown that if we were to use each model's factor definitions separately as proposed in this rule, with adult and child coefficient estimation groups that have identical definitions being sorted together, we would expect 93.4 percent of factors for one benefit year of HHS–RADV to be sorted into the same failure rate group for the subsequent benefit year of HHS–RADV. Similarly, according to our simulation of 1,000 subsequent years of HHS–RADV, if we were to base Super HCCs on the adult models for adults and the child models for children and infants, the percentage of factors whose sorting would remain stable between subsequent years would be 93.2 percent. In contrast, and contrary to expectations, if Super HCCs were only based on the definitions in the adult

[219] See, for example, the August 3, 2021 version of the DIY software is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.*

[220] See 85 FR at 76984–76900.

[221] The 2018 risk adjustment models, to which the 2018 HHS–RADV data were subject, were based on the V05 HHS–HCC classification for the HHS risk adjustment models, which is the version of the HHS–HCC classification that applies through the 2020 benefit year. The 2021 risk adjustment models, to which the 2021 HHS–RADV data will be subject, were based on the V07 HHS-Condition Categories, which applies for the 2021 benefit year and beyond.

models, we would expect only 91.4 percent of factors to remain in the same failure rate group across subsequent benefit years.

This analysis demonstrates that the very small sample sizes for enrollees subject to the infant models would not lead to more overall instability if the Super HCC policy was modified to use each age group's model factor definitions separately, except for where child and adult coefficient estimation groups have identical definitions, to define Super HCCs. In fact, our continued study of these issues found that using each model's factor definitions separately, except for where child and adult coefficient estimation groups have identical definitions, to define Super HCCs could provide more stability than using only the adult models, or a combination of the child and adult models. In addition, we note that beginning with the 2021 benefit year, the risk adjustment models were updated based on Version 07 (V07) of the HHS–HCC classification.[222] When the Super HCC policy was first implemented in the 2020 HHS–RADV Amendments Rule,[223] the risk adjustment models for the earliest HHS–RADV benefit years to which the policy was effective (HHS–RADV benefit years 2019 and 2020) were based on Version 05 (V05) of the HHS–HCC classification.[224] Due to the change in the HHS–HCC hierarchies in the V07 classification,[225] the structure of the coefficient estimation groups for the child models for the 2021 benefit year and beyond differs further from the structure of the coefficient estimation groups for the adult models than it did for the 2019 and 2020 benefit years. For these reasons, we are proposing to define Super HCCs based on each age group's model factor definitions separately, except for where child and adult coefficient estimation groups have identical definitions, as described in the relevant rows in the applicable benefit year's DIY software adult variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software,[226] the ''HCC group'' rows in Table 6: Additional Adult Variables), the relevant rows in the applicable benefit year's DIY software child variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software, the ''HCC group'' rows in Table 7: Additional Child Variables), and the relevant rows in the applicable benefit year's DIY software infant variable logic (for example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software, the ''Severity level'', ''Maturity level'', ''Assign as IHCC AGE1 if needed'', ''Impose hierarchy'', and ''Maturity x severity level interactions'' rows in Table 8: Additional Infant Variables).

These relevant rows of the applicable benefit year's DIY software tables would be applied such that each instance of a Super HCC is only counted once per enrollee, even if that enrollee has multiple HCCs in that Super HCC. Furthermore, any payment HCCs that are not modified by the DIY software table logic rows referenced above would be treated as individual Super HCCs, such that all Super HCCs are aligned with how their component HCCs are treated in the risk adjustment models for the applicable benefit year. We propose to apply this change beginning with the 2021 benefit year of HHS–RADV.

We seek comment on these proposals and whether Super HCCs should continue to be defined for all enrollees based on only the adult models,[227] should be defined for adult enrollees based on the adult models and for child and infant enrollees based on the child models,[228] or should be defined for each age group according to the age group risk adjustment model to which they are subject, as proposed.

c. Negative Failure Rate Constraint

In the 2020 HHS–RADV Amendments Rule,[229] we finalized a policy to constrain outlier issuers' error rate calculations to zero in cases when an issuer is a negative error rate outlier and its failure rate is negative, beginning with 2019 benefit year HHS–RADV. We finalized this policy in order to distinguish between low failure rates due to accurate data submission and failure rates that have been depressed through the presence of HCCs in the audit data that were not present in the EDGE data. If a negative failure rate is due to a large number of found HCCs, it does not reflect accurate reporting through the EDGE server for risk adjustment.

In this rule, we propose modifying the application of that policy beginning with the 2021 benefit year of HHS–RADV to constrain to zero the failure rate of any issuer who is a negative failure rate outlier in a failure rate group, regardless of whether the outlier issuer has a negative or positive error rate. We believe this proposed policy is appropriate and necessary to account for the fact that, because there are three failure rate groups in HHS–RADV, it is possible for a positive error rate outlier issuer to have a negative failure rate in one failure rate group and a positive failure rate in another failure rate group. To address those cases, we propose to amend the application of the negative failure rate constraint policy such that, for the purposes of calculating the group adjustment factor (GAF), we would constrain to zero the failure rate of any failure rate group in which an issuer is a negative failure rate outlier, regardless of whether the outlier issuer has an overall negative or positive error rate. We propose to adopt this policy beginning with the 2021 benefit year HHS–RADV. Although our experience to date leads us to believe that this scenario is unlikely to occur often, this refinement is consistent with the intent of the policy to reduce potential incentives for issuers to use HHS–RADV to identify more HCCs than were reported to their EDGE servers for an applicable benefit year.

We seek comment on this proposal.

9. Disbursement of Recouped High-Cost Risk Pool Funds—Discrepancies of Issuers of Risk Adjustment Covered Plans (§ 153.710(d))

HHS proposes that any funds recouped as a result of an actionable high-cost risk pool-related discrepancy under § 153.710(d) would be used to reduce high cost-risk pool charges for that national high-cost risk pool for the current benefit year if high-cost risk pool payments have not already been calculated for that benefit year. If high-cost risk pool payments have already been calculated for that benefit year, we propose to use the high-cost risk pool funds recouped based on an actionable

[222] 85 FR 29164.

[223] See 85 FR 76984–76990.

[224] See Table 4 of the 2019 DIY software tables, available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/DIY-Tables-2019.04.2020.xlsx.* See also Table 4 of the 2020 DIY software tables, available at *https://www.cms.gov/files/document/hhs-hcc-software-v0520128q2-tables-04132021.xlsx.*

[225] For a discussion of these changes, see 85 FR at 7098–7101 and 85 FR at 29175–29185. Also see the Potential Updates to HHS–HCCs for the HHS-operated Risk Adjustment Program (June 17, 2019), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf.*

[226] The August 3, 2021 version of the DIY software is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.*

[227] If this alternative approach is adopted, for infant enrollees, Super HCCs would not align with the structure of the infant risk adjustment models, as such the HHS–RADV process would involve additional steps analogous to those described in Chapter 11.3.4 of the 2020 Benefit Year HHS–RADV Protocols (available at *https://www.regtap.info/uploads/library/2020_RADV_Protocols__042921_5CR_060421.pdf*). The additional steps described in Chapter 11.3.4 of the 2020 Benefit Year HHS–RADV Protocols would not be necessary if the Super HCCs proposals in this rule are finalized as proposed such that infant enrollee Super HCCs are based on the calculated model factors used for the infant models.

[228] Ibid.

[229] 85 FR at 76994–76998.

discrepancy to reduce the next applicable benefit year's high-cost risk pool charges for all issuers owing high-cost risk pool charges for that national high-cost risk pool. As elsewhere discussed in this preamble, under ''High-Cost Risk Pool Funds—Audits of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))'' and ''Disbursement of Recouped High-Cost Risk Pool Funds—Administrative Appeals of Issuers of Risk Adjustment Covered Plans (§ 156.1220),'' we also propose similar disbursement policies for high-cost risk pool funds HHS recoups as a result of audits of risk adjustment covered plans under § 153.620(c)(5)(ii) and successful administrative appeals under § 156.1220(a)(1)(ii). We propose to treat funds recouped as a result of an actionable high-cost risk pool-related discrepancy the same way. That is, the recouped discrepancy funds would be used to reduce high-cost risk pool charges for that market for the next benefit year for which high-cost risk pool payments have not already been calculated. We also clarify that when HHS recoups high-cost risk pool funds as a result of an actionable discrepancy, the issuer that filed the discrepancy would then be responsible for reporting that adjustment to its high-cost risk pool payments or charges in the next MLR reporting cycle consistent with the applicable instructions in § 153.710(h). Additionally, for any benefit year in which high-cost risk pool charges are reduced as a result of high-cost risk pool funds recouped as a result of an actionable discrepancy, issuers whose charge amounts are reduced would be required to report the high-cost risk pool charges paid for that benefit year net of recouped audit funds in the next MLR reporting cycle consistent with § 153.710(h).

We seek comment on this proposal.

10. Medical Loss Ratio Reporting Requirements (§ 153.710(h))

HHS established a framework in prior rulemakings to guide issuer treatment of certain payments and charges that could be subject to reconsideration for purposes of risk corridors and MLR reporting.[230] For example, because risk adjustment transfer amounts are factors in an issuer's MLR calculations, a delay in resolving final risk adjustment payments and charges, including HHS–RADV adjustments to transfers, could make it difficult for issuers to comply with reporting requirements under the MLR program. A delay in resolving final risk adjustment transfer amounts could occur due to audits, actionable discrepancies, or successful appeals. Therefore, we clarified in § 153.710(h)[231] how issuers should report certain ACA program amounts that could be subject to reconsideration for risk corridors and MLR reporting purposes. In this rule, we propose to amend the introductory sentence in § 153.710(h)(1) and to add a proposed new paragraph (h)(1)(v) to separately address and explicitly capture a reference to HHS–RADV adjustments to make clear that HHS expects issuers to report HHS–RADV adjustments as part of their MLR reports in the same manner as they report risk adjustment payment and charge amounts (including high-cost risk pool payments and charges). That is, notwithstanding any HHS–RADV discrepancy filed under § 153.630(d)(2), or any HHS–RADV request for reconsideration under § 156.1220(a)(1)(vii) and (viii), unless the dispute has been resolved, issuers must report, as applicable, the HHS–RADV adjustment to a risk adjustment payment or charge as calculated by HHS in the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers.[232] We also propose to add a reference to HHS–RADV discrepancies under § 153.630(d)(2) to the introductory sentence in § 153.710(h)(1).

We propose conforming amendments to paragraph (h)(2) to add a reference to HHS–RADV adjustments to address situations where there could be subsequent changes to HHS–RADV adjustments calculated by HHS in the applicable benefit year's HHS–RADV Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers, such as modifications resulting from an actionable discrepancy or successful appeal. In these situations, an issuer would be required to report during the current MLR reporting year any adjustment to an HHS–RADV adjustment made or approved by HHS before August 15, or the next applicable business day, of the current reporting year unless otherwise instructed by HHS. Issuers would be required to report any adjustment to an HHS–RADV adjustment made or approved by HHS where such adjustment has not been accounted for in a prior MLR Reporting Form, in the following reporting year. For example, if an issuer's successful administrative appeal results in changes to HHS–RADV adjustments for a state market risk pool and issuers in that state market risk pool are notified of those modifications in September, those issuers would be required to report these adjusted amounts in the next MLR reporting cycle, after the appeal has been resolved and they receive notice of the adjusted amounts. However, if an appeal is resolved and issuers are notified about modifications to HHS–RADV adjustments for a given benefit year as a result of that appeal before August 15, or the next applicable business day, those issuers must report the adjusted amounts in the current MLR reporting year.

Recognizing that flexibility is often needed in reporting these amounts on MLR forms, consistent with existing framework in § 153.710(h)(3), HHS would have the ability to modify these instructions in guidance in cases where HHS reasonably determines that these reporting instructions would lead to unfair or misleading financial reporting. Our intent in issuing any such guidance would be to avoid having the application of the instructions in exceptional circumstances lead to unfair or misleading financial reporting.[233]

Finally, we propose a technical amendment to § 153.710(h)(3) to replace the current cross-reference to paragraph (g)(1) and (2) of this section with a reference to paragraph (h)(1) and (2) of this section to point to the correct sections that contain the relevant reporting instructions. We inadvertently omitted this update as part of the amendments in the 2022 Payment Notice to incorporate an EDGE materiality threshold as part of § 153.710 that redesignated the risk corridors and MLR reporting instructions provisions from paragraph (g) to paragraph (h).[234]

We seek comments on these proposals.

11. Deadline for Submission of Data (§ 153.730)

A risk adjustment covered plan must submit data to HHS in states where HHS is operating the risk adjustment program that is necessary for HHS to calculate

[230] See 45 CFR 153.710(h). Also see 79 FR at 13789–13790 and 81 FR at 12235–12236.

[231] These instructions were previously codified in 45 CFR 153.710(g) and recently redesignated to 45 CFR 153.710(h). See 79 FR at 13789–13790 and 86 FR at 24194–24195.

[232] See Table 9 in the part 2 of the 2022 Payment Notice, 86 FR at 24201. For example, the 2019 and 2020 benefit year HHS–RADV Summary Report for non-exiting issuers will be published in early summer of 2022 and those issuers would be expected to report those amounts in their 2021 MLR Reports (filed by July 31, 2022).

[233] See, for example, Treatment of Risk Corridors Recovery Payments in the Medical Loss Ratio and Rebate Calculations (December 30, 2020), available at *https://www.cms.gov/files/document/mlr-guidance-rc-recoveries-and-mlr-final.pdf.*

[234] See 85 FR at 78604–78605 and 86 FR at 24194–24195.

risk adjustment payments and charges.[235] [236] In the 2014 Payment Notice, HHS established that the deadline for issuers to submit the required risk adjustment data is April 30 of the year following the applicable benefit year.[237] For example, the deadline for issuers of risk adjustment covered plans to submit the required 2020 benefit year risk adjustment data was April 30, 2021. HHS explained that this deadline provides ample time to allow for claims run-out from the prior benefit year to ensure that diagnoses for the benefit year are captured, while also providing HHS sufficient time to calculate payments and charges and meet the June 30 deadline for notifying issuers of risk adjustment transfer amounts at § 153.310(e).[238]

We are not proposing to change this deadline but propose to amend § 153.730 to address situations when April 30 does not fall on a business day. Currently, when April 30 falls on a non-business day, HHS has exercised enforcement discretion to extend the deadline to the next applicable business day.[239] This occurred in the past for the 2016 and 2017 benefit year data submissions and will occur again for the 2022 benefit year data submissions. Recognizing there will be future benefit years when April 30 does not fall on a business day, HHS proposes to amend § 153.730 to provide that when April 30 of the year following the applicable benefit year falls on a non-business day, the deadline for issuers to submit the required risk adjustment data would be the next applicable business day. We solicit comments on this proposal.

D. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Non-Interference With Federal Law and Non-Discrimination Standards (§ 155.120(c))

We propose to amend 45 CFR 155.120(c) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 155.120(c), but amendments made in 2020 to § 155.120(c) removed any reference to sexual orientation and gender identity. If finalized, this proposal would revert § 155.120(c) to the pre-2020 nondiscrimination protections.

Section 155.120(c) currently provides that in order to avoid interference and comply with applicable non-discrimination statutes, the states and the Exchanges must not discriminate based on race, color, national origin, disability, age, or sex. Previously, in the final rule ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers'' (Exchange Standards final rule), pursuant to the authority provided in section 1321(a)(1)(A) of the ACA to regulate the establishment and operation of an Exchange, we finalized § 155.120(c) to also prohibit discrimination based on sexual orientation and gender identity.[240] However, in the 2020 final rule related to section 1557 of the ACA, HHS revised certain CMS regulations, including those at § 155.120(c), by removing sexual orientation and gender identity as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[241]

CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination in Exchanges pursuant to the authority to establish requirements with respect to the operation of Exchanges in section 1321(a)(1)(A) of the ACA.[242] Pursuant to this authority, HHS finalized in the Exchange Standards final rule that a State must comply with any applicable non-discrimination statutes, specifically finalizing that a State must not operate an Exchange in such a way as to discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. CMS proposes to exercise that same authority here to amend § 155.120(c) to again prohibit states and Exchanges carrying out Exchange requirements from discriminating based on sexual orientation and gender identity. Section 1321(a)(1)(A) of the ACA is the same authority CMS relies upon for implementation of existing nondiscrimination protections at § 155.120(c). Utilizing this same authority to again prohibit discrimination based on sexual orientation and gender identity at § 155.120(c) would be consistent with the authority CMS relies upon for the existing protections at § 155.120(c) that currently prohibit discrimination on the basis of race, color, national origin, disability, age, or sex. We believe such amendments are warranted in light of the existing trends in health care discrimination and are necessary to better address barriers to health equity for LGBTQI+ individuals.

A more in-depth discussion of these developments and other factors considered in proposing these amendments to CMS nondiscrimination protections is included earlier in the preamble to § 147.104 under section III.B.1.b. of this preamble. For brevity, we refer back to § 147.104 under section III.B.1.b. of the preamble rather than restating the issues here.

We seek comment on this proposal.

3. Civil Money Penalties for Violations of Applicable Exchange Standards by Consumer Assistance Entities in Federally-Facilitated Exchanges (§ 155.206)

We propose to make a technical correction to 45 CFR 155.206(i) to add language that would cross-reference to the authority to implement annual inflation-related increases to civil money penalties (CMPs) pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act).[243] Because of an oversight, this language was not added to § 155.206(i) as part of prior efforts and rulemaking to implement the 2015 Act.[244] Additionally, a reference to § 155.206 and any accompanying CMP amounts have not been included in HHS's annual inflation update

[235] See 45 CFR 153.610 and 153.710. Since the 2017 benefit year, HHS has operated the risk adjustment program in all 50 states and the District of Columbia.

[236] Issuers of reinsurance-eligible plans in states where HHS operated the reinsurance program were similarly required to submit the data necessary for HHS to calculate reinsurance payments. See, for example, 45 CFR 153.420 and 153.710. The reinsurance program under section 1341 of the ACA was a temporary program that applied to the 2014–2016 benefit years. The risk adjustment program under section 1343 of the ACA is a permanent program and therefore is the primary focus of this discussion.

[237] See 78 FR 15410 at 15434.

[238] Ibid.

[239] See 81 FR 12204 at 12234 n.20; see also Evaluation of EDGE Data Submissions for 2016 Benefit Year at 1 (Dec. 23, 2016), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2016-Q_Q-Guidance_20161222v1.pdf.*

[240] 77 FR 18310 (March 27, 2012).

[241] 85 FR 37160 (June 19, 2020). *See also id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, and 156.1230).

[242] 85 FR 37218–21 (June 19, 2020).

[243] Sec. 701 of the Bipartisan Budget Act of 2015, Public Law 114–74, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, 104 Stat. 890 (1990).

[244] See, *e.g.,* Department of Health and Human Services; Adjustment of Civil Monetary Penalties for Inflation; Interim Final Rule, 81 FR 61538 (Sept. 6, 2016), available at *https://www.govinfo.gov/content/pkg/FR-2016-09-06/pdf/2016-18680.pdf.*

rulemakings.[245] Therefore, in this rule, we propose to amend § 155.206(i) to add the phrase ''as adjusted annually under 45 CFR part 102'' after the phrase ''$100 for each day'' in order to correct this oversight. The associated CMP table in 45 CFR 102.3 is updated annually, and § 155.206(i) will be included in the next annual update. To date, no CMPs have been imposed under this authority, but any that are will reflect the current inflationary adjusted amount as required by the 2015 Act and will be calculated in accordance with applicable OMB guidance to all Executive Departments on the implementation of the 2015 Act.

4. Ability of States To Permit Agents and Brokers and Web-Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

a. Required QHP Comparative Information on Web-Broker Websites and Related Disclaimer

We propose to amend § 155.220(c)(3)(i)(A) to include at proposed new §§ 155.220(c)(3)(i)(A)(1) through (c)(3)(i)(A)(5) a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We also propose to revise the disclaimer requirement in § 155.220(c)(3)(i)(A) so that web-broker non-Exchange websites would be required to prominently display a standardized disclaimer provided by HHS stating that enrollment support is available on the Exchange website and provide a web link to the Exchange website where enrollment support for a QHP is not available using the web-broker's non-Exchange website.

Currently, § 155.220(c)(3)(i)(A) requires that a web-broker non-Exchange website must disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c). To the extent that not all information required under § 155.205(b)(1) is displayed on the web-broker's website for a QHP, the web-broker's website must prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange website, and provide a link to the Exchange website. The preamble in the proposed [246] and final [247] rules that established the current text in § 155.220(c)(3)(i)(A) explained the intent of this requirement was that a web-broker website must display all information required under § 155.205(b)(1) unless the information was not available to the web-broker, in which case the web-broker website must display the standardized disclaimer. Section 155.220(c)(3)(i)(D) similarly requires web-brokers to display all QHP data provided by an Exchange on its non-Exchange website used to participate in the FFE direct enrollment (DE) program (whether Classic DE or enhanced direct enrollment (EDE)).

In the early years of Exchange operations, we released a data file with limited QHP details (the QHP limited file) that provided web-brokers with a basic set of QHP information that could be used to satisfy the display requirements. Display of the data elements from the QHP limited file, in combination with a standardized disclaimer (the plan detail disclaimer), became the de facto minimum required to satisfy the web-broker's obligation to display QHP information on its non-Exchange website. In adopting this approach, we recognized that the Exchange may not have been able to provide web-brokers with certain data elements necessary to meet the § 155.205(b)(1) requirements, such as premium information, due to confidentiality requirements, web-broker appointments with QHP issuers, and state law. We also recognized some of the data elements, such as quality rating information, were not going to be available in the initial years of the Exchanges' operation.[248]

In the proposed 2022 Payment Notice, we proposed to establish an exception to the web-broker display requirements captured at paragraphs (c)(3)(i)(A) and (D).[249] We proposed to revise paragraph (c)(3)(i)(A) to require a web-broker non-Exchange website to disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), except when a web-broker's website does not support enrollment in a QHP. We proposed a similar revision to § 155.220(c)(3)(i)(D). A web-broker's non-Exchange website may not support enrollment in a QHP if the web-broker does not have an appointment with a QHP issuer and therefore is not permitted under state law to enroll consumers in the coverage offered by that QHP issuer. In such circumstances, we proposed that the web-broker's non-Exchange website would not be required to provide all the information identified under § 155.205(b)(1). Instead, we proposed to require web-brokers to display the following limited, minimum information for such QHPs: Issuer marketing name, plan marketing name, product network type, metal level, and premium and cost-sharing information. To take advantage of this proposed flexibility, we also proposed that web-broker non-Exchange websites would be required to identify to consumers the QHPs, if any, for which the web-broker websites did not facilitate enrollment by prominently displaying the plan detail disclaimer provided by the Exchange. The plan detail disclaimer explains that the consumer can get more information about such QHPs on the Exchange website, and includes a link to the Exchange website. We noted that we believed this proposal struck an appropriate balance by recognizing that web-brokers may not be permitted to assist with enrollments in QHPs for which they do not have an appointment while still providing key information about all QHPs on web-broker non-Exchange websites to allow consumers to window shop and identify whether they may want to explore other QHP options. We noted that it also would minimize burdens for web-brokers by not requiring them to develop processes to display all of the required comparative information listed in § 155.205(b)(1) for those QHPs for which they do not have an appointment to sell. We invited comments on the proposed limited, minimum QHP details that would be required to be displayed for those QHPs that the web-broker does not facilitate enrollment in through its non-Exchange website. We sought comment on whether to require display of any additional elements identified under § 155.205(b)(1) among the limited, minimum information, such as summaries of benefits and coverage.[250]

[245] See, *e.g.,* the Department of Health and Human Services; Annual Civil Monetary Penalties Inflation Adjustment; Final Rule, 85 FR 2869 (Jan. 17, 2020), available at *https://www.govinfo.gov/content/pkg/FR-2020-01-17/pdf/2020-00738.pdf.* See also the Department of Health and Human Services; Adjustment of Civil Monetary Penalties for Inflation and the Annual Civil Monetary Penalties Inflation Adjustment for 2021, 86 FR 62928 (Nov. 15, 2021), available at *https://www.govinfo.gov/content/pkg/FR-2021-11-15/pdf/2021-24672.pdf* and 45 CFR 102.3.

[246] See 78 FR at 37046.

[247] See 78 FR at 54077.

[248] See Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals; Final Rule, 78 FR 54069 at 54077 (August 30, 2013).

[249] See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations; Proposed Rule, 85 FR 78572 at 78614 (December 4, 2020).

[250] 45 CFR 155.205(b)(1) references the following comparative QHP information: Premium and cost-sharing information, the summary of benefits and coverage, metal level, results of enrollee satisfaction surveys, quality ratings, medical loss ratio

Continued

Almost all public comments received in response to the proposal in the proposed 2022 Payment Notice advocated for requiring that web-broker non-Exchange websites display more QHP information than the rule proposed to require, even in cases in which the web-broker non-Exchange website does not support enrollment in a QHP. The vast majority of commenters either advocated for requiring web-broker non-Exchange websites to display all available QHP information for all available QHPs, or generally supported making it easier for consumers to obtain comparative information for all available QHPs when consumers are using web-broker non-Exchange websites. After consideration of the comments received, we did not finalize the proposed amendments to § 155.220(c)(3)(i)(A) and (c)(3)(i)(D). We agreed that the display of more QHP information on web-broker non-Exchange websites is in the best interest of consumers to aid them in comparing QHP options without having to potentially navigate to multiple websites, consistent with the views of a majority of commenters who advocated for requiring that web-broker non-Exchange websites display all of the comparative information listed in § 155.205(b)(1). We also noted our belief that requiring web-broker non-Exchange websites to display additional QHP information is reasonable given that QHP information has been more readily accessible for some time, both through public use files and the Marketplace API.

As a result, we communicated in the preamble of part 2 of the 2022 Payment Notice final rule our intent, pending future rulemaking when these issues could be further clarified, to limit our current use of enforcement discretion that permits web-brokers to only display issuer marketing name, plan marketing name, product network type, and metal level for all available QHPs, beginning with the PY 2022 open enrollment period.[251] We stated that web-broker non-Exchange websites would be required to display all QHP information consistent with § 155.205(b)(1) and (c), with the exception of MLR information and transparency of coverage measures under § 155.205(b)(1)(vi) and (vii), for all available QHPs, beginning with the PY 2022 open enrollment period. We indicated we would not deem a web-broker non-Exchange website out of compliance with § 155.220(c)(3)(i)(A) and (D) with respect to the display of MLR information and transparency of coverage measures if the web-broker non-Exchange website displays the other required standardized comparative information consistent with § 155.205(b)(1) and (c). We also explained that prior to the start of the open enrollment period for PY 2022, if a web-broker's non-Exchange website did not display all QHP information consistent with the requirements of § 155.205(b)(1) and (c), other than MLR information and transparency of coverage measures, it would be required to prominently display the plan detail disclaimer and provide a link to the Exchange website. We noted that this interim approach did not establish new requirements and instead represented a change in the exercise of enforcement discretion regarding the standardized comparative information web-brokers are required to display under existing regulations following our consideration of comments on the proposed changes to the web-broker QHP display requirements in the proposed 2022 Payment Notice.

We now propose to revise § 155.220(c)(3)(i)(A) to incorporate a general requirement that web-broker non-Exchange websites display the QHP comparative information from § 155.205(b)(1), consistent with our forecast in the preamble of part 2 of the 2022 Payment Notice final rule.[252] Specifically, we propose to codify new §§ 155.220(c)(3)(i)(A)(1) through (5) to require web-broker websites to display premium and cost-sharing information, the summary of benefits and coverage established under section 2715 of the PHS Act; identification of the metal level of the QHP as defined by section 1302(d) of the ACA or whether it is a catastrophic plan as defined by section 1302(e) of the ACA; the results of the enrollee satisfaction survey as described in section 1311(c)(4) of the ACA; quality ratings assigned in accordance with section 1311(c)(3) of the ACA; and the provider directory made available to the Exchange in accordance with § 156.230 as the minimum QHP comparative information web-broker non-Exchange websites must display for all available QHPs. Including this information within § 155.220, instead of through a cross-reference to § 155.205(b)(1), would provide better clarity and ease of reference and establish a list of required QHP comparative information consistent with our current enforcement approach, which, as discussed above, does not require the display of MLR information and transparency of coverage measures.

In addition, we propose to modify the language in § 155.220(c)(3)(i)(A) that served as the basis for the plan detail disclaimer requirement to instead require web-broker non-Exchange websites that do not support enrollment in all available QHPs to provide notice to consumers of that fact, and direct consumers to the Exchange website where they may obtain enrollment support. We propose to revise § 155.220(c)(3)(i)(A) to state that web-broker websites must disclose and display the following QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(c), and to the extent that enrollment support for a QHP is not available using the web-broker's website, prominently display a standardized disclaimer provided by HHS stating that enrollment support for the QHP is available on the Exchange website, and provide a web link to the Exchange website. Historically the plan detail disclaimer served as the mechanism and visual cue to convey to consumers where they may find additional information about particular QHPs and how they may enroll in those QHPs (that is, using *HealthCare.gov*). However, requiring the continued display of the plan detail disclaimer is unnecessary and would be confusing as the plan detail disclaimer states more information about QHPs is available on *HealthCare.gov* when in fact web-broker non-Exchange websites will be displaying the same QHP comparative information as *HealthCare.gov*.[253] In the absence of the plan detail disclaimer, the secondary function of conveying those QHPs for which enrollment support is not available through the web-broker's non-Exchange website and how consumers may obtain enrollment support is lost. This proposal to modify the disclaimer requirement in § 155.220(c)(3)(i)(A) to convey to consumers those QHPs for which a web-broker website does not provide enrollment support and to direct them to where they can obtain enrollment support would serve the function lost by

information, transparency of coverage measures, and the provider directory.

[251] See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Final Rule, 86 FR 24140 at 24206 (May 5, 2021).

[252] Ibid.

[253] The Plan Detail Disclaimer states: ''[Name of Company] isn't able to display all required plan information about this Qualified Health Plan at this time. To get more information about this Qualified Health Plan, visit the Health Insurance Marketplace® website at *HealthCare.gov*.'' See p.53 *Federally-Facilitated Exchanges (FFEs) and Federally-Facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual*, section 5.3.2, August 18, 2021, available at *https://www.regtap.info/uploads/library/ENR_FFEFFSHOPEnrollmentManual2020_5CR_090220.pdf https://www.cms.gov/files/document/ffeffshop-enrollment-manual-2021.pdf*.

the elimination of the plan detail disclaimer requirement.

We seek comment on these proposals.

b. Prohibition of QHP Advertising on Web-Broker Websites

Section 155.220(c)(3)(i)(L) prohibits web-broker non-Exchange websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers. We propose to amend § 155.220(c)(3)(i)(L) to make clear that web-broker non-Exchange websites are also prohibited from displaying QHP advertisements, or otherwise providing favored or preferred placement in the display of QHPs, based on compensation agents, brokers, or web-brokers receive from QHP issuers. We have observed a web-broker marketing to QHP issuers on its website the option for their QHPs to receive ''preferred placement'' on the web-broker website for a fee. The marketing materials indicated preferred placement on the web-broker's website would position selected QHPs at the forefront of the user experience on the website. The marketing materials also suggested that users would not be made aware that preferred plan placements were purchased for a fee, and such placements were not assigned based on the specific attributes of the plans in relation to other available plans for which issuers did not purchase preferred placement.

We believe QHP advertising on web-broker websites, whether or not characterized as such or using other terms such as ''preferred placement,'' is not in the best interest of consumers. QHP advertisements on web-broker websites could be perceived by consumers, and agents and brokers assisting consumers, as permissible QHP recommendations by the web-broker based on the best interests of the consumer rather than on the basis of payment from the QHP issuer to the web-broker. Consumers, and agents and brokers assisting consumers, may also inadvertently perceive advertisements placing a QHP in a favored position on a web-broker's website as the result of a neutrally applied filter of all available QHPs. These risks are substantially increased if the advertisements are not clearly identified as advertisements. However, even if QHP advertisements are clearly identified, we believe it is not in the interest of consumers to allow them on web-broker websites. In light of the many different approaches to advertising that exist now or may be adopted in the future, we do not believe that attempting to identify which advertising practices are permissible and which are not is practical or sufficiently protective of consumers' interests. Advertising is intended to bias consumer, agent, or broker perceptions in a way that benefits the advertiser, rather than the consumer or client. QHP advertisements on web-broker websites could take forms other than favored or preferred placement among a list of other QHPs (for example, obscuring the availability of other QHPs), including forms that could be more confusing or deceptive to consumers, in particular those consumers who may have limited familiarity with health insurance products and terminology and may be easily misled by advertising claims.

Although § 155.220(c)(3)(i)(L) prohibits web-broker websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers, it does not explicitly prohibit QHP advertising, or otherwise providing favored or preferred placement in the display of QHPs, based on compensation an agent, broker, or web-broker receives from QHP issuers. Therefore, we propose to amend § 155.220(c)(3)(i)(L) to make clear that when a web-broker website is used to complete the QHP selection, the website must not display QHP advertisements or recommendations, or otherwise provide favored or preferred placement in the display of QHPs, based on compensation the agent, broker, or web-broker receives from QHP issuers. For purposes of this proposal, we intend for advertisements to include any form of marketing or promotion of QHPs based on compensation from QHP issuers, as opposed to the application of a neutral filter or sorting methodology that may promote particular QHPs and that are not based on compensation an agent, broker, or web-broker receives from QHP issuers.

We seek comment on this proposal.

c. Explanation of Rationale for QHP Recommendations on Web-Broker Websites

We propose to amend § 155.220 to add a proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on their websites (for example, alphabetically based on plan name, from lowest to highest premium, etc.). We believe this proposed new requirement would provide consumers with a better understanding of the information being presented to them on web-broker websites, thereby enabling them to make better informed decisions and shop for and select QHPs that best fit their needs.

Web-broker websites typically begin their consumer experiences with a series of screening questions. Often these screening questions are intended to assist consumers with determining whether they may qualify for insurance affordability programs (for example, APTC or Medicaid). Sometimes the screening questions request additional information unrelated to potential eligibility for insurance affordability programs, such as asking about preferred providers, prescription drug needs, or expected need for health care services in the coming year. Some web-brokers use the information collected in response to the preliminary screening questions to recommend one or more QHPs to consumers, or to rank all available QHPs from most to least recommended. Web-broker websites may recommend QHPs so long as they do not do so based on compensation an agent, broker, or web-broker receives from QHP issuers, consistent with § 155.220(c)(3)(i)(L), as described above. Current rules do not require web-broker websites to include an explanation of the rationale for QHP recommendations. All web-broker websites must adopt a default display of QHPs by virtue of providing consumers a list of available QHPs, and the default display implicitly recommends those QHPs displayed at the top of the list.[254] In addition, many web-broker websites offer filtering tools that consumers may use to adjust the default display of QHPs (for example, reordering the QHPs from lowest to highest deductible or limiting the display to silver metal level QHPs). In cases in which QHP display filtering tools are available and prominently displayed on a web-broker website, and when the default application of a filter produces the default ordering of QHPs displayed, the methodology for the default QHP display may be apparent. However, in other cases, consumers may not realize the implications of the default display of QHPs or may find it difficult to understand the methodology underlying the default display. Current rules do not require web-broker websites to include an explanation of the methodology used for their default displays of QHPs.

We support web-broker websites' use of innovative decision-support tools for consumers to help them shop for and select QHPs that best fit their needs. However, web-broker websites that explicitly recommend or rank QHPs do

[254] 45 CFR 155.220(c)(3)(i)(B) requires web-broker websites to provide consumers the ability to view all QHPs offered through the Exchange.

not always provide an explanation for their recommendations or rankings. Similarly, web-broker websites may not include an explanation of the methodology used for their default displays of QHPs, and it may not otherwise be apparent what methodologies are used. The absence of such explanations may cause some consumers to misunderstand the bases for the recommendations displayed to them on web-broker websites (whether explicit or implicit), or may prevent them from assessing the value of the recommendations (for example, whether a recommendation is based on the factors most important to them). In addition, the lack of explanations for QHP recommendations on web-broker websites may obscure that the web-broker is recommending QHPs based on compensation the web-broker receives from QHP issuers in violation of § 155.220(c)(3)(i)(L). For these reasons, we propose to amend § 155.220 to add proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for QHP recommendations and the methodology for its default display of QHPs.

We seek comment on this proposal.

d. Federally-Facilitated Exchange Standards of Conduct (§ 155.220(j))

We propose to amend § 155.220(j)(2)(i) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 155.220(j), but amendments made in 2020 to § 155.220(j) removed any reference to sexual orientation and gender identity. If finalized, this proposal would revert § 155.220(j) to the pre-2020 nondiscrimination protections.

Section 155.220(j)(2)(i) describes that an individual or entity described in paragraph (j)(1) must provide consumers with correct information, without omission of material fact, regarding the FFE, QHPs offered through the FFE, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex. Previously, in the 2017 Payment Notice final rule, we finalized § 155.220(j)(2)(i) to also prohibit discrimination based on sexual orientation and gender identity.[255] However, in the 2020 final rule related to section 1557 of the ACA, HHS revised certain CMS regulations, including § 155.220(j)(2)(i), by removing sexual orientation and gender identity as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[256]

CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination in the group and individual market pursuant to the Secretary's authority to establish procedures for States to permit agents and brokers to enroll consumers in QHPs through the FFEs, as described in sections 1312(e) of the ACA,[257] and the authority to establish requirements with respect to the operation of Exchanges, the offering of QHPs through such Exchanges, and other requirements as the Secretary determines appropriate under sections 1321(a)(1)(A), (B), and (D) of the ACA. Pursuant to this authority, in the 2017 Payment Notice final rule, HHS finalized at § 155.220 standards of conduct for agents and brokers that assist consumers to enroll in coverage through the FFEs to protect consumers and ensure the proper administration of the FFEs, including nondiscrimination standards at § 155.220(j)(2)(i) that prohibited agents, brokers and web-brokers described in paragraph (j)(1) from discriminating based on sexual orientation and gender identity. CMS further explained that such standards of conduct were necessary to protect against agent and broker conduct that is harmful towards consumers, or that prevents the efficient operation of the FFEs. CMS proposes to exercise that same authority here to amend § 155.220(j)(2)(i) to again prohibit an individual or entity described in paragraph (j)(1) from discriminating based on sexual orientation and gender identity. Sections 1312(e) and 1321(a)(1)(A), (B), and (D) of the ACA are the same authorities CMS relies upon for implementation of existing nondiscrimination protections at § 155.220(j)(2)(i). Utilizing these same authorities to again prohibit discrimination based on sexual orientation and gender identity at § 155.220(j)(2)(i) would be consistent with the authority CMS relies upon for the existing protections at § 155.220(j)(2)(i) that currently prohibit discrimination on the basis of race, color, national origin, disability, age, or sex. We believe such amendments are warranted in light of the existing trends in health care discrimination and are necessary to better address barriers to health equity for LGBTQI+ individuals.

A more in-depth discussion of these developments and other factors considered in proposing amendments to CMS nondiscrimination protections is included earlier in the preamble to § 147.104 under section III.B.1.b. of this preamble. For brevity, we refer back to § 147.104 under section III.B.1.b. of the preamble rather than restating the issues here.

We seek comment on this proposal.

i. Providing Correct Information to the FFEs

Section 155.220(j)(2) sets forth the standards of conduct for agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through an FFE or that assist individuals in applying for APTC and CSRs for QHPs sold through an FFE. As explained in the 2017 Payment Notice proposed rule, these standards are designed to protect against agent, broker, and web-broker conduct that is harmful towards consumers or prevents the efficient operation of the FFEs.[258] Pursuant to § 155.220(j)(2)(ii), agents, brokers, or web-brokers must provide the FFEs with ''correct information under section 1411(b) of the Affordable Care Act.'' Section 1411(b) of the ACA details the information required to be provided by applicants to the Exchange to determine eligibility for Exchange coverage, APTC, CSRs, and individual responsibility exemptions, including the applicant's name, address, and information regarding household income.[259] Section 1411(h) of the ACA provides for the imposition of civil penalties if any person fails to provide correct information under section 1411(b) to the Exchange. Consistent with § 155.220(l), agents, brokers and web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in states with SBE–FPs must comply with all applicable FFE standards. This includes, but is not limited to, compliance with the FFE standards of conduct in § 155.220(j). We propose to amend § 155.220(j)(2)(ii) to add proposed new § 155.220(j)(2)(ii)(A) through (D) to codify additional details regarding the requirement that agents,

[255] 80 FR 12204 (March 8, 2016).

[256] 85 FR 37160 (June 19, 2020); *See id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

[257] 85 FR 37218–21 (June 19, 2020).

[258] 80 FR at 75526–75527.

[259] Also see 45 CFR 155.285(a)(1)(i) and (ii).

brokers, and web-brokers provide correct information to FFEs and SBE–FPs. More specifically, we propose to capture specific examples of what it means to provide correct information to the FFEs and SBE–FPs with respect to the consumer's email address, mailing address, telephone number, and household income projection based on our experience operating the FFEs and the Federal platform on which certain State-based Exchanges rely.

HHS has frequently observed applications submitted to the FFEs that contain incorrect consumer information, including applications that contain incorrect email addresses, telephone numbers, and mailing addresses. As administrator of the FFEs, HHS also has received applications that contain incorrect consumer household income projections that do not accurately reflect future consumer household income. These practices can harm consumers and prevent the efficient operation of the FFEs. Therefore, we propose to add language to § 155.220(j)(2)(ii) to address these common problems occurring on Exchange applications and provide clear standards intended to substantially reduce the occurrence of those problems to protect consumers and the efficient operation of the Exchanges. We also propose to amend § 155.220(j)(2)(ii) to make clear that the proposed standards of conduct related to agents, brokers, and web-brokers providing the FFEs and SBE–FPs with correct information that are listed in proposed new § 155.220(j)(2)(ii)(A) through (D) are not exhaustive, but are simply the areas where HHS has thus far identified a need for more direct and clear guidance.

First, we propose to add proposed new § 155.220(j)(2)(ii)(A), which would provide that an agent, broker, or web-broker may only enter an email address on an application for Exchange coverage or for APTC and CSRs for QHPs sold through an FFE or SBE–FP that is secure, not disposable, and belongs to the consumer or the consumer's authorized representative designated in compliance with § 155.227. We also propose to clarify that email addresses may only be entered on Exchange applications with the consent of the consumer or the consumer's authorized representative, and that properly entered email addresses would be required to adhere to the following guidelines pursuant to proposed new § 155.220(j)(2)(ii)(A)(1) through (3): (1) The consumer's email addresses may not have domains that remove email from an inbox after a set period of time; (2) the consumer's email address must be accessible by the consumer, or the consumer's authorized representative designated in compliance with § 155.227, and may not be accessible by the agent, broker, or web-broker, and (3) the consumer's email addresses may not have domains that belong to the agent, broker, or web-broker or their business or agency. These proposed standards align with existing guidance provided to agents, brokers, and web-brokers.[260]

HHS is proposing to codify these standards because it has observed numerous Exchange applications that contain email addresses that are disposable (where emails disappear after a set number of days), unsecure (where emails may be accessed without a password), or temporary (where the email address will cease to receive messages after a set time). HHS' concern arises from the fact that it has observed agents, brokers, and web-brokers submitting unauthorized Exchange applications on behalf of consumers without their knowledge or consent that contain these types of email addresses. HHS recognizes that such email addresses may be used by consumers to avoid receiving spam emails to a main inbox, but the use of these email addresses on Exchange applications defeats the purpose of entering an email address and occurs at a higher rate on applications assisted by agents, brokers, and web-brokers, many of which are unauthorized. Consumers who wish to avoid receiving emails from the Exchange and who are being assisted by an agent, broker, or web-broker may simply omit a contact email address from their Exchange application.

The email address provided as part of an Exchange application should provide a secure place for a consumer to receive vital information from the Exchange about their application. Emails sent to consumers through the Exchange often contain important information. As such, the consumer's email address entered on an Exchange application should be secure and only accessible by the consumer or the consumer's authorized representative designated in compliance with § 155.227. Allowing the use of email addresses that are disposable, unsecure, or temporary may harm the consumer by preventing the consumer from receiving important information from the Exchange regarding their Exchange application. It also could prevent the efficient operation of the Exchange. We therefore propose in this rule to clarify and codify that if an email address is included on the Exchange application, it must be the consumer's, or that of the consumer's authorized representative designated in compliance with § 155.227, to comply with the FFE standard of conduct under § 155.220(j)(2)(ii) to provide correct information to the Exchange.

Second, we propose to add proposed new § 155.220(j)(2)(ii)(B), which would provide that an agent, broker, or web-broker may only enter a telephone number on an application for Exchange coverage or an application for APTC and CSRs for QHPs that belongs to the consumer or their authorized representative designated in compliance with § 155.227. We also propose to provide that telephone numbers entered on Exchange applications may not be the personal number or business number of the agent, broker, or web-broker assisting with or facilitating enrollment through an FFE or assisting the consumer in applying for APTC and CSRs for QHPs, or their business or agency, unless the telephone number is actually that of the consumer or their authorized representative. These proposed standards align with existing guidance provided to agents, brokers, and web-brokers.[261]

Similar to email addresses, a telephone number belongs to the consumer if they, or their authorized representative, are accessible at the number and have access to the number. A telephone number provides a way for the consumer or their authorized representative to be contacted if there is an issue or question with the Exchange application. Allowing an agent, broker, or web-broker to list their telephone number or a telephone number associated with their business or agency in the place of the consumer's telephone number would not serve or benefit the consumer, but may harm the consumer by preventing the consumer from receiving important information from the Exchange regarding their Exchange application. It also could prevent the efficient operation of the Exchange. In addition, unlike email addresses, a telephone number is a required field when creating and submitting an Exchange application. We therefore propose in this rule to clarify and codify that the telephone number included on the Exchange application must be the consumer's, or that of the consumer's authorized representative as designated in compliance with § 155.227, to comply with the FFE standard of conduct under § 155.220(j)(2)(ii) to provide correct information to the Exchange.

[260] *https://www.regtap.info/uploads/library/AB_Slides_Compliance_052021_5CR_062221.pdf* See Compliance with Marketplace Requirements: Reminders for Agents and Brokers, May 20, 2021, available at *https://www.regtap.info/uploads/library/AB_Slides_Compliance_052021_5CR_062221.pdf.*

[261] *Ibid.*

Third, we propose to add proposed new § 155.220(j)(2)(ii)(C), which would provide that an agent, broker, or web-broker may only enter a mailing address on an application for Exchange coverage or an application APTC and CSRs for QHPs that belongs to, or is primarily accessible by, the consumer or their authorized representative designated in compliance with § 155.227. Further, the mailing address entered on the Exchange application must not be for the exclusive or convenient use of the agent, broker, or web-broker, and must be an actual residence or a secure location where the consumer or their authorized representative may receive correspondence, such as a P.O. Box or homeless shelter. These proposed standards align with existing guidance provided to agents, brokers, and web-brokers.[262] We also propose to provide that mailing addresses entered on Exchange applications may not be that of the agent, broker, or web-broker, or their business or agency, unless it is the rare situation where that address is the actual residence of the consumer or their authorized representative. HHS is proposing this change because it has observed numerous instances in which agents, brokers, or web-brokers have engaged in unauthorized enrollments of consumers in Exchange coverage without their knowledge or consent that involve the use of the same common mailing address on multiple Exchange applications that are not the actual residence of the consumer or their authorized representative.

As with telephone numbers, Exchange applications must provide a mailing address where the consumer or their authorized representative may be reached. Application or plan information may be sent to this mailing address, which is why it is important that the mailing address be the actual residence or a secure location where the consumer or their authorized representative may receive correspondence. Entering an incorrect mailing address on a consumer's Exchange application would result in situations where the consumer would not receive this information. This would harm consumers and prevent the efficient operation of the Exchange. We therefore propose in this rule to clarify and codify that the mailing address included on the Exchange application must be the consumer's, or the consumer's authorized representative as designated in compliance with § 155.227, to comply with the FFE standard of conduct under § 155.220(j)(2)(ii) to provide correct information to the Exchange.

Fourth, to minimize consumer harm stemming from the IRS reconciliation process, as well as to protect Exchange operations from inaccurate APTC and CSR determinations, we propose to add proposed new § 155.220(j)(2)(ii)(D), which would provide that when submitting household income projections on applications submitted to the Exchange to determine a tax filer's eligibility for APTC in accordance with § 155.305(f) or CSRs in accordance with § 155.305(g), an agent, broker, or web-broker may only enter a household income projection for a consumer that the consumer or the consumer's authorized representative designated in compliance with § 155.227, has authorized and confirmed is an accurate estimate. We propose to require that household income projections on Exchange applications must be attested to by the consumer or their authorized representative, and clarify that the agent, broker, or web-broker may answer questions posed by the consumer or their authorized representative related to household income projection, such as helping determine what qualifies as household income.

HHS is proposing this change because it has observed several instances in which agents, brokers, and web-brokers have provided inaccurate consumer household income projections on Exchange applications to obtain the lowest monthly premium rate for QHP coverage. This is problematic in situations when consumers are enrolled without their knowledge or consent because if a consumer is enrolled in an Exchange policy with a zero-dollar monthly payment, the consumer may not be aware they have been enrolled because there would not be a monthly bill. HHS has observed several instances where consumers have gone months without realizing they are enrolled in a QHP with APTC, typically finding out about the unauthorized enrollment when the IRS contacts them regarding money they owe due to not qualifying for all or part of the APTC paid for this coverage or when the IRS delays release of a tax refund.

Pursuant to § 155.305(f), a tax filer is, in general, not eligible for APTC unless the Exchange determines that the tax filer is expected to have household income, as defined in 26 CFR 1.36B–1(e), of greater than or equal to 100 percent but not more than 400 percent of the FPL for the year for which coverage is requested.[263] It is crucial that consumers applying for a QHP or applying for APTC and CSRs for QHPs provide an estimate of their projected household income that is as accurate as possible for an Exchange to be able to determine their eligibility for APTC. Failure to provide correct information on household income can harm consumers by creating liability during the reconciliation process or delaying the issuance of a tax refund, as well as prevent the efficient operation of the Exchange. More specifically, although eligible consumers may use APTC to lower their monthly premiums for QHP coverage through an Exchange if a consumer's projected household income on his or her Exchange application submission is inaccurate and lower than the actual household income, the consumer is likely to have excess APTC (the extent to which APTC exceeds the allowed PTC), all or a portion of which must be repaid when the consumer files his or her federal income tax return for the year of coverage as required under 26 U.S.C. 36B(f) and 26 CFR 1.36B–4. Each year, consumers for whom APTC is paid must submit Form 8962 with their annual federal income tax return to the IRS. On Form 8962, the consumer must reconcile the APTC paid on his or her behalf with the PTC[264] the consumer is allowed. Generally, consumers whose projected household annual income at enrollment is less than the actual annual household income will have excess APTC that must be repaid, subject to a repayment limit for consumers with household income below 400 percent of the FPL. Consumers are required to repay excess APTC by increasing their tax liability for the year by all or a portion of the excess APTC. Good-faith income projections, versus an income projection designed to achieve the lowest monthly rate, better protect the consumer from the unexpected cost and burden of repaying large amounts of APTC. Additionally, per § 155.305(b), Exchange enrollees must report changes that may impact their eligibility for financial assistance or coverage, including their projected annual household income, within 30 days of the change.

CSRs are similarly tied to a consumer's household income and they lower the amount that certain eligible individuals have to pay for deductibles, copayments, and coinsurance. Incorrect projections of a consumer's household income would also lead to incorrect CSR determinations, which would harm

[262] Ibid.

[263] Section 9661 of the American Rescue Plan Act of 2021 makes individuals with household incomes above 400 percent of the FPL who meet all other eligibility criteria eligible for APTC, but only through PY 2022.

[264] *https://www.irs.gov/pub/irs-pdf/p974.pdf.*

QHP issuers and prevent the efficient operation of the Exchange.

An estimate of a consumer's household income is required on the Exchange application if the consumer is applying for APTC and CSRs. As outlined above, agents, brokers, or web-brokers who are intentionally or negligently entering inaccurate household income projections on a consumer's Exchange application can harm consumers and prevent the efficient operation of the Exchange. We therefore propose in this rule to clarify and codify that if household income projections are included on the Exchange application, the estimate must be attested to by the consumer or the consumer's authorized representative as designated in compliance with § 155.227 to comply with the FFE standard of conduct under § 155.220(j)(2)(ii) to provide correct information to the Exchange.

As noted previously in this rule, the proposal to amend § 155.220(j)(2)(ii) to add proposed new § 155.220(j)(2)(ii)(A) through (D) is not intended to constitute an exhaustive list of practices that govern providing correct information to the Exchange under § 155.220(j)(2)(ii); rather, these are areas where HHS has thus far identified a need for more direct and clear guidance to protect consumers and the efficient operation of the Exchanges.

We seek comment on these proposals.

ii. Prohibited Business Practices

We propose to amend § 155.220(j)(2) to add several new standards of conduct for agents, brokers, and web-brokers that assist consumers with applying for and enrolling in coverage through an FFE or SBE–FP, with or without APTC and CSRs. Similar to the standards first established in the 2017 Payment Notice, these additional standards are also intended to protect against agent, broker, and web-broker conduct that is harmful towards consumers or frustrates the efficient operation of the Exchange. More specifically, we propose to codify standards related to the use of scripting and other automation interactions with CMS Systems or the DE Pathways (including both Classic DE and EDE), identity proofing consumer accounts on *HealthCare.gov,* and providing assistance with SEP enrollments. HHS is proposing these new FFE standards of conduct for agents, brokers, and web-brokers assisting consumers in FFEs and SBE–FPs because it has observed practices in these areas that have caused or can cause harm to consumers, as well as impede the efficient operation of the Exchange.

iii. Prohibited Automated Interactions With CMS Systems

In order to enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange and assist individuals in applying for APTC and CSRs for QHPs, agents, brokers, and web-brokers must comply with the regulatory requirements contained in § 155.220, including the requirement that such agents, brokers, and web-brokers comply with the terms of applicable agreements between the agent, broker, or web-broker and the Exchange.[265] One such agreement, the ''Agent Broker General Agreement for Individual Market Federally-Facilitated Exchanges and State-Based Exchanges on the Federal platform (IM General Agreement),'' [266] sets forth requirements related to automation. Specifically, section IV(c)(i)(4) of the IM General Agreement provides that scripting and other automation of interactions with CMS Systems or the DE Pathways are strictly prohibited, unless approved in advance by CMS. While these requirements are addressed in the IM General Agreement, they are not currently explicitly set forth in regulation. Therefore, we propose to amend § 155.220(j)(2) to add proposed new § 155.220(j)(2)(vi) to codify requirements and limitations on the use of automation and align the regulation with the IM General Agreement. New proposed § 155.220(j)(2)(vi) would provide that an agent, broker, or web-broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through an FFE or SBE–FP, or assists individuals in applying for APTC and CSRs for QHPs sold through an FFE, or SBE–FP must not engage in scripting and other automation of interactions with CMS Systems or DE Pathways, unless approved in advance in writing by CMS.

CMS Systems to which CMS-registered agents, brokers, and web-broker may have access include *HealthCare.gov,* and the CMS Enterprise Portal. Codifying a regulation that addresses the use of automation in relation to these systems and platforms would help to establish clear and enforceable standards that would govern the behavior of agents, brokers, and web-brokers when assisting Exchange applicants. It would also clarify CMS' authority to take enforcement action against agents, brokers, and web-brokers for violations of these requirements.

HHS is proposing this standard of conduct because it has observed instances where unauthorized automated browser-based interactions with Exchange systems have led to unauthorized enrollments, unauthorized application changes, or unauthorized access to consumer PII. The risk of harm to consumers and the efficient operation of the Exchange is heightened when automated interactions occur because more consumer information can be downloaded using automation than through a manual process. Automated browser-based interactions with Exchange systems can lead to increases in unauthorized enrollments, unauthorized application changes, or unauthorized access to consumer PII because agents, brokers, and web-brokers could find far more consumer information using automation, which could result in the unauthorized taking, use, or sale of significant amounts of consumer PII for unlawful purposes. Allowing automation would also create significant traffic in the system, which could result in increased risk of system speed slowdowns and stability issues, as these automated interactions would cause a lot more system activity per user than anticipated and planned for. We seek comments on these concerns and this proposal. While this proposed rule is under consideration, CMS will continue to take appropriate enforcement action in response to situations resulting from unauthorized use of automation in connection with CMS Systems.[267]

We note that certain web-broker interactions with the Exchange were created with the intention of being automated, including the plan finder Application Program Interface (API) and Marketplace API. Thus, this proposal to prohibit use of automation in other circumstances is sufficiently narrowly tailored to accommodate these limited instances when automation is permitted in connection with CMS Systems or DE Pathways when approved in advance in writing by CMS. CMS believes that other uses of automation beyond what is currently approved may have appropriate business use cases. We therefore seek comment on appropriate uses of automation that may contribute to the efficient operation of the FFEs and SBE–FPs, and the DE Pathways.

iv. Identity Proofing

HealthCare.gov utilizes identity proofing to verify the identity of a consumer when a new Exchange

[265] 45 CFR 155.220(d).

[266] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ab_py2020_im_general_agreement_final_1.pdf.*

[267] See 45 CFR 155.220(g), (k), and (m).

account is created. We propose to amend § 155.220(j)(2) to add proposed new § 155.220(j)(2)(vii), which would provide that when identity proofing accounts on *HealthCare.gov,* agents, brokers, or web-brokers must only use an identity that belongs to the consumer. Currently, identity proofing is required when a consumer creates an account on *HealthCare.gov* via an EDE site, and when a consumer works with an agent or broker in person.[268] When a consumer creates an account on *HealthCare.gov* or an EDE site, they go through a remote identity proofing (RIDP) process. The RIDP process is an Experian service that takes basic demographic information regarding the consumer and requires the consumer to answer multiple choice questions correctly to proceed. This is done to ensure the consumer is a real person, to protect the consumer's personal information, and to prevent someone else from creating an Exchange account and applying for Exchange coverage in another's name without their knowledge or consent.

We are proposing this amendment to § 155.220(j)(2), as we have observed situations in which agents have used the same identity information to complete the identity proofing process for multiple consumer Exchange accounts, which can harm to consumers and prevent the efficient operation of the Exchange, undermines the purpose of identity proofing consumers and is often associated with unauthorized enrollments, identity theft, and fraud.

We seek comment on this proposal.

v. Providing Information to Federally-Facilitated Exchanges in Connection With Special Enrollment Periods

Finally, § 155.420(a)(1) provides that the Exchange must provide SEPs during which qualified individuals may enroll in QHPs and enrollees may change QHPs. We propose to amend § 155.220(j)(2) to add proposed new § 155.220(j)(2)(viii), which would state that when providing information to FFEs that may result in a determination of eligibility for an SEP under § 155.420, agents, brokers, and web-brokers must obtain authorization from the consumer to submit the request for a determination of eligibility for a SEP (although this authorization does not need to be in writing) and make the consumer aware of the specific triggering event and SEP for which the agent, broker, or web-broker will be submitting an eligibility determination request on the consumer's behalf. Under this new proposed standard of conduct, agents, brokers, and web-brokers providing assistance with SEP enrollments would be required to make reasonable, good faith efforts to ascertain the consumer's eligibility for the SEP, consistent with the existing standard under § 155.220(j)(3). We propose this requirement to address circumstances HHS has observed under which consumers who apply for QHP enrollment through an SEP with the assistance of an agent, broker, or web broker are not made aware of the basis upon which their QHP application claims entitlement to an SEP, or who otherwise did not authorize an agent, broker, or web-broker to enroll them in a QHP or make a change to their current QHP enrollment.

The purpose of SEPs is to promote access to health insurance coverage and continuous coverage by allowing individuals to enroll outside of the open enrollment period only if they experience certain SEP triggering events; this helps to avoid and control against adverse selection that would destabilize the Exchanges. The purpose of proposing to codify this requirement in proposed new § 155.220(j)(2)(viii) is to ensure the validity and integrity of the SEP process, avoid Exchange destabilization, and to create clear, enforceable standards to help mitigate consumer harm by establishing that agents, brokers, and web-brokers are responsible for providing information to the FFE that is accurate to the best of their knowledge, and to which the consumer has attested.

We seek comment on these proposals.

5. Premium Calculation (§ 155.240(e))

HHS proposes to add language at § 155.240(e)(2) to apply the premium calculation methodology currently applicable in the FFEs and SBE–FPs to all Exchanges, beginning with PY 2024. This proposed amendment to § 155.240(e), along with the proposed amendments to §§ 155.305(f)(5) and 155.340, support HHS's proposal to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of APTC in cases where an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. We further discuss these proposed changes in the Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340) section of this proposed rule where we propose to require all Exchanges to prorate premium and APTC amounts in cases where an enrollee is enrolled in a particular policy for less than the full coverage month. We seek comment on these proposals.

6. Eligibility Standards (§ 155.305)

We are proposing a technical amendment to § 155.305(f)(1)(i) to clarify that the income eligibility standards used by the Exchange for determining whether an individual is an applicable taxpayer for purposes of APTC eligibility are the same as the income thresholds at IRS regulation 26 CFR 1.36B–2(b). Whereas the current regulation states expected household income must be ''greater than or equal to 100 percent but not more than 400 percent of the FPL for the benefit year for which coverage is requested,'' the proposed amendment specifies the individual must have an expected household income which will qualify the tax filer as an applicable taxpayer according to 26 CFR 1.36B–2(b). In turn, 26 CFR 1.36B–2(b) outlines the FPL percentage thresholds that are used for determining PTC eligibility. In practice, the federal and state Exchanges have always relied on thresholds outlined in 26 CFR 1.36B–2(b) to determine APTC eligibility, but we note that this proposed change allows for greater regulatory consistency and minimizes the need to update § 155.305(f)(1)(i) in response to legislative changes that may alter FPL percentage thresholds, as occurred for certain years under the ARP.

7. Eligibility for Advance Payments of the Premium Tax Credit (§ 155.305(f)(5))

HHS proposes to amend § 155.305(f)(5) to require that APTC must be calculated in accordance with 26 CFR 1.36B–3 and would be subject to the prorating methodology at proposed § 155.340(i). This proposed amendment to § 155.305(f)(5), along with the proposed amendments at §§ 155.240(e), and 155.340, detailed elsewhere in this rule, support HHS's proposal to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of APTC in cases where an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. We further discuss these proposals in the Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340) section of this proposed rule. We seek comment on this proposal.

[268] Section 1411(g)(1) of the ACA.

8. Verification Process Related to Eligibility for Insurance Affordability Programs—Employer Sponsored Plan Verification (§ 155.320)

Strengthening program integrity with respect to subsidy payments in the individual market continues to be a top HHS priority. Accordingly, we propose to revise § 155.320(d)(4) to provide each Exchange with the flexibility to tailor its employer sponsored plan verification process based on its assessment of the risk of inappropriate payments of APTC and CSRs as a result of associated risk and composition of their enrolled population.

Currently, Exchanges must verify whether an applicant for APTC and CSRs is eligible for or enrolled in an eligible employer sponsored plan for the benefit year for which coverage is requested using available data sources, if applicable, as described in § 155.320(d)(2). For any coverage year that an Exchange does not reasonably expect to obtain sufficient verification data as described in § 155.320(d)(2)(i) through (iii), an alternate procedure applies. Specifically, Exchanges must select a random sample of applicants and meet the requirements under § 155.320(d)(4). For benefit years 2016 through 2019, Exchanges also could use an alternative process approved by HHS.

In the 2021 Payment Notice final rule, we finalized the policy that for PYs 2020 and 2021, HHS would not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4), when the Exchange does not reasonably expect to obtain sufficient verification data as described in § 155.320(d)(2)(i) through (iii). This policy was designed to reduce burden on Exchanges while HHS finalized the results of a study to determine the potential risk and risk factors, if any, that may be associated with applicants that choose to enroll in an Exchange QHP with APTC/CSRs, rather than coverage offered through their employer. In the 2022 Payment Notice Final Rule, we extended this non-enforcement to PY 2022.

As we will discuss later in this preamble, HHS reviewed the results of the 2019 study and found that the risk for inappropriate eligibility or payment of APTC and CSRs based on applicant eligibility for or enrollment in qualifying employer sponsored coverage was low. Therefore, we are now proposing a new optional alternate procedure to replace the current procedures under § 155.320(d)(4). Under this proposed option, an Exchange would have flexibility to design its verification process based on the Exchange's assessment of risk for inappropriate eligibility or payment for APTC or CSRs. Until a new alternate procedure becomes effective, Exchanges must continue to use the procedures set forth under § 155.320(d)(4)(i), subject to the enforcement policy in effect for PYs 2021 and 2022.

HHS' experience conducting random sampling revealed that the burden associated with the verification activity far outweighed the activity's value to the integrity of the program. We found that employer response rates to HHS' requests for information were low. We further found that the manual verification process described in § 155.320(d)(4)(i) requires significant resources and government funds, and the value of the results ultimately did not appear to outweigh the costs of conducting the work because only a small percentage of sampled enrollees had been determined by HHS to have received APTC or CSRs inappropriately. Based on our experiences with the random sampling methodology under § 155.320(d)(4)(i), HHS concluded that the methodology may not be the best approach for all Exchanges to assess the risk for inappropriate payment of APTC/CSRs associated with applicants who may be eligible for or enrolled in qualifying employer sponsored coverage.

As a result, in 2019, HHS conducted a study to: (1) Determine the unique characteristics of the population with offers of employer sponsored coverage that meets minimum value and affordability standards, (2) compare premium and out-of-pocket costs for consumers enrolled in affordable employer sponsored coverage to Exchange coverage, and (3) identify the incentives, if any, that drive consumers to enroll in Exchange coverage rather than coverage offered through their current employer. The results of this study were finalized in early 2020 and aligned with HHS' previous findings from past studies that there is likely a very low volume of applicants with offers of affordable coverage through their employer that choose to inappropriately enroll in an Exchange QHP with APTC and CSRs.

Specifically, the study found that no more than 2 percent of enrollees received APTC/CSR inappropriately, and that lower income individuals and families had the most incentive to enroll in an Exchange QHP with APTC/CSR rather than coverage offered through an employer. HHS is therefore of the view that the risk for inappropriate payment of APTC and CSRs is low; thus, we propose to provide each Exchange with the flexibility to tailor its verification process based on its assessment of the risk of inappropriate payments of APTC/CSRs as a result of associated risk and composition of their enrolled population. This includes the ability of State Exchanges that operate their own eligibility and enrollment platform and have implemented, or are finalizing their implementation of, the current random sampling requirements under § 155.320(d)(4)(i), to continue employing the random sampling process and requirements and refining the process, as needed, under the proposed risk-based approach under § 155.320(d)(4)(i). HHS believes that these changes will serve to protect the integrity of the Exchange program by allowing all Exchanges to proactively identify risk factors attendant to QHP enrollees' receipt of APTC/CSRs for which they may not be eligible.

Specifically, we propose to allow Exchanges to implement a verification method that utilizes an approach based on a risk assessment identified through analysis of an Exchange's experience in relation to APTC/CSRs payments. HHS expects that this risk assessment would be informed by and identified through research and analysis of an Exchange's experiences with current and past enrollments, and not solely based on previously published research or literature. Furthermore, there are certain standards that HHS requires that all Exchanges adhere to when designing a risk-based approach to verify an applicant's offer of employer sponsored coverage. As such, HHS requires that any risk-based verification process be reasonably designed to ensure the accuracy of the data and is based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's own enrollment data. For example, if an Exchange's experience is that applicants from large companies that have different classes of employees, who may or may not qualify for employer sponsored coverage due to the number of hours they work per week, represent a higher risk of improper APTC/CSR payments, then the Exchange may implement a risk-based verification process to confirm whether applicants employed by such companies appropriately received APTC/CSRs.

Given that the proposed risk-based approach to verify whether an applicant has received an offer of coverage through an employer or is enrolled in employer sponsored coverage depends largely on an Exchange's assessment of risk and unique populations, HHS believes that there are various ways in which a risk-based approach can be

operationalized. Below we outline a few scenarios to provide illustrative examples of the procedures an Exchange may follow.

The first scenario concerns Exchanges that do not have access to an approved trusted data source that provides accurate and up-to-date information regarding enrollment or pre-enrollment in coverage offered through an employer and have determined that manual verification, such as conducting random sampling of enrollees to determine if any had an offer of affordable coverage through their employer but chose to enroll in an Exchange QHP with APTC/CSR instead, requires significant resources to conduct and have determined that the risk for improper APTC/CSR payment is low. In this scenario, Exchanges may make a reasonable determination and decide to accept a consumer(s)' attestation without any further manual verification, similar to current procedures to accept attestation only for residency and incarceration status. Conversely, if an Exchange has determined a high risk for improper APTC/CSR payment exists within its enrolled population, but also doesn't have access to an approved trusted data source for electronic verification, an Exchange may make a reasonable determination that conducting manual verification as part of its risk-based approach, such as conducting random sampling, is the appropriate risk-based approach to conduct employer sponsored coverage verification. Finally, there may be Exchanges that have determined that they do have access to an approved, accurate, and up-to-date trusted data source that allows for electronic verification of offers of employer sponsored coverage. In this scenario, an Exchange may choose to conduct electronic verification of their entire population through that trusted data source to verify offers of employer sponsored coverage. HHS believes that any of these approaches will serve to satisfy the requirement to conduct employer sponsored coverage verification using a risk-based approach while providing flexibility for all Exchanges to determine the process that best meets the needs of their populations.

Because HHS found that the risk for improper APTC payment is low in Exchanges using the federal eligibility and enrollment platform, such Exchanges would leverage the current attestation questions on the single, streamlined application and accept attestation without further verification against other trusted data sources. The attestation questions include, ''Are any of these people currently enrolled in health coverage?'' and ''Will any of these people be offered health coverage through their job, or through the job of another person, like a spouse or parent?''. HHS would also accept attestations related to employer sponsored coverage because HHS currently lacks access to another approved data source to verify whether an applicant has an offer of employer sponsored coverage that is affordable and meets minimum value standards. In the 2019 study referenced earlier in the preamble, HHS examined whether the use of other data sources would be feasible to verify offers and affordability of employer sponsored coverage, such as the National Directory of New Hires (NDNH) database. HHS determined that all available data sources were insufficient and did not provide the necessary information to satisfy the requirement, or would require legislative changes to give Exchanges permission to access and use them for verification of employer sponsored coverage. CMS notes that additional data source access, such as the NDNH, would improve accuracy and reduce administrative burden to consumers for the income verification step during the eligibility process.

Finally, under this proposal, we clarify that since SBE–FPs use the *HealthCare.gov* platform for eligibility and enrollment determinations, SBE–FPs would be required to follow the approach outlined above consistent with CMS regulations and the agreements SBE–FPs sign with CMS. Current Federal platform agreements require that SBE–FPs adhere to the same policy and operations as Exchanges that use the federal eligibility and enrollment platform regarding eligibility for and enrollment in QHP coverage.

Furthermore, in accordance with § 155.120(c), an Exchange's verification program cannot be discriminatory in nature, and State Exchange's verification processes will be monitored by HHS in accordance with its authority under §§ 155.1200 and 155.1210. In designing their verification program, Exchanges should pay special attention to known risks, including risk pool manipulation or steering high risk employees from the group health market into the Exchanges. The goal of this proposed policy is to ensure that only applicants eligible to receive APTC/CSRs receive these subsidies, and we would exercise our oversight authorities to ensure an Exchange's verification policies are not used to prevent any particular class of applicants from enrolling in QHP coverage with APTC/CSRs. We believe this approach would allow Exchanges to proactively identify and target applicants who may, for example, have an incentive to enroll in Exchange coverage with APTC/CSRs rather than their employer sponsored plan that meets minimum value and affordability standards. Further, we believe that a risk-based approach for verification of eligibility for employer sponsored eligibility or coverage verification would allow Exchanges to identify a larger population of Exchange enrollees who would be ineligible for APTC/CSRs due to an offer of employer sponsored coverage, as compared to the random sampling method. We believe the new policy we propose would more effectively protect the integrity of Exchange programs, as Exchanges would be able to mitigate the risk of improper federal payments in the form of APTC during the year more effectively.

Therefore, we propose to revise § 155.320(d)(4) by removing the requirement that the Exchange select a random sample of applicants for whom the Exchange does not have data as specified in § 155.320(d)(2)(i) through (iii) effective upon the finalization of the final rule. we encourage State Exchanges to submit comments on the proposed timing, especially if the proposal causes operational challenges or undue hardship as a result. We propose adding new language at § 155.320(d)(4) under which an Exchange would be permitted to design its verification process for enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan based on the Exchange's assessment of risk for inappropriate payment of APTC/CSRs or eligibility for CSRs, as appropriate. The proposed language at § 155.320(d)(4) would provide all Exchanges with the flexibility to determine the best means to design and implement a process to verify an applicant's enrollment in or eligibility for employer sponsored coverage, through analyses of relevant Exchange data, research, studies, and other means appropriate and necessary to identify risk factors for inappropriate payment of APTC or eligibility for CSRs. As previously discussed earlier in this rule, Exchanges must continue to use the procedures set forth in § 155.320(d)(4)(i) until a new alternate procedure becomes effective. We also propose to retain the current requirement at § 155.320(d)(4)(i)(A) that the Exchange provide notice to the applicant, but amend it such that it is contingent on whether the Exchange will be contacting the employer of an applicant to verify whether an applicant is enrolled in an

eligible employer sponsored plan or is eligible for qualifying coverage in an eligible employer sponsored plan for the benefit year for which coverage is requested. Second, to provide more flexibility for Exchanges, we propose no longer applying the requirement at § 155.320(d)(4)(i)(D), which requires the Exchange to make reasonable attempts to contact an employer listed on an applicant's Exchange application to verify whether an applicant is enrolled in an employer sponsored plan or is eligible for qualifying coverage in an eligible employer sponsored plan.

As we explained above, HHS' experience has been that employer compliance with these notices was low, which led to the proposal to remove the random sampling requirement. However, Exchanges may continue to send notification to employers as part of their risk-based verification processes if they so choose. Third, we propose removing the requirement at § 155.320(d)(4)(i)(F), which states that after 90 days from the date on which the Exchange first provides notice to an applicant as described in § 155.320(d)(4)(i)(A), the Exchange must redetermine eligibility for APTC and CSRs if the Exchange is unable to obtain the necessary information from an applicant's employer regarding enrollment in or eligibility for qualifying coverage in an employer sponsored plan. We believe these proposed changes provide Exchanges with the flexibility to implement a verification process for enrollment in or eligibility for an employer sponsored plan that is tailored to risks observed in their respective populations. As previously discussed earlier in preamble, Exchanges must continue to use the procedures set forth in § 155.320(d)(4)(i) until a new alternate procedure becomes effective.

Finally, we propose to remove the option for Exchanges to follow the procedures outlined in § 155.320(d)(4)(ii) to develop an alternative verification process that is approved by HHS. The revisions to § 155.320(d)(4)(i) provide enough flexibility for Exchanges to develop a risk-based verification process for eligibility for or enrollment in employer sponsored coverage. Therefore, extending § 155.320(d)(4)(ii) indefinitely would prove to be redundant in light of the proposed changes discussed earlier in preamble.

We seek comment on these proposals.

9. Annual Eligibility Redetermination (§ 155.335)

We solicit comments on incorporating the net premium, MOOP, deductible, and annual out-of-pocket costs (OOPC) of a plan into the re-enrollment hierarchy as well as additional criteria or mechanisms HHS could consider to ensure the Exchange hierarchy for re-enrollment aligns with plan generosity and consumer needs, such as, re-enrolling a current bronze QHP enrollee into an available silver QHP with a lower net premium and higher plan generosity offered by the same QHP issuer.

In the Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges final rule, we established the renewal and re-enrollment hierarchy at § 155.335(j) to minimize potential enrollment disruptions. Under § 155.335(j), we modified the standards for re-enrollment in coverage through Exchanges by proposing, in paragraph (j)(1), that if an enrollee remains eligible for enrollment in a QHP through the Exchange upon annual redetermination, and the product under which the QHP in which he or she was enrolled remains available for renewal, consistent with § 147.106 such enrollee will have his or her enrollment in a QHP through the Exchange under the product renewed unless he or she terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. In this situation, we proposed that the QHP in which the enrollee will be renewed will be selected according to the following order of priority: (1) In the same plan as the enrollee's current QHP; (2) if the enrollee's current QHP is not available, the enrollee's coverage will be renewed in a plan at the same metal level as the enrollee's current QHP; (3) if the enrollee's current QHP is not available and the enrollee's product no longer includes a plan at the same metal level as the enrollee's current QHP, the enrollee's coverage will be renewed in a plan that is one metal level higher or lower than the enrollee's current QHP; and (4) if the enrollee's current QHP is not available and the enrollee's product no longer includes a plan that is at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee's coverage will be renewed in any other plan offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll.

Under paragraph (j)(2), we finalized standards to address re-enrollment in situations in which no plans under the product under which an enrollee's QHP is offered are available through the Exchange for renewal, consistent with § 147.106. In this situation, the enrollee may be enrolled in a QHP under a different product offered by the same issuer, to the extent permitted by applicable state law, unless the enrollee terminates coverage including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. In such cases, the re-enrollment will occur according to the following order of priority: (1) In a QHP through the Exchange at the same metal level as the enrollee's current QHP in the product offered by the issuer that is the most similar to the enrollee's current product; (2) if the issuer does not offer another QHP through the Exchange at the same metal level as the enrollee's current QHP, the enrollee will be re-enrolled in a QHP through the Exchange that is one metal level higher or lower than the enrollee's current QHP in the product offered by the issuer through the Exchange that is the most similar to the enrollee's current product; and (3) if the issuer does not offer another QHP through the Exchange at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee will be re-enrolled in any other QHP offered through the Exchange by the QHP issuer in which the enrollee is eligible to enroll.

In the 2017 Payment Notice, we finalized the rule that provides for auto-reenrollment in a QHP offered by another issuer through the Exchange, as opposed to permitting a QHP issuer that no longer has a QHP available to an enrollee through an Exchange to reenroll the enrollee outside the Exchange in order to maintain coverage with APTC and CSRs for the majority of Exchange enrollees who are receiving these subsidies. Under this rule, we established, beginning in PY 2017, that if no QHP from the same issuer is available to enrollees through the Exchange, then to the extent permitted by applicable State law, the Exchange could direct alternate enrollments for such enrollees into a QHP from a different issuer unless the enrollee terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. If the applicable State regulatory authority declines to act to direct this activity, such alternate enrollments would be directed by the Exchange. With regard to how Exchanges will determine which plans such enrollees should be auto-

reenrolled into, we noted that this policy provided considerable flexibility to Exchanges to implement this rule, in recognition of the operational realities of implementing a re-enrollment hierarchy in the often unique circumstances in which an issuer no longer has QHPs available to an enrollee through the Exchange.

HHS is aware of stakeholder concerns that the enrollees in the FFEs may fail to return to the Exchange to make an active plan selection in situations in which changing plans could be beneficial to the enrollee, and that re-enrollment rules may default enrollees into less beneficial plans than other available plans.

We solicit comments on whether factors such as net premium, MOOP, deductible, and OOPC should be reflected in a revised re-enrollment hierarchy for all Exchanges, with consideration for the potential impact of the actuarial value de minimis guidelines proposed in this rule at §§ 156.135 and 156.140 on cost-sharing. For example, HHS could consider re-enrolling a current bronze QHP enrollee into an available silver QHP with a lower net premium and higher plan generosity offered by the same QHP issuer. Additionally, HHS could consider re-enrolling a current silver QHP enrollee into another available silver QHP, under the enrollee's current product and with a service area that is serving the enrollee that is issued by the same QHP issuer, that has lower OOPC. We also solicit comments on additional criteria or mechanisms HHS could consider to ensure the hierarchy for re-enrollment in all Exchanges takes into account plan generosity and consumer needs beyond merely the retention of the most similar plan available.

10. Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340)

HHS is proposing to amend §§ 155.240(e), 155.305(f)(5), and 155.340 to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of the APTC in cases where an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. HHS would require all Exchanges, including the Exchanges on the Federal platform and State Exchanges that operate their own eligibility and enrollment platforms to implement the proposed proration methodology in the PY 2024 benefit. HHS is limiting this proposed requirement to individual market policies because many SHOP Exchanges, particularly those that operate in a leaner fashion, like the federally-facilitated SHOP Exchanges, do not calculate premiums. Additionally, APTC are not available through SHOPs.

Currently, Exchanges apply APTC to an applicable taxpayer's monthly premium based on calculation, eligibility, and administration requirements from two sources: (1) IRS regulations at 26 CFR 1.36–B–1 through 1.36B–3, and (2) HHS regulations at 45 CFR part 155. IRS regulation at 26 CFR 1.36B–3(d) calculates PTC eligibility for a partial month of coverage as the lesser of the premiums for the month (reduced by any amount of such premiums refunded), or the monthly premium for the second lowest cost silver plan (SLCSP) reduced by the taxpayer's monthly contribution amount. Although 26 CFR 1.36B–3(d) defines the calculation of the premium assistance amount for a coverage month, and thus defines the calculation of the maximum APTC amount an applicable taxpayer may apply to their monthly premium, it does not describe how APTC is administered, which is regulated by HHS. When administering APTC, Exchanges must adhere to requirements at 45 CFR 155.305(f), which establishes eligibility and calculation requirements for APTC, 45 CFR 155.310(d)(2)(i), which requires the Exchange to permit an applicable taxpayer to accept less than the full amount of APTC for which they are eligible, and 45 CFR 155.340, which defines how Exchanges must administer and allocate APTC amounts applied to enrollees' monthly premiums.

Calculating maximum APTC as required under § 155.305(f) obligates the Exchange to calculate payments of the APTC in accordance with the way PTC is calculated at 26 CFR 1.36B–3. The IRS methodology described at 26 CFR 136.B–3 is appropriate for PTC, as PTC is calculated retrospectively and can account for the changes in an applicable taxpayer's premium across the entire tax year before the applicable final amount is calculated at the time of tax filing. Conversely, Exchanges administer APTC prospectively to issuers by advancing premium assistance to issuers based on enrollees' eligibility determinations and elections, which could change month-to-month before final reconciliation occurs. Currently, HHS regulations governing APTC eligibility and administration do not contain specific requirements on how APTC should be administered for a policy in which an enrollee is enrolled for less than the full coverage month. While the FFEs and SBE–FPs already prorate APTC and premium amounts, State Exchanges presently handle this scenario inconsistently, which may result in over-payment of APTC to issuers that exceeds the monthly PTC amount for which an applicable taxpayer will be eligible, thereby potentially triggering a federal income tax liability for the applicable taxpayer.[269]

By amending §§ 155.240(e), 155.305(f)(5) and 155.340 to require that the Exchange prorate the calculation of premiums and APTC in cases where an enrollee is enrolled in a particular policy for less than the full coverage month, HHS would provide needed clarification for all Exchanges, resulting in greater consistency in APTC administration and the consumer experience.

As explained earlier in this preamble, HHS proposes to add language at § 155.240(e)(2) to apply the methodology currently applicable in the FFEs and SBE–FPs to all Exchanges, beginning with PY 2024. This proposed amendment to § 155.240(e) would support the accurate and consistent calculation of partial-month enrollment premium amounts in a way that aligns with the method of administering the APTC that we propose in §§ 155.305(f)(5) and 155.340.

HHS also proposes to amend § 155.305(f)(5) by adding that APTC must be calculated in accordance with 26 CFR 1.36B–3, subject to the prorating methodology at proposed § 155.340(i). This would create uniform standards for taxpayers on how the APTC will be calculated for months in which an enrollee is enrolled in a particular policy for less than the full coverage month.

Finally, HHS proposes to amend § 155.340 by adding paragraph (i) to establish that, beginning with the PY 2024 benefit, all Exchanges would be required to calculate applied APTC when an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, as equal to the product of (1) the APTC applied on the

[269] HHS notes that an applicable taxpayer's excess APTC and accompanying tax liability for such excess APTC is determined after the taxpayer's PTC for the year of coverage has been calculated. Consequently, the potential to incur income tax liability for excess APTC is not limited to situations in which a consumer is enrolled in a policy for less than a full coverage month and our proposed policy will not completely eliminate an applicable taxpayer's risk of incurring tax liability from excess APTC.

policy for 1 month of coverage divided by the number of days in the month, and (2) the number of days for which coverage is provided on that policy during the applicable month. This methodology would align with the prorated calculation of premium amounts under § 155.240(e). Furthermore, this proposed methodology would provide Exchanges with a consistent method of prorating applied APTC amounts that aligns with the calculation of PTC under 26 CFR 1.36B–3(d) while ensuring that the calculation of APTC in situations in which an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, does not cause the APTC to exceed the PTC for the month as calculated per 26 CFR 1.36B–3(d). This proposal would create consistency for issuers across all Exchanges, help the enrollee by keeping the enrollee's share of premiums stable, and reduce the instances in which a taxpayer would have to repay excess APTC during tax filing per section 36B(f)(2) of the Code and 26 CFR 1.36B–4. If the proposal results in an excess of PTC over the amount of APTC paid for an enrollee's coverage (net PTC), the applicable taxpayer would claim the net PTC as a refundable tax credit.

These proposals are intended to protect consumers. State Exchanges are not currently required to prorate APTC for mid-month policy changes and, as a result, HHS may overpay APTC amounts to issuers in State Exchanges not currently prorating in this manner. Income tax liability due to excess APTC could pose significant financial burden to applicable taxpayers, particularly low-income taxpayers, and creates confusion about the affordability of health care coverage offered by an Exchange.

Additionally, E.O. 14009 [270] calls for a review of policies or practices that may present unnecessary barriers to individuals and families attempting to access Medicaid or ACA coverage, or that may reduce the affordability of coverage or financial assistance for coverage. Low-income populations are more likely to qualify for many federal and state health and human services programs, including APTC.[271] The proposed methodology aligns with the goals of E.O. 14009, as it would promote consumer protection, encourage continuity of coverage for individuals, and ensure consistent application of APTC which makes Exchange coverage more affordable.

Establishing a proration methodology that would apply universally across all Exchange types—FFEs, SBE–FPs, and State Exchanges—would ensure all Exchanges and issuers report and pay APTC similarly when enrollees are enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. HHS notes that this proposal would codify a methodology that the FFEs, SBE–FPs, and some State Exchanges already utilize to prorate APTC.

We are proposing to require this proposed proration methodology for all Exchanges to implement beginning with the PY 2024 benefit, as HHS acknowledges that implementing this proposed methodology will require implementation and operational costs and time on the part of most State Exchanges. HHS seeks comment on this proposal. HHS also seeks comment on whether PY 2023 benefit implementation is feasible.

10. Special Enrollment Periods—Special Enrollment Period Verification (§ 155.420)

In 2017, the HHS Market Stabilization Rule preamble explained that HHS would implement pre-enrollment verification of eligibility for certain special enrollment periods in all Exchanges on the Federal platform.[272] HHS also clarified its intention to not establish a regulatory requirement that all Exchanges conduct special enrollment period verifications in order to allow State Exchanges additional time and flexibility to adopt policies that fit the needs of their state.[273] However, all State Exchanges conduct verification of at least one special enrollment period type, and most State Exchanges have implemented a process to verify the vast majority of special enrollment periods requested by consumers.

We are now proposing to amend § 155.420 to add new paragraph (g) to state that Exchanges may conduct pre-enrollment verification of eligibility for special enrollment periods, at the option of the Exchange, and that Exchanges may provide an exception to pre-enrollment special enrollment period verification for special circumstances, which could include natural disasters or public health emergencies that impact consumers or the Exchange. This is in order to encourage State Exchanges to conduct special enrollment period verification but also allow the FFEs, SBE–FPs, and State Exchanges to maintain flexibility in implementing and operating special enrollment period verification.

Since 2017, Exchanges on the Federal platform implemented pre-enrollment special enrollment period verification for certain special enrollment period types commonly used by consumers to enroll in coverage. New consumers, meaning consumers who are not currently enrolled in coverage through the Exchange, who apply for coverage through a special enrollment period type that requires pre-enrollment verification by the Exchanges on the Federal platform must have their eligibility electronically verified using available data sources or submit supporting documentation to verify their eligibility for the special enrollment period before their enrollment can become effective. As stated in the HHS Marketplace Stabilization Rule, pre-enrollment special enrollment period verification is only conducted for consumers newly enrolling due to the potential for additional burden on issuers and confusion for consumers if required for existing enrollees.[274]

While pre-enrollment special enrollment period verification can decrease the risk for adverse selection and improve program integrity, it can also deter eligible consumers from enrolling in coverage through a special enrollment period because of the barrier of document verification. Younger, often healthier consumers submit acceptable documentation to verify their special enrollment period eligibility at much lower rates than older consumers, which can negatively impact the risk pool. Additionally, our experience operating the FFEs and the Federal platform shows that pre-enrollment special enrollment period verification disproportionately negatively impacts Black and African American consumers who submit acceptable documentation to verify their special enrollment period eligibility at much lower rates than White consumers.

To support program integrity and streamline the consumer experience, we are also proposing that the Exchanges on the Federal platform would only continue to conduct pre-enrollment verification of eligibility for one type of special enrollment period: The special

[270] Executive Order 14009; 86 FR 7793 (Feb. 2, 2021).

[271] See *https://familiesusa.org/wp-content/uploads/2021/04/2021-79_ARP-Coverage-Summary_Analysis_03_2021.pdf.*

[272] 82 FR at 18355 through 18358.

[273] Ibid.

[274] 82 FR at 18355 through 18360.

enrollment period for new consumers who attest to losing minimum essential coverage.[275] The loss of minimum essential coverage special enrollment period type comprises the majority, about 58 percent, of all special enrollment period enrollments on the Exchanges on the Federal platform and has electronic data sources that can be leveraged for auto-verification. By verifying eligibility for this special enrollment period type and not for other special enrollment periods, the Exchanges on the Federal platform could limit the negative impacts of special enrollment period verification and decrease overall consumer burden without substantially sacrificing program integrity.

We seek comment on these proposals.

11. General Program Integrity and Oversight Requirements (§ 155.1200)

The Payment Integrity Information Act of 2019 (PIIA) [276] requires federal agencies to annually identify, review, measure, and report on the programs they administer that are considered susceptible to significant improper payments. Pursuant to the PIIA, HHS is in the planning phase of establishing a State Exchange Improper Payment Measurement (SEIPM) program, as HHS has determined that APTC payments may be susceptible to significant improper payments and are subject to additional oversight. Therefore, we announced that we would be implementing the SEIPM program and establishing requirements, which are laid out in proposed provisions in a new subpart P.[277]

The SEIPM program would allow for the accurate calculation of an improper payment rate through the development of annual improper payment estimates and subsequent reporting of improper payments. To ensure improper payments can be calculated accurately, the SEIPM program would require State Exchanges to provide HHS with access to certain State Exchange data, including eligibility determinations and enrollment information. State Exchanges with significant improper payments may also be required to develop corrective action plans (CAP) to correct the causes of the identified improper payments.

Currently, HHS approves or conditionally approves a state's Blueprint Application to establish a State Exchange based on an assessment of a state's attested compliance with relevant Exchange statutory and regulatory requirements at section 1311 of the ACA and 45 CFR part 155. Thereafter, State Exchanges must meet specific program integrity and oversight requirements specified at section 1313(a) of the ACA, as well as §§ 155.1200 and 155.1210. These requirements provide HHS with the authority to oversee the Exchanges after their establishment. There are various annual reporting requirements for State Exchanges at § 155.1200(b) including the annual submission of: (1) A financial statement presented in accordance with generally accepted accounting principles (GAAP); (2) an annual report showing compliance with Exchange requirements; (3) performance monitoring data; and (4) the annual submission of a report on instances in which the State Exchange did not reduce an enrollee's premium by the amount of the APTC in accordance to § 155.340(g)(1) and (2).

Additionally, under § 155.1200(c), each State Exchange is required to engage or contract with an independent qualified auditing entity that follows generally accepted government auditing standards (GAGAS) to perform annual independent external financial and programmatic audits. State Exchanges are required to provide HHS with the results of the audits, to inform HHS of any material weakness or significant deficiency identified in the audit, to develop and inform HHS of any CAPs for such material weakness or significant deficiency, and to make a public summary of the results of the external audit. The CAPs are monitored by HHS until the findings are resolved. Specifically, for the annual programmatic audit requirement, State Exchanges must ensure that auditors address compliance with subparts D and E under 45 CFR part 155, and other requirements under part 155, as specified by HHS. This allows HHS to oversee compliance with eligibility and enrollment standards to ensure that State Exchanges are conducting accurate eligibility determinations and enrollment transactions.

We propose to add new § 155.1200(e) to permit a State Exchange to meet the requirement to conduct an annual independent external programmatic audit, as described at § 155.1200(c), by completing the required annual SEIPM program process. Therefore, HHS would generally accept a State Exchange's completion of the SEIPM process for a given benefit year as acceptable to meet the annual programmatic audit requirement for that benefit year. We also propose to amend § 155.1200(c) to cross-reference proposed § 155.1200(e) to ensure the coordination of these two requirements. We believe that these proposed changes would ensure HHS retains necessary oversight authority of the State Exchanges, particularly in the event that there are changes to the SEIPM program in future benefit years. However, we would strive to provide ample advance notice of any potential changes to the SEIPM program, or to potentially allow for flexibility to satisfy requirements at paragraph (c) in the event the SEIPM program is unexpectedly suspended. These proposed changes would eliminate duplicate efforts specific to the annual programmatic audit requirement and reduce burden on the State Exchanges. They would also allow HHS to continue to require programmatic audits of other subparts beyond eligibility and enrollment, should HHS deem it necessary in future years to ensure programmatic oversight and program integrity.

As described in new proposed subpart P, section 14, HHS intends to implement the SEIPM program beginning with the 2023 benefit year. Thus, measurement of improper payments for the 2023 benefit year would take place in benefit year 2024, and reporting of the improper payment rate would not occur until November 2025, at the earliest. Thereafter, State Exchanges that HHS determines must submit CAPs would do so no sooner than 2026. We would continue to closely coordinate with State Exchanges as these timeframes are finalized and provide as much advance notice as possible of relevant deadlines as they come due.

We seek comment on these proposals.

12. State Exchange Improper Payment Measurement Program (§§ 155.1500 Through 155.1540)

In 2016, HHS completed a risk assessment of the APTC program. Similar to other public-facing benefit programs, HHS determined that the APTC program is susceptible to significant improper payments, and as a result, HHS announced plans to increase the oversight of the APTC program through the development and reporting of annual improper payment estimates, and facilitating corrective actions.[278] At that time, we also announced that we would undertake rulemaking before implementing the improper payment measurement methodology.

[275] See 45 CFR 155.420(d)(1)(i).

[276] Public Law 116–117 (Mar. 2, 2020).

[277] Presentation and materials provided to the then operational State Exchanges as part of ''All States'' meeting held on February 21, 2019.

[278] Ibid.

In line with our prior announcement[279] HHS is establishing a pilot program and, as mentioned in section 12, is proposing regulations governing HHS' SEIPM program. The SEIPM program would address all HHS and State Exchange responsibilities so that HHS can accurately calculate the SEIPM improper payment rate. Specifically, these proposed regulations would pertain to State Exchanges that operate their own eligibility and enrollment platform. These proposed regulations would not pertain to State Exchanges that use the Federal platform to conduct eligibility determinations and enrollment transactions. Additionally, the proposed regulations would contain key SEIPM program definitions and specify the manner in which HHS would collect information from State Exchanges in order to estimate the SEIPM improper payment rate. The proposed regulations would also account for the State Exchanges' obligation to provide the required information and the manner in which State Exchanges can contest HHS' findings regarding errors. Also, the proposed regulations would convey State Exchange responsibilities regarding CAPs that State Exchanges must submit to HHS for approval in order to correct improper payments.

We would calculate the SEIPM improper payment rate for each benefit year and expect the first calculation beginning with the 2023 benefit year. Since the rate cannot be calculated until all SEIPM appeals are resolved, we anticipate that the improper payment rate for the 2023 benefit year would be published in approximately November 2025. The proposed regulations are necessary for HHS to properly oversee the State Exchanges and ensure that errors resulting in improper payments are corrected.

Current regulations found at 45 CFR 155.1200 and 155.1210 require that a State Exchange have financial and operational safeguards in place to avoid making inaccurate eligibility determinations, including those related to APTC, CSR, and enrollments. However, as we stated in our 2013 regulation, §§ 155.1200 and 155.1210 were not intended to be a part of any measurement program that may have been required under the Improper Payments Elimination and Recovery Act of 2010,[280] as updated by PIIA.[281] Current program integrity audits, especially as they relate to subparts D (eligibility) and E (enrollment) of part 155, focus on the processes and procedures that a State Exchange has established to verify that a qualified individual meets eligibility requirements. Current regulations at § 155.1200(c) require State Exchanges to hire an independent qualified auditing entity and submit the external audit results to HHS. These programmatic audits do not review, estimate, or report on the amounts or rates of improper payments as the result of eligibility determination errors made by State Exchanges. To meet the requirements of PIIA, to reduce burden on State Exchanges, and to ensure consistency across State Exchanges in terms of our review methodology, we propose to update programmatic auditing requirements such that the completion of the annual SEIPM program, as required by this subpart P, would satisfy the current auditing requirements prescribed in § 155.1200(c). As we transition, we would coordinate our efforts with the CMS Center for Consumer Information and Insurance Oversight and the CMS Office of Financial Management. The goal of this coordination is to gain efficiencies and avoid duplicative requirements that would unnecessarily increase State Exchanges' workload, as well as the requirement and burden of hiring independent qualified auditing entities. Doing so would enable HHS and its Federal contractors to obtain consistent information across all State Exchanges and to meet our statutory mandate under PIIA. Therefore, we propose to establish a new subpart P under 45 CFR part 155 (containing §§ 155.1500 through 155.1540) to codify the SEIPM program requirements.

We propose that the proposed regulations at subpart P would be applicable in 2023 when the SEIPM program is proposed to begin its operations.

a. Purpose and Definitions (§ 155.1500)

We are proposing to add new subpart P to part 155, which would address various State Exchange and HHS responsibilities. HHS may use Federal contractors as needed to support the performance of statistical, review, or other activities.

We are proposing to add new § 155.1500 to convey the purpose of subpart P and definitions that are relevant to the SEIPM program.

- At paragraph (a), we are proposing the purpose of subpart P as setting forth the requirements of the SEIPM program for State Exchanges.
- At paragraph (b), we are proposing to codify the definitions that are specific to the SEIPM program and key to understanding the process requirements.
- We are proposing the definition of ''Appeal of redetermination decision (or appeal decision)'' to mean HHS' appeal decision resulting from a State Exchange's appeal of a redetermination decision.
- We are proposing the definition of ''Corrective action plan (CAP)'' to mean the plan a State Exchange develops in order to correct errors resulting in improper payments.
- We are proposing the definition of ''Error'' to mean a finding by HHS that a State Exchange did not correctly apply a requirement in subparts D and E of part 155 regarding eligibility for and enrollment in a qualified health plan; APTC, including the calculation of APTC; redeterminations of eligibility determinations during a benefit year; or annual eligibility redeterminations.
- We are proposing the definition of ''Error findings decision'' to mean HHS' enumeration of errors made by a State Exchange, including a determination of how the enumerated errors inform improper payment estimation and reporting requirements.
- We are proposing the definition of ''Redetermination of an error findings decision (or redetermination decision)'' to mean HHS' decision resulting from a State Exchange's request for a redetermination of HHS' error findings decision.
- We are proposing the definition of ''Review'' to mean the process of analyzing and assessing data submitted by a State Exchange to HHS in order for HHS to determine a State Exchange's compliance with subparts D and E of part 155 as it relates to improper payments.
- We are proposing the definition of ''State Exchange improper payment measurement (SEIPM) program'' to mean the process for determining

[279] Ibid.

[280] Public Law 111–204, 124 Stat. 2224 (July 22, 2010). The original Improper Payment Information Act, Public Law 107–300 (2002) has been updated by it successors, which include the Improper Payment Elimination and Recovery Act, Public Law 111–204 (2010), the Improper Payment Elimination and Recovery Improvement Act, Public Law 112–248 (2012), and the Payment Integrity Information Act, Public Law 116–117 (2020).

[281] Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, Premium Stabilization Programs, and Market Standards, Proposed Rule, 78 FR 37032 at 37053 (Jun. 19, 2013).

estimated improper payments and other information required under the PIIA, and implementing guidance, for APTC, which includes a review of a State Exchange's determinations regarding eligibility for and enrollment in a QHP; the calculation of APTC; redeterminations of eligibility determinations during a benefit year; and annual eligibility redeterminations.

b. Program Notification and Planning Process (§ 155.1505)

We are proposing to add new § 155.1505 to outline the annual program notification requirements related to the SEIPM program.

• At paragraph (a), we are proposing the requirements associated with HHS' responsibility to notify the State Exchanges prior to the start of the measurement year regarding information pertinent to the SEIPM program and the program's upcoming measurement cycle, which may include but would not be limited to review criteria; key changes from prior measurement cycles, where applicable; or other modifications regarding specific SEIPM activities. This notification would occur during the benefit year (that is, the year under review for which data would be collected), which immediately precedes the measurement year (that is, the year in which the measurement will be completed). The measurement cycle would conclude with the reporting year during which all data issues would be resolved and the improper payment rate would be calculated and published.

• At paragraph (b), we are proposing the requirements associated with HHS' responsibility to notify the State Exchanges prior to the measurement year regarding SEIPM schedules, which will include relevant timelines. For example, among other things, the SEIPM annual program schedule would detail the time period during which HHS would provide the SEIPM data request form to State Exchanges with instructions regarding how to complete each part of the form. The SEIPM annual program schedule would also provide the deadlines prescribed for State Exchanges to complete each part of the form.

• At paragraph (c), we are proposing the requirements associated with information to be provided by State Exchanges to HHS regarding the operations and policies of the State Exchange, and changes that have been made by the State Exchange which could impact the SEIPM review process such as changes to business rules, business practices, policies, and information systems (for example, data elements and table relationships), which are used to review the State Exchange's execution of consumer verifications, verification inconsistency resolutions, eligibility determinations, enrollment management, and APTC calculations. HHS anticipates that State Exchanges may make changes periodically that could affect a State Exchange's eligibility determinations or other decisions relating to the SEIPM program. For example, HHS would need to be made aware of changes to the State Exchange's technical platform or modifications to its policies or procedures as these changes may impact specific review criteria, the data to be reviewed and ultimately a State Exchange's eligibility determinations. Other decisions or changes by a State Exchange could affect the SEIPM program, including any changes regarding items such as naming conventions or definitions of specific data elements used in the SEIPM program, since any lack of clarity in how determinations and payment calculations are being made could impact HHS' decisions regarding errors made by the State Exchanges.

c. Data Collection (§ 155.1510)

We are proposing to add new § 155.1510 to address the data collection requirements to support the SEIPM process. Consistent with this, we are establishing an SEIPM data request form that would incorporate two basic parts: (1) The pre-sampling data request; and (2) the sampled unit data request. We would use this form to compile information from each State Exchange in an ongoing manner.

• At paragraph (a)(1), we are proposing the requirement that the State Exchange annually provide pre-sampling data to HHS by the deadline provided in the annual program schedule. The pre-sampling data request would provide HHS with essential information about the composition of the State Exchange's application population in order to appropriately stratify and sample the population. In the pre-sampling data request, HHS would provide each State Exchange with a list of policy identifications (that is, policy ID, which is a unique identifier for a policy) that would have been analyzed to produce an aggregate applied APTC greater than $0. HHS would request each State Exchange to map the given policy IDs for their State Exchange to a tax household identifier (or a proxy if the State Exchange does not have an equivalent identifier) and provide characteristics of the population, which include counts of (or an indication of the presence in) different verification inconsistency types and the number of tax household members. HHS would then analyze these characteristics and select a statistically valid sample according to OMB requirements for estimating improper payments. For these sampled units, HHS would also request associated application and enrollment data and supporting consumer documentation, which will be used to conduct its review. HHS has submitted a PRA package to OMB for approval as detailed in ICR sections IV.G.1. and 2 of this proposed rule.

As explained below in section IV, Collection of Information Requirements, the SEIPM data request form has been submitted to the OMB for review and approval. The pre-sampling data are a building block for the development of the sampled unit data, which associate consumer attestation documentation to each sampled unit. As such, the timely receipt of the completed pre-sampling data from the State Exchange is imperative.

The cumulative sample size across all State Exchanges and the associated State Exchange-specific sample size would be determined using a statistically valid sampling and estimation methodology, in a manner that is consistent with Appendix C of OMB Circular A–123 and that would be designed to produce an aggregate estimated improper payment rate across all State Exchanges with a 3 percent margin of error and a 95 percent confidence interval.[282] HHS researched various sampling methodologies, for example, simple random sampling, stratified random sampling, and probability proportional to size sampling, taking into account level of burden, (for example, time and resources), on State Exchanges as well as enabling meaningful reviews for each State Exchange. Based on information currently available, we expect that a sample size of approximately 100 tax households for each State Exchange will be necessary to achieve this precision level. HHS will provide State Exchanges with an annual program notification that may include sampling methodology and sample size. Burden estimates contained within this document have been created using that sample size estimate. There are a variety of factors that we may consider each review cycle to determine the sample size and

[282] While OMB Memorandum M–21–19, dated March 5, 2021 at *https://www.whitehouse.gov/wp-content/uploads/2021/03/M-21-19.pdf* no longer includes the requirements of a 95 percent confidence interval or a 3% margin of error, we are using those measures that were included in Appendix C to the OMB circular prior to the 2021 changes.

methodology. Such factors may include the size of the State Exchange measured either by the number of payments or by the total dollar amount, specific factors that drive the improper payment rate, the number of State Exchanges under measurement for a given review cycle, or improper payment rates and margins of error from previous benefit years. Regardless of potential variations from one review cycle to the next, we would continue to use a methodology that supports statistically valid sampling and estimation.

• As stated previously, we would provide to each State Exchange an SEIPM data request form that includes the sampled unit data request. At paragraph (a)(2) we are proposing the requirement that annually the State Exchange provide to HHS, in a manner and within a deadline specified by HHS in the annual program schedule, sampled unit data. To meet this requirement, a State Exchange can submit consumer-submitted documentation in one or more batches so long as all of the batches are provided to HHS within the deadline specified in the annual program schedule. The sampled unit data request would include the list of sampled units and the associated information specific to each unit. The information required for the sampled units would include data and supporting documentation regarding various State Exchange functions, for example, electronic verifications, manual reviews of data matching inconsistencies, special enrollment period verifications, eligibility determinations, redeterminations, enrollment reconciliation, and plan management.

• At paragraph (b), we are proposing language regarding requests for extension which may be submitted by State Exchanges. Given the importance of the time frames associated with the measurement process, we do not anticipate granting extensions in most situations. The approval of extension requests would be reserved for extreme circumstances that directly impact operations of the particular State Exchange. This includes situations such as natural disasters, interruptions in business operations such as major system failures, or other extenuating circumstances.

• At paragraph (c), we are proposing language regarding potential consequences as a result of a State Exchange's failure to timely provide the information in accordance with the schedule and deadlines detailed in the annual program schedule, or in response to a request for extension in paragraph (b). As a result of not timely providing required data, we may cite errors due to lack of documentation to support the state's eligibility or payment decisions, inadvertently resulting in an increase in the State Exchange's improper payment rate.

d. Review Process and Improper Payment Rate Determination (§ 155.1515)

We are proposing to add new § 155.1515 to address the review process and the determination of the improper payment rate.

• At paragraph (a), we are proposing that HHS would keep a record of the status of receipt for information requested from each State Exchange for a minimum of 10 years.

• At paragraph (b), we are proposing to review the following for compliance with subparts D and E of part 155: A State Exchange's determinations regarding eligibility for and enrollment in a QHP; APTC, including the calculation of APTC; redeterminations of eligibility determinations during a benefit year; and annual eligibility redeterminations. As part of the review process, HHS would issue error findings decisions and render redeterminations of error findings decisions within the timeframe specified in the annual program schedule.

• At paragraph (c), we are proposing to notify each State Exchange of HHS' error findings decisions for that State Exchange and HHS' calculation of that State Exchange's improper payment rate.

e. Error Findings Decisions (§ 155.1520)

We are proposing to add new § 155.1520 to address the issuance of error findings decisions and the content of error findings decisions.

• At paragraph (a), we are proposing that HHS will issue error findings decisions to each State Exchange. While we anticipate that error findings decisions would be issued at regular and recurring points of time within the measurement year during each review cycle, we recognize that certain events could result in necessary delays, for example, public health emergencies, natural disasters, interruptions in business practices, or other extenuating circumstances. Thus, should these types of events warrant additional time, we would notify State Exchanges of the delay via the CMS website. In the situation where no errors are found during the course of the review, HHS will still issue an error findings decision to the State Exchange indicating that no errors were identified. The error findings decisions are intended to be communicated to each respective State Exchange only and would not be published publicly.

• At paragraph (b), we are proposing language regarding the specific information that would be included in error findings decisions. We propose that, at a minimum, error findings decisions will include HHS' findings regarding errors made by the State Exchange and information about the State Exchange's right to request a redetermination of the error findings decision in accordance with proposed § 155.1525. We anticipate that these are the key items to be conveyed through the error findings decision. However, should we determine that other information is warranted, the language of proposed § 155.1520 does not prohibit additional information from being included within the error findings decision.

f. Redetermination of Error Findings Decisions (§ 155.1525)

We are proposing to add new § 155.1525 to address a State Exchange's request for a redetermination as well as HHS' issuance of the redetermination decision and the content of that decision.

• At paragraph (a), we are proposing language indicating a State Exchange's ability to request a redetermination of the error findings decision within the deadline prescribed in the annual program schedule. During the period for a State Exchange to request a redetermination of the error findings decision, HHS would consider a request for an extension in extreme circumstances, which includes but is not limited to situations such as natural disasters, interruptions in business operations such as major system failures, or other extreme circumstances. While we recognize that each State Exchange has a multitude of responsibilities, HHS would not otherwise accept any request for a redetermination received after the expiration of the deadline prescribed by the annual program schedule, which is designed to enable HHS to meet deadlines for publication of the improper payment rate.

• At paragraph (a)(1), we are proposing language requiring that the State Exchange identify the specific error(s) for which the State Exchange is requesting a redetermination. This identification may pertain to a single individual's application or to a type of error affecting a class of applications. Since this redetermination constitutes a review of the initial decision and not a de novo investigation, the State Exchange must base its request on documentation and other information

already submitted to HHS (for example, if the application lacked income information, the State Exchange may not retrospectively seek this documentation and add it to the record). Any issues that do not relate to an error identified by HHS in the initial error findings decision would not be addressed.

• At paragraph (a)(2), we are proposing language that the State Exchange must include all data and information that support the State Exchange's request for a redetermination. Note that while State Exchanges are able to submit data and information in requesting a redetermination, new information submitted as part of the request for redetermination should supplement data previously submitted as part of the SEIPM data request form for the benefit year under review and would be accepted at HHS' discretion. State Exchanges may not use the redetermination process as a means to circumvent prior deadlines for submitting data or information to HHS.

• At paragraph (a)(3), we are proposing language that would require a State Exchange to provide an explanation of how the data and information submitted under paragraph (a)(2) pertains to the error(s) identified in the error findings decision. The State Exchange should clearly articulate how the data and information is related to HHS' findings, and also how it impacts HHS findings. If a State Exchange does not provide this explanation, HHS would not anticipate or assume a State Exchange's reasoning in requesting a redetermination on a particular error.

• At paragraph (b), we are proposing language regarding the issuance of redetermination decision. The redetermination of an error findings decision would be issued within the deadline prescribed in the annual program schedule. Our goal is to ensure that each State Exchange has ample time to assess the error findings decision, give HHS adequate time to thoroughly evaluate a State Exchange's request for a redetermination, and calculate an improper payment rate in adequate time to publish aggregate findings across all State Exchanges in the Agency Financial Report. As with the error findings decision, we anticipate HHS' redetermination decisions would be issued at regular and recurring points of time within the measurement year during each review cycle and in accordance with the annual program schedule. However, we also recognize that certain circumstances could result in necessary delays, for example, public health emergencies, natural disasters, interruptions in business operations, or other extenuating circumstances. Thus, we are proposing that if these types of circumstances result in HHS needing additional time to render the redetermination decisions, a state Exchange would be notified of the delay.

• At paragraph (c), we are proposing language conveying the minimum content requirements for HHS' redetermination decision.

• At paragraph (c)(1), we are proposing language specifying that HHS' decision must address its findings regarding the impact of any additional data and information provided by the State Exchange on the error(s) for which the State Exchange requested a redetermination.

• At paragraph (c)(2), we are proposing language that would establish HHS' responsibility to give a State Exchange information about the right to request an appeal of the redetermination of error findings decision in accordance with proposed § 155.1530.

g. Appeal of Redetermination Decision (§ 155.1530)

We are proposing to add new § 155.1530 to address a State Exchange's ability to request an appeal of the redetermination decision. Appeals will be administered by HHS.

• At paragraph (a), we are proposing language regarding a State Exchange's right to request an appeal of a redetermination within the deadline prescribed in the annual program schedule. Moreover, we are proposing that, in the request for an appeal, the State Exchange must indicate the specific error(s) identified in the redetermination decision for which the State Exchange is requesting an appeal. In accordance with proposed § 155.1530(d), which specifies that findings would be restricted to those errors for which a redetermination was sought, this proposed language also indicates that a State Exchange is prohibited from requesting an appeal of any error(s) that were not specified in a State Exchange's redetermination request.

• At paragraph (b), we are proposing language that conveys the appeal entity's review would be an on-the-record review, meaning that the appeal entity would only review data and information provided at the time of a State Exchange's redetermination request. No additional new data or information submitted in support of the request for appeal would be considered.

• At paragraph (c), we are proposing language that the appeal decision would be issued within the deadline prescribed in the annual program schedule. Again, as with the earlier time frames set in the annual program schedule, the time frame for appeal allows HHS adequate time to review information provided by the State Exchange, assess errors, and calculate an improper payment rate in adequate time to publish findings in the Agency Financial Report. We also acknowledge that unforeseen circumstances could result in necessary delays in the issuance of the appeal decision for example, public health emergencies, natural disasters, interruptions in business practices, or other extenuating circumstances. Thus, we are proposing that if these types of circumstances necessitate the appeals entity's need for additional time in rendering an appeal decision, the State Exchange would be notified about the delay.

• At paragraph (d), we are proposing the content of the appeal decision.

• At paragraph (d)(1), we are proposing that the appeal decision would include the final disposition of the on-the-record review and that findings would be restricted to those error(s) for which an appeal was sought.

• At paragraph (d)(2), we are proposing that the appeal decision would include the estimated improper payment rate for the State Exchange.

• At paragraph (e), we are proposing that upon completion of the review and the closure of all appeals, HHS would issue to each individual State Exchange, a report containing the error findings and the estimated improper payment rate for their respective program. That report will not be made public. The estimated improper payment rates for each State Exchange will be used to estimate an aggregate improper payment rate across all State Exchanges. That aggregate rate will be published in the agency's Annual Financial Report.

h. Corrective Action Plan (§ 155.1535)

We propose to add new § 155.1535 to address the scenario in which a State Exchange's improper payment rate for a given benefit year, in HHS's reasonable discretion, necessitates a CAP to correct the causes of any payment errors. Our goal is to lay out a set of minimum requirements in future rulemaking, using the standards provided under Appendix C to OMB Circular No. A–123, to support State Exchanges in satisfying the requirement of developing, implementing, and monitoring a CAP. Otherwise, State Exchanges should have the flexibility to conduct these activities in a manner that is tailored to their specific needs, including any standard practices, policies and procedures, or business needs. We also anticipate that there

would be collaboration required between HHS and the State Exchange to ensure the effectiveness of any CAP, and we underscore the importance of maintaining open lines of communication on significant CAP-related updates. As needed, a State Exchange should be prepared to consult with HHS and provide timely responses to any requests for clarification or additional information regarding the CAP.

As we gather additional information and data, and observe trends based on experience with implementing the SEIPM program, we will detail CAP parameters or requirements in future rulemaking. We note, as well, that the first improper payment report would not be released until November 2025 at the earliest, and so the first SEIPM program CAP likely would not be due until early 2026.

- At paragraph (a), we propose that, depending on a State Exchange's error rate for a given benefit year, we may require the State Exchange to develop and submit a CAP to HHS to correct errors resulting in improper payments. In future rulemaking, we may define a threshold error rate, dollar amount, or other scenarios that could necessitate a CAP. We do not, however, anticipate that these standards would deviate significantly from the standards of other improper payment measurement programs, such as the standards under the Medicaid and CHIP Payment Error Rate Measurement (PERM) program.
- At paragraph (b), we propose that Appendix C to OMB Circular No. A–123 would serve as a minimum set of guidelines to any State Exchange that is developing a CAP. The State Exchange otherwise has broad discretion to utilize a format tailored to its specific needs, so long as it can demonstrate that the CAP is effectively and timely correcting error causes.
- At paragraph (c), we propose that a State Exchange would be required to develop an implementation schedule to accompany its CAP, and implement any CAP initiatives in accordance with that schedule. In conjunction with completing CAP initiatives timely, a State Exchange would be required to regularly evaluate whether those initiatives are effective at correcting errors identified. It is critical that the State Exchange maintains regular communications with HHS of any evaluation findings, particularly for any CAP initiatives that are not correcting errors. In this situation a State Exchange may need to revise or discontinue these initiatives, or develop new ones.
- At paragraph (d), we propose the recourse HHS has in the event that a State Exchange that is required to submit a CAP fails to timely do so by stating that HHS may take actions consistent with § 155.1540.

i. Failure To Comply (§ 155.1540)

We propose to add new § 155.1540 that would address failures to comply with SEIPM requirements. At paragraph (a), we propose that HHS would have discretion to address failures of compliance with audit data submission and CAP requirements contained in subpart P, consistent with authorities HHS possesses under title I of the ACA or any other Federal law.

Based on experiences with other audit programs, HHS is of the view that without measures to ensure State Exchanges' compliance with SEIPM requirements, the audit program could easily become frustrated and inefficient, needlessly burdensome to the government and wasteful of government funds and resources, as well as ineffective to detect and prevent improper payments of APTC in State Exchanges. HHS finds that such failures would undermine or prohibit HHS's efficient administration of Exchange activities, including the administration of APTC. For this reason, we propose that if a State Exchange fails to substantially comply with the data collection requirements or the CAP provisions contained in subpart P, HHS may implement measures or procedures in relation to the State Exchange that HHS determines are appropriate to secure compliance with data collection and CAP provisions contained in subpart P of this part, and to detect, prevent, or reduce abuses in the administration of APTC under title I of the ACA, so long as such actions are within HHS's authorities under title I of the ACA or any other Federal law.

The ACA grants HHS broad discretion to ensure the effective and efficient administration of Exchange activities through audits and other authorized means, such as those HHS proposes in this rule to support its compliance with the PIIA.[283] Section 1313(a)(5) of the ACA authorizes HHS to implement any measure or procedure it determines appropriate to reduce fraud and abuse in the administration of title I of the ACA, which includes the conduct of APTC eligibility determinations and the administration of APTCs. HHS is considering exercising this authority to ensure State Exchange compliance with SEIPM program data collection and CAP requirements. For instance, upon a State Exchange's failure to substantially comply with data collection requirements, HHS could require the State Exchange to provide on-site access to required data and Exchange personnel capable of displaying requested data directly to HHS personnel or contractors.[284] If a State Exchange failed to substantially comply with requirements under an existing CAP, HHS could require the State Exchange to revise the CAP and its related implementation plan to contain revised or additional requirements specifically designed to address the State Exchange's compliance failures and ensure the State Exchange's future compliance with CAP requirements. We seek comment on these measures and invite suggestions for other measures HHS might undertake in relation to State Exchanges to incentivize compliance with data collection and CAP requirements (or cure non-compliance) and to ensure the efficient administration of APTCs.

We note that if the proposed SEIPM program requirements are finalized, HHS does not anticipate broad or willful noncompliance with data collection and CAP requirements by State Exchanges. Rather, we expect that HHS and State Exchanges would continue to work collaboratively to ensure the accuracy and integrity of APTC eligibility determinations and payments during SEIPM audits. Where a State Exchange's compliance failure is due to impediments outside of the Exchange's control or due to its need for technical assistance, HHS would provide such technical assistance and, when appropriate, could grant reasonable accommodations (such as additional time to submit data or implement elements of a CAP), in order to provide the State Exchange the resources and support it needs to meet SEIPM audit requirements. Considering the extremely close working relationships between HHS and State Exchanges and their combined interests in ensuring the integrity of APTC eligibility determinations, HHS does not anticipate that it would need to exercise its authority under title I of the ACA to impose financial penalties for substantial noncompliance resulting from serious or willful noncompliance with SEIPM requirements. Rather, we

[283] Although proposed § 155.1540 and other rules we propose to codify in part 155, subpart P, are specifically intended to support compliance with requirements under the PIIA, section 1313(a)(3) also authorizes HHS to subject State Exchanges to annual financial audits.

[284] See, for example, section 1313(a)(2) of the ACA (HHS may investigate the affairs of an Exchange, may examine the properties and records of an Exchange, and may require periodic reports in relation to activities undertaken by an Exchange, and an Exchange must fully cooperate in any investigation conducted under this paragraph).

expect that such penalties would be necessary to address only the most egregious situations that would amount to serious misconduct in relation to a State Exchange's administration of APTCs and its failure to comply with audit requirements.[285]

We invite comment on these proposals.

E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. FFE and SBE–FP User Fee Rates for the 2023 Benefit Year (§ 156.50)

Section 1311(d)(5)(A) of the ACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a state does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the ACA directs HHS to operate an Exchange within the state. Accordingly, in § 156.50(c), we specified that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP.

OMB Circular No. A–25 established federal policy regarding user fees; it specifies that a user fee charge will be assessed against each identifiable recipient of special benefits derived from federal activities beyond those received by the general public.

a. FFE User Fee Rates for the 2023 Benefit Year

Activities performed by the federal government that do not provide issuers participating in an FFE with a special benefit are not covered by the FFE user fee. As in benefit years 2014 through 2022, issuers seeking to participate in an FFE in the 2023 benefit year will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. For the 2023 benefit year, issuers participating in an FFE will receive special benefits from the following federal activities:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and
- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification).

To provide additional transparency into HHS' user fee calculation, we set forth below the costs, premium, and enrollment projections that went into calculating the proposed 2023 FFE user fee rates based on the best available data at the time of this proposed rulemaking, to the extent that none of this information is considered proprietary for issuers or confidential for the federal government. For the 2023 benefit year, we anticipate that spending on consumer outreach and education, eligibility determinations, and enrollment process activities will increase by approximately $140 million above the 2022 benefit year level. We anticipate spending on consumer assistance tools, management of a Navigator program, regulation of agents and brokers, and certification of QHPs activities will be similar to what was estimated for the 2022 benefit year. We do not anticipate any new services or contracts will fall under the FFE user fees for the 2023 benefit year.

Additionally, we considered a range of premium and enrollment projections in setting the proposed 2023 benefit year FFE user fee rates.[286] The weighted average premium projections that we considered ranged from $618 to $625 per month. The annual enrollment percentage change projections that we considered ranged from −1 percent to 2 percent. We took a number of factors into consideration in choosing which premium and enrollment projections should inform the proposed 2023 FFE user fee rates. The assumption that the enhanced premium tax credit subsidies in section 9661 of the ARP will expire after the 2022 benefit year significantly influenced our development of the 2023 enrollment and premium projections.[287] We expect the expiration of this provision of the ARP to revert enrollment and premium projections to the pre-ARP level observed in the 2020 benefit year. Our 2023 enrollment estimates also account for the 2021 benefit year transition (and projected transitions through the 2023 benefit year) of states from FFEs or SBE–FPs to State Exchanges, as well as the enrollment impacts of section 1332 state innovation waivers. We project that 2023 benefit year premiums will generally increase at the rate of medical inflation after expiration of the enhanced premium tax credit subsidies in section 9661 of the ARP. After considering the range of costs, premium and enrollment projections, we propose a 2023 user fee rate that will not result in a substantial increase to consumer premiums from prior years, and that also ensures adequate funding for federal Exchange operations.

As such, based on estimated costs, enrollment, and premiums for the 2023 benefit year, we propose a 2023 benefit year user fee rate for all participating FFE issuers of 2.75 percent of total monthly premiums. This is the same user fee rate that we established for the 2022 benefit year.[288] We seek comment on this proposal.

b. SBE–FP User Fee Rates for the 2023 Benefit Year

As discussed above, OMB Circular No. A–25 established federal policy regarding user fees, and specified that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. SBE–FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between state and federal programs. Accordingly, in § 156.50(c)(2), we specified that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an SBE–FP, unless the SBE–FP and HHS agree on an alternative mechanism to collect the funds from the SBE–FP or state instead of direct collection from SBE–FP issuers.

The benefits provided to issuers in SBE–FPs by the federal government include use of the federal Exchange

[285] See, for example, section 1313(a)(4) of the ACA (in such cases, the Secretary may rescind from payments due to the State an amount not to exceed one percent of such payments until corrective actions are taken by the State and determined to be adequate by the Secretary).

[286] We used the most recent projections from the Congressional Budget Office, the Office of Management and Budget, the Office of the Actuary, and the Office of Financial Management.

[287] Public Law 117–2.

[288] Part 3 of the 2022 Payment Notice (86 FR 53412).

information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs, as defined at section 1413(e) of the ACA, and QHP enrollment functions under 45 CFR part 155, subpart E. The user fee rate for SBE–FPs is calculated based on the proportion of user fee eligible FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE–FPs. To calculate the proposed SBE–FP rates for the 2023 benefit year, we used the same assumptions on contract costs, enrollment, and premiums as the proposed FFE user fee rates. We calculated the SBE–FP user fee rate based on the proportion of all FFE functions that are also conducted for SBE–FPs. The final SBE–FP user fee rate for the 2022 benefit year of 2.25 percent of premiums was based on HHS' calculation of the percent of costs of the total FFE functions utilized by SBE–FPs—the costs associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs, which we estimate to be approximately 80 percent. Based on this methodology, we propose to charge issuers offering QHPs through an SBE–FP a user fee rate of 2.25 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP for the 2023 benefit year. This is the same user fee rate that we established for the 2022 benefit year. We seek comment on this proposal.

2. User Fees for FFE–DE and SBE–FP–DE States

Consistent with the removal of § 155.221(j) and the repeal of the Exchange DE option in part 3 of the 2022 Payment Notice,[289] we propose a technical correction to remove from § 156.50 all references to the Exchange DE option and cross-references to § 155.221(j). In that rule, we also finalized the repeal of the accompanying user fee rate for FFE–DE and SBE–FP–DE states for 2023; however, HHS inadvertently did not amend the accompanying regulatory text in § 156.50 related to the Exchange DE option user fees.[290] As such, we propose to make conforming changes to § 156.50(c) and (d) to remove all references to the Exchange DE option and § 155.221(j). Specifically, we propose to remove § 156.50(c)(3), and amend §§ 156.50(d)(1); (d)(2)(i)(A) and (B); (d)(2)(ii); (d)(2)(iii)(B); (d)(3); (d)(4); (d)(6); and (d)(7) to remove the references to the Exchange DE option. We seek comment on these proposed technical amendments.

3. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

a. States' EHB-Benchmark Plan Options

At § 156.111(a), we allow a state to modify its EHB-benchmark plan by: (1) Selecting the EHB-benchmark plan that another state used for PY 2017; (2) replacing one or more EHB categories of benefits in its EHB-benchmark plan used for PY 2017 with the same categories of benefits from another state's EHB-benchmark plan used for PY 2017; or (3) otherwise selecting a set of benefits that would become the state's EHB-benchmark plan. In implementing this section, we stated in the 2019 Payment Notice that we would propose EHB-benchmark plan submission deadlines in the HHS annual Notice of Benefit and Payment Parameters.

Since we finalized that rule, we have set an early-May deadline for the submission of EHB-benchmark plans by states for each year from PY 2021–2024.[291] We believe that requiring these submissions in the first week of May that is two years before the effective date of the new EHB-benchmark plan has worked well. The feedback received from states that have submitted new EHB-benchmark plans indicates that this timeframe provides the states with enough time to prepare EHB-benchmark submissions. It also provides CMS with sufficient time to review and respond to these submissions in advance of issuers needing to make changes to plan design to conform with EHB changes.

Thus, we do not believe it is necessary to continue proposing deadlines for EHB-benchmark submissions under § 156.111 in each annual Notice of Benefit and Payment Parameters. We believe that it is in the interest of states and issuers that we formalize a consistent, permanent annual deadline in early-May for EHB-benchmark submissions. Accordingly, we propose that the first Wednesday in May that is two years before the effective date of the new EHB-benchmark plan to be the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for that PY. For example, under this proposal, the deadline for PY 2025 would be May 3, 2023, and the deadline for PY 2026 would be May 4, 2024. We propose corresponding edits to § 156.111(d) and (e) to reflect this proposed deadline.

If finalized, this proposed deadline would obviate the need to propose deadlines in future annual Notices of Benefit and Payment Parameters. We invite comment on this approach, including whether there are any unforeseen consequences to establishing this perpetual deadline.

We again emphasize that this would be a firm deadline, and that states should optimally have one of their points of contact who has been predesignated to use the EHB Plan Management Community reach out to us using the EHB Plan Management Community well in advance of the deadline with any questions. Although not a requirement, we recommend states submit applications at least 30 days prior to the submission deadline to ensure completion of their documents by the proposed deadline. We also remind states that they must complete the required public comment period and submit a complete application by the deadline. We seek comment on the proposed deadline.

b. Annual Reporting of State-Required Benefits

In the 2021 Payment Notice, we amended § 156.111(d) and added paragraph (f) to require states to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any state-required benefits applicable to QHPs in the individual or small group market that are considered to be ''in addition to EHB'' in accordance with § 155.170(a)(3) and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination.

Under this requirement, a state's submission must describe all benefits requirements under state mandates applicable to QHPs in the individual or small group market that were imposed on or before December 31, 2011, and that were not withdrawn or otherwise no longer effective before December 31, 2011, as well as all benefits requirements under state mandates that were imposed any time after December

[289] 86 FR 53412 at 53424–53429, 53445. We also clarified that the repeal of the Exchange DE option is specific to removing the Exchange DE option codified at § 155.221(j) and the accompanying FFE–DE and SBE–FP–DE user fees, and that the other federal requirements applicable to the FFE DE Pathways, as outlined in §§ 155.220, 155.221, and 156.1230, remain intact. See 86 FR at 53427.

[290] 86 FR at 53429.

[291] For PY 2021, the deadline was May 6, 2019 (see 84 FR at 17534); for PY 2022, it was May 8, 2020 (84 FR at 17534); for PY 2023, it was May 7, 2021 (85 FR at 29226); for PY 2024 it is May 6, 2022 (86 FR at 24232).

31, 2011, applicable to the individual or small group market. The state's report is also required to describe whether any of the state benefit requirements in the report were amended or repealed after December 31, 2011. Information in the state's report is required to be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS.

Pursuant to § 156.111(d)(2), if the state does not notify HHS of its required benefits considered to be in addition to EHB by the annual reporting submission deadline, or does not do so in the form and manner specified by HHS, HHS will identify which benefits are in addition to EHB for the state for the applicable PY.

In the 2021 Payment Notice, we finalized July 1, 2021 as the first deadline for states to submit annual reports to HHS. Additionally, in the 2022 Payment Notice, HHS finalized July 1, 2022 as the deadline for states to submit to HHS their annual reports for the second year of annual reporting. However, we simultaneously announced our intent to exercise enforcement discretion with regard to the first annual reporting submission deadline of July 1, 2021 due to delays in finalizing the reporting templates that states are required to use for their submissions, delays in issuing additional technical assistance on defrayal, and the added burden of the COVID–19 PHE on states. Pursuant to this enforcement posture, we explained that we would not take enforcement action against states that do not submit an annual report in 2021. Rather, we would begin enforcing the annual reporting requirement on July 1, 2022.

Since finalizing the annual reporting requirement in the 2021 Payment Notice, we have received consistent feedback from states and stakeholders restating the concerns raised by the majority of public comments on the annual reporting requirement in the 2021 and 2022 Payment Notices. Although we received some comments agreeing that this policy is important to ensure states are defraying state benefit requirements consistently, most commenters objected to the policy as unnecessary, burdensome on states, and without adequate justification. Several commenters explained that, contrary to HHS' concerns expressed in the 2021 and 2022 Payment Notices, states are already regularly making careful assessments about whether their state benefit requirements are in addition to EHB and are doing so in accordance with federal requirements. Commenters opposing the reporting policy as unnecessary also stated that existing regulations already establish robust requirements for states and issuers to follow when a state benefit requirement is in addition to EHB and requires defrayal, including performing actuarially sound analyses of costs associated with state benefit requirements in addition to EHB when calculating APTCs. Commenters noted that HHS already has existing authority to investigate states that are not complying with defrayal requirements and that, as such, imposing a reporting requirement on states is not necessary for federal oversight purposes. Other commenters expressed concern about the lack of transparency around the annual reporting and review process, requesting that HHS delay the reporting requirement until HHS provides further clarification and releases additional guidance clarifying its defrayal policies.

We have reassessed the value of the annual reporting policy in light of these comments and other stakeholder feedback and believe it is important to explore whether there may be ways to achieve compliance with the defrayal policy without imposing a requirement on states to submit detailed annual reports on state-required benefits. We therefore propose to eliminate the requirement at § 156.111(d) and (f) to require states to annually notify HHS of any state-required benefits applicable to QHPs in the individual or small group market that are considered to be ''in addition to EHB'' and any benefits the state has identified as not in addition to EHB and not subject to defrayal. We also propose to revise the section heading to § 156.111 to reflect the proposed removal of the annual reporting requirements such that it would instead read, ''State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.''

Under this proposal, we would continue to engage in technical assistance with states to help ensure state understanding of when a state-benefit requirement is in addition to EHB and requires defrayal. We also intend to provide additional written technical assistance and outreach to clarify the defrayal policy more generally and to provide states with a more precise understanding of how HHS analyzes and expects states to analyze whether a state-required benefit is in addition to EHB pursuant to § 155.170. We believe this approach would still effectively promote state compliance with the defrayal requirement in the interim as we reassess whether or when an annual reporting policy may be warranted.

Although this proposal would relieve states of the annual reporting requirements, it would not pend or otherwise impact the defrayal requirements under section 1311(d)(3)(B) of the ACA, as implemented at § 155.170. Under this proposal, states remain responsible for making payments to defray the cost of additional required benefits and issuers are still responsible for quantifying the cost of these benefits and reporting the cost to the state. We also note that the obligation for a state to defray the cost of QHP coverage of state-required benefits in addition to EHB is an independent statutory requirement from the annual reporting policy finalized at § 156.111(d) and (f).

We solicit comment on this proposal, including on whether we should retain the reporting requirement or make it voluntary.

4. Provision of EHB (§ 156.115)

In the 2019 Payment Notice, we finalized flexibility through which states may opt to permit issuers to substitute benefits between EHB categories. In the preamble to that rule, we stated that this option would promote greater flexibility, consumer choice, and plan innovation through coverage and plan design options. Under this policy, a state must notify HHS if will permit issuers to substitute benefits between EHB categories by the deadlines specified by HHS in future Payment Notices.

To date, no state has ever notified HHS that it would permit issuers to substitute benefits between EHB categories. To our knowledge, no state has ever even approached HHS to discuss the merits of allowing this flexibility. In addition, we have received feedback from consumer advocates that the potential for between-category substitution could be particularly harmful to people living with chronic conditions and disabilities. Given that this policy has never been utilized, it has not promoted greater flexibility, consumer choice, or plan innovation through coverage and plan design options as intended. Rather, HHS is of the view that it may only create potential harm for consumers with chronic conditions and disabilities. Accordingly, whatever theoretical flexibility this policy could have afforded to states, such untapped flexibility is not justified given the potential negative effects on consumers. Thus, we propose to withdraw this flexibility by amending § 156.115 to no longer allow states to permit issuers to substitute benefits between EHB categories.

In the event we do not finalize this proposal to eliminate the state option

for between-category substitution, we propose to publish in guidance future deadlines for states to notify HHS that they wish to permit issuers to substitute benefits between EHB categories. We believe that it is in the interest of states and issuers that we establish a static, permanent annual deadline for such notifications. Accordingly, consistent with the deadline proposed for state submission of EHB-benchmark plans, we propose the first Wednesday in May to be the deadline for states to submit notifications to HHS that they wish to permit issuers to substitute benefits between EHB categories for the PY that is 2 years before the PY that the state wishes to permit. For example, under this alternate proposal, the deadline for issuers to notify HHS that they wish to permit issuers to substitute benefits between EHB categories for PY 2025 would be May 3, 2023; and the deadline for PY 2026 would be May 4, 2024. States wishing to make such an election must continue to do so via the EHB Plan Management Community. For additional discussion of this proposed deadline, see the preamble to § 156.111.

We seek comment on these proposals.

5. Prohibition on Discrimination (§ 156.125)

If the proposed nondiscrimination protections are finalized at § 156.200(e) that would explicitly prohibit discrimination based on sexual orientation and gender identity; § 156.125(b) would accordingly require issuers providing EHB to comply with such nondiscrimination requirements. Specifically, § 156.125(b) states that an issuer providing EHB must comply with the requirements of § 156.200(e), which currently states that a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex. Elsewhere in this rule we propose to amend § 156.200(e) to prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 156.200(e), simultaneously requiring that issuers providing EHB comply with such requirements by virtue of the cross-reference in § 156.125(b) to § 156.200(e). However, amendments made in 2020 to § 156.200(e) removed any reference to sexual orientation and gender identity. If the proposals at § 156.200(e) are finalized, issuers providing EHB would again be required under § 156.125(b) to comply with nondiscrimination protections in § 156.200(e) that prohibit discrimination on the basis of sexual orientation and gender identity.

In the March 27, 2012 Exchange Standards final rule, we finalized § 156.200(e) to also prohibit discrimination based on sexual orientation and gender identity.[292] In the February 2013 ''Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule'' (EHB final rule), we finalized at § 156.125 that the nondiscrimination requirements in § 156.200 also apply to all issuers required to provide coverage of EHB, thereby prohibiting discrimination based on factors such as sexual orientation and gender identity.[293] In the 2020 section 1557 final rule, HHS revised certain CMS regulations, including § 156.200(e), by removing sexual orientation and gender identity as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[294] As a result, § 156.200(e) currently prohibits a QHP issuer from discriminating on the basis of race, color, national origin, disability, age, or sex with respect to its QHP, but does not reference sexual orientation or gender identity.

CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination in the small group and individual markets pursuant to the authority to define EHB at section 1302(b) of the ACA.[295] The statute specifies that in defining EHB the Secretary must take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups. The EHB requirements apply to non-grandfathered health insurance coverage in the individual and small group markets under section 2707(a) of the PHS Act. CMS has the authority to interpret and implement these provisions under its general rulemaking authorities in sections 1321(a)(1)(B) and (D) of the ACA and section 2792 of the PHS Act. Pursuant to those authorities, HHS finalized in the EHB final rule that § 156.125 prohibits benefit discrimination on the grounds articulated by Congress in section 1302(b)(4) of the ACA, as well as those in § 156.200(e), which at the time included race, color, national origin, disability, age, sex, gender identity, and sexual orientation. It is under that same exercise of authority here that § 156.125 would again prohibit discrimination on the basis of sexual orientation and gender identity if the proposed changes to include such factors in the nondiscrimination protections at § 156.200(e) are finalized. Sections 1302(b) and 1321(a)(1)(B) and (D) of the ACA and section 2707(a) and 2792 of the PHS Act are the same authorities CMS relies upon for implementation of existing nondiscrimination protections at § 156.125. Utilizing these same authorities to again prohibit discrimination based on sexual orientation and gender identity at § 156.125 by cross-reference to the nondiscrimination protections at § 156.200(e) would be consistent with the authority CMS relies upon for the existing protections at § 156.125 that prohibit discrimination on the basis of race, color, national origin, disability, age, or sex by cross-reference to § 156.200(e). We believe such protections are warranted in light of the existing trends in health care discrimination and are necessary to better address barriers to health equity for LGBTQI+ individuals.

A more in-depth discussion of these developments and other factors considered in proposing amendments to CMS nondiscrimination protections is included earlier in the preamble to § 147.104 under section III.B.1.b. of this preamble. For brevity, we refer back to § 147.104 under section III.B.1.b. of the preamble rather than restating the issues here.

We seek comment on this proposal.

a. Refine EHB Nondiscrimination Policy for Health Plan Designs (§ 156.125)

We propose refining the EHB nondiscrimination policy and propose a clear regulatory framework for entities that are required to comply with EHB nondiscrimination policy. This proposed refinement would not only ensure consistent application of EHB nondiscrimination policy but would also better safeguard consumers who depend on nondiscrimination protections.

Under § 156.125(a) an issuer does not provide EHB ''if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.''[296] Section

[292] 77 FR 18310 (March 27, 2012).

[293] 78 FR 12834 (February 25, 2013).

[294] 85 FR 37160 (June 19, 2020); *See id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

[295] 85 FR 37218–21 (June 19, 2020).

[296] ACA section 1302(b)(4) prohibits discrimination based on ''age, disability, or expected length of life'' and requires that benefits not be subject to denial based on ''age or expected length of life, present or predicted disability, degree of medical dependency, or quality of life.''

156.125(b) provides that issuers must also comply with § 156.200(e) which states that ''a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex.'' [297] Section 156.110(d) states that an EHB benchmark plan may not include discriminatory benefit design that contravenes § 156.125. In the 2016 Payment Notice, we provided examples of potentially discriminatory practices, and in the 2017 Payment Notice we noted that we would consider providing further guidance regarding discriminatory benefit designs in the future.[298]

First, we propose revisions to § 156.125.The proposed revisions are intended to ensure that benefit designs, and particularly benefit limitations and plan coverage requirements are based on clinical evidence. Specifically, we propose that a nondiscriminatory benefit design that provides EHB is one that is clinically based, that incorporates evidence-based guidelines into coverage and programmatic decisions and relies on current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources. Uniformity of applying this policy will ensure that enrollees are able to access covered benefits fairly, regardless of the coverage or issuer they choose. Although this proposal specifically applies to issuers that are required to provide EHB, we expect that states and other entities will also find this standard illustrative and helpful when, for example, conducting form review, issuing guidance, and drafting bills for mandated benefits. Furthermore, because providing a nondiscriminatory benefit design is a prerequisite to issuers fulfilling EHB requirements, we would expect that issuer questions and concerns regarding whether a particular benefit design may be discriminatory would be addressed the same way as other EHB issues—by issuers working primarily and cooperatively with states, where applicable. While states are generally the primary enforcers of EHB requirements, CMS will be available to assist states with their enforcement efforts by providing relevant technical assistance, available data, research, or other information. CMS will continue to monitor issuer compliance with EHB nondiscrimination requirements and states' oversight and enforcement activities to discern whether additional CMS assistance, policy changes, or rulemaking is necessary.

Under this proposal, unscientific [299] evidence, disreputable sources, and other bases or justifications that lack the support of relevant, clinically based evidence would be an unacceptable basis upon which to dispute a claim that an issuer's benefit design is discriminatory. Examples of peer-reviewed medical journals that we would generally consider reputable for purposes of disputing a discriminatory benefit design claim include the Journal of the American Medical Association (JAMA), published by the American Medical Association; Anesthesia, published by the Association of Anesthetists; Pediatrics, published by the American Academy of Pediatrics; Physical Therapy and Rehabilitation Journal, published by the American Physical Therapy Association; the New England Journal of Medicine (NEJM), published by the Massachusetts Medical Society; and the American Journal of Psychiatry, published by the American Psychiatric Association. We do not propose limiting the scope of acceptable peer-reviewed journal articles to those authored by persons who have earned the degree Doctor of Medicine (or M.D.). Rather, we would consider sufficient peer-reviewed articles authored by other relevant, licensed health professionals, including, for example, doctors of osteopathy, chiropractors, optometrists, nurses, occupational therapists, pharmacists, and dentists.

We would not consider to be acceptable articles that are not peer-reviewed or that are written primarily for a lay audience. For example, we would not find relevant or consider a WebMD article or blog acceptable, in and of itself, even where it cites and provides links to supporting peer-reviewed journal materials. We would also not consider sufficient a peer-reviewed journal article that has not been accepted for publication in a reputable medical publication. For example, Health Affairs would not provide sufficient and reliable support for this purpose because, although it is peer-reviewed, it is not a medical journal.

We also believe current evidence-based practice guidelines, sometimes called clinical guidelines, and recommendations from reputable governing bodies that are applicable to be a credible source. For example, we believe that practice guidelines from U.S. government bodies and government-created bodies, such as the HHS Agency for Healthcare Research and Quality (AHRQ) and the U.S. Preventive Services Task Force to be sufficient. Similarly, practice guidelines by health professional associations such as the American Academy of Family Physicians, American Academy of Pediatrics, American Society for Reproductive Medicine, and American Occupational Therapy Association would be relevant and credible. We also believe that any applicable source representing current thinking and subject to the previously discussed criteria would be relevant, since medicine is a constantly evolving field.

We seek comment on the types of clinically based justifications and level of clinical evidence that should be acceptable. Specifically, we seek comment on whether we should further define the types of acceptable clinical evidence.

Second, we are providing examples that illustrate presumptively discriminatory practices that HHS believes amount to prohibited discrimination. Individuals enrolled in health plans that have discriminatory benefit designs have been negatively impacted by the inherent design of such health plans. We are concerned that individuals with significant health needs have been discouraged from enrolling in such health insurance coverage altogether. Individuals may experience substantial improvements in health insurance coverage if the EHB nondiscrimination policy is refined.

In addition, we explain the rationale of why an example benefit design is presumptively discriminatory under § 156.125. HHS identified these examples as presumptively discriminatory practices based on clinical evidence related to each circumstance. We believe providing examples of presumptively discriminatory benefit designs will clarify EHB nondiscrimination policy and lead to greater protections for individuals seeking medically necessary treatment.

These presumptively discriminatory practice examples may point to a state's

[297] 45 CFR 156.200(e) states that a QHP issuer may not discriminate based on ''race, color, national origin, disability, age, or sex.''

[298] 80 FR 10750 (Feb. 27, 2015). The examples of potentially discriminatory practices were: (1) Attempting to circumvent coverage of medically necessary benefits by labeling the benefit as a ''pediatric service,'' thereby excluding adults; (2) refusing to cover a single-tablet drug regimen or extended release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal; and (3) placing most or all drugs that treat a specific condition on the highest cost tiers; 81 FR 12244.

[299] *See* Merriam-Webster.com Dictionary, s.v. ''unscientific,'' accessed November 5, 2021, *https://www.merriam-webster.com/dictionary/unscientific* (defining 'unscientific' as ''not based on or exhibiting scientific knowledge or scientific methodology: Not in accord with the principles and methods of science'').

benchmark plan, state law, or an issuer's application of a state's benchmark plan or law as being the source of the discriminatory benefit design. A benefit design that is discriminatory and inconsistent with § 156.125 must be cured regardless of how it originated. Thus, for example, if a state EHB-benchmark plan has a discriminatory benefit design, that state may issue guidance to issuers in the state explaining that to be compliant plans providing benefits that are substantially equal to the EHB-benchmark plan must not replicate this design. Similarly, if a state-mandated benefit has a discriminatory benefit design, the state may attempt to remedy this through revising the mandate or issuing guidance. Regardless, plans required to provide EHB would need to alter the benefit design or justify their approach with clinical evidence when designing plans that meet EHB standards. We seek comment on whether there are any unforeseen barriers in the ability to remedy inconsistencies with this refined EHB nondiscrimination policy.

In ensuring that benefit designs are not discriminatory, issuers should also consider the method that EHB are delivered and not inadvertently discriminate based on the service delivery model. Accessibility to EHB delivered virtually has significantly increased during the COVID–19 PHE as enrollees had limited options for in-person health care visits. We note that some issuers have designed health plans that deliver services virtually with no copay compared to in-person health care services with a copay. This type of health plan design could inadvertently incentivize enrollees to access EHB in a certain delivery method. Although this approach may not be a discriminatory practice pursuant to § 156.125, such a health plan design could influence whether an enrollee seeks medically-necessary in-person care due to the variation in the amount of copayment, potentially leading to adverse health outcomes. We intend to monitor the issue and remind issuers that while we encourage expanded use of EHB virtually, it should be done in a nondiscriminatory manner.

The following is a non-exhaustive list of examples of presumptively discriminatory benefit designs that address some of the issues that we have seen most frequently.

Examples: Discrimination Based on Age

1. Limitation on Hearing Aid Coverage Based on Age

a. *Background:* The National Institute on Deafness and Other Communication Disorders (NIDCD) defines a hearing aid as a small electronic device that you wear in or behind the ear. It makes some sounds louder so that a person with hearing loss can listen, communicate, and participate more fully in daily activities.[300] The FDA defines a hearing aid as ''any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.'' [301]

b. *Circumstance:* We note that some states have included age limits in their benefit mandates that require coverage for hearing aids by specifying in the mandate that such coverage applies only to enrollees in a certain age group. For example, a state has required hearing aid coverage for enrollees only up to age 21 with certain cost-sharing conditions.

c. *Rationale:* Individuals can experience hearing loss at any stage of life, and therefore the limitation in coverage would impact an individual in a different age group who has impaired hearing. Neither the FDA definition of hearing aid nor NIDCD specifies an age when individuals need hearing aids. However, the definitions explain that a hearing aid is for ''a person with hearing loss'' and as ''aiding persons with or compensating for, impaired hearing.'' Access to hearing aids can positively affect an individual's communication abilities, quality of life, social participation, and health.[302]

d. *Conclusion:* Age limits, when applied to services that have been found clinically indicated for all ages, are presumed to be discriminatory under § 156.125. Therefore, limiting coverage of hearing aids that are medically necessary to enrollees based on age presumptively conflicts with the prohibition under § 156.125 against discriminatory health plan design. For example, it would be arbitrary and discriminatory to limit a hearing aid to a subset of individuals such as enrollees who are 6 years of age and younger since there may be some older enrollees for whom a hearing aid is medically necessary.[303]

2. Autism Spectrum Disorder (ASD) Coverage Limitations Based on Age

a. *Background:* According to the American Psychiatric Association, ''[p]eople with ASD may have communication deficits, such as responding inappropriately in conversations, misreading nonverbal interactions, or having difficulty building friendships appropriate to their age. In addition, people with ASD may be overly dependent on routines, highly sensitive to changes in their environment, or intensely focused on inappropriate items.'' [304]

b. *Circumstance:* We note that some states have mandated coverage for the diagnosis and treatment for ASD up to a certain age. For example, a state has required coverage for enrollees up to age 18 with certain cost-sharing conditions. Similarly, some states' benchmark plans that cover applied behavior analysis (ABA therapy) include age limits.

c. *Rationale:* The CDC recognizes the American Psychiatric Association's fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM–5) as standardized criteria to help diagnose ASD.[305] Under the DSM–5 criteria, individuals with ASD must show symptoms from early childhood, but may not be fully recognized until later in life.[306] We note that screening for ASD is usually done at a young age although an individual may not be diagnosed until later in life. The CDC estimates that 2.21 percent of adults in the U.S. have ASD.[307]

d. *Conclusion:* Limiting coverage of the diagnosis and treatment of ASD in a plan benefit design on the basis of the individual's age is presumed to be discriminatory under § 156.125. Limiting coverage that is medically necessary in a subset of individuals presumptively conflicts with the prohibition under § 156.125 against discriminatory benefit design.

3. Age Limits for Infertility Treatment Coverage When Treatment Is Clinically Effective for the Age Group

a. *Background:* The National Center for Health Statistics reported that 8.8 percent of couples in the U.S. have

[300] National Institute on Deafness and Other Communication Disorders FAQ on Hearing Aids: *https://www.nidcd.nih.gov/health/hearing-aids#hearingaid_01.*

[301] 21 CFR 801.420.

[302] National Academies of Sciences, Engineering, and Medicine. 2016. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/23446.*

[303] In the 2016 Payment Notice (which finalized as proposed), we cautioned ''both issuers and States that age limits are discriminatory when applied to services that have been found clinically effective at all ages. For example, it would be arbitrary to limit a hearing aid to enrollees who are 6 years of age and younger since there may be some older enrollees for whom a hearing aid is medically necessary.''

[304] *https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/DSM/APA_DSM-5-Autism-Spectrum-Disorder.pdf.*

[305] *https://www.cdc.gov/ncbddd/autism/hcp-dsm.html.*

[306] American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed. Arlington, VA: American Psychiatric Association; 2013.

[307] *https://www.cdc.gov/ncbddd/autism/features/adults-living-with-autism-spectrum-disorder.html.*

experienced infertility issues while 9.5 percent have received infertility services (for example, medical assistance, counseling, testing for the woman and man, ovulation drugs, fallopian tube surgery, artificial insemination, assisted reproductive technology, and miscarriage preventive services).[308]

b. *Circumstance:* We note that some states have defined ''infertility'' in state law, which impacts insurance companies, hospitals, medical service corporations, and health care centers providing coverage for medically necessary expenses of the diagnosis and treatment of infertility. For example, a state restricted coverage for treatment of infertility to individuals who are ''presumably healthy,'' thus excluding from coverage of treatment for infertility those who are not presumably healthy.

c. *Rationale:* We note that an individual's age is an important factor for reproductive health and development. Fertility, especially in women, declines with age, which makes natural conception more unlikely as women get older.[309] However, we also note that the mean age for individuals experiencing their first childbirth has increased in recent years.[310] We also understand that not all individuals would be eligible for infertility treatment if they are not at the stage of development for reproduction or have certain medical conditions. Younger individuals, for example, who are not at the stage of reproductive development would reasonably not require treatment for infertility. Older adults as well would not need treatment for infertility, for example women who have reached post-menopause.

d. *Conclusion:* Age limits are presumptively discriminatory when applied to services that have been found clinically effective in certain age groups under § 156.125. Limiting coverage of the treatment of infertility in a plan benefit design based on age presumptively conflicts with the prohibition under § 156.125 against discriminatory benefit design unless clinical evidence acceptable under the proposed refinements to § 156.125 demonstrates that such a limitation is justifiable considering an individual's reproductive health and development. We would expect an issuer to be able to rebut a presumption that the plan's age limit on coverage for treatment of infertility is discriminatory by demonstrating clinical evidence that infertility treatments have low efficacy for the excluded age groups and/or are not clinically indicated for the excluded age groups.

Examples: Discrimination Based on Health Conditions

4. Limitation on Foot Care Coverage Based on Diagnosis (Whether Diabetes or Another Underlying Medical Condition)

a. *Background:* Routine foot care includes cutting or removing corns and calluses; trimming, cutting, or clipping or debriding of nails; and hygienic or other preventive maintenance care, such as using skin creams, cleaning and soaking the feet.[311] Although basic foot care is part of an individual's personal self-care, a health care provider in certain situations may perform routine foot care for a patient to the degree that is medically necessary to prevent perpetuation of chronic conditions.

b. *Circumstance:* We note that some issuers have restricted coverage for routine foot care to individuals diagnosed with diabetes. For example, several issuers have limited coverage for routine foot care to diabetes care only.

c. *Rationale:* The American Diabetes Association estimates that over 10 percent of the American population has diabetes, which costs $237 billon for direct medical costs.[312] The annual cost of diabetic foot ulcer treatment, for example, is significantly greater than non-diabetic foot ulcer treatment, estimated at $1.38 billion versus $0.13 billion.[313] Although diabetes is a vast medical expenditure in the United States, individuals may need routine foot care to treat other conditions associated with metabolic, neurologic, or peripheral vascular disease.[314]

d. *Conclusion:* Limiting coverage of routine foot care in a health plan based on an individual's diagnosis, whether for diabetes or another underlying medical condition, is presumed to be discriminatory under § 156.125. Limiting coverage of routine foot care that is medically necessary for a subset of individuals with other health conditions presumptively conflicts with the prohibition under § 156.125 against discriminatory benefit designs.

Examples: Discrimination Based on Sociodemographic Factors

5. Coverage of EHB for Gender-Affirming Care

a. *Background:* We refer to other nondiscrimination proposed provisions in § 156.200(e) of this rulemaking related to protecting individuals from discrimination based on sexual orientation and gender identity. If the proposed provisions in that section are finalized, the below example will be illustrative of a presumptively discriminatory benefit design that denies coverage of medically necessary gender-affirming care on the prohibited basis of gender identity. This example of presumptive discrimination also aligns with Executive Order 13988, which stated the Administration's policy on preventing and combating discrimination on the basis of gender identity and sexual orientation.[315]

b. *Circumstance:* The American Psychiatric Association describes ''gender dysphoria'' in transgender individuals as an experience of psychological distress that results from an incongruence between one's sex assigned at birth and one's gender identity.[316] *HeathCare.gov* notes that many health plans have unclear terms of coverage for transgender individuals.[317] Several states' EHB-benchmark plans contain either no language addressing coverage for gender dysphoria or limits coverage for specific gender-affirming services. Some states have updated their benchmark plan to add specific gender-affirming care benefits while other states prohibit discrimination based on sexual orientation and gender identity. We also note that issuers have published policies [318] related to specific coverage of gender affirming-care.

[308] *https://www.cdc.gov/nchs/nsfg/key_statistics/i_2015-2017.htm#infertility.*

[309] *https://www.acog.org/womens-health/faqs/having-a-baby-after-age-35-how-aging-affects-fertility-and-pregnancy.*

[310] Mean Age of Mothers is on the Rise: United States, 2000–2014, NCHS Data Brief No. 232, January 2016, *https://www.cdc.gov/nchs/products/databriefs/db232.htm.*

[311] Medicare Benefit Policy Manual. Routine Foot Care. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

[312] *https://www.diabetes.org/resources/statistics/statistics-about-diabetes.*

[313] Hicks CW, Selvarajah S, et al. Burden of infected diabetic foot ulcers on hospital admissions and costs. *Ann Vasc Surg* 2016;33:149–58. 10.1016/j.avsg.2015.11.025.

[314] *https://wayback.archive-it.org/2744/20191012061156/https:/www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1113.pdf.*

[315] American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed. Arlington, VA: American Psychiatric Association; 2013; Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, January 20, 2021, *see* 86 FR 7023.

[316] *https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria.*

[317] *HealthCare.gov* states that ''many health plans are still using exclusions such as 'services related to sex change' or 'sex reassignment surgery' to deny coverage to transgender people for certain health care services. Coverage varies by state.'' ''These transgender health insurance exclusions may be unlawful sex discrimination.'' *https://www.HealthCare.gov/transgender-health-care/.*

[318] *See, for example,* Aetna Gender Affirming Surgery *http://www.aetna.com/cpb/medical/data/600_699/0615.html.*

c. *Rationale:* As discussed in more detail in the preamble to § 147.104(e), transgender individuals face health and health care disparities, and are at higher risk for many concomitant conditions.[319] Clinical evidence supports medically necessary gender affirming care and demonstrates that such coverage can significantly improve the health and well-being of individuals accessing medically necessary care. For example, for individuals diagnosed with gender dysphoria, the American Medical Association's Council on Science and Public Health supports the use of hormone therapy and supports health care providers that prescribe hormone therapy based on scientific evidence or sound medical opinion.[320] In addition, other professional societies have published criteria for guidelines in treating gender dysphoria and gender-affirming care for transgender people.[321]

d. *Conclusion:* Pursuant to §§ 156.125 and 156.200(e), as we have proposed to amend these provisions, benefit designs that restrict coverage of EHB due to gender identity are presumptively discriminatory. A health plan design, for example, is presumed to be discriminatory §§ 156.125 and 156.200(e) if it limits coverage of an EHB based on gender identity in treating gender dysphoria when clinical evidence demonstrates that such coverage is medically necessary to provide gender-affirming care. For example, excluding coverage of medically necessary hormone therapy for treatment of gender dysphoria where hormone therapy is otherwise a covered EHB is presumptively discriminatory.

6. Access to Prescription Drugs for Chronic Health Conditions: Adverse Tiering

Adverse tiering of prescription drugs presents unique issues different from presumptively discriminatory benefit designs in other categories of EHB. We acknowledge that cost is often an important factor in how plans and issuers, and their pharmacy benefit managers (PBMs) where applicable, tier their drugs and note that plans and issuers are permitted to use reasonable medical management practices and consider cost in structuring plan designs and cost sharing. However, we clarify that relying on cost alone is an insufficient basis to defend an otherwise discriminatory benefit design. An issuer providing EHB must not discriminate in its prescription drug tiering structure by discouraging enrollment of individuals with significant health needs. As proposed in § 156.125(a), in order to not discriminate, the issuer's EHB prescription drug benefit design must be clinically based. Factors that might be relevant to successfully demonstrating to CMS that the prescription drug tiering is not discriminatory would be demonstrating that neutral principles were used in assigning tiers to drugs and that those principles were consistently applied across types of drugs, particularly as related to other drugs in the same class (for example, demonstrating that the issuer or PBM weighed both cost and clinical guidelines in setting tiers).

a. *Background:* QHP issuers are allowed to structure and offer tiered prescription drug formularies. As a result, QHPs will have different tier structures depending on decisions, including on the basis of cost, that issuers make about their formulary structures. However, there is concern that formulary tiers may also be structured to discourage enrollment by consumers with certain chronic conditions. One approach to this, called adverse tiering, occurs when plans structure the formulary by assigning all or the majority of drugs for certain medical conditions to a high-cost prescription drug tier.[322]

b. *Circumstance:* Individuals with certain chronic health conditions, for example, have reported that the majority of their prescription drugs have been designated as specialty drugs and placed in the highest cost tier. Individuals have also seen most or all prescription drugs in the same therapeutic class, used to treat their chronic health condition, placed on the highest cost tiers.

c. *Rationale:* More than half of U.S. adults are diagnosed with a chronic condition. In 2018, prevalence of multiple chronic conditions was higher among women, non-Hispanic white adults, older adults, adults aged 18–64 enrolled in Medicaid, adults dually eligible for Medicare and Medicaid, and adults in rural areas.[323] Adults with certain high-cost chronic conditions require long-term treatment to manage their chronic health conditions. Health benefit designs with adverse tiering may discriminate based on an individual's present or predicted disability or other health conditions in a manner prohibited by § 156.125(a).

d. *Conclusion:* The 2016 Payment Notice provides that if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, that such plan designs possibly discriminate against, individuals who have those chronic high cost conditions under § 156.125. We are clarifying that such instances of adverse tiering are presumptively discriminatory and that issuers and PBMs assigning tiers to drugs should weigh cost of drugs on their formulary with clinical guidelines for any such drugs used to treat high-cost chronic health conditions to avoid tiering such drugs in a manner that would discriminate based on an individual's present or predicted disability or other health conditions in a manner prohibited by § 156.125(a).

In addition, we indicated in the 2014 Letter to Issuers that we will notify an issuer when we see an indication of a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices.[324] Issuers should expect to cover and provide sufficient access to treatment recommendations that have the highest degree of clinical consensus based on available data, such as professional clinical practice guidelines. Placing all drugs for a high cost chronic condition on the highest formulary tier is a presumed discriminatory benefit design, even when those drugs are costly. Plans and issuers that tier specialty drugs higher

[319] *See, for example,* Lesbian, Gay, Bisexual, and Transgender Health, Healthy People 2020, *https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health#:~:text=Research%20suggests%20that%20LGBT%20individuals,%2C%2C%203%20and%20suicide;* Hafeez, Hudaisa et al. ''Healthcare Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review.'' *Cureus* vol. 9,4 e1184. 20 Apr. 2017, doi:10.7759/cureus.1184 (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478215/*); Fredriksen-Goldsen KI, Kim H–J, Barkan SE, Muraco A and Hoy-Ellis CP (2013) Health disparities among lesbian, gay, and bisexual older adults: Results from a population-based study. *American Journal of Public Health* 103, 1802–1809; Billy A. Caceres et al. ''A Systematic Review of Cardiovascular Disease in Sexual Minorities'', American Journal of Public Health 107, no. 4 (April 1, 2017): pp. e13–e21.

[320] Report of the Council on Science and Public Health, AMA. *Hormone Therapies: Off-Label Uses and unapproved Formulations (Resolution 512–A–15). https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/2016-interim-csaph-report-4.pdf.*

[321] World Professional Assn for Transgender Health, Standards of Care Version 7 (2018), available at *https://www.wpath.org/publications/.* J Clin Endocrinol Metab, November 2017, 102(11):3869–3903 *https://academic.oup.com/jcem.*

[322] Jacobs, Douglas B. and Sommers, Benjamin D. ''Using Drugs to Discriminate—Adverse Selection in the Insurance Marketplace.'' *New England Journal of Medicine.* 372:399–402. 29 Jan 2015. <*http://www.nejm.org/doi/citedby/10.1056/NEJMp1411376#t=citedby*>.

[323] Boersma P, Black LI, Ward BW. Prevalence of Multiple Chronic Conditions Among U.S. Adults, 2018. Prev Chronic Dis 2020;17:200130. DOI: *http://dx.doi.org/10.5888/pcd17.200130.*

[324] Letter to Issuers on Federally-facilitated and State Partnership Exchanges, April 5, 2013, page 15 and 2015 Letter to Issuers in the Federally facilitated Marketplaces, March 14, 2014, page 29.

for certain chronic conditions should expect to demonstrate that neutral principles were used in assigning tiers to such drugs and that those principles were consistently applied across types of drugs (for example, that the issuer weighed both cost and clinical guidelines in setting tiers).

For example, a generic drug requiring no special handling that is inexpensive to obtain might be rightly placed on a generic tier or the lowest tier whereas a specialty drug requiring special handling and counseling, and that is also very costly, might be rightly placed on specialty tier that has the highest cost sharing. However, a generic drug or common brand drug that does not require special handling, counseling, or medication management, and is not expensive, should not be placed on a specialty tier just because it is used to treat a condition that is a high-cost chronic condition. Furthermore, issuers and PBMs should pay close attention to any instances where all drugs to treat chronic conditions are placed on the highest-cost tiers.

In relation to the proposed refinement of the nondiscrimination standard under § 156.125, we propose that the policy become effective 60 days after publication of the final rule in the **Federal Register**. We seek comment on this proposed effective date.

In addition, we recognize that other nondiscrimination and civil rights law may apply. These laws are distinct from the nondiscrimination requirements in CMS regulations, and compliance with § 156.125 is not determinative of compliance with any other applicable requirements, nor is additional enforcement precluded. Section 156.125 does not apply to the Medicaid and CHIP programs, but a parallel provision applies to EHB furnished by Medicaid Alternative Benefit Plans.[325] We intend to provide additional examples and illustrative fact patterns of benefit designs that are discriminatory pursuant to § 156.125 in the future, as warranted. We seek comment on the nondiscrimination examples in this proposal and whether the proposed effective date is sufficient to implement the refined policy.

7. Publication of the 2023 Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing and Required Contribution Percentage in Guidance (§ 156.130)

As established in part 2 of the 2022 Payment Notice, HHS will publish the premium adjustment percentage, the required contribution percentage, and maximum annual limitations on cost sharing and reduced maximum annual limitation on cost sharing, in guidance annually starting with the 2023 benefit year. We note that these parameters are not included in this rulemaking, as HHS does not propose to change the methodology for these parameters for the 2023 benefit year and therefore, HHS is required to publish these parameters in guidance no later than January 2022.

8. Levels of Coverage (Actuarial Value) (§§ 156.140, 156.200, 156.400)

HHS proposes to change the de minimis ranges at § 156.140(c) beginning in PY 2023 to +2/−2 percentage points for all individual and small group market plans subject to the AV requirements under the EHB package, other than for expanded bronze plans,[326] for which HHS proposes a de minimis range of +5/−2. Under § 156.200, HHS proposes, as a condition of QHP certification, to limit the de minimis range to +2/0 percentage points for individual market silver QHPs; HHS also proposes under § 156.400 to specify a de minimis range of +1/0 percentage points for income-based silver CSR plan variations.

Section 2707(a) of the PHS Act and section 1302 of the ACA direct issuers of non-grandfathered individual and small group health insurance plans (including QHPs) to ensure that these plans adhere to the levels of coverage specified in section 1302(d)(1) of the ACA. A plan's level of coverage, or actuarial value (AV), is determined based on its coverage of the EHB for a standard population. Section 1302(d)(1) of the ACA requires a bronze plan to have an AV of 60 percent, a silver plan to have an AV of 70 percent, a gold plan to have an AV of 80 percent, and a platinum plan to have an AV of 90 percent. Section 1302(d)(2) of the ACA directs the Secretary of HHS to issue regulations on the calculation of AV and its application to the levels of coverage. Section 1302(d)(3) of the ACA authorizes the Secretary to develop guidelines to provide for a de minimis variation in the actuarial valuations used in determining the level of coverage of a plan to account for differences in actuarial estimates.

In the EHB Rule at § 156.140(c), we established that the allowable de minimis variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan was +2/−2 percentage points. In the 2018 Payment Notice, we revised § 156.140(c) to permit a de minimis variation of +5/−2 percentage points for bronze plans that either cover and pay for at least one major service other than preventive services before the deductible or meet the requirements to be a high deductible health plans (HDHP) within the meaning of section 223(c)(2) of the Code. In the 2017 Market Stabilization final rule, effective for PY 2018, we expanded the de minimis range for standard bronze, silver, gold, and platinum plans to +2/−4.[327] In that final rule, we stated that we believed that flexibility was needed for the AV de minimis range for metal levels to help issuers design new plans for future PYs, thereby promoting competition in the market.[328] In addition, we noted that changing the de minimis range would allow more plans to keep their cost sharing the same as well as provide additional flexibility for issuers to make adjustments to their plans within the same metal level. We stated our view that a de minimis range of +2/−4 percentage points provided the flexibility necessary for issuers to design new plans while ensuring comparability of plans within each metal level.

Since we finalized these de minimis ranges in the 2018 Payment Notice and the 2017 Market Stabilization final rule, we have observed an increasing percentage of bronze plans offered on *HealthCare.gov* with AVs in the upper end of the current de minimis range. In PY 2018, 8.45 percent of all bronze plans offered on *HealthCare.gov* had an AV between 64 and 65 percent. In PYs 2019 and 2020, this number grew to 14.29 percent and 24.44 percent, respectively. For PY 2021, 67.55 percent of bronze plans offered on *HealthCare.gov* had an AV between 64 and 65 percent. As the cost of health care services continues to increase, we

[325] 42 CFR 440.347(e).

[326] Expanded bronze plans are bronze plans currently referenced in § 156.140(c) that cover and pay for at least one major service, other than preventive services, before the deductible or meet the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Code.

[327] We did not in that rule modify the de minimis range for the income-based silver CSR plan variations (the plans with an AV of 73, 87 and 94 percent) under §§ 156.400 and 156.420. The de minimis variation for an income-based silver CSR plan variation is a single percentage point. In the Actuarial Value and Cost-Sharing Reductions Bulletin (2012 Bulletin) issued on February 24, 2012, we explained why we did not intend to require issuers to offer a silver CSR plan variation with an AV of 70 percent; to align with this change, we also modified the de minimis range for expanded bronze plans from +5/−2 to +5/−4.

[328] 82 FR at 18369.

expect more bronze plans to have an AV of at least 64 percent in future PYs.

TABLE 10: Distribution of Bronze Plans by Actuarial Value Percentage, PY 2018-2021

PY	< 60%	60.00 to 61.99%	62.00 to 63.99%	64.00 to 65.00%
2018	19.41%	61.50%	10.64%	8.45%
2019	26.64%	43.20%	15.87%	14.29%
2020	16.98%	22.64%	35.93%	24.44%
2021	0.00%	20.41%	12.04%	67.55%

During PYs 2018 through 2021, as the percentage of bronze plans within the upper limit of the +5/−4 percentage point range increases, the percentage of silver plans offered on *HealthCare.gov* within the lower end of the current +2/−4 percentage point range has remained consistent, with less than a third of silver plans having an AV between 66 and 68 percent.

TABLE 11: Distribution of Silver Plans by Actuarial Value Percentage, PY 2018-2021

PY	66.00 to 67.99%	68.00 to 69.99%	70.00 to 71.99%
2018	25.65%	29.47%	44.88%
2019	30.59%	17.59%	51.82%
2020	26.27%	23.44%	50.28%
2021	28.43%	34.20%	37.37%

Despite the consistency of silver plan distribution by AV percentage, the number of enrollees in silver plans on *HealthCare.gov* within the lower end of the current +2/−4 percentage point range has decreased each year since 2018, while the number of enrollees in bronze plans within the upper end of the current +5/−4 percentage point range has increased each year since 2018.

TABLE 12: Number of HealthCare.gov Enrollees in Plans by AV Percentage, PY 2018-2021

PY	62.00 to 63.99%	64.00 to 64.99%	66.00 to 67.99%	68.00 to 69.99%
2018	481,209	335,164	289,230	275,767
2019	511,823	514,874	197,918	160,841
2020	1,037,700	827,694	132,939	173,399
2021	395,175	2,184,483	102,878	144,818

As the availability of and enrollment in bronze plans within the upper end of the current de minimis range increases and the enrollment in silver plans within the lower end of the current de minimis range decreases, we believe that it is increasingly important for consumers to be able to distinguish the levels of coverage between bronze plans and silver plans and be assured that the level of coverage of their plan corresponds to the relevant metal tier. We are not confident that consumers can reliably distinguish plans that have similar AV percentages, but significantly different cost sharing. Despite their similar AVs, there is generally a 10 percentage point difference in median coinsurance per EHB between expanded bronze and base silver plans offered on *HealthCare.gov*. The difference between copayment amounts for expanded bronze plan and base silver plan is also apparent.

TABLE 13: Median Pre-Deductible Copays for Standard Silver and Expanded Bronze Plans on HealthCare.gov, PY 2021

Service	Expanded Bronze (56 to 65% AV)	Standard Silver (66 to 72% AV)
Primary Care Visit	$40	$30
Specialist Visit	$90	$65
Mental Health/ Substance Use Disorder Outpatient Office Visit	$50	$35
Generic Drugs	$25	$20
Preferred Brand Drugs	$165	$60
Non-Preferred Brand Drugs	$250	$150

Thus, we are no longer of the view that a silver de minimis range of +2/−4 percentage points ensures the meaningful comparison of plans between the silver and bronze levels of coverage. However, we continue to recognize the importance of permitting issuers to offer expanded bronze plans because the rationale for expanding the upper limit of the de minimis range for these plans to +5 still applies to the current market: Issuers continue to require greater flexibility for bronze plan design to assist with innovation, premium impact, and future impacts to the AV Calculator methodology, to ensure that bronze plans can continue to be more generous than catastrophic plans, and to ensure that HDHPs can be offered at the bronze level. At the same time, the 2017 Market Stabilization final rule also noted the narrow difference in bronze and silver QHPs and therefore, to improve a consumer's ability to meaningfully compare the bronze and silver levels of coverage, pursuant to our authority under sections 1302(d)(3) and 1321(a)(1)(A) and (D) of the ACA, and sections 2707 and 2792 of the PHS Act, we propose changing the de minimis range for standard silver plans.

Additionally, as shown in Tables 14 and 15, we have observed a shift in enrollment for gold plans in 2021 and bronze plans since 2019 within the +2/−4 de minimis towards the center of the de minimis (+2/−2).

TABLE 14: Distribution of Gold Plan Enrollment by AV Percentage, PY 2018-2021

PY	76.00 to 77.99%	78.00 to 79.99%	80.00 to 81.99%
2018	155,725	237,202	135,160
2019	247,467	185,302	196,882
2020	273,623	68,308	271,174
2021	80,624	175,056	234,361

TABLE 15: Distribution of Bronze Plan Enrollment by AV Percentage, PY 2018-2021

PY	56.00 to 57.99%	58.00 to 59.99%	60.00 to 61.99%	62.00 to 63.99%	64.00 to 64.99%
2018	161,536	282,003	1,192,625	481,209	335,164
2019	159,121	410,260	952,680	511,823	514,874
2020	110,689	193,673	568,351	1,037,700	827,694
2021	0	0	450,022	395,175	2,184,483

Because of this shift, and for consistency across the metal levels, which would help reduce potential consumer confusion, we believe it is appropriate to propose, starting with PYs beginning in 2023, to change the de minimis ranges for the standard bronze, gold, and platinum levels of coverage from +2/−4 percentage points to +/−2 percentage points. Likewise, we have observed a similar shift in enrollment for expanded bronze plans that currently utilize a +5/−4 de minimis range. Because of this shift, and to align with the proposal above, we also propose, starting with PYs beginning in 2023, to change the de minimis range for expanded bronze plans from +5/−4 to +5/−2.

Further, states generally remain the primary enforcers of the requirement to meet AV requirements, including, to the extent required by § 156.135, the use of the federal AV Calculator or an AV Calculator that utilizes state-specific data under § 156.135(e). In the 2017 Market Stabilization rule, we stated that states are the primary enforcers of AV requirements and can apply stricter AV standards that are consistent with federal law.[329] We also stated that a state cannot require issuers to design plans that apply an AV range that is not consistent with our implementation of section 1302(d)(1) and (d)(3) of the ACA (which defines the metal levels and de minimis ranges). We reiterate those statements here. Under this proposal, a state cannot apply an AV range that exceeds +2/−2 percentage points, except for under the proposed expanded bronze range originally provided for in § 156.140(c).

In addition to the proposal applicable to non-grandfathered individual and small group market health insurance coverage market-wide, we also propose to amend § 156.200(b)(3) to state that, beginning with year PY 2023, as a requirement for certification, the allowable variation in AV for individual market silver QHPs would be + 2/0 percentage points. Through the authority granted to HHS in sections 1311(c) and 1321(a) of the ACA to establish minimum requirements for QHP certification, we propose this narrower de minimis range for individual market silver QHPs in order to maximize PTC and APTC for subsidized enrollees. Narrowing the de minimis range of individual market silver QHPs would influence the generosity of the SLCSP, the benchmark plan used to determine an individual's PTC. A subsidized enrollee who has a SLCSP that is currently below 70 percent AV would see the generosity of their current SLCSP increase, likely accompanied by a corresponding increase in premium, resulting in an increase in PTC. As shown in Table 12, since 2018, enrollment in 66.00 to 69.99 percent AV silver plans has decreased and enrollment in 62 to 64.99 percent AV bronze plans has increased; enrollees in such bronze plans now outnumber enrollees in such silver plans by more than 10 to 1. In addition, after implementation of the ARP enhanced financial subsidies, there are even fewer enrollees remaining in silver QHPs with AVs between 66.00 and 69.99 percent offered through Exchanges that use the Federal platform. Approximately 248,000 enrollees remain, of which about 91,000 are unsubsidized. By comparison, enrollment for the income-based silver CSR variations corresponding to the above silver QHPs has increased to about 4.2 million. This proposal would reduce the cost of insurance coverage for an increasing population of subsidized enrollees. It would also mitigate the net burden of the additional cost to a decreasing population of unsubsidized enrollees by incentivizing healthier, subsidy-eligible enrollees to participate in the Marketplaces.

Thus, we believe maximizing PTC for all subsidized enrollees justifies a narrower de minimis range on

[329] 82 FR at 18369.

individual market silver QHPs that have fewer enrollments each year. We solicit comment on other cost implications the proposal might have.

Finally, we propose changing the de minimis variation for individual market income-based silver CSR plan variations from +1/−1 to +1/0 with a proposed revision to the definition of ''De minimis variation for a silver plan variation'' at § 156.400. Similar to the +2/0 de minimis proposal for individual market silver QHPs, this proposal would deliver further subsidization of premiums via increased APTC and PTC for subsidized enrollees in the income-based silver CSR plan variations and increase the generosity of these plans. While there would be an expected increase to the premium for the CSR plan variations as a result of the increased generosity, it would be substantially offset by increases to the APTC and PTC. We do not propose edits to the minimum AV differential in § 156.420(f) for silver QHPs and 73 percent income-based plan variations, where the AVs must differ by at least 2 percentage points. We would note for issuers that, similar to the current de minimis ranges, standard silver QHPs with plan AVs between 71 and 72 percent would require the corresponding 73 percent income-based plan variation AV to be at least 2 percentage points above the standard plan's AV.

We seek comment on this proposal.

9. QHP Issuer Participation Standards (§ 156.200)

We propose to amend 45 CFR 156.200(e) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 156.200(e), but amendments made in 2020 to § 156.200(e) removed any reference to sexual orientation and gender identity. If finalized, this proposal would revert § 156.200(e) to the pre-2020 nondiscrimination protections.

Section 156.200(e) states that a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex. Previously, in the March 27, 2012 Exchange Standards final rule, we finalized § 156.200(e) to also prohibit discrimination based on sexual orientation and gender identity.[330] However, in the 2020 final rule related to section 1557, HHS revised certain CMS regulations, including § 156.200(e), by removing sexual orientation and gender identity in § 156.200(e) as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[331]

CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination by issuers of QHPs. Pursuant to section 1311(c)(1)(A) of the ACA, QHP issuers are required to comply with applicable state laws and regulations regarding marketing by health insurance issuers and not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs. CMS is authorized to interpret and implement this requirement, and to set additional requirements for QHPs under its authority to establish requirements with respect to the offering of QHPs through the Exchanges in section 1321(a)(1)(B) of the ACA.[332] Pursuant to this authority to set QHP standards in section 1321(a)(1)(B) of the ACA, HHS finalized in the 2012 Exchange Standards final rule requirements at § 156.200(e) intended to protect enrollees and potential enrollees from discriminatory practices, including on the basis of sexual orientation and gender identity. CMS proposes to exercise that same authority here to amend § 156.200(e) to again prohibit QHPs from discriminating based on sexual orientation and gender identity. Section 1321(a)(1)(B) of the ACA is the same authority CMS relies upon for implementation of existing nondiscrimination protections at § 156.200(e). Utilizing this same authority to again prohibit discrimination based on sexual orientation and gender identity at § 156.200(e) would be consistent with the authority CMS relies upon for the existing protections at § 156.200(e) that currently prohibit discrimination on the basis of race, color, national origin, disability, age, or sex. We believe such amendments are warranted in light of the existing trends in health care discrimination and are necessary to better address barriers to health equity for LGBTQI+ individuals.

A more in-depth discussion of these developments and other factors considered in proposing amendments to CMS nondiscrimination protections is included earlier in the preamble to § 147.104 under section III.B.1.b. of this preamble. For brevity, we refer readers back to § 147.104 under section III.B.1.b. of the preamble, rather than restating the issues here.

We seek comment on this proposal.

10. Standardized Options (§ 156.201)

Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA with respect to, among other things, the offering of QHPs through such Exchanges. HHS proposes to exercise these authorities to require issuers of QHPs in FFEs and SBE–FPs, for PY 2023 and beyond, to offer through the Exchange standardized QHP options at every product network type, as described in the definition of ''product'' at § 144.103, metal level, and throughout every service area that they offer non-standardized QHP options. For example, if an issuer offers a non-standardized gold health maintenance organization (HMO) plan in a particular service area, that issuer must also offer a standardized gold HMO plan in that same service area. HHS does not propose to limit the number of non-standardized QHP options that issuers of QHPs in FFEs and SBE–FPs can offer through the Exchange in PY 2023. As discussed later, HHS is considering whether for future years it would be appropriate to limit the number of non-standardized QHP options that issuers of QHPs in FFEs and SBE–FPs can offer through the Exchange.

Standardized options were first introduced in the 2017 Payment Notice. In the first iteration of standardized options, HHS proposed one set of standardized options designed to be similar to the most popular QHPs in the 2015 individual market FFEs at the bronze, silver, and gold metal levels. Issuers were not required to offer standardized options. To facilitate plan shopping and to educate consumers about the distinctive cost sharing features of standardized options, standardized options were differentially displayed on *HealthCare.gov* per the authority at § 155.205(b)(1). Specifically, consumers had the ability to filter plan options to view only standardized options and received an accompanying message explaining how standardized options differed from non-standardized options.

In the 2018 Payment Notice, HHS proposed three new sets of standardized options. The original standardized options from the 2017 Payment Notice were updated to reflect changes in QHP enrollment data in 2016, to include

[330] 77 FR 18310 (March 27, 2012).

[331] 85 FR 37160 (June 19, 2020); *See id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

[332] 85 FR 37218–37221 (June 19, 2020).

SBE–FP data, and to account for state cost sharing laws. Standardized options were once more differentially displayed, but this time, they were also labeled ''Simple Choice'' plans to make them more easily distinguishable from non-standardized options. HHS also established display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. [333] [334] Per these requirements, these entities were required to differentially display standardized options in accordance with the requirements under § 155.205(b)(1) in a manner consistent with how standardized options were displayed on *HealthCare.gov*, unless HHS approved a deviation.

Standardized options were then discontinued in the 2019 Payment Notice, but the discontinuance was challenged in the United States District Court for the District of Maryland. On March 4, 2021, the court decided City of Columbus, *et al.* v. Cochran.[335] The court reviewed nine separate policies HHS had promulgated in the 2019 Payment Notice, vacating four of them. The court specifically vacated the portion of the 2019 Payment Notice that ceased HHS's practice of designating some plans in the FFEs as ''standardized options,'' a policy that the 2019 Payment Notice stated was seeking to maximize innovation by issuers in designing and offering a wide range of plans to consumers.[336] As such, HHS announced its intent to engage in rulemaking under which it would propose to resume standardized options in time for PY 2023.[337] More recently, President Biden's Executive Order on Promoting Competition in the American Economy directed HHS to implement standardized options in order to facilitate the plan selection process for consumers on the Exchanges.[338]

The standardized options that we are proposing are as follows: One bronze plan, one bronze plan that meets the requirement to have an AV up to 5 points above the 60 percent standard, as specified in § 156.140(c) (known as an expanded bronze plan), one standard silver plan, one version of each of the three income-based silver CSR plan variations, one gold plan, and one platinum plan. We do not propose to require FFE and SBE–FP issuers to offer standardized options for the Indian CSR plan variations given that the cost sharing parameters for these variations are already largely standard. Further, we do not propose to require State Exchange issuers to offer the standardized options in this proposal. We also propose that FFE and SBE–FP issuers that are already required to offer standardized options under state action taking place on or before January 1, 2020, such as issuers in the state of Oregon,[339] be exempt from the standardized options requirements in this proposal.

Additionally, in an approach similar to that taken in the 2018 Payment Notice, we propose two sets of standardized options to accommodate different states' cost sharing laws. Specifically, we propose that the first set of standardized options apply to all FFE and SBE–FP issuers, excluding Delaware and Louisiana, and we propose that the second set of standardized options apply to issuers in Delaware and Louisiana in order to accommodate these two states' specialty tier prescription drug cost sharing laws.

In conjunction with our standardized options proposal, we are considering exercising the existing authority under § 155.205(b)(1) to differentially display standardized options on *HealthCare.gov*. Similarly, we are considering resuming enforcement of the standardized options display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. If we were to resume enforcement of these requirements, these entities would be required to differentially display standardized options beginning with the PY 2023 open enrollment period [340] in accordance with the requirements under § 155.205(b)(1) in a manner consistent with how standardized options are displayed on *HealthCare.gov*, unless HHS approves a deviation. Any requests from web-brokers and QHP issuers seeking approval for an alternate differentiation format would be reviewed based on whether the same or similar level of differentiation and clarity is being provided under the requested deviation as is provided on *HealthCare.gov*.

We continue to believe that the differential display of standardized options will not require significant modification of web-broker and QHP issuer platforms, but that such display would provide an important service and information for consumers seeking to enroll in Exchange coverage. However, consistent with the approach finalized in the 2018 Payment Notice,[341] we also continue to recognize that system constraints may prevent some web-brokers and QHP issuers from precisely mirroring the *HealthCare.gov* display, which is why we would continue to allow these entities to submit a request to deviate from the manner in which standardized options are differentially displayed on *HealthCare.gov.*

If we were to resume enforcement of these requirements, we reaffirm that a QHP issuer using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—would only need to differentially display those standardized options it offers.[342] Additionally, we intend to provide access to information on standardized options to web-brokers and QHP issuers through the Health Insurance Marketplace Public Use Files (PUFs) and QHP Landscape file to further minimize burden on these entities. We seek comment on this potential approach to display requirements.

We are proposing this approach for several reasons. The 2019 Payment Notice eliminated standardized options with the intention of maximizing innovation and variety at a time when the individual market was considered to be at risk of destabilization. We believe that current market conditions differ significantly from the market conditions that defined the individual market when standardized options were eliminated. For example, the number of issuers offering plans on the Exchanges has increased considerably, the number of counties with a single issuer offering plans through the Exchange has decreased significantly, and the number of plan options that consumers have access to on the Exchanges has increased substantially since standardized options were discontinued in the 2019 Payment Notice. With

[333] See 81 FR at 94117—94118, 94148.

[334] See 45 CFR 155.220(l) and 155.221(i).

[335] 523 F. Supp. 3d 731 (D. Md. 2021).

[336] 83 FR 16974—16975.

[337] In part 3 of the 2022 Payment Notice final rule, we explained that we would not be able to fully implement those aspects of the court's decision regarding standardized options in time for issuers to design plans and for Exchanges to be prepared to certify such plans as QHPs for PY 2022, and therefore intended to address these issues in time for plan design and certification for PY 2023. See 86 FR 24140, 24264.

[338] Executive Order 14036 on Promoting Competition in the American Economy, July 9, 2021, *see* 86 FR 36987.

[339] See Or. Admin. R. 836–053–0009.

[340] The PY 2023 OEP is scheduled from November 1, 2022 to January 15, 2023. See 45 CFR 155.410(e)(3).

[341] See 81 FR at 94118.

[342] Ibid.

increased enrollment, increased issuer participation, decreased single issuer counties, and increased plan options available to consumers, we believe that resuming standardized options at this time can play a constructive role in enhancing consumer experience, increasing consumer understanding, simplifying the plan selection process, combatting discriminatory benefit designs that disproportionately impact disadvantaged populations, and advancing health equity.

We are proposing to require issuers offering QHPs through FFEs and SBE–FPs to offer standardized options, as opposed to allowing them to choose to offer these standardized options, as was done in the past, due in large part to the enhanced stability of the market as well as the consumer benefits derived from the ability to compare the same plans across different issuers. For example, in the FFEs and SBE–FPs in PY 2019, there was an enrollee-weighted average of 1.2 catastrophic plans, 7.9 bronze plans, 12.3 silver plans, 4.6 gold plans, and 1.1 platinum plans available per enrollee, amounting to a total of 25.9 plans available per enrollee. In the FFEs and SBE–FPs in PY 2022, based on current filing data, it is expected that there will be an enrollee-weighted average of 2.7 catastrophic plans, 40.4 bronze plans, 45.3 silver plans, 19.2 gold plans, and 1.6 platinum plans available per enrollee, amounting to a total of 106.5 plans available per enrollee. The proliferation of choices available to consumers on the Exchanges that makes it more difficult to meaningfully assess all available plan options.

The significant increase of plan offerings available on the Exchanges over the last several PYs highlights the need to facilitate the plan selection process for consumers. This is because when consumers are faced with an overwhelming amount of plan choices, each with slightly different cost sharing structures, these consumers can experience choice paralysis. Along with plan standardization, there are additional ways to facilitate more meaningful consumer choice, for example though directly limiting the number of allowable offerings by metal level or the imposition of strong meaningful difference standards. For example, six states limit the number of plans that issuers can offer through the Exchanges. We believe that requiring issuers to offer these standardized options will play a constructive role in facilitating the plan selection process, and we believe it will enable consumers to make more meaningful comparisons between plan offerings, thus optimizing the plan selection process. We also believe that given the large number of plan offerings on the Exchanges, a sufficiently diverse range of plan offerings exists for consumers to continue to select innovative plans that meet their unique health needs. We thus do not believe that requiring issuers to offer standardized options will hamper innovative plan designs, as we noted in the preamble to the 2017 Payment Notice.

We are proposing to require issuers in FFEs and SBE–FPs, but not issuers in State Exchanges to offer standardized options for several reasons. Eight State Exchanges already require or will require issuers to offer standardized options by PY 2023. Imposing duplicative federal standardized options requirements on issuers in State Exchanges that already have existing state standardized options requirements runs counter to the aforementioned goals of enhancing the consumer experience, increasing consumer understanding, simplifying the plan selection process, combatting discriminatory benefit designs, and advancing health equity.

Second, we believe State Exchanges are uniquely positioned to best understand the nature of their respective markets as well as the consumers in these markets. The eight State Exchanges that require or will require issuers to offer standardized options by PY 2023 have conducted extensive stakeholder engagement in designing standardized options that meet the unique needs of their respective consumers and stakeholders. As such, we believe State Exchanges are best positioned to design standardized options for their respective markets. We further believe that states that have invested the necessary time and resources to become State Exchanges have done so in order to implement innovative policies that differ from those on the FFEs. We do not wish to impede this innovation, so long as these innovations comply with existing legal requirements. However, because we propose to impose this requirement in the FFEs, and because the SBE–FPs use the same platform as the FFEs, we propose to apply the requirements equally on FFEs and SBE–FPs. Changing the platform to permit distinction on this proposal between FFEs and SBE–FPs would require a very substantial financial and operational burden that we believe outweighs the benefit of permitting such a distinction.

We propose one exemption to the above requirement for FFE and SBE–FP issuers to offer the specific standardized options that we propose in this rule. Specifically, we propose that FFE and SBE–FP issuers that are subject to existing state standardized options requirements under state action taking place on or before January 1, 2020, such as issuers in the state of Oregon, be exempt from being required to offer the specific standardized options that we propose in this rule. We do not wish to impose duplicative requirements that could conflict with these existing state standardized options requirements and the QHP plan designs applicable in such states. Regardless, HHS intends to differentially display these existing state standardized options on the Federal platform in the same manner as it displays the specific standardized options that we propose in this rule.

We also believe that requiring FFE and SBE–FP issuers to offer standardized options at every product network type, metal level, and throughout every service area that they also offer non-standardized options will ensure consumers have access to plans that have greater pre-deductible coverage, as the standardized options included in this proposal have greater pre-deductible coverage than most of the most popular QHPs in the FFEs and SBE–FPs in PY 2021. Additionally, the fact that these plans have standardized cost sharing parameters will enable consumers to more meaningfully compare other meaningful plan attributes, such as networks, formularies, and quality ratings during the plan selection process, optimizing the plan selection process.

We are not proposing standardized options for the Indian CSR plan variations at §§ 156.420(b)(1) and (2) for several reasons. First, the cost sharing parameters for the zero cost-sharing Indian CSR plan variations are already designated. Specifically, in the zero cost-sharing Indian CSR plan variations, eligible consumers do not have to pay for any out-of-pocket costs for EHB. Second, in the limited cost-sharing Indian CSR plan variations, eligible consumers also pay no out-of-pocket costs for EHB, but only when they receive them from an Indian health care provider or from another provider with a referral from an Indian health care provider.

Similar to how we have not specified the cost-sharing parameters for more than one tier of in-network providers or for out-of-network providers for the standardized option plan designs that we are proposing, we are proposing to not specify the cost-sharing parameters for EHBs received from non-Indian health care providers for limited cost-sharing Indian CSR plan variations. This is because eligible consumers will also pay no costs for EHBs provided by

Indian health care providers or from another provider with a referral from an Indian health care provider, obviating the need to specify the cost-sharing parameters for this type of plans. Altogether, we believe that proposing standardized options for the two Indian CSR plan variations, as well as applying the aforementioned requirements to the two Indian CSR plan variations, would impose duplicative requirements with little potential benefit since the cost sharing parameters for these plans are already specified.

We believe that not limiting the number of non-standardized QHPs that issuers can offer through the FFEs and SBE–FPs in PY 2023 will ensure that consumers continue to have access to a range of plans that meet their unique health needs. Furthermore, we do not wish to cause an excessive amount of disruption, particularly in too condensed a timeframe, and we do not wish to cause an excessive number of consumers to have their coverage under their current plan discontinued for a future plan year due to limits on the number of non-standardized options. Therefore, to address choice overload and enhance consumer choice-making ability, we are considering whether to limit the number of non-standardized QHPs that issuers can offer through the FFEs and SBE–FPs in future PYs, particularly in light of the significant growth in the number of plan choices offered.

We also believe concurrently resuming differential display of standardized options on *HealthCare.gov* per the authority at § 155.205(b)(1) as well as resuming enforcement of the accompanying display requirements applicable to approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively, is important considering that a steadily increasing number of consumers are enrolling in Exchange plans via these pathways. In addition, it will further streamline the plan selection and enrollment process for Exchange consumers, aid consumers in distinguishing standardized options from non-standardized options, and enhance consumer understanding of the benefits of standardized options, such as having more pre-deductible coverage, regardless of whether the consumer uses *HealthCare.gov* or a non-Exchange website.

We also note that the comments we received in response to part 3 of the 2022 Payment Notice informed our decision to resume the designation of standardized options as well as our specific approach for doing so. We received substantial comment from diverse stakeholders and carefully considered these comments. Many commenters recommended requiring issuers to offer standardized options and differentially or preferentially displaying standardized options. Commenters explained the importance of simplifying the complex process of purchasing insurance and the role that standardized options could play in that simplification.

Specifically, commenters explained that there is significant variation in the cost sharing structures of non-standardized options, much of which cannot be identified without a detailed analysis of benefit designs. Commenters explained that many individuals do not have the time, resources, or health literacy necessary for this level of analysis. Commenters explained that enrollees instead typically choose plans based on more readily available comparison points, like premiums, rather than factors that would be illuminated by a more detailed examination of plan designs, like expected out-of-pocket costs. Commenters further explained that selecting a plan solely based on its premium without taking into consideration other attributes of its design, such as its cost sharing structure, deductible, or expected out-of-pocket costs, can result in unexpected costs and financial harm for consumers.

Commenters also explained that barriers to conducting a detailed analysis of plan designs are particularly pronounced for those whose resources are already severely constrained, including those with limited English proficiency, those with inadequate internet access, and those with complex health needs. Commenters explained that facilitating consumer understanding and streamlining decision-making in the plan selection process would benefit these populations as well as populations with disproportionately high rates of chronic diseases.

Commenters also explained that standardized options could help individuals more easily identify plans that may have potentially discriminatory benefit designs. These commenters explained that discriminatory benefit designs target individuals with particular disabilities or health conditions by leaving them with substantial out-of-pocket costs. Commenters explained that conditions that are typically targeted, including HIV, diabetes, cancer, and mental health conditions, disproportionately affect individuals of color. Commenters explained that discriminatory benefit designs continue to violate the PPACA's protections for people with preexisting conditions and its prohibition on discrimination based on race, sex, and disability.

All of these considerations informed our decision to resume the designation of standardized options as well as our specific approach for designing and implementing standardized options requirements.

Regarding the methodology employed in designing these standardized options, similar to the approach taken in past iterations of standardized options in the 2017 and 2018 Payment Notices, we designed these plans to be similar to the most popular QHPs in FFEs and SBE–FPs in PY 2021.Several comments we received in response to part 3 of the 2022 Payment Notice proposed rule expressed support for continuing to use this methodology in our approach to standardized options. Commenters explained that continuing to use this methodology and designing plans to be similar to the most popular QHPs in FFEs and SBE–FPs would minimize the degree of disruption when these requirements are implemented.

We designed the proposed standardized options to be similar to the most popular QHPs based on an examination of the proportion of consumers enrolled in plans with different cost sharing types (including copay exempt from the deductible, copay subject to the deductible, coinsurance exempt from the deductible, and coinsurance subject to the deductible) for every benefit category in the actuarial value calculator (AVC) at each metal level. We chose the cost sharing type with the majority or plurality of enrollees. We then chose the enrollee-weighted median values for this cost sharing type as the copay amount or coinsurance rate for each benefit category before modifying these plans to have an AV near the lower end of the de minimis range for each metal level to ensure the competitiveness of these plans. Nothing in the design of these standardized options supersedes the obligation to cover certain benefits, such as the preventive services required under § 147.130, without cost sharing, even if such benefits would also fall into a category for which cost sharing is specified for the standardized option.

We applied this same methodology in selecting the deductible MOOPs for the proposed plans at each metal level. Specifically, we selected the enrollee-weighted median values for deductibles

and MOOPs to ensure these plans would be similar to plans that the majority or plurality of consumers are already currently enrolled in.

In addition to designing the proposed standardized options to be similar to the enrollee-weighted medians for each benefit category, we designed two sets of standardized options to accommodate applicable state cost sharing laws in different sets of FFE and SBE–FP states. This is similar to the approach taken the last time standardized options were offered. Specifically, In the 2018 Payment Notice, we designed three sets of plans tailored to unique cost sharing laws in different states. The second and third sets of these standardized options differed from the first set only to the extent necessary to comply with state cost sharing laws. The second set of standardized options in the 2018 Payment Notice was designed to work in states that: (1) Require that cost sharing for physical therapy, occupational therapy, and speech therapy be no greater than the cost sharing for primary care visits; (2) limit the cost-sharing amount that can be charged for a 30-day supply of prescription drugs by tier; or (3) require that all drug tiers carry a copayment rather than coinsurance. The second set of standardized options applied to Arkansas, Delaware Iowa, Kentucky, Louisiana, Missouri, Montana, and New Hampshire. The third set was designed to work in a state with maximum deductible requirements and other cost sharing standards. The third set of standardized options was designed to work in the Exchange in New Jersey, which has since transitioned to become a State Exchange and is thus outside the intended scope of this rulemaking for reasons described above.

We included several of the defining features of the second set of standardized options from the 2018 Payment Notice in the first set of standardized options we are proposing in this rulemaking. As a result, in the first set of standardized options, there is cost sharing parity between the primary care visit, the speech therapy, and the occupational and physical therapy benefit categories. There are also copays for all prescription drug tiers, including the non-preferred brand and specialty tiers, instead of coinsurance rates. Finally, the copayment for the mental health/substance use disorder in-network outpatient office visit sub-classification is equal to the least restrictive level for copayments for medical/surgical benefits in the in-network, outpatient office visit sub-classification (and copayments apply to substantially all medical/surgical benefits in this sub-classification), to ensure issuers are able to design plans that comply with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and its implementing regulations.[343] We propose that this first set of standardized options apply to all FFE and SBE–FP issuers, excluding issuers in Delaware and Louisiana.

We included all of the defining features of the second set of standardized options from the 2018 Payment Notice in the second set of standardized option plan designs we are proposing in this rule. As a result, in this set of standardized options, similar to the first set of standardized options, there is cost sharing parity between the primary care visit, the speech therapy, and the occupational and physical therapy benefit categories, and there are copays for all prescription drug tiers, including the non-preferred brand and specialty tiers, instead of coinsurance rates. Finally, the copayment for the mental health/substance use disorder in-network outpatient office visit sub-classification is equal to the least restrictive level for copayments for medical/surgical benefits in the in-network, outpatient office visit sub-classification (and copayments apply to substantially all medical/surgical benefits in this sub-classification), to ensure issuers are able to design plans that comply with MHPAEA and its implementing regulations.

The feature that distinguishes the first set of standardized options from the second is that the second set of standardized options have copays of $150 or less for the specialty drug tiers of standardized options at all metal levels. This feature was included in the second set of standardized options to accommodate relevant specialty tier prescription drug cost sharing laws in Delaware and Louisiana. We therefore propose that this set of standardized options apply to issuers in these two specific states.

The list of states for which these sets of standardized options apply differs slightly from the list of states for which the sets applied in the 2018 Payment Notice. Specifically, in the 2018 Payment Notice, the second set of standardized options applied to Arkansas, Delaware, Iowa, Kentucky, Louisiana, Missouri, Montana, and New Hampshire (with the first set applying to the rest of the FFE and SBE–FP states), whereas in the current proposal, we propose that the second set of standardized options apply only to Delaware and Louisiana (with the first set applying to the rest of the FFE and SBE–FP states).

This is because we incorporated the other two defining features of the second set of standardized options in the 2018 Payment Notice (that is, cost sharing parity between the physical therapy, occupational therapy, and speech therapy AVC benefit categories with the primary care visit AVC benefit category, and all drug tiers carry a copayment rather than coinsurance) in both sets of standardized options in the current proposal. We made this decision primarily because incorporating these two design features into the plan designs had a negligible impact to these plans' AVs, and including these features in both sets of standardized options decreases operational complexity and allows plan designs targeted to these specific states. As a result, the first set of standardized options can now be used in Arkansas, Iowa, Kentucky, Missouri, Montana, and New Hampshire.

We seek comment on this proposal, including comment on (1) requiring FFE and SBE–FP issuers to offer standardized options at every product network type, metal level, and throughout every service area that they offer non-standardized options; (2) not limiting the number of non-standardized options that issuers can offer through the Exchanges; (3) the feasibility, advantages, and disadvantages of gradually limiting the number of plan options over the course of several PYs; (4) whether standardized options should be differentially displayed on *HealthCare.gov* as well as the best manner for doing so; (5) whether web-brokers and issuers using the Classic DE and EDE Pathways should remain subject to differential display requirements; (6) the continuation of an exceptions process that allows these entities to deviate from the display of standardized options on *HealthCare.Gov*; (7) exempting State Exchange issuers from these requirements; (8) whether these plan designs should apply to State Exchanges that do not use the Federal platform and that have not implemented their own standardized options; (9) exempting FFE and SBE–FP issuers that are subject to existing state standardized options requirements under state action taking place on or before January 1, 2020 from being required to offer the standardized options in this proposal; (10) the

[343] In general, MHPAEA requires that the financial requirements (such as coinsurance and copays) and treatment limitations (such as visit limits) imposed on mental health or substance use disorder benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits in a classification.

methodology used to design these standardized options; (11) if these standardized options are compliant with state cost sharing laws in FFE and SBE–FP states; (12) the cost sharing parameters and plan designs for these standardized options; (13) how these plans can be designed in a way that maximizes the likelihood that plans will be able to comply with MHPAEA; (14) the policy approach for PYs 2023 and beyond; and (15) having two sets of standardized options (that is, a separate set for Delaware and Louisiana).

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TABLE 16: 2023 Standardized Options Set One (For All FFE and SBE-FP States, Excluding Delaware and Louisiana)

	Bronze	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	59.86%	64.06%	70.04%	73.10%	87.04%	94.02%	78.00%	88.00%
Deductible	$9,100	$7,500	$5,800	$5,700	$800	$0	$2,000	$0
Annual Limitation on Cost Sharing	$9,100	$9,000	$8,900	$7,200	$3,000	$1,700	$8,700	$3,000
Emergency Room Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Urgent Care	No charge after deductible	$75*	$60*	$45*	$30*	$5*	$45*	$15*
Specialist Visit	No charge after deductible	$100*	$80*	$60*	$40*	$10*	$60*	$20*
Mental Health/Substance Use Disorder Outpatient Office Visit	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Laboratory Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*
X-rays and Diagnostic Imaging	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*
Skilled Nursing Facility	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician and Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*

	Bronze	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Generic Drugs	No charge after deductible	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	No charge after deductible	$50	$40*	$40*	$20*	$15*	$30*	$10*
Non-Preferred Brand Drugs	No charge after deductible	$100	$80	$80	$60	$50*	$60*	$50*
Specialty Drugs	No charge after deductible	$500	$350	$350	$250	$150*	$250*	$150*

*Benefit category not subject to the deductible

TABLE 17: 2023 Standardized Options Set Two (For Delaware and Louisiana)

	Bronze	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	59.86%	64.07%	70.05%	73.01%	87.05%	94.02%	78.02%	88.01%
Deductible	$9,100	$7,500	$5,800	$4,100	$800	$0	$2,000	$0
Annual Limitation on Cost Sharing	$9,100	$9,000	$8,900	$7,200	$3,000	$1,800	$8,700	$3,000
Emergency Room Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Urgent Care	No charge after deductible	$75*	$60*	$60*	$30*	$5*	$45*	$15*
Specialist Visit	No charge after deductible	$100*	$80*	$80*	$40*	$10*	$60*	$20*
Mental Health/ Substance Use Disorder Outpatient Office Visit	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Laboratory Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*
X-rays and Diagnostic Imaging	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*

Skilled Nursing Facility	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician and Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Generic Drugs	No charge after deductible	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	No charge after deductible	$50	$40*	$40*	$20*	$5*	$30*	$10*
Non-Preferred Brand Drugs	No charge after deductible	$100	$80	$80	$60	$10*	$60*	$50*
Specialty Drugs	No charge after deductible	$150	$125	$125	$100	$20*	$100	$75*

*Benefit category not subject to the deductible

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11. Network Adequacy (§ 156.230)

We propose to adopt FFE QHP certification standards that would ensure that QHP enrollees would have sufficient access to providers. HHS is of the view that strong network adequacy standards are necessary to achieve greater equity in health care and enhance consumer access to quality, affordable care through the Exchanges. We have engaged and received feedback from numerous stakeholders representing diverse perspectives in developing these policy proposals.

a. Background of Network Adequacy Standards

Section 1311(c)(1)(B) of the ACA directs HHS to establish by regulation certification criteria for QHPs, including criteria that require QHPs to ensure a sufficient choice of providers (in a manner consistent with applicable provisions under section 2702(c) of the PHS Act), and provide information to current and prospective enrollees on the availability of in-network and out-of-network providers. Federal network adequacy standards were first detailed in the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers [344] and codified at § 156.230. HHS seeks to ensure that quantitative, prospective network adequacy reviews [345] occur for QHPs offered through the FFEs so that enrollees have reasonable, timely access to health care providers.

The FFEs conducted network adequacy reviews of time and distance standards for QHPs for PYs 2015–2017. The Market Stabilization [346] final rule deferred reviews of network adequacy for QHPs to states that HHS determined to have a sufficient network adequacy review process, an approach that was extended by the 2019 Payment Notice.[347] Specifically, CMS deferred to states that possessed sufficient authority to enforce standards that were at least equal to the reasonable access standard defined in § 156.230 and that had the means to assess the adequacy of plans' provider networks. For PYs 2018–2022, HHS determined that all states had sufficient legal authority and means to assess the adequacy of plans' provider networks. On March 4, 2021, as noted previously, the United States District Court for the District of Maryland decided City of Columbus, *et al.* v. Cochran.[348] One of the policies the court vacated was the 2019 Payment Notice's elimination of the Federal Government's reviews of the network adequacy of QHPs and plans seeking QHP certification to be offered through the FFEs.

As such, we announced in Parts 2 and 3 of the 2022 Payment Notice final rules our intent to undertake rulemaking to establish network adequacy standards, beginning in this proposed rule for PY 2023.

b. FFE Network Adequacy Reviews

For the QHP certification cycle for PYs beginning in 2023, HHS proposes to evaluate the adequacy of provider networks of QHPs offered through the FFEs, or of plans seeking certification as FFE QHPs, except for FFEs in certain states. HHS would not evaluate QHP network adequacy in FFE states performing plan management functions that elect to perform their own reviews of plans seeking QHP certification in their state, so long as the state applies and enforces quantitative network adequacy standards that are at least as stringent as the federal network adequacy standards established for QHPs under § 156.230, and that network adequacy reviews are conducted prior to QHP certification. States performing plan management functions are states served by an FFE where the state has agreed to assume primary responsibility

[344] *https://www.federalregister.gov/documents/2012/03/27/2012-6125/patient-protection-and-affordable-care-act-establishment-of-exchanges-and-qualified-health-plans.*

[345] Prospective network adequacy reviews would occur during the QHP certification process.

[346] *https://www.federalregister.gov/documents/2017/04/18/2017-07712/patient-protection-and-affordable-care-act-market-stabilization.*

[347] *https://www.federalregister.gov/documents/2018/04/17/2018-07355/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2019.*

[348] 523 F. Supp. 3d 731 (D. Md. 2021).

for reviewing issuer-submitted QHP certification material and making certification recommendations to HHS.

We seek comment on this proposal.

c. FFE Network Adequacy Standards Beginning With PY 2023

i. Network Adequacy Standards Applicable to Plans That Use a Provider Network

Section 1311(c)(1)(B) of the ACA directs HHS to establish criteria for the certification of health plan as QHPs, which includes the requirement that QHPs must ''ensure a sufficient choice of providers.'' HHS codified QHP network adequacy requirements under § 156.230(a)(2). In the 2012 Exchange final rule, we established the minimum network adequacy criteria that health and dental plans must meet to be certified as QHPs at § 156.230. This regulation provided that an issuer of a QHP that uses a provider network must maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to ensure that all services will be accessible to enrollees without unreasonable delay. In the 2016 Payment Notice, we modified § 156.230(a) in part to specify that network adequacy requirements only apply to QHPs that use a provider network, and that a provider network includes only providers that are contracted as in-network.

Later in this section of the preamble, we propose to refine the FFE's QHP certification standards regarding the adequacy of plans' provider networks by imposing time and distance standards, appointment wait time standards, and standards related to tiered networks.

ii. Time and Distance Standards

For the certification cycle for PYs beginning in 2023, HHS proposes to adopt for QHPs offered through the FFEs time and distance standards that HHS would use to assess whether FFE QHPs (or QHP candidates) fulfill network adequacy standards applicable to plans that use provider networks.

The proposed provider specialty lists for time and distance standards for PY 2023 are informed by prior HHS network adequacy requirements, consultation with stakeholders, and other federal and state health care programs, such as Medicare Advantage and Medicaid. The provider specialty lists cover more provider types than previously evaluated under FFE standards so that QHP networks will be more robust, comprehensive, and responsive to QHP enrollees' needs. The proposed provider specialty lists are generally consistent with standards used for plans in the Medicare Advantage program. For brevity purposes, when discussing provider types for network adequacy, we will use the term ''behavioral health'' to encompass mental health and substance use disorders.

HHS proposes reviewing additional specialties for time and distance, beyond those included by Medicare Advantage, that are necessary to meet the health care needs of QHP enrollees since Medicare Advantage and the FFEs serve different enrollee populations. The additional specialties proposed are: Emergency medicine, outpatient clinical behavioral health, pediatric primary care, and urgent care. Individual market health insurance has typically provided coverage of these specialties, as well.

We are aware of issues faced by consumers where in-network emergency physicians are in limited supply or not available at in-network hospitals. To provide proactive consumer protections, and, similar to the No Surprises Act, incentivize contracting between emergency medicine physicians and issuers to increase enrollee access to in-network providers, we propose adding emergency medicine physicians to our provider specialty list for time and distance standards. Behavioral health services are similarly critical to meeting QHP enrollees' health needs, so we also propose to add outpatient clinical behavioral health to our provider specialty list for time and distance standards. Since QHP enrollees include dependents under the age of 18, we propose adding pediatric primary care as a specialty. We further propose to include urgent care facilities in our time and distance standards because they help meet QHP enrollees time-sensitive health care needs when primary care is unavailable and the issues do not require emergency intervention. We seek to ensure the QHP enrollees have access to a variety of behavioral health facilities at the residential and inpatient levels of care. Consequently, we are also proposing to broaden the inpatient psychiatry facility specialty to be inpatient or residential behavioral health facility.

HHS proposes that time and distance standards would be calculated at the county level and vary by county designation. CMS would use a county type designation method that is based upon the population size and density parameters of individual counties, in alignment with Medicare Advantage. The time and distance standards would apply to the provider specialty lists contained in Tables 18 and 19. To count towards meeting the time and distance standards, individual and facility providers listed on Tables 18 and 19 would have to be appropriately licensed, accredited, or certified to provide services in their state, as applicable, and would need to have in-person services available.

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TABLE 18: Proposed Individual Provider Specialty List for Time and Distance Standards

Individual Provider Specialty Types
Allergy and Immunology
Cardiology
Cardiothoracic Surgery
Chiropractor
Dental
Dermatology
Emergency Medicine
Endocrinology
ENT/Otolaryngology
Gastroenterology
General Surgery
Gynecology, OB/GYN
Infectious Diseases
Nephrology
Neurology
Neurosurgery
Occupational Therapy
Oncology – Medical, Surgical
Oncology – Radiation
Ophthalmology
Orthopedic Surgery
Outpatient Clinical Behavioral Health (Licensed, accredited, or certified professionals)
Physical Medicine and Rehabilitation
Physical Therapy
Plastic Surgery
Podiatry
Primary Care – Adult
Primary Care – Pediatric
Psychiatry
Pulmonology
Rheumatology
Speech Therapy
Urology
Vascular Surgery

TABLE 19: Proposed Facility Specialty List for Time and Distance Standards

Facility Specialty Types
Acute Inpatient Hospitals (Must have Emergency services available 24/7)
Cardiac Catheterization Services
Cardiac Surgery Program
Critical Care Services - Intensive Care Units (ICU)
Diagnostic Radiology (Free-standing; hospital outpatient; ambulatory health facilities with Diagnostic Radiology)
Inpatient or Residential Behavioral Health Facility Services
Mammography
Outpatient Infusion/Chemotherapy
Skilled Nursing Facilities
Surgical Services (Outpatient or ASC)
Urgent Care

The county-specific time and distance parameters that plans would be required to meet would be detailed in future guidance. These parameters would be informed by industry standards.

Issuers that are unable to meet the specified standards would be able to submit a justification to account for variances. HHS would review such justifications to determine whether the variance(s) is/are reasonable based on circumstances, such as the local availability of providers and variables reflected in local patterns of care, and whether offering the plan through the FFE would be in the interest of qualified individuals and employers. We propose to codify the network adequacy justification process in regulation at § 156.230.

HHS seeks comment on this proposal, including on the specific parameters for time and distance standards, and flexibilities that may be needed in rural areas when there are provider or plan shortages. In particular, HHS seeks comment on the parameters that should apply with respect to behavioral health providers in order to ensure adequate access to these services. HHS also seeks comment on the specialty list to which time and distance standards would apply and whether HHS should establish time and distance standards for additional specialties in future PYs.

iii. Appointment Wait Times

For the certification cycle for PYs beginning in 2023, HHS proposes to adopt appointment wait time standards to assess whether QHPs offered through the FFEs fulfill network adequacy standards applicable to plans that use a provider network. We are proposing a short list of critical service categories for which appointment wait time standards would be assessed. The proposed provider specialty list for appointment wait time standards for PY 2023 is included below and is informed by prior federal network adequacy requirements and consultation with stakeholders, including issuers and other federal and state health care programs, such as Medicare Advantage and Medicaid.

The appointment wait time standards would apply to medical QHPs. For stand-alone dental plans (SADPs), only the dental provider specialty within the Specialty Care (Non-Urgent) category of appointment wait time standards would apply. To count towards meeting appointment wait time standards, providers listed in Table 20 must be appropriately licensed, accredited, or certified to practice in their state, as applicable, and must have in-person services available.

TABLE 20: Proposed Provider Specialty List for Appointment Wait Time Standards

Provider/Facility Type
Behavioral Health Services
Primary Care (Routine)
Specialty Care (Non-Urgent)

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The specific appointment wait time parameters that plans would be required to meet, including specifications for individual provider and facility types, would be detailed in future guidance. These parameters would be informed by industry standards. Issuers applying for FFE QHP certification would need to attest that they meet these standards as part of the certification process. HHS proposes to conduct post-certification reviews to monitor compliance with these standards. These compliance reviews would occur in response to access to care complaints or through random sampling.

Similar to the proposed justification process for time and distance standards, issuers that are unable to meet the appointment wait time standards would be able to submit a justification to account for variances. HHS would review such justifications to determine whether the variance(s) is/are reasonable based on circumstances,

such as the local availability of providers and variables reflected in local patterns of care, and whether offering the plan through the FFE would be in the interest of qualified individuals and employers. We propose to codify the network adequacy justification process in regulation at § 156.230.

HHS seeks comment on this proposal, including on the specialty list to which appointment wait time standards would apply, specific parameters for appointment wait time standards, and other ideas to strengthen network adequacy policy in future years, such as provider-enrollee ratios, provider demographics, and accessibility of services and facilities. We also seek comment on possible methods to collect and analyze claims data to inform future network adequacy standards and other aspects of QHP certification that impact health equity.

iv. Tiered Networks

HHS proposes that, for plans that use tiered networks, to count toward the issuer's satisfaction of the network adequacy standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For example, a QHP issuer cannot use providers contracted with their PPO network when certifying a plan using their HMO network, if use of PPO network providers would result in higher cost-sharing obligations for HMO plan enrollees. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers would be counted towards network adequacy standards. We propose to codify the network tiering requirement for network adequacy in regulation at § 156.230.

Network adequacy standards are tailored to ensure QHP enrollees have reasonable access to a sufficient number and type of providers to meet their health care needs. HHS is aware of instances in which issuers have attempted to satisfy QHP certification requirements related to networks, such as ECP standards, using providers that would require enrollees to pay higher cost sharing. We seek to ensure that QHP enrollees have access to networks with sufficient numbers and types of providers without the imposition of a higher cost-sharing requirement.

HHS seeks comment on this proposal.

v. Telehealth Services

HHS proposes to require all issuers seeking certification of plans to be offered as QHPs through the FFEs to submit information about whether network providers offer telehealth services. HHS proposes that this requirement would be applicable beginning with the QHP certification cycle for PY 2023. We believe this information could be relevant to HHS' analysis of whether a QHP meets network adequacy standards. For PY 2023, this data would be for informational purposes; it would be intended to help inform future development of telehealth standards and would not be displayed to consumers. Issuers should not construe this proposal to mean that telehealth services could be counted in place of in-person service access for the purpose of network adequacy standards.

As further explained in the ICRs and Regulatory Impact Analysis sections for network adequacy, we believe the telehealth data collection would create some additional burden for issuers who do not already have this data. The estimated burden for the telehealth data collection is included as part of the total burden for completing and submitting the ECP/NA template and is detailed in the ICRs and Regulatory Impact Analysis sections for network adequacy. We believe that the potential benefits of obtaining this information and using it to inform future network adequacy standards are in the best interests of both QHP enrollees and QHP issuers. As such, we anticipate that the additional burden would be mitigated by the expected benefits.

HHS seeks comment on this proposal, including comments on how HHS might incorporate telehealth availability into network adequacy standards in future PYs. We specifically seek comment on whether HHS should consider aligning the FFE network adequacy standards with Medicare Advantage's telehealth approach in which issuers are offered a credit towards meeting time and distance standards.

vi. Solicitation of Comments—Unintended Impacts of Stronger Network Adequacy Standards

HHS is of the view that the network adequacy standards we propose in this rule are reasonable, necessary, and appropriate to ensure that QHPs enrollees have the access to the in-network providers the ACA requires. We acknowledge, however, that there is some risk that stronger network adequacy standards could be leveraged to create an uneven playing field in network agreement negotiations that could result in higher health care costs for consumers. We are also interested in exploring rules and policies that would promote competition, taking into consideration the interests of issuers, providers, and consumers by limiting the potential that network adequacy standards may be used by parties to network agreements as leverage to obtain more favorable contract terms, leading to higher health care costs for consumers.

Strengthening network adequacy standards may increase the market power of some providers and inadvertently increase the cost of health care—for issuers, and, consequently, for enrollees. Some issuers seek to counteract these costs by incentivizing enrollees to seek care from lower-cost providers. However, some providers impose contractual steering restrictions in contracts with issuers. For example, where only one hospital is available to an issuer to meet the network adequacy standard, that hospital could charge higher prices without the threat of being excluded from the issuer's network. Such a price increase may be avoided if the issuer can include the hospital in its network, while giving incentives to its enrollees to use a more cost-effective alternative. This procompetitive option to ''steer'' patients away from high-cost providers can be precluded by the provider imposing contractual steering restrictions on issuers. A rule that circumscribes such steering restrictions may prevent providers from exploiting network adequacy standards to charge higher prices. We seek comment on the feasibility and parameters of such a rule and other solutions that would balance bargaining power between issuers and providers in a way that protects the interests of consumers.

The risk that a network adequacy standard may inadvertently empower a provider to charge higher prices is particularly problematic when the provider is part of a multi-provider hospital system and that system contracts on an all-or-nothing basis with issuers. An all-or-nothing contract is one that requires that an issuer contract with all facilities in a health system if the issuer wants to include any of the health system's facilities in its plan networks. When a multi-provider hospital system requires an all-or-nothing provision in its network agreements with issuers, issuers may be required to contract with the entire system in order to meet the network adequacy standard, and this may compel issuers to pay higher prices across the system, or else fail to meet the network adequacy standard. For this reason, we are interested in exploring how limiting ''all-or-nothing'' contracting provisions in payer contracts might counteract the potential for stronger network adequacy standards

to increase health care costs and seek comment on this topic. We understand that provider organizations typically use all-or-nothing provisions to leverage the status of their facilities that plan networks must have to satisfy network adequacy standards. These circumstances may compel the issuer to pay higher prices across the system. We are interested in understanding how this practice affects enrollees' use of and access to in-network care and how it may contribute to the cost of care. We seek comment on these issues, including comments on ways that HHS could help stem the use of all-or-nothing contracts that may drive up health care costs for consumers; how issuers can use provider networks to drive costs down; and what impact all-or-nothing contracting has on enrollees, plans, providers, and the market.

vii. Solicitation of Comments—Network Adequacy in State Exchanges

HHS is interested in learning more about network adequacy in states with State Exchanges. HHS understands that State Exchanges have a mix of network adequacy policies in place, and that about 75 percent of those states have at least one quantitative standard for time and distance, appointment wait times, or both. While the new proposed network adequacy standards for QHP issuers in FFEs differ from those in State Exchanges, HHS has not been inclined to propose additional regulations that specifically target network adequacy reviews for QHP issuers in State Exchanges, and we are not inclined to propose regulating network adequacy for State Exchanges at this time. However, we are considering whether there is a need for greater alignment in FFE and State Exchange network adequacy standards.

Starting in PY 2022, there will be 21 State Exchanges. We are concerned that there is no preferred network adequacy model that is shared among states, which indicates that there is no general agreement among states or Exchanges regarding what exactly constitutes an adequate network. Moreover, the proliferation of narrower networks in recent years presents a number of potential consumer protection concerns, including whether a narrow network has sufficient capacity to serve plan enrollees, or whether providers may be too geographically dispersed to be reasonably accessible. We are aware of the NAIC Health Benefit Plan Network Access and Adequacy Model Act,[349] which includes recommendations for network adequacy standards to which states could hold their issuers accountable, and requires submission of access plans. Since there has been limited uptake of the full Model Act by states, there remains a lack of consistency in network adequacy standards among states and Exchanges.

HHS seeks comment on whether these conditions necessitate a more coordinated, national approach to network adequacy rules across all Exchanges that is suited to address contemporary conditions in the health care markets. For example, we seek comment on whether in future PYs, HHS should consider imposing network adequacy rules in FFEs and State Exchanges that would be intended to increase the standardization of network adequacy across the Exchanges. Moreover, we seek comment on specific measures to support such standardization to ensure that all Exchange enrollees can access the benefits and services under their plans as required by the ACA. We further seek comments that identify specific gaps in provider accessibility that exist under disparate State Exchange network adequacy standards that might be addressed through greater federal regulation of network adequacy standards across all Exchanges.

12. Essential Community Providers (§ 156.235)

Essential community providers (ECPs) include providers that serve predominantly low-income and medically underserved individuals, and specifically include providers described in section 340B(a)(4) of the PHS Act and section 1927(c)(1)(D)(i)(IV) of the Social Security Act. The ECP categories include: Family planning providers, Indian health care providers, Federally Qualified Health Centers, hospitals, Ryan White providers, and other ECP providers. QHP issuers must include a sufficient number and geographic distribution of ECPs in their networks, where available. Section 156.235 establishes the requirements for inclusion of ECPs in QHP provider networks and provides an alternate standard for issuers that provide a majority of covered services through physicians employed directly by the issuer or a single contracted medical group.

In assessing the appropriate PY 2023 ECP standard for medical QHP and SADP QHP certification, HHS has considered multiple options for strengthening our ECP policy. After careful consideration, HHS proposes the approaches described below. States performing plan management functions in the FFEs would be permitted to use a similar approach.

Section 156.235(a)(2)(i) provides that a plan has a sufficient number and geographic distribution of ECPs if it demonstrates, among other criteria, that the network includes as participating practitioners at least a minimum percentage, as specified by HHS. HHS proposes that for PY 2023 and beyond, the required ECP provider participation standard be raised from 20 percent to 35 percent of available ECPs based on the applicable PY HHS ECP list, including approved ECP write-ins that would also count toward a QHP issuer's satisfaction of the 35 percent threshold. HHS would consider a plan to have satisfied the regulatory standard if the issuer contracts with at least 35 percent of available ECPs in each plan's service area to participate in the plan's provider network. The calculation methodology outlined in the 2018 Letter to Issuers in the federally-facilitated Marketplaces and 2018 Payment Notice would remain unchanged for issuers offering plans with a provider network.

The PY 2023 HHS ECP list will be based on data maintained by HHS as well as provider data that HHS receives directly from providers through the ECP petition process for PY 2023. HHS will include on the PY 2023 HHS ECP list those providers that submitted an ECP petition during the ECP petition window that closed on August 18, 2021, and that meet the definition of an ECP under § 156.235.

In developing this proposal, HHS considered that when the ECP threshold was 30 percent in PYs 2015–2017, all QHP issuers satisfied the 30 percent threshold with minimal reliance on ECP write-ins and justifications. In PYs 2018–2021, when the ECP threshold was 20 percent, all QHP issuers satisfied the lower threshold with ease and very little reliance on ECP write-ins and justifications. Beginning in 2019, HHS began publication of the ''Rolling Draft ECP list'', which significantly eased issuer burden for satisfying a higher threshold by allowing issuers to preview changes (that is, additions and removals) to the ECP list year-round in preparation for upcoming plan year contracting. Finally, in PY 2021, the percentage of medical and dental FFE issuers that could have satisfied a 35 percent ECP threshold was 80 percent and 74 percent, respectively; while the mean and median ECP score across all FFE issuers was 55 percent and 54 percent, respectively.

HHS anticipates that any QHP issuers falling short of the 35 percent threshold for PY 2023 could satisfy the standard by using ECP write-ins and

[349] *https://content.naic.org/sites/default/files/inline-files/MDL-074.pdf.*

justifications. As in previous years, if an issuer's application does not satisfy the ECP standard, the issuer would be required to include as part of its application for QHP certification a satisfactory justification describing how the issuer's provider networks, as presently constituted, provides an adequate level of service for low-income and medically underserved individuals and how the issuer plans to increase ECP participation in the issuer's provider network(s) in future years. At a minimum, such justification must include the number of contracts offered to ECPs for PY 2023, the number of additional contracts an issuer expects to offer and the timeframe of those planned negotiations, the names of the specific ECPs to which the issuer has offered contracts that are still pending, and contingency plans for how the issuer's provider network, as currently designed, will provide adequate care to enrollees who might otherwise be cared for by relevant ECP types that are missing from the issuer's provider network.

HHS also proposes that, for plans that use tiered networks, to count toward the issuer's satisfaction of the ECP standard, ECPs must be contracted within the network tier that results in the lowest cost sharing obligation. For example, a QHP issuer cannot use the number of ECPs contracted with their PPO network when certifying a plan using their HMO network, if use of PPO network providers would result in higher cost sharing obligations for HMO plan enrollees. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only the preferred network would be counted towards ECP standards. We propose to codify the network tiering requirement for ECP in regulation at § 156.235.

Additionally, for PY 2023 and beyond, HHS proposes that issuers could comply with the requirement at § 156.235(a)(2)(ii)(B) to offers contracts to at least one ECP in the category of 'other ECP providers'' by offering a contract to a Substance Use Disorder Treatment Center. These facilities are critical to HHS' efforts to ensure that low-income, medically underserved individuals have sufficient access to this EHB. We are also considering making non-substantive revisions to § 156.235, which requires QHPs to offer contracts to at least one ECP in each of the ECP categories, to improve readability and clarity, and to more closely reflect how Exchanges may operationalize this requirement. For example, the regulation text presently does not include language that specifically identifies which providers may fit the category of 'Other ECP Providers.' We solicit comments on whether clarifying revisions are necessary and on how best to clarify this requirement in the regulation text.

In addition to these proposed changes, HHS seeks comment on whether and how QHP issuers should increase the use of telehealth services as part of their contingency planning to ensure access to adequate care for enrollees who might otherwise be cared for by relevant ECP types that may be missing from the issuer's provider network. We also seek comment on if we should consider adding newly Medicare-certified Rural Emergency Hospitals to our Hospitals ECP category.

These proposed changes are consistent with the directive from E.O. 13985. HHS anticipates positive health equity impact as we believe these changes will increase access to quality, relevant health care for low-income and medically underserved individuals. HHS seeks comment on these proposals, including from ECPs and issuers serving low-income and medically underserved populations. HHS also seeks comment on ideas for further strengthening ECP policy.

14. Standards for Downstream and Delegated Entities (§ 156.340)

We propose to amend and add language to § 156.340 to extend the existing downstream and delegated standards to QHP issuers on all Exchange models, including State Exchanges and State Exchange SHOPs, and Exchange models that use the Federal platform, including, FFEs, SBE–FPs, FF–SHOPs; and HHS also proposes to add a requirement that all agreements between QHP issuers and their downstream and delegated entities include language stating that the relevant Exchange authority, including State Exchanges, may demand and receive the downstream or delegated entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period. These changes would hold QHP issuers in all models of Exchange responsible for their downstream and delegated entities' adherence to applicable federal standards related to Exchanges, and to make their oversight obligations, and the obligations of their downstream and delegated entities, explicit in regulation and in the QHP issuers' agreements with their downstream and delegated entities. We also propose to amend the title of subpart D of 45 CFR part 156 from ''Standards for Qualified Health Plan Issuers on Federally Facilitated Exchanges and State-Based Exchanges on the Federal platform'' to ''Standards for Qualified Health Plan Issuers on Specific Types of Exchanges'' to align with the proposed changes to extend the applicability of the § 156.340 to all Exchange models.

Section 156.340 was originally adopted in 2013 as part of the first Program Integrity Rule and is similar to existing standards for downstream and delegated entity that contract with Medicare Advantage Organizations.[350] It currently provides that, notwithstanding any relationship(s) that a QHP issuer may have with delegated or downstream entities, the QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities, with all applicable federal standards related to Exchanges, including those at § 156.340(a)(1) through (4). Specifically, these paragraphs reference obligations set forth under: Subpart C of part 156, which governs QHP minimum certifications standards for all types of Exchange, with several provisions specific to FFEs or to Exchanges that use the Federal platform; subpart K of part 155, which governs Exchange functions pertaining to QHP certification for all types of Exchange, with several provisions specific to FFEs; subpart H of part 155, which governs the Exchange functions of the SHOP, including State Exchange SHOPs, SBE–FP–SHOPs and FF–SHOPs; standards in § 155.220 with respect to agents, brokers, and web-brokers assisting with enrollment in QHPs offered through FFEs, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs; and standards in §§ 156.705 and 156.715 for maintenance of records and compliance reviews for QHP issuers operating in an FFE and an FF–SHOP. In the 2019 Payment Notice, we amended § 156.340(a)(2) to include language incorporating cross-references to SHOP provisions, to ensure consumers on the FF–SHOPs received the protections the provision intended for them to receive.[351]

In this rule, we propose to amend paragraph (a) by adding language stating that the applicable standards for which the QHP issuers and their downstream and delegated entities are responsible depend on the Exchange model in which the issuer provides coverage. We propose to remove existing paragraphs

[350] 78 FR at 54120.

[351] 83 FR at 17028.

(a)(1) through (a)(4) that currently identify the key applicable standards as examples of the requirements with which QHP issuers must ensure their downstream and delegated entities comply, and create a new paragraph (a)(1) that outlines the standards applicable to QHP issuers participating in State Exchanges. In proposed new paragraph (a)(1), QHP issuers participating in State Exchanges, including State Exchange SHOPs, would be responsible for ensuring their downstream and delegated entities comply with the standards of subpart C of part 156 with respect to each of its QHPs on an ongoing basis and the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155, including §§ 155.705 and 155.706 for the small group market, unless the standard is specifically identified as applicable to only the FFE or FF–SHOP. This new proposed paragraph (a)(1) would generally extend applicability of the current downstream and delegated standards captured in existing paragraphs (a)(1)–(a)(2) of § 156.340 to QHP issuers participating in State Exchanges, including State Exchange SHOPs, if the standard is otherwise applicable to the Exchange type in which the QHP issuer is operating.

We further propose to create a new paragraph (a)(2) to outline the standards applicable to QHP issuers providing coverage on Exchange models that use the Federal platform. In proposed new paragraph (a)(2), QHP issuers participating in FFEs, FF–SHOPs, SBE–FPs, or SBE–FP–SHOPs would be responsible for ensuring their downstream and delegated entities comply with the standards of subpart C of part 156 with respect to each of its QHPs on an ongoing basis; the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155, including §§ 155.705 and 155.706 for the small group market; the standards of § 155.220 with respect to agents, brokers and web-brokers assisting with enrollment in QHPs; and the standards of §§ 156.705 and 156.715 for maintenance of records and compliance reviews if applicable to the Exchange type in which the QHP issuer is operating. This new proposed paragraph (a)(2) would apply the current downstream and delegated standards in existing paragraphs (a)(1) through (a)(4) of § 156.340 to QHP issuers participating in FFEs, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs if the standard is otherwise applicable to the Exchange type in which the QHP issuer is operating.

We also propose to add a new paragraph (b)(5), pertaining to record retention, incorporating the requirement that contracts between QHP issuers and their downstream and delegated entities include language that the relevant Exchange authority, including State Exchanges, may demand and receive the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period. This amendment would ensure the relevant Exchange authority—whether the FFE, SBE–FP or State Exchange—has access to the records and information from delegated and downstream entities that are necessary to ensure compliance with applicable minimum Federal standards related to Exchanges.

These proposed amendments to § 156.340 will better align the regulation with its intent and prevent confusion on the part of regulated entities and their downstream and delegated entities.

We propose this amendment be applicable as of the effective date of the final rule. We seek comment on these proposed amendments.

15. Payment for Cost-Sharing Reductions—Clarification of CSR Payment and Data Collection Processes (§ 156.430)

HHS proposes to amend § 156.430 to clarify when CSR data submission is mandatory or voluntary. Section 156.430 establishes parameters for the advance payment for CSRs, the associated data submission standards, and how final CSR payment and charges are reconciled. On October 11, 2017, the Attorney General issued a legal opinion that HHS did not have a valid Congressional appropriation with which to make CSR payments to issuers.[352] As a result, CSR payments ceased as of October 12, 2017.[353] Because issuers were not receiving CSR payments from HHS, beginning with the 2018 benefit year CSR Reconciliation Data Submission process, HHS made the CSR data submission process voluntary. To clarify the data submission requirements, we propose to amend § 156.430 to clarify that this data submission is mandatory for those issuers that receive CSR payments from HHS for any part of the benefit year and voluntary for other issuers.

To do this, we are proposing several modifications to § 156.430. First, we propose to amend § 156.430(b)(1) to clarify that when there is an HHS appropriation to make CSR payments to issuers, an issuer will receive periodic advance payments to the extent permitted by the appropriation and based on the advance payment amounts established in guidance. We believe that this proposed change clarifies that the data submission requirements are mandatory for those issuers that receive CSR payments from HHS for any part of the benefit year. Further, and in line with the current practice, HHS will continue to provide those issuers that do not receive CSR payments from HHS the option to submit CSR data.

Second, we propose to amend § 156.430(d) to reflect a change of focus from reconciliation of CSR amounts to the timing and nature of CSR data submissions, specifically when CSR payments are made. We propose to amend § 156.430(d) to state that HHS will periodically provide a submission window for issuers to submit CSR data documenting CSR amounts issuers paid, as specified in § 156.430(d)(1) and (2), in a form and manner specified by HHS in guidance, and calculated in accordance with § 156.430(c). When an appropriation is available for HHS to make CSR payments to QHP issuers, HHS will notify QHP issuers that the submission of the CSR data is mandatory for those issuers that received CSR payments from HHS for any part of the benefit year, and will use the data to reconcile advance CSR payments to issuers against the actual amounts of CSRs issuers provided, as determined by HHS based on amounts specified in § 156.430(d)(1) and (2), and calculated in accordance with § 156.430(c).

When CSR payments are not made, HHS will notify those QHP issuers that did not receive CSR payments from HHS for any part of the benefit year that the submission of the CSR data is voluntary. The CSR data that must be submitted in either a voluntary or mandatory submission includes the data elements listed in § 156.430(d)(1) and (2). The purpose of this change is to clarify when HHS will use CSR data to reconcile CSR payments. Specifically, we are proposing that to the extent that CSR payments from HHS are made to issuers, the CSR data submission process would be mandatory for those issuers having received CSR payments for any part of the benefit year from HHS, and would be voluntary for issuers that did not receive CSR

[352] Acting Secretary's memorandum enclosing Attorney General's opinion regarding CSR payments (2017), available at *https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf.*

[353] Ibid.

payments from HHS for any part of the benefit year. This approach is consistent with how HHS has conducted these data submission processes since the 2018 benefit year CSR data submission process.

Third, we propose to amend the title of § 156.430(e) from ''Payment of discrepancies'' to ''Cost-sharing Reductions Payments and Charges'' to reflect that this section governs both payments to issuers for CSR and charges levied against issuers for CSR.

Lastly, we propose to amend § 156.430(e)(1) to clarify that HHS will collect data regarding the CSRs actually provided by issuers to their enrollees as opposed to collecting data on the dollar value of CSRs HHS provided to the issuer, and to further clarify that HHS only pays reconciled CSR amounts when there is an appropriation to make CSR payments and to the extent permitted by such appropriation. We believe these proposed changes would provide issuers with further clarity regarding the intention of CSR data submission requirements.

We note that, regardless of whether HHS makes CSR payments, issuers are required to provide CSRs to enrollees as specified at § 155.1030. We solicit comment on these proposals.

16. Quality Standards: Quality Improvement Strategy (§ 156.1130)

In accordance with section 1311(c)(1)(E) of the ACA, quality improvement strategies described in section 1311(g)(1) of the ACA must be implemented across Exchanges as a QHP certification requirement. Section 1311(g)(1) of the ACA defines a QIS as a payment structure that provides increased reimbursement or other incentives for implementing activities related to the five health care topic areas defined in statute: Improving health outcomes of plan enrollees, preventing hospital readmissions, improving patient safety and reducing medical errors, promoting wellness and health, and reducing health and health care disparities. Under § 156.1130(a), a QHP issuer participating in an Exchange for 2 or more consecutive years must implement and report on a QIS, including a payment structure that provides increased reimbursement or other market-based incentives in accordance with the health care topic areas in section 1311(g)(1) of the ACA, for each QHP offered in an Exchange, consistent with the guidelines developed by HHS under section 1311(g) of the ACA. In the 2016 Payment Notice, HHS established a phase-in approach for QIS implementation standards and reporting requirements to provide QHP issuers the necessary time to understand the populations enrolling in a QHP offered through the Exchange and to build quality performance data on their respective QHP enrollees.[354] HHS noted that implementation of a QIS should be a continuous improvement process for which QHP issuers define the health outcome needs of their enrollees, set goals for improvement, and provide increased reimbursement to their providers or other market-based incentives to reward achievement of those goals.[355] In line with this approach and pursuant to the authority granted under § 156.1130(a) and section 1311(g) of the ACA, HHS proposes to update the QIS standards and enter the next phase of implementation by adopting a new guideline that would apply to QHP issuers beginning in 2023. Specifically, we propose a new guideline under which QHP issuers would be required to address health and health care disparities as a specific topic area within their QIS, in addition to at least one other topic area described in section 1311(g)(1) of the ACA beginning in 2023. We propose this expansion of the QIS standards, which aligns with health equity efforts across federal government policies and programs; however, we are not proposing amendments to the regulatory text outlined in § 156.1130.

Persistent inequities in health care outcomes exist in the United States, including among populations enrolling in QHPs across Exchanges. Belonging to a racial or ethnic minority group, living with a disability, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQI+) community, having limited English proficiency, living in a rural area, or being near or below the poverty level, is often associated with worse health outcomes.[356] Such disparities in health outcomes are the result of a number of factors and exist irrespective of health insurance coverage type. Although not the sole determinant, poor health care access and provision of lower quality health care contribute to health disparities. In fact, research has shown that the expansion of health insurance coverage, for example through Medicaid expansion under the ACA, and the resulting increased access to health care, is linked to reductions in disparities in health insurance coverage as well as reductions in disparities in health outcomes.[357]

We are specifically committed to achieving equity in health care outcomes for QHP enrollees by supporting QHP issuers in quality improvement activities to reduce health and health care disparities, and promoting issuer accountability for improving equity in the health and health care of their enrollee populations. For the purposes of this proposed rule, we are using the definition of ''equity'' established in Executive Order 13985, issued on January 20, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities who have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQI+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [358] In light of the COVID–19 PHE, which is having a disproportionate and severe impact on underserved populations, and in line with the goals of Executive Order 13985, CMS is strengthening efforts across all programs to address disparities and advance health equity. This is a topic area that QHP issuers across the Exchanges have increasingly been focusing on in their QIS submissions.

Upon CMS evaluation of QHP issuer QIS submissions in the FFEs, an estimated 60 percent of QIS submissions in PY 2020 did address health care disparities. Building on the phase-in

[354] 80 FR 10750 at 10844 (Feb. 27, 2015).

[355] Ibid.

[356] See Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346; Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308; Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316; Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018; *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf; www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm;* Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[357] Guth M, Garfield R, Rudowitz R. The Effects of Medicaid Expansion Under the ACA: Studies from Jan 2014 to Jan 2020.

[358] 86 FR 7009 (Jan. 25, 2021), available at *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

approach established in the 2016 Payment Notice and our experiences evaluating QIS submissions over the years and during the COVID–19 PHE, we now propose to update the QIS standards. We propose to require QHP issuers to address health and health care disparities as one topic area of their QIS in addition to at least one other topic area described in section 1311(g)(1) of the ACA beginning in 2023. As previously noted, we are proposing this expansion of the QIS standards, which aligns with health equity efforts across federal government policies and programs; however, we are not proposing amendments to the regulatory text outlined in § 156.1130. We seek comment on this proposal.

17. Disbursement of Recouped High-Cost Risk Pool Funds—Administrative Appeals of Issuers of Risk Adjustment Covered Plans (§ 156.1220)

HHS proposes that any funds recouped as a result of a successful high-cost risk pool administrative appeal under § 156.1220(a)(1)(ii) would be used to reduce high cost-risk pool charges for that national high-cost risk pool for the current benefit year, if high-cost risk pool payments have not already been calculated for that benefit year. If high-cost risk pool payments have already been calculated for that benefit year, we propose to use any funds recouped as a result of a successful high-cost risk pool administrative appeal to reduce high-cost risk pool charges for that national high-cost risk pool for the next benefit year. As discussed earlier in this rule, we also proposed similar treatment of high-cost risk pool funds HHS recoups as a result of audits of risk adjustment covered plans under § 153.620(c)(5)(ii) and as a result of actionable discrepancies under § 153.710(d). We propose to treat high-cost risk pool funds recouped as a result of a successful appeal the same way, that is, the recouped funds would be used to reduce high-cost risk pool charges for that national high-cost risk pool for the next benefit year for which high-cost risk pool payments have not already been calculated.

We also clarify that when HHS recoups high-cost risk pool funds as a result of a successful administrative appeal, the issuer that filed the appeal would then be responsible for reporting that adjustment to its high-cost risk pool payments or charges in the next MLR reporting cycle consistent with the applicable instructions in 45 CFR 153.710(h). Additionally, for any benefit year in which high-cost risk pool charges are reduced as a result of high-cost risk pool funds recouped as a result of an actionable discrepancy, issuers whose charge amounts are reduced would report the high-cost risk pool charges paid for that benefit year net of recouped audit funds in the next MLR reporting cycle consistent with 45 CFR 153.710(h).

We seek comment on this proposal.

18. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

We propose to amend § 156.1230 such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. HHS previously codified such nondiscrimination protections at § 156.1230, but amendments made in 2020 to § 156.1230 removed any reference to sexual orientation and gender identity. If finalized, this proposal would revert § 156.1230 to the pre-2020 nondiscrimination protections.

Section 156.1230(b)(2) states that the QHP issuer must provide consumers with correct information, without omission of material fact, regarding the FFE, QHPs offered through the FFE, and insurance affordability programs, and refrain from marketing or conduct that is misleading a consumer into believing they are visiting *HealthCare.gov*, coercive, or discriminates based on race, color, national origin, disability, age, or sex. Previously, in the 2017 Payment Notice final rule, HHS finalized at § 155.220(j)(2)(i) standards that prohibited agents, brokers and web-brokers from discriminating on the basis of sexual orientation and gender identity, among other factors.[359] In the 2018 Payment Notice final rule, we added this nondiscrimination standard from § 155.220(j) to § 156.1230(b) so that the nondiscrimination protections on the basis of sexual orientation and gender identity also applied to issuers using direct enrollment on an FFE.[360] However, in the 2020 final rule related to section 1557, HHS revised certain CMS regulations, including § 156.1230(b)(2), by removing sexual orientation and gender identity as bases of discrimination subject to the CMS regulations' nondiscrimination protections.[361]

CMS possesses statutory authority independent of section 1557 of the ACA to prohibit discrimination in enrollment through the Exchanges by issuers of QHPs on the Exchanges under the authority to establish requirements with respect to the operation of Exchanges, the offering of QHPs through such Exchanges, and other requirements as the Secretary determines appropriate in sections 1321(a)(1)(A), (B), and (D) of the ACA. Pursuant to this authority, in the 2018 Payment Notice final rule, HHS finalized at § 156.1230(b)(2) standards applicable to issuers using direct enrollment on an FFE to require that issuers refrain from marketing or conduct that is misleading, coercive, or discriminatory, including on the basis of sexual orientation or gender identity. HHS explained it was adding this nondiscrimination standard from § 155.220(j) to § 156.1230(b) so that the nondiscrimination protections on the basis of sexual orientation and gender identity also applied to issuers using direct enrollment on an FFE. HHS proposes to exercise that same authority here to amend § 156.1230(b) to again prohibit issuers using direct enrollment on an FFE from discriminating based on sexual orientation and gender identity. Sections 1321(a)(1)(A), (B), and (D) of the ACA are the same authority CMS relies upon for implementation of existing nondiscrimination protections at § 156.200(e). Utilizing this same authority to again prohibit discrimination based on sexual orientation and gender identity at § 156.1230(b) would be consistent with the authority CMS relies upon for the existing protections at § 156.1230(b) that currently prohibit discrimination on the basis of race, color, national origin, disability, age, or sex. We believe such amendments are warranted in light of the existing trends in health care discrimination and are necessary to better address barriers to health equity for LGBTQI+ individuals.

A more in-depth discussion of these developments and other factors considered in proposing these amendments to CMS nondiscrimination protections is included earlier in the preamble to § 147.104 under section III.B.1.b. of this preamble. For brevity, we refer back to that section of the preamble rather than restating the issues here.

19. Solicitation of Comments—Choice Architecture and Preventing Plan Choice Overload

One of the primary goals of the ACA is to provide consumers access to quality, comprehensive health coverage options, as well as the information and assistance they need to make coverage choices that are right for them. For this reason, both Federal and State Exchanges invest significant time and resources to building Exchanges that

[359] 81 FR 12204 (March 8, 2016).

[360] 81 FR 94058 (December 22, 2016).

[361] 85 FR 37160 (June 19, 2020); *See id.* at 37218–21 (the 2020 section 1557 final rule revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

support consumer access to competitive health plan options that offer sufficiently diverse benefit options that give consumers a meaningful choice between Exchange coverage options. Exchanges also work to ensure that QHP information is presented to consumers in a manner that is clear and easy to understand, and allows consumers to accurately recognize the material differences between plan options.

Although HHS continues to prioritize competition and choice on the Exchanges, we are concerned about plan choice overload which can result when consumers have too many choices in plan options on an Exchange. A 2016 report by the RAND Corporation reviewing over 100 studies concluded that having too many health plan choices can lead to poor enrollment decisions due to the difficulty consumers face in processing complex health insurance information.[362]

Earlier under this section E. of the preamble, we introduced a proposal to require that FFE and SBE–FP issuers offer certain standardized options to be designed by HHS. Standardized options offer a solution to the problems of choice overload through simplifying cost sharing structures and increasing plan comparability by allowing consumers to focus on premium price, provider network, and plan quality.[363] In light of the proliferation of seemingly similar plans offered through the Exchanges over the last several years, HHS wishes to explore whether it should limit the total number of plans issuers may offer through the FFEs and SBE–FPs in future PYs in order to further streamline and optimize the plan selection process for consumers on the Exchanges.

HHS's desire to limit the number of plans that issuers can offer through the Exchanges arises following the sharp increase in plan offerings in recent years. For example, in the FFEs and SBE–FPs in PY 2019, there was an enrollee-weighted average of 1.2 catastrophic plans, 7.9 bronze plans, 12.3 silver plans, 4.6 gold plans, and 1.1 platinum plans available per enrollee, amounting to a total of 27.1 plans available per enrollee. In the FFEs and SBE–FPs in PY 2022, based on current filing data, it is expected that there will be an enrollee-weighted average of 2.7 catastrophic plans, 40.4 bronze plans, 45.3 silver plans, 19.2 gold plans, and 1.6 platinum plans available per enrollee, amounting to a total of 109.2 plans available per enrollee.

In PY 2022, it is expected that several rating areas will have more than 50 silver plans, excluding CSR variations, available to consumers—a number we expect will make it difficult for consumers to make reasonably informed decisions. This proliferation of plans is only partially attributable to new market entrants, since in PY 2019, consumers could select QHPs from an enrollee-weighted average of 2.8 issuers per enrollee, while in PY 2022, it is expected consumers will be able to select QHPs from an enrollee-weighted average of 6.3 issuers per enrollee. The fact that the enrollee-weighted average number of plan offerings increased by a factor of four while the enrollee-weighted average number of issuers only increased by a factor of just over two between PYs 2019 and 2022 suggests consideration of the need to limit the proliferation of seemingly similar plans in order to further streamline and optimize the plan selection process for consumers on the Exchanges.

HHS is concerned that having an excessive number of health plan options may make consumers less likely to complete any plan selection and more likely to select a plan that does not match their health needs. In studies of consumer behavior in Medicare Part D, Medicare Advantage, and Medigap, a choice of 15 or fewer plans was associated with higher enrollment rates, while a choice of 30 or more plans led to a decline in enrollment rates.[364] These conclusions are supported by the comments received during prior rulemaking in which a significant number of commenters raised concerns that removing tools that facilitate the plan selection process causes consumers to face choice paralysis and leads to a reduction in overall enrollment in QHPs, undermining the purpose of Exchanges—to allow people to compare and purchase QHPs.

HHS's experience during its annual open enrollment period also suggests that ''many consumers, particularly those with a high number of health plan options, find the large variety of cost-sharing structures available on the Exchanges difficult to navigate.'' [365] Thus, in order to streamline and optimize the plan selection process for consumers on the Exchanges, HHS is interested in exploring possible methods of improving choice architecture. Several proposals within this rulemaking complement this goal, including the standardized options proposal at § 156.201 and the proposals to change the applicable AV de minimis range at §§ 156.140, 156.200, and 156.400.

Specifically, the standardized options proposal at § 156.201 proposes to require FFE and SBE–FP issuers to offer plans with standardized cost-sharing parameters at every product network type, metal level, and throughout every service area that they offer non-standardized options. Though this proposal does not limit the number of non-standardized options, HHS intends to consider and propose future rulemaking, as appropriate, to determine whether to limit the number of non-standard plans that FFE and SBE–FP issuers may offer through the Exchanges in PYs beginning on or after January 1, 2024.

Additionally, the proposals at §§ 156.140, 156.200, and 156.400 propose to modify the AV de minimis ranges. HHS proposes to modify the de minimis ranges at § 156.140(c) beginning in PY 2023 to +2/−2 percentage points for all individual and small group market plans subject to the AV requirements under the EHB package, other than for expanded bronze plans, for which HHS proposes a de minimis range of +5/−2. Under § 156.200, HHS proposes, as a condition of certification as a QHP, to limit the de minimis range to +2/0 percentage points for individual market silver QHPs. HHS also proposes under § 156.400 to specify de minimis ranges of +1/0 percentage points for income-based silver CSR plan variations. HHS anticipates that these proposals will have the effect of decreasing the number of plan offerings due to more restricted AV de minimis ranges.

HHS is also considering resuming the meaningful difference standard that was previously codified at 45 CFR 156.298. The meaningful difference standard was first finalized in the 2015 Payment Notice, revised in the 2017 Payment Notice, and discontinued and removed from regulation in the 2019 Payment Notice. The meaningful difference standard was originally intended to enhance consumer understanding of the differences between plans and enable optimal consumer choice. It was then considered to be no longer necessary given the decreased number of issuers and plans offered through the FFEs and SBE–FPs in PY 2019. Given that the

[362] Taylor EA, Carman KG, Lopez A, Muchow AN, Roshan P, and Eibner C. Consumer Decisionmaking in the Health Care Marketplace. RAND Corporation. 2016.

[363] ''Facilitating Consumer Choice: Standardized Plans in Health Insurance Marketplaces.'' Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. December 2021. Available at *https://aspe.hhs.gov/*.

[364] Chao Zhou and Yuting Zhang, ''The Vast Majority of Medicare Part D Beneficiaries Still Don't Choose the Cheapest Plans That Meet Their Medication Needs.'' *Health Affairs,* 31, no.10 (2012): 2259–2265.

[365] 80 FR 75,488, 75,542 (Dec. 2, 2015).

number of plans offered through the Exchanges has increased sharply over the last several years, HHS believes that resuming the meaningful difference standard could play a constructive role in limiting the proliferation of seemingly similar plans on the Exchanges, thus further streamlining and optimizing the plan selection process for consumers on the Exchanges.

HHS also acknowledges that a number of State Exchanges have successfully employed an active purchaser model in which these Exchanges selectively negotiate contracts with issuers, limit the total number of issuers that can offer QHPs through the Exchange, require issuers to offer standardized options exclusively, and exclude plans that have not demonstrated the administrative capability, prices, networks or product designs that improve consumer value. HHS intends to consider whether such a model would be appropriate in future PYs to achieve the aforementioned goals of streamlining the plan selection process for consumers on the Exchanges.

We seek comment on the utility of limiting the number of plans that FFE and SBE–FP issuers can offer through the Exchanges in future PYs in order to avoid plan choice overload and to further streamline and optimize the plan selection process for consumers on the Exchanges. We also seek comment on the impact of limiting the number of plans that issuers can offer through the Exchanges and on effective methods to achieve this goal, the advantages and disadvantages of these methods, and if there are alternative methods we have not considered.

We also seek comment on other evidence-based approaches to improve choice architecture within the Exchanges.

F. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Reimbursement for Clinical Services Provided to Enrollees (§ 158.140)

We propose to amend § 158.140(b)(2)(iii) to clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes.

Section 2718(a) of the PHS Act requires health insurance issuers offering group or individual health insurance coverage (including a grandfathered health plan) to, for MLR purposes, separately report the percentage of total premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under such coverage, for activities that improve health care quality, and on all other non-claims (administrative) costs. Section 2718(b) of the PHS Act requires a health insurance issuer to provide an annual rebate to each enrollee if the issuer's MLR falls below the applicable MLR standard established in section 2718(b)(1)(A)(i) and (ii). Section 158.140 sets forth the MLR reporting requirements related to the reimbursement for clinical services provided to enrollees, including a requirement in § 158.140(b)(2)(iii) that issuers must include in incurred claims the amount of incentive and bonus payments made to providers. Incentive and bonus payments made to providers were originally required to be included in incurred claims to reflect certain claim liability accounting practices of HMOs,[366] but due to the lack of clarity and specificity in the regulations, have resulted in inclusion of a variety of incentive and bonus payments to providers. However, inclusion of many types of provider incentives and bonuses in incurred claims is appropriate and consistent with the purpose of the statute to the extent such bonuses reward or incentivize providers to deliver higher-quality care to consumers and thus lead to higher value for consumers' premium payments.

In the course of conducting MLR examinations pursuant to §§ 158.401 and 158.402, we have observed some issuers reporting incentive or bonus payments to providers that are not based on quality or performance metrics, but rather, involve transferring excess premium revenue to providers to circumvent MLR rebate requirements and avoid paying MLR rebates when issuers do not meet the applicable MLR standard.

Most provider incentive and bonus agreements we encounter during MLR examinations tend to have clinical metrics that must be met by the provider, rather than the issuer, in order for payment to occur. However, we have observed arrangements where the issuer's failure to meet the MLR standard is itself the metric that triggers the payment of a bonus to the provider. Under such arrangements, any time an issuer's MLR falls below a specified threshold, including below the applicable MLR standard (or, similarly, a metric tied to the issuer's profitability or surplus exceeds a specified threshold), the issuer must pay the excess profits to a provider group or hospital system. If such payments are labeled as a provider ''incentive'' or ''bonus'' and are included in the issuer's incurred claims, the issuer's MLR is artificially raised so that it is close to or meets the applicable MLR standard. This artificial inflation of MLR often eliminates most, or in some cases even all, of the rebate owed to enrollees, regardless of how low enrollees' claims costs are relative to premiums those enrollees pay. Such artificial inflation of MLR denies consumers the protection of receiving premium rebates guaranteed by the statute for the years when claims costs are low due to low utilization of health care services, such as the years when numerous medical procedures are deferred due to a pandemic. In some cases, when such payments to providers are inappropriately labeled as ''incentives'' or ''bonuses,'' they inflate paid claims by as much as 30 percent to 40 percent. The incentive for such arrangements is particularly high for integrated medical systems where the issuer is the subsidiary, owner, or affiliate of a provider group or a hospital system. Further, in some cases these ''incentives'' or ''bonuses'' are not even paid to the clinical providers, but rather to the non-clinical parent holding company of the hospital or provider group and the issuer.

Although we consider inclusion of the provider ''incentives'' and ''bonuses'' described above in incurred claims inappropriate under existing regulations because the described approach directly contravenes the statute, in order to increase compliance and improve program integrity, we propose to amend § 158.140(b)(2)(iii) to clarify that only those provider incentives and bonuses made to providers that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. We seek comment on this proposal.

2. Activities That Improve Health Care Quality (§ 158.150)

We propose to amend § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes.

Section 2718(a) of the PHS Act requires health insurance issuers offering group or individual health insurance coverage (including a

[366] *See* 75 FR 74874 *and https://www.govinfo.gov/content/pkg/FR-2010-12-01/pdf/2010-29596.pdf.*

grandfathered health plan) to, for MLR purposes, report the percentage of total premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under such coverage, for activities that improve health care quality, and on all other non-claims costs. Section 158.221 defines the numerator of an issuer's MLR to include the issuer's incurred claims plus the issuer's expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151. Section 158.150 describes the types of activities that qualify as QIA, but does not specify the types of expenses that may be included as QIA expenses, or the extent to which such expenses must relate to the activity. The lack of clarity in existing regulations has caused wide discrepancies in the types of expenses that issuers include in QIA expenses and creates an unequal playing field among issuers. Some issuers appropriately include only direct expenses, such as the salaries of the staff performing actual QIA functions in QIA expenses. However, other issuers additionally allocate indirect expenses such as overhead, marketing, lobbying, corporate or holding group overhead, and vendor profits in QIA expenses. To the extent they can be quantified, such indirect expenses often inflate QIA amounts by 33 percent to 50 percent, potentially reducing rebates provided to enrollees while providing no value for consumers' premium dollars. In many other cases, the amounts of indirect expenses included in QIA expenses appear to be arbitrary because there is no reasonable method to allocate them to QIA as the expenses have no direct or quantifiable relationship to health care quality.

A significant portion of QIA expenses is attributable to salaries of employees actually performing the QIA. However, issuers' employees often perform QIA only part of the time, while performing cost containment and other strictly administrative and profit-generating functions (such as negotiating provider rates, or claims adjustment and appeals) the rest of the time. As a result, numerous fixed costs that some issuers allocate to QIA simply because some of their staff spend some of their time performing QIA would, for the most part, exist even if the issuer did not engage in any QIA. Examples of such indirect expenses include: Office space (including rent or depreciation, facility maintenance, janitorial, utilities, property taxes, insurance, wall art), human resources, salaries of general counsel and executives, computer and telephone usage, and company parties and retreats, including catering and travel.

Some issuers additionally allocate a fixed percentage of their entire IT cost centers to QIA, even though the IT infrastructure disproportionately supports regular business functions such as billing, claims processing, financial analysis, and cost containment, and for the most part would exist even if the issuer did not engage in any QIA. Examples of such expenses include: Salaries of IT staff and call center or help desk staff, data centers and warehouses, mainframe equipment, network system applications and equipment, enterprise data management, as well as depreciation, maintenance, and utilities associated with IT equipment.

Some issuers include in QIA expenses amounts exceeding the cost of providing the actual QIA service. For example, some issuers make a profit when providing wellness incentives to enrollees, but structure cost reporting in a manner that includes such profits in QIA expenses. In addition, some issuers include the promotion or marketing of their QIA services to group policyholders or enrollees as QIA expenses. Some issuers also include the cost of developing the prices of QIA services sold to group policyholders, or costs associated with calculating and reporting QIA expenses.

Section 2718 of the PHS Act created the first national MLR reporting and rebating program with the goal of putting downward pressure on issuers' administrative expenses and encouraging issuers to devote more of the premium dollars to medical spending and enrollee health. Section 2718 of the PHS Act recognizes that investing in QIA may improve enrollee health, thereby increasing the value of their premium dollars. However, facility maintenance, utilities, human resources, salaries of counsel and executives, computers, travel and entertainment, IT systems, and marketing of issuers' products provide no benefit to an enrollee's health. By including such costs in the MLR numerator, the value of the enrollee's premium dollars is actually reduced. Thus, indirect expenses such as those are described here are classified as non-claims, administrative costs for purposes of reporting incurred claims under § 158.140. Allowing issuers to report these same excluded expenses as expenditures on QIA is inappropriate and would undermine the very purpose and intent of section 2718 of the PHS Act. It would allow issuers to inflate QIA costs by including expenses that do not actually improve health care quality, particularly since these expenses are often fixed costs that would occur regardless of whether the issuer engages in QIA. Further, some issuers are not able to precisely determine what portion of indirect costs is tied to QIA, as many issuers do not have an accurate method to quantify the actual cost of each expense category as it relates to each QIA, and thus issuers are often arbitrarily determining or apportioning indirect expenses without adequate documentation to support their determinations. The lack of clarity in § 158.150 as to what expenses may be included in QIA expenses has created an uneven playing field that is unfairly boosting the MLRs of issuers that include indirect or overhead expenses in QIA expenses as compared to those that are not reporting these expenses in QIA expenses, thus driving up health care spending and depriving consumers of value for their premium dollars.

In order to ensure reporting consistency among issuers and ensure that QIA expenses included in the MLR numerator represent actual value provided for consumers' premium dollars, we propose to amend § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses.

We seek comment on this proposal.

3. Allocation of Expenses (§ 158.170)

As noted in part 2 of the 2022 Payment Notice final rule, on March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus, et al.* v. *Cochran*, 523 F. Supp. 3d 731 (D. Md. 2021). Among other things, the court vacated § 158.221(b)(8), which provided that beginning with the 2017 MLR reporting year, an issuer had the option of reporting an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuer's actual expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151.[367] Accordingly, in part 2 of the 2022 Payment Notice final rule, we finalized the deletion of § 158.221(b)(8) and removed the option allowing issuers to report the fixed, standardized amount of QIA and reverted to requiring issuers to itemize QIA expenditures, beginning with the 2020 MLR reporting year (MLR reports that were due by July 31, 2021). However, we inadvertently failed to make a conforming amendment to

[367] 86 FR 24140.

§ 158.170(b). Section 158.170 addresses allocation of expenses in relation to MLR reporting in general. Section 158.170(b) requires issuers to describe the methods used to allocate expenses. Specifically, § 158.170(b) requires the report required in § 158.110 to include a detailed description of the methods used to allocate, among other things, ''quality improvement expenses (unless the report utilizes the percentage of premium option described in § 158.221(b)(8), in which case the allocation method description should state so),'' to each health insurance market in each State. Given the deletion of § 158.221(b)(8) in part 2 of the 2022 Payment Notice final rule, the reference in § 158.170(b) to the percentage of premium QIA reporting option described in § 158.221(b)(8) is no longer applicable. Accordingly, we propose make a technical amendment to § 158.170(b) to correct this oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8).

G. Solicitation of Comments on Health Equity, Climate Health, and Qualified Health Plans

On January 20, 2021, President Biden issued Executive Order 13985, titled ''Advancing Racial Equity and Support for Underserved Communities through the Federal Government,'' which established a government-wide approach to advancing equity and addressing disparities for historically marginalized communities in the United States. The order defines equity as ''the consistent and systematic fair, just and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment.'' [368]

CMS' Office of Minority Health (CMS OMH) aligns with Healthy People 2030 that defines health disparities as ''a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion.'' [369]

In alignment with the objectives set forth by the President's Executive Order and CMS OMH, CMS aims to proactively advance health equity and improve the health of all Americans, including racial and ethnic minorities, sexual and gender minorities, people with disabilities, individuals with limited English proficiency, rural populations, and historically underserved communities.

Section 1311(e)(1)(B) of the ACA states an Exchange may certify a health plan as a QHP if the Exchange determines that making available such health plan through such Exchange is in the interests of qualified individuals and qualified employers. Section 1321(a)(1) of the ACA provides the Secretary with general rulemaking authority, including with respect to setting standards for meeting the requirements for offering QHPs through Exchanges and such other requirements as the Secretary determines appropriate. In addition to the proposals in this rule,[370] CMS is considering other ways to incorporate health equity standards by using the Secretary's authority to enhance criteria for the certification of QHPs and/or leverage existing QHP requirements, such as the Network Adequacy Standards at 45 CFR 156.230 and Accreditation of QHP Issuers at 45 CFR 156.275. Furthermore, CMS seeks input on additional ways to incentivize QHP issuers to improve health equity and improve conditions in enrollees' environments, as well as to address other SDOH outside of the QHP certification process.

CMS seeks comment from stakeholders on advancing health equity through QHP certification standards; advancing CMS's understanding of the existing landscape of issuer collection of health equity data; and assessing data sources that focus on population-level factors made available by governments, quasi-governmental entities, data vendors and other organizations, both generally and with respect to the following specifics:

- CMS seeks input on:

++ Requiring QHP issuers to obtain the National Committee for Quality Assurance (NCQA) Health Equity Accreditation in addition to their existing accreditation requirements,

++ Other health equity assessment tools that achieve this goal, and (3) the challenges QHP issuers could face implementing a new accreditation product on health equity.[371]

- What demographic and/or SDOH data do QHP issuers currently collect from enrollees? Should QHP issuers be required to collect demographic and other SDOH data to help issuers gain a better understanding of the populations they serve, and thereby develop more equity-focused QHPs? Which data elements should be considered to advance health equity within QHPs? What are some of the challenges and barriers to collect this data?
- What datasets related to population factors could CMS leverage to analyze whether QHP networks are providing adequate access to health care services for members within specific geographic areas?
- What ability do QHP issuers have to tailor provider networks based on the health needs of enrollees in specific geographic areas?
- What health conditions or outcome variables should CMS analyze to identify gaps in the health care services? What are some of the ways that CMS could measure QHP issuers' progress toward advancing health equity?
- Should CMS encourage QHP issuers to be accountable for improving health outcomes across all populations equitably, while acknowledging variations in SDOH?
- Are there ways that CMS could incentivize QHP issuers to advance health equity outside of the QHP certification requirement, such as through other federal reporting requirements, including MLR reporting?
- What are the challenges QHP issuers face in promoting and advancing health equity? What are some strategies that could overcome those challenges?
- What other health equity tools made available by organizations should CMS consider to address health disparities within QHPs?

HHS further seeks to explore how Exchanges and their constituent organizations can more fully prepare for the harmful impacts of climate change on their enrollees. Since we know that climate change causes great and growing harm to Americans (through both catastrophic events and chronic disease) and since we know that it will disproportionately harm vulnerable populations, including those groups subject to health disparities described

[368] Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Executive Office of the President. 2021, *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[369] *https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/questions-answers.*

[370] See, for example, the proposed updated quality standards under 45 CFR 156.1130 for QHP issuer quality improvement strategies and interoperability requirements under 45 CFR 156.221 for QHP issuers in the FFE to implement and maintain a patient access application programming interface.

[371] *https://store.ncqa.org/accreditation/health-equity-he.html.*

above, HHS and CMS believe that it is critical to study and prepare for these dire impacts. Generally, HHS seeks input on how Qualified Health Plans can more effectively: (1) Determine likely climate impacts on their enrollees and particularly the most vulnerable enrollees; (2) determine potential costs of these impacts; (3) develop plans to mitigate catastrophic and chronic impacts for these populations (that is, plans for resilience); and (4) take responsibility for greenhouse gas emission reduction across the networks of organizations that make up their exchanges. Specific questions include:

- Do Exchanges and issuers have a plan to assess, reduce or mitigate its emissions in its operations or organizations?
- What data do Exchanges and issuers currently collect with respect to the climate threats faced by their enrollees and particularly their most vulnerable enrollees? Do they complete risk assessments or surveys that have a geographic or population focus?
- What types of utilization reviews could issuers perform of medical or prescription data to better understand the impact of climate change events on their enrollees?
- Do National Committee for Quality Assurance (NCQA) health equity requirements include reviews of climate resilience?
- What would incentivize Exchanges and issuers participating in those Exchanges to more fully prepare for climate change's impacts on vulnerable populations? What would incentivize them to take action on decarbonization? How can issuers strengthen the overall health of their enrollees to be more resilient to harmful climate change events?
- Do issuers currently use, or could they use, apps and/or AI to alert enrollees of severe climate events and steps to mitigate related harmful effects (for example, extreme heat or wildfire events)?
- What measures would be appropriate for assessing QHP performance on climate change and health equity?

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. This proposed rule contains information collection requirements that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 22. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[372] Table 21 in this proposed rule presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage. As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 21: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Management Analyst	13-1111	$46.91	$46.91	$93.82
Business Operations Specialist	13-1199	$37.66	$37.66	$75.32
Operations Manager	11-1021	$60.45	$60.45	$120.90
Computer and Information Systems Manager	11-3021	$77.76	$77.76	$155.52
Eligibility Interviewers, Government Programs	43-4061	$23.07	$23.07	$46.14
Computer System Analyst	15-1121	$47.61	$47.61	$95.22
Computer Programmer	15-1251	$45.98	$45.98	$91.96
Computer & Information Systems Manager	11-3021	$77.76	$77.76	$155.52
Compliance Officer	13-1041	$36.35	$36.35	$72.70
Web Developer and Digital Interface Designer	15-1257	$41.10	$41.10	$82.20

[372] See May 2020 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at *https://www.bls.gov/oes/current/oes_stru.htm.*

B. ICRs Regarding State Flexibility for Risk Adjustment (§ 153.320)

We are proposing to generally repeal the ability of states to request a reduction in risk adjustment state transfers in any state market risk pool starting with the 2024 benefit year, with an exception for states that previously participated in risk adjustment state flexibility. We propose to provide an exception for states that previously submitted state flexibility requests under § 153.320(d) so that only those states would be able to continue to request this flexibility in 2024 and future benefit years. We further propose to remove as an option for a prior participant justification and HHS approval of a state flexibility request the demonstration of state-specific circumstances that warrant an adjustment to more precisely account for relative risk differences in the state individual catastrophic, individual non-catastrophic, small group, or merged market risk pool, and to retain as the only option for state justification and HHS approval the demonstration that the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments. This change would also apply beginning with 2024 prior participant benefit year requests from prior participant states. As such, we propose various amendments to the risk adjustment state flexibility regulations at § 153.320(d) to reflect the general repeal of this flexibility, with the exception for states that previously participated, and to remove one of the criteria for state justification and HHS approval beginning with benefit year 2024 requests. The burden associated with this requirement is the time and effort for the state regulator to submit its request and supporting evidence and analysis to HHS. We estimate that submitting the request and supporting evidence and analysis will take a business operations specialist 40 hours (at a rate of $75.32 per hour) to prepare the request and 20 hours for a senior operations manager (at a rate of $120.90 per hour) to review the request and transmit it electronically to HHS. We estimate that each state seeking a reduction will incur a burden of 60 hours at a cost of approximately $5,430.80 per state to comply with this reporting requirement (40 hours for the insurance operations analyst and 20 hours for the senior manager). The estimated burden related to submission of these requests would be reduced as a result of these proposed changes, since only one state, Alabama, previously participated and would still be able to request this flexibility. In the 2019 Payment Notice,[373] we estimated that 25 states would submit requests and provided a total burden of approximately 1,500 hours across all states, which would total $135,770 based on current wage estimates. Since there is only one prior participating state, we estimate that this burden will be reduced by $130,339.20 to a total annual cost of $5,430.80, reflecting the burden associated with one state's submission. This information collection is approved under OMB control number 0938–115, and if this proposal is finalized, HHS would revise the information collection under OMB control number 0938–1155 accordingly and provide the applicable comment periods.

C. ICRs Regarding Distributed Data and Risk Adjustment Data Submission Requirements (§§ 153.610 and 153.710)

Pursuant to section 1343(b) of the ACA, the Secretary, in consultation with states, shall establish criteria and methods to be used in carrying out the risk adjustment activities under this section. Consistent with section 1321(c) of the ACA, the Secretary is responsible for operating the risk adjustment program in any state that fails to do so. As described in § 153.610, health insurance issuers are required to maintain risk adjustment data in order for HHS to operate risk adjustment on behalf of a state. HHS employs a distributed data approach when running risk adjustment on behalf of a state and uses the same data for the purpose of determining the risk adjustment user fee for each issuer. In this proposed rule, we propose to collect five new data elements from issuers' EDGE servers through issuers' Edge Server Enrollment Submission (ESES) files and risk adjustment recalibration enrollment files: ZIP code, race, ethnicity, ICHRA indicator and subsidy indicator. We also propose to extract these new data elements as part of the enrollee-level EDGE data beginning with the 2023 benefit year. In addition, we propose to begin extracting three data elements issuers already report to their EDGE servers—plan ID, rating area and subscriber indicator—as part of the enrollee-level EDGE data beginning with the 2022 benefit year.

Section 153.700(a), requires an issuer of a risk adjustment covered plan in a state where HHS is operating the risk adjustment program to provide HHS, through its dedicated distributed data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by plan ID, rating area, and subscriber indicator. Thus, the proposals to extract these data elements will not pose additional operational burden to issuers, since the creation and storage of the extract—which issuers do not receive—is mainly handled by HHS. Therefore, we are not proposing to change the existing burden for the proposal to extract plan ID, rating area, and subscriber indicator.

For the five new data elements we propose to collect beginning with the 2023 benefit year, we estimate that approximately 600 issuers would be subject to this new data collection. We propose to collect these new data elements via issuers' ESES files and risk adjustment recalibration enrollment files. We estimate a cost of approximately $375.28 in total labor costs for each issuer, which reflects 4 hours of work by a management analyst per issuer at an average hourly rate of $93.82 per hour. The cumulative additional cost estimate as a result of this proposal is $225,168 for 600 issuers (2,400 total hours per year for all issuers). The proposals to extract these data elements will not pose additional operational burden to issuers, since the creation and storage of the extract is mainly handled by HHS. If the proposed collection of ZIP code, race, ethnicity, the ICHRA indicator, and the subsidy indicator are finalized, we would revise the information collection under OMB control number 0938–1155 accordingly and provide the applicable comment periods.

D. ICRs Regarding Ability of States To Permit Agents and Brokers and Web-Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

We propose to revise § 155.220(c)(3)(i)(A) to include at proposed new §§ 155.220(c)(3)(i)(A)(1) through (5) a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We also propose to revise the disclaimer requirement in § 155.220(c)(3)(i)(A) so that web-broker non-Exchange websites would be required to prominently display a standardized disclaimer provided by HHS stating that enrollment support is available on the Exchange website and provide a web link to the Exchange website where enrollment support for a QHP is not available using the web-broker's non-Exchange website.

[373] 82 FR at 51118.

This proposal should result in very limited new burden for web-brokers. The proposed new standardized disclaimer would require web-brokers to make minor updates to their non-Exchange websites in cases where they do not support enrollment in all available QHPs. However, in those cases, web-brokers would be displaying a disclaimer much like the plan detail disclaimer that they have historically been required to display.

We estimate this proposal will affect approximately 20 web-brokers based on the number of web-brokers currently approved by CMS and our internal knowledge of entities that have expressed interest in becoming web-brokers. Given the minor modifications necessary to implement the revised disclaimer in this proposal, we estimate a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this proposal is $8,220 for 20 web-brokers in the 2022 benefit year. If this proposal is finalized, we would revise the information collection under OMB control number 0938–1349 accordingly and provide the applicable comment periods.

We propose to amend § 155.220 to add a proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on their websites (for example, alphabetically based on plan name, from lowest to highest premium, etc.). We believe this proposed new requirement would provide consumers with a better understanding of the information being presented to them on web-broker websites, thereby enabling them to make better informed decisions and shop for and select QHPs that best fit their needs.

We support web-broker websites' use of innovative decision-support tools for consumers to help them shop for and select QHPs that best fit their needs. However, web-broker websites that explicitly recommend or rank QHPs do not always provide an explanation for their recommendations or rankings. Similarly, web-broker websites may not include an explanation of the methodology used for their default displays of QHPs, and it may not otherwise be apparent what methodologies are used. The absence of such explanations may cause some consumers to misunderstand the bases for the recommendations displayed to them on web-broker websites (whether explicit or implicit), or may prevent them from assessing the value of the recommendations (for example, whether a recommendation is based on the factors most important to them). In addition, the lack of explanations for QHP recommendations on web-broker websites may obscure that the web-broker is recommending QHPs based on compensation the web-broker receives from QHP issuers in violation of § 155.220(c)(3)(i)(L). For these reasons, we propose to amend § 155.220 to add proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for QHP recommendations and the methodology for their default display of QHPs.

This proposal should result in very limited new costs for web-brokers, since the information it would require they display on their websites would only require text-based changes that are relatively easy to implement. Furthermore, the extent of those textual updates should be relatively minor in most cases. For example, if a web-broker is recommending a QHP based on the fact that it has the lowest monthly premiums for a consumer, that can likely be communicated in one or two sentences of informational text, or possibly even in a single phrase or set of short bullet points. Some web-brokers are already providing the information that would be required by this proposal, and therefore would not have to make any website updates. Other web-broker websites do not explicitly recommend QHPs, and therefore the impact of this proposal would be limited to providing similar information about the methodology for their default display of QHPs (for example, explaining QHPs are sorted from lowest to highest premium, etc.), assuming they do not already provide that information.

We estimate this proposal will affect approximately 20 web-brokers. Given the minor text-based changes necessary to implement the informational text detailing the rationale for QHP recommendations and the methodology for a default display of QHPs, we estimate a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this proposal is $8,220 for 20 web-brokers in the 2022 benefit year. If this proposal is finalized, we would revise the information collection under OMB control number 0938–1349 accordingly and provide the applicable comment periods.

E. ICRs Regarding Verification of Eligibility for Special Enrollment Periods (§ 155.420)

Since 2017, the Exchanges on the Federal platform have implemented pre-enrollment special enrollment period verification for special enrollment period types commonly used by consumers to enroll in coverage. We propose to amend § 155.420 to add new paragraph (g) to state that Exchanges may conduct pre-enrollment eligibility verification for special enrollment periods at the option of the Exchange. The Exchanges on the Federal platform would verify special enrollment period eligibility for the most common special enrollment period type, loss of minimum essential coverage. This special enrollment period type comprises the majority of all special enrollment period enrollments on the Exchanges on the Federal platform.

Since consumers on Exchanges on the Federal platform currently must provide eligibility verification documentation for more special enrollment period types, the provision would decrease burden on consumers applying for special enrollment period types that no longer require pre-enrollment verification. We expect that it takes an individual, on average, about 1 hour to gather and submit the relevant documentation needed for pre-enrollment special enrollment period eligibility verification. This estimate is based on the assumption that each individual required to submit documentation will submit, on average, two documents for review. It could take significantly less time if an individual already has the documents on hand, or more time if the individual needs to procure documentation from a government agency or other source.

Based on enrollment data for Exchanges on the Federal platform, we estimate that HHS eligibility support staff members would conduct pre-enrollment verification for 194,000 fewer individuals. We estimate that Once individuals have submitted the required verification documents, it would take an Eligibility Interviewer approximately 12 minutes (at an hourly cost of $46.14) to review and verify submitted verification documents. In 2017, the Exchanges on the Federal platform expanded pre-enrollment special enrollment period verification to include five special enrollment period types and estimated an annual additional administrative burden of

130,000 hours at a cost of $5,306,600.[374] Limiting pre-enrollment verification to one special enrollment period type would decrease the annual administrative burden of special enrollment period verification. The proposed change would result in a decrease in annual burden for the federal government of 38,800 hours at a cost of $1,790,232. It would also result in a decrease in annual burden for consumers attesting to special enrollment period types that no longer require document verification of 194,000 hours.

The proposed information collection requirements and the related burden decrease discussed in this section will be submitted for OMB review and approval as part of a revision of the information collection currently approved under OMB control number 0938–1207 (Expiration date: February 29, 2024).[375]

F. ICRs Regarding General Program Integrity and Oversight Requirements (§ 155.1200)

We propose to add § 155.1200(e) to permit a State Exchange to meet the requirement to conduct an annual independent external programmatic audit, as described at § 155.1200(c), by completing an audit that year under the SEIPM audit process we propose under Part 155, subpart P. We estimate that there would be a burden reduction for State Exchanges related to the programmatic audit requirement under § 155.1200(c). In particular, the 18 State Exchanges that manage their own eligibility and enrollment platforms would no longer be required to dedicate resources to procure and reimburse auditing entities for services rendered to complete the annual independent external programmatic audits, assuming the State Exchanges were instead completing the required SEIPM program process that year. Based on industry estimates of the average cost of contracting an auditor to conduct an independent external programmatic audit, HHS estimates that the cessation of contracting such audit entities would result in an annual cost reduction of approximately $90,000 for each State Exchange, which is described in detail in the RIA section of this rule.

Additionally, staff resources would no longer be needed to submit the results of the programmatic audit as a component of the State-based Marketplace Annual Reporting Tool (SMART). This would result in a reduction in cost and staff resources for each State Exchange. We anticipate a reduction in cost associated with compiling data, summarizing the programmatic audit results, and submitting to CMS. State Exchanges are required to provide the results of the programmatic audit in a public summary. This proposal would remove the burden associated with reporting requirements, which includes the burden for a management analyst taking 3 hours (at $93.82 an hour) to pull data into a report, the time and effort necessary for a policy analyst taking 2 hours (at $93.82) to prepare the report of the audit results, and the time for a senior manager taking 1 hour (at $155.52 an hour) to review and submit to CMS. We estimate the burden of 6 hours at a cost of $624.62 for each State Exchange. Therefore, the aggregate burden for the 18 State Exchanges that manage their own eligibility and enrollment platforms is 108 hours at a cost of $11,243.16.

Based on these estimates we expect the cost reduction associated with compiling and reporting audit data to total $11,243.16 across all 18 State Exchanges beginning in the 2024 benefit year. The information collection associated with the burden being reduced is covered under OMB Control Number 0938–1244. If this rule is finalized as proposed, we would revise the burden estimates covered under 0938–1244 before the implementation of the SEIPM program.

We estimate this impact to take effect in June 2024 at the earliest, which is when the State Exchanges would otherwise be providing completed independent external audits as a component of their PY 2023 SMART submissions. There would, however, be a corresponding new burden created to complete the SEIPM process. For an estimate of the burden created under SEIPM, please refer to section 14.

We request comment on the reduction in burden proposed, and specifically seek feedback from State Exchanges regarding the annual cost of the programmatic audit process.

G. ICRs Regarding State Exchange Improper Payment Measurement Program (§§ 155.1500–155.1540)

1. Data Collection (§ 155.1510)

In the preamble to § 155.1510, we explain the sampling process for each SEIPM review cycle. In § 155.1510(a)(1), we propose that HHS will provide State Exchanges with the pre-sampling data request, which State Exchanges will complete and return to HHS. Both the pre-sampling data request and the requested source data are in an electronic format. The burden associated with completion and return of the pre-sampling data request would be the time it would take each State Exchange to interpret the requirements, analyze and design the database queries based on the data elements identified in the SEIPM data request form, develop the database queries, test the data, perform verification and validation of the data, and return the form to HHS.

Once the pre-sampling data request is returned to HHS, HHS will draw the sample for each State Exchange. In § 155.1510(a)(2), we propose that HHS will provide the sampled unit data request to the State Exchange for completion and return to HHS. The sampled unit data request will include the sampled units specific to each State Exchange. Both the sampled unit data request and the requested source data are in an electronic format. The burden associated with completion and return of the sampled unit data request would be the time it would take each State Exchange to interpret the requirements, analyze and design the database queries based on the data elements identified in the SEIPM data request form, develop the database queries, test the data, perform verification and validation of the data, and return the form to HHS.

We expect respondent costs will not substantially vary since the data being collected is largely in a digitized format and that each State Exchange will be providing information for approximately 100 sampled units. We do not expect reporting costs to vary considerably based on sample size. We seek comment on these assumptions.

We estimate completion of the pre-sampling data request would take 12 hours per respondent at an estimated $1,364 per respondent. We estimate completion of the sampled unit data request would take 707 hours per respondent at an estimated cost of $73,054 per respondent. To compile our estimates, we referenced our experience in collecting data in our FFE pilot initiative. We identified specific personnel and the number of hours that would be involved in collecting the sampled unit data broken down by specific area (for example, eligibility verification, auto re-enrollment, periodic data matching, enrollment reconciliation, plan management, and manual reviews including document retrieval). Additionally, to account for the time needed for any State Exchanges to convert hard copies to a digitized format, we added 20 hours for each

[374] 82 FR 18346.

[375] Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment (CMS–10468).

State Exchange into the burden estimates.

Hourly wage rates are based on May 2020 Bureau of Labor Statistics Occupational Codes and vary from $45.98 (adjusted to $91.96 to account for overhead) to $77.76 (adjusted to $155.52 to account for overhead) depending on occupation code and function. With a mean hourly rate of $103.50 for the respective occupation codes, the burden across the 18 State Exchanges equals 12,942 hours for a total cost of up to $1,339,523. The burden related to this information collection is being submitted to OMB for approval with this proposed regulation.

2. Determination of Error Findings Decision and Appeal Redetermination (§§ 155.1525 and 155.1530)

As described in the preamble to § 155.1525, Redetermination of Error Findings Decision, a State Exchange may file a request with HHS to resolve issues with HHS' findings within the deadline prescribed in the annual program schedule.

The burden associated with the information collection requirements contained in §§ 155.1525 and 155.1530 is the time and effort necessary to draft and submit a request for a redetermination of an error findings decision and, if requested, an appeal of a redetermination decision. In accordance with 5 CFR 1320.4, information collected during the conduct of an administrative action is not subject to the PRA. As a result, we believe the burden associated with these requirements is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i).

3. Corrective Action Plan (§ 155.1535)

As described in the preamble to § 155.1535, we are proposing that State Exchanges may be required to develop and implement corrective action plans following a completed SEIPM measurement designed to reduce improper payments as a result of eligibility determination errors. The burden associated with this requirement is the time and effort put forth by State Exchanges to develop and submit a corrective action plan to HHS. We estimate that it would take each selected State Exchange up to 1,000 hours to develop a CAP. We estimate that the total annual burden associated with this requirement for up to 18 State Exchange respondents would be up to 18,000 hours. Assuming the management analyst average hourly rate of $93.82 per hour, we estimate that the cost of a corrective action plan per State Exchange could be up to $93,820, and for all 18 State Exchanges, up to $1,688,760. The burden related to this information collection will be submitted to OMB for approval after future rulemaking has been completed regarding the CAP process and requirements.

H. ICRs Regarding State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

We are proposing to eliminate the requirement at § 156.111(d) and (f) to require states to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any state-required benefits applicable to QHPs in the individual or small group market that are considered to be in addition to EHB in accordance with § 155.170(a)(3) and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination.

Under this proposal, states would no longer be required to submit an annual report that complies with each requirement listed at § 156.111(f)(1) through (6), nor would HHS identify which benefits are in addition to EHB for the applicable PY in the state if a state does not submit an annual reporting package.

As states are already required under § 155.170 to identify which state-required benefits are in addition to EHB and to defray the cost of QHP coverage of those benefits, the 2021 Payment Notice estimated that a majority of states, approximately 41, would submit annual reports and that 10 states would not submit annual reports.[376]

The 2021 Payment Notice estimated that the burden for each state to meet this reporting requirement in the first year would be 30 hours, with an equivalent cost of approximately $2,459, with a total first year burden for all 41 states of 1,230 hours and an associated total first year cost of approximately $100,829. Because the first year of annual reporting was intended to set the baseline list of state-required benefits which states would update as necessary in future annual reporting cycles, the 2021 Payment Notice explained that the burden associated with each annual reporting thereafter would be lower than the first year. The 2021 Payment Notice therefore estimated that for each annual reporting cycle after the first year the burden for each state to meet the annual reporting requirement would be 13 hours with an equivalent cost of approximately $1,117, with a total annual burden for all 41 states of 533 hours and an associated total annual cost of approximately $45,817. The average annual burden over 3 years was estimated at approximately 765 hours with an equivalent average annual cost of approximately $64,154.

Given that we did not require states to submit annual reports in 2021 pursuant to our enforcement posture in part 2 of the 2022 Payment Notice final rule, if finalized as proposed, repealing the annual reporting requirement would also remove the associated ICRs and the anticipated burden on states submitting such reports. Thus, if finalized as proposed, we will request discontinuation of the ICRs associated with the repealed annual reporting requirement (OMB control number: 0938–1174 Essential Health Benefits Benchmark Plans (CMS–10448)/ Expiration date: February 29, 2024).

I . ICR Regarding Differential Display of Standardized Options on the Websites of Web-Brokers (§ 155.220) and QHP Issuers (§ 156.265)

In the current rulemaking, we consider resuming the differential display of standardized options per the existing authority at § 155.205(b)(1). We also consider resuming enforcement of the standardized options differential display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively.

We estimate that a total of 110 web-brokers and QHP issuers participating in the FFEs and SBE–FPs would be required to comply with these requirements. We estimate that it would take a web developer/digital interface designer (OES occupational code 15–1257) 2 hours annually, at an average hourly cost of $82.20 per hour, to implement these changes, at a total annual cost of $164.40 per entity. We therefore estimate a total annual burden of 220 hours at a cost of $18,804 for all applicable web-brokers and QHP issuers.

Consistent with the approach finalized in the 2018 Payment Notice,[377] we continue to recognize that system constraints may prevent web-broker and QHP issuers from mirroring the *HealthCare.gov* display. We would therefore continue to permit web-brokers and QHP issuers that use a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP to submit a request to deviate from the display on *HealthCare.gov*, with approval from HHS. Any requests from

[376] 85 FR 29164, 29244.

[377] See 81 FR at 94118.

web-brokers and QHP issuers seeking approval for an alternate differentiation format would be reviewed based on whether the same level of differentiation and clarity is being provided under the requested deviation as is provided on *HealthCare.gov*.

We estimate that 55 of the above web-brokers and QHP issuers would submit a request to deviate from the manner in which standardized options are differentially displayed on *HealthCare.gov*. We estimate it would take a compliance officer (OES occupational code 13–1041) approximately 1 hour annually, at a rate of $72.70 per hour, to complete the request to deviate from the display on *HealthCare.gov* as well as the justification for the request. We therefore estimate a total annual burden for all web-brokers and issuers subject to the differential display requirements submitting a request to deviate of approximately $3,998.50 beginning in 2023.

To account for the burden associated with this ICR, HHS will submit a revised version of the existing PRA package for Non-Exchange Entities (under OMB control number: 0938–1329 (CMS–10633)) which was previously discontinued on March 4, 2020. This proposed rule serves as the initial notice for the revised PRA package.

J. ICRs Regarding Network Adequacy and Essential Community Providers (§§ 156.230 and 156.235)

In this rule, HHS is proposing amendments to § 156.230, including adoption of standards related to time and distance and appointment wait time to assess QHP issuers' fulfillment of the reasonable access network adequacy standard. HHS is proposing to raise the ECP threshold from 20 percent to 35 percent. Issuers will continue to submit provider facility information and geographic location of participating ECPs participating in an issuer's provider network or other documentation necessary to demonstrate that an issuer has a sufficient number and geographic distribution of ECPs for the intended service areas. This is done to ensure QHP enrollees have reasonable and timely access to providers that serve predominantly low-income, medically underserved individuals in accordance with ECP inclusion requirements found at § 156.235.

Additionally, issuers must collect and submit provider information necessary to demonstrate satisfaction of time and distance standards and appointment wait time standards to ensure that an issuer's network has fulfilled the network adequacy reasonable access standard found at § 156.230. Lastly, an issuer must report the offering of telehealth services for each provider to help inform future development of telehealth standards. We would provide the definition of telehealth and ask issuers to respond yes or no as to whether each network provider offers telehealth. As described in the preamble, issuers who do not have the information available by the time of the QHP certification process would be able to respond that they have requested the information from the provider and are awaiting the response.

HHS anticipates burden for completing the ECP/NA template will increase based on the changes in this proposed rule to an estimated 20 hours in total for each medical QHP submitted by issuers and 4 hours in total for each SADP submitted by issuers. This estimate is inclusive of the requirement to report provider facility information and geographic location of ECPs in an issuer's provider network. Since we propose to raise the ECP threshold from 20 percent to 35 percent, QHP issuers will need to submit information on a sufficient number of their contracted ECPs to meet the higher threshold.[378] Some issuers have previously only included enough contracted ECPs on the template in order to meet the current threshold for that year's certification process. For those issuers, the proposed increase in the ECP threshold would somewhat increase burden in completing the ECP/NA template as they would need to include more contracted ECPs on the template to meet the standard. Notwithstanding, HHS estimates that the burden associated with showing compliance with the increased ECP threshold will account for 3 hours of the total 20 hours we estimate for completing the ECP/NA template for medical QHPs and 1 hour of the total 4 hours we estimate for SADPs.

The 20-hour burden estimate for the ECP/NA template also includes burden resulting from the requirement that QHP issuers report information relevant to compliance with time and distance standards and appointment wait time standards. For PYs 2018–2022, HHS deferred reviews of network adequacy for QHPs to states that HHS determined to have a sufficient network adequacy review process, which was all FFE states for that time period. As HHS resumes network adequacy reviews, we are proposing to include a broader provider specialty list for time and distance standards than was evaluated for PYs 2015–2017, and to add appointment wait time standards. HHS estimates that the burden associated with the requirement that QHPs report information sufficient to show compliance with the proposed network adequacy standards would account for 12 of the total 20 hours we estimate for completing the ECP/NA template for medical QHPs, and 1 hour of the total 4 hours we estimate for SADPs.

The 20-hour estimate also includes the burden associated with the requirement that issuers report whether network providers provide telehealth services. HHS believes that many QHP issuers already collect and maintain information on whether network providers furnish telehealth services. Approximately half of the parent companies of issuers on the FFEs also offer Medicare Advantage plans. Since Medicare Advantage offers a telehealth credit for network adequacy, we expect those issuers would already have telehealth information available for their providers. HHS further is of the view that those QHP issuers that do not currently collect this information may do so using the same means and methods by which they already collect information from their network providers relevant to time and distance standards and provider directory information. For these reasons, HHS estimates that any additional burden relative to the requirement that QHP issuers report whether each network provider is furnishing telehealth services would lead to a minimal increase in burden for many issuers. The requirement to report whether providers offer telehealth services would account for four of the total 20 hours we estimate for completing the ECP/NA template for medical QHPs and 1 of the total 4 hours we estimate for SADPs. Finally, we estimate it will take 1 hour for issuers, including both medical QHPs and SADPs, to submit the ECP/NA template and complete the portions of the Issuer Module that are relevant to these reviews.

We estimate that the total annual burden associated with completing the additional requirements proposed in this rule within the ECP/NA template for medical QHPs for up to 215 issuers would be up to 4,300 hours. Assuming the compliance officer average hourly rate of $36.35 per hour, we estimate that the cost of completing the ECP/NA template for an individual medical QHP could be up to $1,454, and for all 215 issuers, up to $312,610. We estimate that the total annual burden associated

[378] The ECP/NA template requires QHP issuers to report only that number of providers sufficient to demonstrate compliance with relevant requirements.

with this requirement for SADPs for up to 270 issuers would be up to 1,080 hours. Assuming the compliance officer average hourly rate of $36.35 per hour, we estimate that the cost of completing the ECP/NA template for an individual SADP could be up to $290.80, and for all 270 issuers, up to $78,516. The total estimated cost for the annual burden associated with completing the ECP/NA template across both medical QHP and SADP issuers is $391,126.

HHS is submitting a new information collection package to OMB to cover data collection related to essential community provider and network adequacy requirements, which will include the changes proposed in this proposed rule. This proposed rule serves as the initial notice for the PRA package. The existing information collection package for QHP certification (under OMB control number: 0938–1187 (CMS–10433)/Expiration date: June 30, 2022) includes the data collection and burden information for the ECP/NA template, outside of what is proposed in this rule.

K. ICRs Regarding Payment for Cost-Sharing Reductions (§ 156.430)

In this rule, HHS is proposing several amendments to § 156.430 to clarify that CSR data submission is mandatory for those issuers that received CSR payments from HHS for any part of the benefit year, and voluntary for other issuers. The currently approved burden estimate is a total cost of $235,683 (2,362.50 hours) across 150 issuers ($1,571.22 per issuer), which accounts for 0.75 hours per issuer to complete and submit the Issuer Summary Report to HHS each year and 15 hours per issuer to complete and submit the Standard Methodology Plan and Policy Report to HHS each year.[379] We expect that these proposals will reduce the burden associated with the CSR data submission process when HHS is not making CSR payments to QHP issuers, as we expect that the number of issuers submitting CSR data each year will decrease due to these proposals. We have revised the information collection currently approved under OMB control number: 0938–1266 (Cost-Sharing Reduction Reconciliation (CMS–10526)/Expiration date: July 31, 2024) to account for this decreased burden when HHS is not making CSR payments to QHP issuers.

L. ICRs Regarding Quality Improvement Strategy (§ 156.1130)

We are not proposing to amend regulatory text in 45 CFR 156.1130 which outlines QIS standards established in the 2016 Payment Notice. The information collections associated with QIS data collection and submission requirements are approved under OMB control number 0938–1286 (Quality Improvement Strategy Implementation Plan and Progress Report (CMS–10540)/Expiration date: February 25, 2024) and encompasses the estimated burden and costs associated with a QIS submission that may include several QIS topic areas. In this proposed rule, we propose that beginning in 2023, a QHP issuer would be required to address reducing health and health care disparities as one of their QIS topic areas in addition to at least one other topic area outlined in section 1311(g)(1) of the ACA, including: Improving health outcomes of plan enrollees, preventing hospital readmissions, improving patient safety and reducing medical errors, and promoting wellness and health. We do not estimate additional burden to be accounted for since the QIS submission form currently approved under OMB control number: 0938–1286 (Quality Improvement Strategy Implementation Plan and Progress Report (CMS–10540)/Expiration date: February 25, 2024) already encompasses the estimated burden and costs associated with a QIS submission that may include several QIS topic areas.

M. ICRs Regarding Medical Loss Ratio (§§ 158.140, 158.150, 158.170)

We propose to amend § 158.140 to clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. We also propose to amend § 158.150 to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes. We further propose to make a technical amendment to § 158.170(b) to correct an oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8), which was deleted in part 2 of the 2022 Payment Notice final rule. We anticipate that implementing these provisions would require minor changes to the MLR Annual Reporting Form Instructions, but would not significantly increase the associated reporting burden. The burden related to this information collection is currently approved under OMB control number: 0938–1164 (Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS–10418)). The control number is currently set to expire on July 31, 2024.

O. Summary of Annual Burden Estimates for Proposed Requirements

[379] OMB control number 0938–1266 (Cost-Sharing Reduction Reconciliation (CMS–10526)/Expiration date: July 31, 2024).

TABLE 22: Proposed Annual Recordkeeping and Reporting Requirements (New Burden)

Regulation Section(s)	OMB control number	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Cost ($)
§§ 153.610 and 153.710	0938-1155	600	600	4	2,400	$225,168	$225,168
§ 155.220	0938-1349	20	40	5	200	$16,440	$16,440
§ 155.1510	0938-NEW	18	18	719	12,942	$1,339,523	$1,339,523
§ 155.1535	0938-NEW	18	18	1,000	18,000	$1,688,760	$1,688,760
§§ 156.230 and 156.235	0938-NEW	485	485	20	5,380	$391,126	$391,126
§§ 155.220 and 156.265	0938-1329	55	55	1	55	$3,998.50	$3,998.50
§§ 155.220 and 156.265	0938-1329	110	110	2	220	$18,804	$18,804
Total				1,751	39,197	$3,683,819.50	$3,683,819.50

TABLE 23: Proposed Annual Recordkeeping and Reporting Requirements (Reduction)

Regulation Section(s)	OMB control number	Original Number of Respondents	Number of Respondents (if reduced)	Burden per Response (hours)	Reduced Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Cost ($)
§ 153.320	0938-1155	25	1	60	-1,440	-$130,339.20	-$130,339.20
§ 155.1510*	0938-1207	n>10		.2	-38,800	-$1,790,232	-$1,790,232
§ 155.1200	0938-1244	18	0	6	-108	-$11,243.16	-$11,243.16
§156.111	0938-1174	41	0	13	-533	-$45,817	-$45,817
Total				79.2	-40,881	-$1,977,631.36	-$1,977,631.36

*This proposal estimates a decrease in annual burden for consumers attesting to special enrollment period types that no longer require document verification, because the number of consumers enrolling through a loss of minimum essential coverage is represented as n>10 since the number is undefined.

This proposed rule includes several proposals, including information collection requests for which we seek to use this rulemaking as the **Federal Register** notice through which to receive comment on their proposed revisions to or submissions of PRA packages. These proposals include Verification of Eligibility for Special Enrollment Periods (§ 155.420), Data Collection and Corrective Action Plans related to the SEIPM Program(§ 155.1510, 155.1535), and the proposals on Network Adequacy and Essential Community Providers (§§ 156.230 and 156.235) and the proposal regarding Differential Display of Standardized Options (§§ 155.220) and 156.265).

The following proposals with associated information collection requests, including the proposal regarding State Flexibility for Risk Adjustment (§ 153.320), the proposal regarding risk adjustment Distributed Data and Risk Adjustment Data Submission Requirements (§§ 153.610 and 153.710), the proposal on General Program Integrity and Oversight Requirements (§ 155.1200), will be submitted for PRA approval outside of this rulemaking, through a separate **Federal Register** notice.

The proposals for Quality Improvement Strategy (§ 156.1130), Medical Loss Ratio (§§ 158.140, 158.150, 158.170), and Payment for Cost-Sharing Reductions (§ 156.430) contain information collections which are covered by existing PRA packages. One proposal, the State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111), proposes to discontinue the associated information collections and remove them from the PRA package, and the information collection in the Determination of Error Findings Decision and Appeal Redetermination (§§ 155.1525 and 155.1530) proposal is exempt from the PRA.

P. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS's website at *https://www.cms.gov/regulations-and-guidance/legislation/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the

ADDRESSES section of this proposed rule and identify the rule (CMS–9911–P), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due March 7, 2022.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This rule proposes standards related to the risk adjustment program for the 2023 benefit year and beyond, as well as standards for the HHS–RADV program beginning with the 2021 benefit year. This rule proposes additional standards related to eligibility redetermination, special enrollment periods, requirements for agents, brokers, web-brokers, and issuers assisting consumers with enrollment through Exchanges that use the Federal platform; state selection of EHB-benchmark plan and annual reporting of state-required benefits, termination of coverage, the MLR program, and 2023 FFE and SBE–FP user fees. This rule also proposes to remove the annual reporting requirement on states to report state-required benefits to HHS. In addition, it proposes to reinstate nondiscrimination provisions related to sexual orientation and gender identity. The rule also proposes to refine the EHB nondiscrimination framework by including examples of presumptively discriminatory cases. The rule also proposes to require issuers in FFEs and SBE–FPs to offer standardized options. This rule proposes to expand QIS standards and require QHP issuers to address health and health care disparities in their QIS submissions in addition to at least one other topic area outlined in section 1311(g)(1) of the ACA. Finally, this proposed rule would implement the PIIA requirements for State Exchanges.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4) and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any one year).

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. An RIA must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a ''significant'' regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of $100 million or more in at least 1 year. Based on HHS estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The provisions in this proposed rule aim to ensure that consumers continue to have access to affordable coverage and quality health care. Although there is still some uncertainty regarding the net effect on premiums, we anticipate that the provisions of this proposed rule would help further HHS' goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 24 depicts an accounting statement summarizing HHS' assessment of the benefits, costs, and transfers associated with this regulatory action.

This proposed rule implements standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this proposed rule. The effects in Table 24 reflect qualitative assessment of impacts and estimated direct monetary costs and transfers resulting from the provisions of this proposed rule for health insurance issuers and consumers. The annual monetized transfers described in Table 24 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers and the potential increase in rebates from issuers to consumers due to proposed amendments to MLR requirements.

We are proposing the risk adjustment user fee of $0.22 PMPM for the 2023 benefit year to operate the risk adjustment program on behalf of states, which we estimate to cost approximately $60 million in benefit year 2023.[380] We expect risk adjustment user fee transfers from issuers to the federal government to remain steady at $60 million, the same as estimated for the 2022 benefit year; this is included in Table 24.

Additionally, for 2023, we are proposing maintaining the FFE and the SBE–FP user fee rates at current levels, 2.75 and 2.25 percent of premiums, respectively.

For our proposed implementation of the State Exchange Improper Payment Measurement program, we estimate record keeping costs for data collection and corrective action plan development and implementation to be approximately $3.0 million annually beginning in PY 2023.

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[380] As noted previously in this proposed rule, no state has elected to operate the risk adjustment program for the 2023 benefit year; therefore, HHS will operate the program for all 50 states and the District of Columbia.

TABLE 24: Accounting Table

Benefits:

Qualitative:

Increased access to health insurance coverage for individuals who are currently unable to enroll in coverage because of past-due premiums.

Greater market stability resulting from updates to the risk adjustment models.

Increased access to health insurance coverage due to the proposal to decrease the scope of special enrollment period verification.

Greater protection of individuals in the LGBTQI+ community from discrimination on the basis of their sexual orientation and gender identity.

Greater consistency in protections based on EHB nondiscrimination.

Potential direct benefit of reducing improper payments, with secondary effects including a boost of insurer confidence in State Exchanges through implementation of the proposed State Exchange Improper Payment Measurement program.

- Increased access to more comprehensive provider networks and enhanced health equity[381] due to the network adequacy and ECP proposals which would better ensure that individuals have reasonable, timely access to an adequate number, type, and distribution of providers and facilities to manage their health care needs.
- Enhanced access to behavioral health providers who provide key services for vulnerable populations via the network adequacy and ECP proposals

Greater access to primary care and OB/GYN providers in recognition of the importance of preventive care for underserved populations through the network adequacy and ECP proposals

Encourage continuous quality improvement among QHP issuers to help strengthen health care system-wide efforts to improve health outcomes, lower costs, and advance health equity.

Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	-$97.7 Million	2021	7 percent	2022-2026
	-$98.9 Million	2021	3 percent	2022-2026

Quantitative:

Recordkeeping costs incurred by State Exchanges as detailed in the Collection of Information Requirements section, related to SEIPM data collection and corrective action plan development and implementation estimated to be approximately $3.0 million annually beginning in 2023.

Reduction in costs for states related to annual reporting of state-required benefits, estimated to be one-time savings of $100,829 in 2022 and annual savings of $45,817 each year thereafter.

Reduction in potential costs to Exchanges since they would not be required to conduct random sampling as a verification process for enrollment in or eligibility for employer-based insurance when the Exchange reasonably expects that it will not obtain sufficient verification data, estimated to be one-time savings of $49.5 million in 2022 and annual savings of $113 million in 2023 and onwards.

Increased costs to Exchanges to design a risk-based verification process for enrollment in or eligibility for employer sponsored coverage based on a risk assessment for inappropriate subsidy payments estimated to be about $4.7 million in one-time costs in 2022.

Annual cost savings of $5.2 million related to the proposal to decrease the scope of special enrollment period verification beginning in 2023.

- Reduction of $130,339.20 in reporting costs across states participating in risk adjustment associated with repealing the ability of states to request a reduction in risk adjustment state transfers in any state market risk pool starting with the 2024 benefit year.

Cumulative additional cost estimate for the collection of five new data elements for risk adjustment estimated to be approximately $225,168 for 600 issuers, or $375.28 per issuer annually, beginning in 2023.

Increased cost to 10 State Exchanges to implement system builds to prorate APTC and premium amounts, as proposed. Estimated $10,000,000in one-time costs for State Exchanges in the 2024 benefit year.

Increased cost to web-brokers to implement minor text-based changes to their websites to add or modify a disclaimer. Estimated $8,220 in one-time costs for 20 web-brokers in the 2022 benefit year.

- Increased cost to web-brokers to implement minor text-based changes to their websites to add text-based explanations for how they display QHPs. Estimated $8,220 in one-time costs for 20 web-brokers in the 2022 benefit year.

- Increased annual cost of $18,804 across all web- brokers and QHP issuers utilizing the Classic DE and EDE Pathways to comply with the standardized options differential display requirements in the 2023 benefit year.
- Increased annual cost of $3,998.50 across the subset of web-brokers and issuers subject to the differential display requirements submitting a request to deviate from the requirements beginning in the 2023 benefit year.
  - Increased cost to issuers for completing the updated ECP/NA template that includes a longer provider specialty list for network adequacy, appointment wait time standards, and a question on providers offering telehealth. The total estimated annual burden for medical QHP and SADP issuers to complete the updated ECP/NA template is $391,126 beginning in PY 2023.
  - Estimated Reduction in cost of $1,631,243.16 beginning in the 2024 benefit year to State Exchanges associated with new standards for completing external audits under 155.1200. This total reflects a reduction of roughly $11,000 for audit data collection and reporting, and a reduction of roughly $1.6 million for annual audit firm contracts across all State Exchanges.

Qualitative:
Potential reduction in costs and increased access to coverage to enrollees who are currently unable to enroll in coverage because of past-due premiums related to searching for a new plan from another issuer when seeking to enroll in health care coverage.
Potential increased costs of coverage of medical services for health insurance issuers (if health insurance enrollment increases).
Potential administrative burden on State Exchanges due to SEIPM program.
Potential administrative burden on states and regulated entities that would need to take action to come into compliance with the updated nondiscrimination policies (for example, regulated entities under § 156.125).
Potential administrative burden on states if they choose to align their network adequacy standards with the new federal standards (instead of having HHS complete the reviews).

Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$1.125 Billion	2021	7 percent	2022-2026
	$1.150 Billion	2021	3 percent	2022-2026

Quantitative:
- Federal Transfers to Consumers: Increase in PTC payments estimated to be approximately $1.32 billion in 2023, $1.41 billion in 2024, $1.43 billion in 2025, and $1.44 billion in 2026.

Other Transfers: Increase in rebate payments from issuers to consumers due to the clarification regarding the reporting of provider incentives and bonuses and the removal of indirect expenses from QIA in MLR and rebate calculations, estimated to be $61.8 million annually, beginning in 2023.

Qualitative:
Potential transfers from issuers who would have been able to recoup unpaid premiums from enrollees to those enrollees who would now be able to enroll in coverage from the same issuer or another issuer in the same controlled group without having to pay past-due premiums.
- Potential transfer from consumers to issuers: An estimated two percent premium increase for individuals not eligible for PTC due to the proposal to require individual market silver QHPs to provide an AV between 70-72 percent and associated income-based CSR plan variations to follow a de minimis range of +1/0 (impact on approximately 248,000 enrollees in HealthCare.gov silver plans below 70 percent AV, with approximately 4.2 million enrollees in corresponding CSR plan variations).

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This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the ACA's impact on federal spending, revenue collection, and insurance enrollment. Table 25 summarizes the effects of the risk adjustment program on the federal budget from fiscal years 2023 through 2027, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the

[381] Healthy People 2030 defines health equity as ''the attainment of the highest level of health for all people.'' *https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/questions-answers.*

provisions of this proposed rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 25.

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that, quantitatively, the effects of the provisions proposed in this rule are consistent with our previous estimates in the 2022 Payment Notice for the impacts associated with the APTCs, the premium stabilization programs, and FFE (including SBE–FP) user fee requirements.

TABLE 25: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2023-2027, in billions of dollars[382]

Year	2023	2024	2025	2026	2027	2023-2027
Risk Adjustment and Reinsurance Program Payments	6	6	6	7	7	32
Risk Adjustment and Reinsurance Program Collections	6	6	7	7	7	33

Note: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time.
Source: Congressional Budget Office. Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2020 to 2030 Table A-2. September 29, 2020. Available at https://www.cbo.gov/system/files/2020-09/56571-federal-health-subsidies.pdf.https://www.cbo.gov/system/files/2020-09/56571-federal-health-subsidies.pdf.

1. Guaranteed Availability of Coverage (§ 147.104(i))

This proposed rule proposes amendments to § 147.104(i), which would reverse the policy allowing an issuer to attribute a premium payment made for new coverage to any past-due premiums owed for coverage from the same issuer or another issuer in the same controlled group within the prior 12-month period preceding the effective date of coverage before effectuating enrollment in new coverage. Under current rules, individuals may have to pay up to 3 months of past-due premiums plus a binder payment before enrolling in coverage.[383] CMS lacks information on the frequency with which consumers miss payments or the frequency with which binder payments are currently being made, and seeks data or information related to past-due premiums. CMS is also interested in learning more about the population and characteristics of individuals with past-due premiums.

Individuals often stop making premium payments or forgo health insurance because they are unable to afford the premium payments. In a 2019 survey, 42 percent of insured adults reported being worried about paying for their monthly health insurance premium, with 18 percent being ''very worried'' and 24 percent being ''somewhat worried''.[384] In addition, 28 percent of insured adults reported having a difficult time covering the cost of health insurance each month. In 2019, 73.7 percent of uninsured adults pointed to high cost of coverage as the reason for being uninsured.[385]

Based on internal analysis, we estimate that approximately 7.8 percent of enrollees in Exchanges using the Federal platform had their coverage terminated in 2020 for non-payment of premiums. That figure was 10.7 percent in 2019, 12.4 percent in 2018, and 17.3 percent in 2017.[386] Among those enrollees who had their coverage terminated in 2019 and lived in an area where their issuer (or a different issuer in the same controlled group) had plans available the next year, we estimate that 16.9 percent enrolled with the same issuer (or a different issuer in the same controlled group) the following year. That figure was 16.5 percent in 2018 and 16.8 percent in 2017.[387] For those enrollees with household incomes below the federal poverty level, 15.3 percent of enrollees who had their coverage terminated in 2019 and lived in an area where their issuer (or a different issuer in the same controlled group) was available the next year enrolled with the same issuer (or a different issuer in the same controlled group) the following year.[388] That figure was 13.5 percent in 2018 and 13.2 percent in 2017. Our analysis also suggests that those enrollees with lower household incomes (specifically, household incomes below the federal poverty level) were less likely to enroll in coverage from the same issuer or another issuer in the same controlled group the following year. In 2017, 2018, and 2019, those enrollees who were less than 35 years old were also less likely to enroll in coverage from the same issuer or another issuer in the same controlled group the following year than those aged 35 to 54.

Due to data limitations, we are unable to directly attribute any changes in enrollment behavior in the Exchanges using the Federal platform to the interpretation of the guaranteed availability requirement stated in the Market Stabilization final rule. However, this proposed rule would

[382] Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities.

[383] Section 156.270(d) requires issuers to observe a 3-consecutive month grace period before terminating coverage for those enrollees who upon failing to timely pay their premiums are receiving APTC. Section 155.430(d)(4) requires that when coverage is terminated following this grace period, the last day of enrollment in a QHP through the Exchange is the last day of the first month of the grace period. Therefore, individuals whose coverage is terminated at the conclusion of a grace period would owe at most 1 month of premiums, net of any APTC paid on their behalf to the issuer. Individuals who attempt to enroll in new coverage while in a grace period (and whose coverage has not yet been terminated) could owe up to 3 months of premiums, net of any APTC paid on their behalf to the issuer.

[384] Kirzinger, Ashley et al., Data Note: Americans' Challenges with Health Care Costs, KFF, June 11, 2019. *https://www.kff.org/health-costs/issue-brief/data-note-americans-challenges-health-care-costs/.*

[385] Tolbert, J. and Orgera, K., Key Facts about the Uninsured Population, KFF, November 6, 2020. *https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.*

[386] The annual figures presented in this section should not necessarily be interpreted as trends, as some states moved from Exchanges using the Federal platform to State Exchanges and the overall composition of the dataset may have changed.

[387] As we reported in the April 18, 2017 **Federal Register** (82 FR 18346), that figure was approximately 16 percent in 2016.

[388] Of the 936,637 enrollees who had their coverage terminated in 2019 and lived in an area where their issuer (or a different issuer in the same controlled group) was available the next year, 24,784 (or 2.6 percent) had incomes below the federal poverty level. Many, but not all, of these enrollees lived in states that did not expand Medicaid eligibility following the implementation of the ACA.

increase access to health insurance coverage for individuals who stop paying premiums due to reasons such as financial hardship or affordability and who are currently unable to enroll in coverage because they cannot afford to pay past-due premiums. This increased access could lead to better health outcomes, if these individuals are able to maintain coverage.[389] This proposed rule would also increase the ability for enrollees to access coverage with the same issuer in the next year. This would be of particular benefit to those Exchange enrollees living in counties with only one or two participating issuers.[390] It could also reduce the costs and burden to enrollees related to searching for a new plan from another issuer when seeking to enroll in health care coverage. Being able to enroll with the same issuer would also allow individuals to have access to the same network of services and providers, which could improve continuity of care.

This policy could result in transfers from issuers who would have been able to recoup unpaid premiums from enrollees to those enrollees who would now be able to enroll in coverage from the same issuer or another issuer in the same controlled group without having to pay past-due premiums. However, we anticipate that these transfers would be minimal, as issuers are not permitted to waive past-due premiums and would be expected to pursue other means of collecting them.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

2. Nondiscrimination Based on Sexual Orientation and Gender Identity (§§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b)), and EHB Nondiscrimination Policy for Health Plan Designs (§ 156.125)

Many of the entities regulated by §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) may have previously incorporated the proposed nondiscrimination protections related to sexual orientation and gender identity into their operations in response to the inclusion of these protections in these regulations prior to the effective date of the June 19, 2020 rulemaking on section 1557 that eliminated the references to these protections from these regulations. These regulated entities may have incurred any administrative costs at that time. We do not anticipate coming into compliance with these proposed changes would substantially impose administrative costs on any regulated entities that did not subsequently revise nondiscrimination policies based on the 2020 section 1557 final rule. Although costs may be incurred by any regulated entities that did subsequently revise nondiscrimination policies in response to the removal of such protections from the affected regulations based on the 2020 section 1557 final rule, we believe such costs are justified in light of the potential significant benefits the proposed changes could provide to individuals in the LGBTQI+ community, by ensuring they are not subject to discrimination on the basis of their sexual orientation or gender identity.

The EHB nondiscrimination policy proposals in this rulemaking will most likely impact the vast majority of state EHB-benchmark plans. If the nondiscrimination policy proposals become final, issuers subject to § 156.125 and states subject to the standards under § 156.125 through the cross-reference at § 156.111(b)(2)(v) will most likely need to take action to come into compliance with the updated nondiscrimination policies, and states may choose to provide guidance to assist issuers in doing so. The actions necessary to come into compliance with the updated nondiscrimination policies will likely impact and minimally increase premiums (for example, Colorado 2023 EHB-benchmark plan[391] noted a minimal increase to premiums with the updated benefits). States have the flexibility to design their EHB-benchmark plans consistent with § 156.111, which provides more options in plan designs. We note that several states have already used this flexibility to update their EHB-benchmark plans. CMS provides states with greater flexibility to select their EHB-benchmark plans by providing three new options for selection in PY 2020 and beyond, including: (1) Selecting the EHB-benchmark plan that another state used for PY 2017, (2) replacing one or more categories of EHBs under its EHB-benchmark plan used for PY 2017 with the same category or categories of EHB from the EHB-benchmark plan that another state used for PY 2017, or (3) otherwise selecting a set of benefits that would become the state's EHB-benchmark plan. Under each of these three options, the new EHB-benchmark also must comply with additional requirements, including scope of benefits requirements, under § 156.111(b).[392]

We seek comment on the potential costs, benefits, and transfers associated with this provision.

3. Risk Adjustment (§§ 153.320, 153.610, 153.620, 153.700, 153.710, and 153.730)

Beginning with the 2023 benefit year, we propose the following model specification changes to the HHS risk adjustment models: (1) To add a two-stage weighted model specification to the adult and child risk adjustment models, (2) to remove the existing severity illness factors in the adult models and add interacted HCC counts factors to the adult and child risk adjustment models, and (3) to revise the enrollment duration factors for the adult models. By prioritizing simplicity and limiting the number of changes to the current model structure, we minimize administrative burden for HHS, and as HHS runs risk adjustment in all 50 states and the District of Columbia, we do not expect these policies to place additional burden on state governments. These proposed model specifications would result in limited changes to the number and type of risk adjustment model factors; therefore, we do not expect these changes to impact issuer burden beyond the current burden for the risk adjustment program.[393] To

[389] We request comment on whether there would be any impact on premiums, affordability, and access for the individuals who reliably pay. We are interested in comments regarding whether issuers who implemented policies requiring payment of past due premiums prior to reenrollment experienced declines in administrative costs related to the collection of past-due premiums.

[390] According to recent figures from KFF, in 2021, there were only two issuers participating in the ACA Exchanges in 44 percent of counties, and there was only one issuer participating in the ACA Exchanges in 10 percent of counties. Source: McDermott, Daniel and Cynthia Cox (2020). ''Insurer Participation on the ACA Marketplaces, 2014–2021.'' KFF, November 23. *https://www.kff.org/private-insurance/issue-brief/insurer-participation-on-the-aca-marketplaces-2014-2021/*; This was noted by Sandy Ahn and JoAnn Volk in their analysis of the previous interpretation of the guaranteed availability requirement. Reference: Ahn, Sandy and JoAnn Volk (2017). ''Relaxing the Affordable Care Act's Guaranteed Issue Protection: Issues for Consumers and State Options.'' CHIRblog, June 2. *http://chirblog.org/relaxing-the-affordable-care-acts-guaranteed-issue-protection-issues-for-consumers-and-state-options/.*

[391] *See for example,* Colorado 2023 EHB Benchmark Plan Actuarial Report: Suite of Gender-affirming care benefits to treat gender dysphoria resulted cost estimate was 0.04% of the total allowed claims assuming utilization would be for adults. *https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.*

[392] Section 156.111(b). *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-B/part-156.*

[393] See current burden estimates in the Supporting Statement of OMB control number 0938–1155 (Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS–10401)),

Continued

further assist issuers in understanding the potential impact of these changes on risk adjustment transfers, we released the 2021 RA Technical Paper and conducted an EDGE transfer simulation that estimated the impact on risk scores and transfers with and without these proposed changes using 2020 benefit year risk adjustment data.[394] Based on results from this simulation, we estimate the impact of these policies on risk adjustment transfers to be relatively minor.[395]

Additionally, we propose to recalibrate the HHS risk adjustment models for the 2023 benefit year using the 2017, 2018, and 2019 enrollee-level EDGE data. We believe that the approach of blending (or averaging) 3 years of separately solved coefficients will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2022 benefit year to the 2023 benefit year. We also propose to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models, consistent with the approach adopted beginning with the 2020 models. For the 2023 benefit year, we propose to recalibrate the models using the final, fourth quarter (Q4) RXC mapping document that was applicable for the 2018 and 2019 benefit year, with the exception of the 2017 enrollee-level EDGE data year, for which we propose to use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018) for consistency with prior model year recalibrations, as we did not include RXCs in the adult risk adjustment models until 2018.[396] For the 2024 benefit year and beyond, we propose to recalibrate the models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the current year's model recalibration. We also propose to continue to apply a pricing adjustment for Hepatitis C drugs for all three model types (adult, child, and infant), as well as outline our consideration for targeted removal of the mapping of hydroxychloroquine sulfate to RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions for the 2018 and 2019 benefit years' enrollee-level EDGE data used for model recalibration,[397] as well as our consideration for the targeted removal of the mapping of Descovy® to RXC 01 ((Anti-HIV Agents) from all three benefit year datasets used for model recalibration. For the 2023 benefit year, we are proposing to maintain the CSR adjustment factors finalized in the 2019–2022 Payment Notices. Overall, we do not estimate that these changes will impact issuer burden beyond the current burden for the HHS-operated risk adjustment program.

For the 2023 benefit year, HHS will operate a risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS' operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. For the 2023 benefit year, we propose to use the same methodology that we finalized in the 2022 Payment Notice to estimate our administrative expenses to operate the program. Risk adjustment user fee costs for the 2023 benefit year are expected to remain steady from the prior 2022 benefit year estimates. However, we project a small increase in billable member months in the individual and small group markets overall in the 2023 benefit year based on the enrollment increases observed in the 2020 benefit year. We estimate that the total cost for HHS to operate the risk adjustment program on behalf of states for 2023 will be approximately $60 million, and therefore, the proposed risk adjustment user fee would be $0.22 PMPM. Because overall risk adjustment costs estimated for the 2023 benefit year are similar to 2022 costs, we do not expect the proposed risk adjustment user fee for the 2023 benefit year to materially impact the transfer amounts collected or paid by issuers of risk adjustment covered plans.

We also propose to generally repeal the ability for states to request a reduction in risk adjustment state transfers of up to 50 percent in all state market risk pools beginning with the 2024 benefit year, with an exception for prior participants. We propose to provide an exception for states that have previously submitted risk adjustment state flexibility requests, so only such states may continue to request this flexibility beginning with the 2024 benefit year. We also propose to remove as a criterion for state justification and HHS approval of these requests the demonstration of state-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool. As proposed, we would retain as the sole requirement for state justification and criterion for HHS approval the demonstration that the requested reduction would have a de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments beginning with the 2024 benefit year.

We anticipate that the proposed changes to risk adjustment state flexibility requests would have a minimal impact on states and other interested parties. Only one state, Alabama, has requested a reduction in risk adjustment state transfers since this flexibility was first made available beginning in the 2020 benefit year, and under this proposal, Alabama would be considered a prior participant and could continue to request such reductions. We do not anticipate any new burden or costs as a result of this policy.

We also propose to collect and extract five new data elements from issuers' EDGE servers through issuers' Edge Server Enrollment Submission (ESES) files and risk adjustment recalibration enrollment files: ZIP code, race, ethnicity, subsidy indicator, and ICHRA indicator beginning with the 2023 benefit year. In addition, we propose to begin extracting three data elements issuers already report to their EDGE servers—plan ID, rating area and subscriber indicator—as part of the enrollee-level EDGE data beginning with the 2022 benefit year. The proposal to extract plan ID, rating area, and subscriber indicator will pose minimal burden on issuers (only the burden associated with running of a command) since the creation and storage of the extract—which issuers do not receive—is mainly handled by HHS. For the collection of the five new data elements we propose to collect and extract beginning with the 2023 benefit year, the cumulative additional cost estimate is $225,168 for 600 issuers. We estimate that the addition of these five new data elements to the risk adjustment data

which is currently being updated. The previous version of the Supporting Statement is available at *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201712-0938-015.*

[394] See the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.* Issuers that participated in the simulation also received detailed issuer-specific data, including risk score and transfer estimates for the simulated results.

[395] We estimate that the impact of the model specification changes between the proposed and final 2022 benefit year risk adjustment models in total absolute value change in transfer over premium is –0.3 in the individual marker and –0.2 in the small group market.

[396] See 81 FR at 94075.

[397] The same concerns were not present for the 2017 enrollee-level EDGE data because hydroxychloroquine sulfate was not included in the RXC crosswalk until 2018.

submission requirements would be $375.28 per issuer. The proposal to extract these data elements will pose minimal burden on issuers (only the burden associated with running of a command) since the creation and storage of the extract—which issuers do not receive—is mainly handled by HHS. We expect minimal costs to HHS as a result of these proposals.

We also propose to amend § 153.730 to clarify that in situations where the April 30 deadline for issuers to submit risk adjustment data to HHS in states where HHS is operating the risk adjustment program falls on a non-business day, the deadline for issuers to submit the required data would be the next applicable business day. We believe this proposal would not pose additional burden since it does not change any of the data submission requirements and only clarifies the deadline when April 30 falls on a non-business day.

We seek comment on estimated costs and transfers and potential benefits associated with these provisions.

4. Risk Adjustment Data Validation (§§ 153.350 and 153.630)

In this proposed rule, we propose updates to the HHS–RADV error rate calculation methodology beginning with the 2021 benefit year to (1) extend the application of Super HCCs from their current application only in the sorting step that assigns HCCs to failure rate groups to broader application throughout the HHS–RADV error rate calculation processes, (2) specify that Super HCCs will be defined separately according to the age group model to which an enrollee is subject, and (3) constrain to zero any negative failure rate outlier in a failure rate group, regardless of whether the outlier issuer has a negative or positive error rate. Although we anticipate the proposed changes will have a small impact on issuers' HHS–RADV risk adjustment transfer adjustments, risk adjustment is a budget neutral program and we expect these proposals to refine the HHS–RADV error rate calculation methodology will not have an impact on the administrative burden to issuers subject to the current HHS–RADV process because HHS is responsible for calculating error rates and applying error rates to adjust risk scores and state market risk pool transfers. Furthermore, we expect these changes will have minimal impacts on administrative costs to the federal government as the described changes do not impact the underlying HHS–RADV data, the amount of data HHS collects, or the SVA, which is conducted by an entity HHS retains.

We seek comment on these burden estimates.

5. Agents, Brokers, and Web-Brokers (§ 155.220)

a. Required QHP Comparative Information on Web-Broker Websites and Related Disclaimer

We propose to amend § 155.220(c)(3)(i)(A) to include at proposed new §§ 155.220(c)(3)(i)(A)(1) through (c)(3)(i)(A)(5) a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We also propose to revise the disclaimer requirement in § 155.220(c)(3)(i)(A) so that web-broker non-Exchange websites would be required to prominently display a standardized disclaimer provided by HHS stating that enrollment support is available on the Exchange website and provide a web link to the Exchange website where enrollment support for a QHP is not available using the web-broker's non-Exchange website.

In the preamble of part 2 of the 2022 Payment Notice final rule, we announced our intention to enforce the requirement that web-brokers display the QHP comparative information described under § 155.205(b)(1) beginning with the PY 2022 open enrollment period.[398] Specifically, we propose to create proposed new §§ 155.220(c)(3)(i)(A)(1) through (5) to list premium and cost-sharing information, the summary of benefits and coverage established under section 2715 of the PHS Act, identification of the metal level of the QHP as defined by section 1302(d) of the ACA or whether it is a catastrophic plan as defined by section 1302(e) of the ACA, the results of the enrollee satisfaction survey as described in section 1311(c)(4) of the ACA, quality ratings assigned in accordance with section 1311(c)(3) of the ACA, and the provider directory made available to the Exchange in accordance with § 156.230 as the minimum QHP comparative information web-broker non-Exchange websites must display for all available QHPs. Including this information within § 155.220, instead of through a cross-reference to § 155.205(b)(1), would provide better clarity and ease of reference and establish a list of required QHP comparative information consistent with our current enforcement approach, which, as discussed above, does not require the display of MLR information and transparency of coverage measures.

We propose to revise § 155.220(c)(3)(i)(A) to state that web-broker websites must disclose and display the following QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(c), and to the extent that enrollment support for a QHP is not available using the web-broker's website, prominently display a standardized disclaimer provided by HHS stating that enrollment support for the QHP is available on the Exchange website, and provide a web link to the Exchange website.

These proposals should result in very limited new burden for web-brokers. As we explained in Section III of the preamble, given CMS's current enforcement policies relative to these requirements, the QHP comparative information we propose to require web-broker websites to display is consistent with current requirements. As a result, this proposed requirement would not present new burden to web-brokers.

The proposed new disclaimer would require web-brokers to make minor updates to their websites in cases when they do not support enrollment in all available QHPs. However, in those cases, they would be displaying a standardized disclaimer much like the plan detail disclaimer that they have historically been required to display.

We estimate this proposal will affect approximately 20 web-brokers. Given the minor modifications necessary to implement the revised disclaimer in this proposal, we estimate a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this proposal is $8,220 for 20 web-brokers in the 2022 benefit year.

We seek comment on the estimated burden associated with these proposals.

b. Prohibition of QHP Advertising on Web-Broker Websites

Section 155.220(c)(3)(i)(L) prohibits web-broker non-Exchange websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers. We propose to amend § 155.220(c)(3)(i)(L) to make clear that web-broker non-Exchange websites are also prohibited from displaying QHP advertisements, or otherwise providing

[398] See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Final Rule, 86 FR 24140 at 24206 (May 5, 2021).

favored or preferred placement in the display of QHPs, based on compensation agents, brokers, or web-brokers receive from QHP issuers.

This proposal should impose no new costs on web-brokers so long as they are not displaying QHP advertisements on their websites. We believe that very few web-brokers are currently doing so. However, for those few web-brokers that are displaying QHP advertisements on their websites, they would be required to update their websites to remove those advertisements and would lose any advertising revenue associated with such placements. Since advertisements on websites are inherently subject to change, even for those web-brokers that would be required to make updates to their websites if this proposal is finalized, the costs may be very limited, although we request comment on this assumption and acknowledge that there may be loss of advertising revenue. We also realize, to the extent advertising revenue is lost, web-brokers may seek to recoup the lost revenue from other sources resulting in a transfer of costs. For example, web-brokers may seek to increase fees received from agents and brokers using their websites or may pursue increased commissions from QHP issuers.

We seek comment on the potential costs, benefits, and transfers associated with this proposal.

c. Explanation of Rationale for QHP Recommendations on Web-Broker Websites

We propose to amend § 155.220 to add a proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on their websites (for example, alphabetically based on plan name, from lowest to highest premium, etc.). We believe this proposed new requirement would provide consumers with a better understanding of the information being presented to them on web-broker websites, thereby enabling them to make better informed decisions and shop for and select QHPs that best fit their needs.

We support web-broker websites' use of innovative decision-support tools for consumers to help them shop for and select QHPs that best fit their needs. However, web-broker websites that explicitly recommend or rank QHPs do not always provide an explanation for their recommendations or rankings. Similarly, web-broker websites may not include an explanation of the methodology used for their default displays of QHPs, and it may not otherwise be apparent what methodologies are used. The absence of such explanations may cause some consumers to misunderstand the bases for the recommendations displayed to them on web-broker websites (whether explicit or implicit), or may prevent them from assessing the value of the recommendations (for example, whether a recommendation is based on the factors most important to them). In addition, the lack of explanations for QHP recommendations on web-broker websites may obscure that the web-broker is recommending QHPs based on compensation the web-broker receives from QHP issuers in violation of § 155.220(c)(3)(i)(L). For these reasons, we propose to amend § 155.220 to add proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for QHP recommendations and the methodology for its default display of QHPs.

This proposal should result in very limited new costs for web-brokers, since the information it would require they display on their websites would only require text-based changes that are relatively easy to implement. Furthermore, the extent of those textual updates should be relatively minor in most cases. For example, if a web-broker is recommending a QHP based on the fact that it has the lowest monthly premiums for a consumer, that can likely be communicated in one or two sentences of informational text, or possibly even in a single phrase or set of short bullet points. Some web-brokers are already providing the information that would be required by this proposal, and therefore would not have to make any website updates. Other web-broker websites do not explicitly recommend QHPs, and therefore the impact of this proposal would be limited to providing similar information about the methodology for their default display of QHPs (for example, explaining QHPs are sorted from lowest to highest premium, etc.), assuming they do not already provide that information.

We estimate this proposal will affect approximately 20 web-brokers. Given the minor text-based changes necessary to implement the informational text detailing the rationale for QHP recommendations and the methodology for a default display of QHPs, we estimate a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this proposal is $8,220 for 20 web-brokers in the 2022 benefit year.

We seek comment on the potential costs and benefits associated with this proposal.

d. Providing Correct Information to the FFEs and Prohibited Business Practices

These proposed revisions to § 155.220(j)(2) are focused on addressing various areas where HHS has thus far identified a need for more direct and clear guidance, including ensuring that correct consumer information is entered onto Exchange applications. This includes contact information, such as the consumer's email address, telephone number, and mailing address, as well as information related to projected consumer household income. They also set forth prohibited business practices, such as using automation when interacting with CMS Systems or the DE Pathways without CMS' advance written approval and failing to properly identity proof Exchange applicants. These proposed changes will clarify HHS' expectations in these areas, and create clear, enforceable standards and bases for taking enforcement action for violations of these requirements.

HHS believes these proposals would not impose any burden on any of the parties the proposals would impact, including agents, brokers, and web-brokers. None of these proposals propose to impose new requirements. Rather, these proposals are intended to address common problems that HHS has observed, and provide clear, enforceable standards intended to protect consumers and support the efficient operation of Exchanges by substantially reducing the occurrence of those problems.

We seek comment on any potential costs or benefits associated with these proposals.

6. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)

We propose to amend § 155.320(d)(4) to remove the requirement that Exchanges that do not reasonably expect to obtain sufficient verification data related to enrollment in or eligibility for employer sponsored coverage conduct random sampling to verify whether an applicant is eligible for or enrolled in an eligible employer sponsored plan in favor of a verification process that is based on risk for inappropriate APTC/CSRs. We believe this proposal would benefit employers, employees, Exchanges using the Federal platform, and State Exchanges that operate their own eligibility and enrollment platform,

as this proposal would relieve them from the burden of investing resources to conduct and respond to random sampling, as applicable.

In the 2019 Payment Notice final rule, we discussed a study that HHS conducted in 2016 and the burden associated with sampling based in part on the alternative process used for the Exchanges.[399] HHS incurred approximately $750,000 in costs to design and operationalize this study, and the study indicated that $353,581 of APTC was potentially incorrectly granted to individuals in the sampled population who inaccurately attested to their enrollment in or eligibility for a qualifying eligible employer sponsored plan. We placed calls to employers to verify 15,125 cases but were only able to verify 1,948 cases. A large number of employers either could not be reached or were unable to verify a consumer's information, resulting in a verification rate of approximately 13 percent. The sample size involved in the 2016 study did not represent a random sample of the target population and did not fulfill all regulatory requirements for sampling under § 155.320(d)(4)(i).

Taking additional costs into account—namely, the cost of sending notices to employees as required under § 155.320(d)(4)(i)(A), the cost of building the infrastructure and implementing the first year of operationalizing this process, and the cost of expanding the number of cases to a random sample size of approximately 1 million cases—we estimate that the overall one-time cost of implementing sampling would have been approximately $8 million for the Exchanges using the Federal platform, and between $2 million and $7 million for other Exchanges, depending on their enrollment volume and existing infrastructure. Therefore, we estimate that the average per-Exchange cost of implementing sampling that resembles the approach taken by the Exchanges using the Federal platform would have been approximately $4.5 million for State Exchanges that operate their own eligibility and enrollment platform, for a total cost of $67.5 million for the 15 State Exchanges that operate their own eligibility and enrollment platform (operating in 14 states and the District of Columbia). However, we are aware that 4 State Exchanges that operate their own eligibility and enrollment platform have already incurred costs to implement sampling and estimate that they have incurred one-time costs of approximately $4.5 million per Exchange with a total of $18 million and will only experience savings related to recurring costs. Therefore, the one-time savings for Exchanges using the Federal platform and the remaining State Exchanges that operate their own eligibility and enrollment platform will be approximately $49.5 million.

We estimate the annual costs to conduct sampling on a random sample size of approximately 1 million cases to be approximately $8 million for the Exchanges using the Federal platform and $7 million on average for each State Exchange that operates its own eligibility and enrollment platform. This estimate includes operational activities such as noticing, inbound and outbound calls to the Marketplace call center, and adjudicating consumer appeals. The total annual cost to conduct sampling would have been $105 million for 15 State Exchanges. Therefore, the total annual cost for the Exchanges using the Federal platform and the 15 State Exchanges that operate their own eligibility and enrollment platform would have been $113 million in 2022 and onward.

Eliminating these estimated costs would be offset by the costs of designing and implementing an appropriate verification process. We estimate that the cost to conduct research for Exchanges using the Federal platform to be approximately $295,000 and for the 15 State Exchanges that operate their own eligibility and enrollment platform to be approximately $4.4 million. In addition to significant cost savings, this proposal would provide more flexibility for states to design and implement a verification process for employer sponsored coverage that is tailored to their unique populations, and would protect the integrity of states' respective individual markets. Furthermore, we believe that this proposal would reduce burden on employers and employees, as compliance with the current random sampling, notification, and information gathering processes require significant time and resources, which likely would be reduced if this proposal is finalized.

HHS requests comment on the estimated and potential costs and impacts of this proposal.

7. Proration of Advance Premium Tax Credit and Premium (§§ 155.240(e), 155.305(f)(5), and 155.340)

HHS is proposing amendments to part 155, specifically at §§ 155.240(e), 155.305(f)(5), and 155.340 to establish the requirement that all Exchanges prorate both premiums and APTCs for enrollees enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month using a specified methodology. In line with calculating PTC according to the provisions at 26 CFR 1.36B–3, this method of administering APTC would reduce instances of payments of APTC in excess of an applicable taxpayer's monthly PTC for a month in which an enrollee is enrolled for less than a full calendar month and thus would protect the applicable taxpayer from incurring income tax liability due to excess APTC.

This would benefit both issuers and enrollees by preventing APTC overpayment and eliminating wasted resources dedicated to resolving overpayment issues. While the FFEs and SBE–FPs already prorate APTC and premium amounts, State Exchanges do not currently prorate consistently the amount of applied APTC administered to issuers in their applicable states.

HHS acknowledges that those State Exchanges that do not currently prorate APTC or premium amounts will be financially impacted by the proposed requirement to implement this methodology, and this proposal will likely require operational systems builds to support this new proration requirement.

Based on historical cost data for SBEs to implement changes to their IT systems and operations related to premium processing functionality and similar functionality, such as functionality for processing consumer failures to reconcile APTC received for a previous plan year, HHS estimates that State Exchanges that currently do not implement proration of APTC or premium amounts according to the proposed methodology could expect to incur one-time implementation costs. HHS anticipates that each affected State Based Exchange that does not already prorate APTC or premium amounts according to the proposed methodology would expect an estimated $1 million one-time burden to account for the IT build to support the new calculation and reporting systems associated with this requirement.

HHS estimates that 8 State Exchanges currently prorate premium amounts but do not prorate APTC amounts. HHS anticipates that those State Exchanges which already prorate premium amounts will have the operational and systems capacity to calculate the prorated premium and APTC amounts as required in this proposed policy.

Currently, State Exchanges vary in their approaches to implementing the proposed APTC and premium proration. In order to provide the most conservative estimate of this proposal's

[399] See *https://www.govinfo.gov/content/pkg/FR-2017-11-02/pdf/2017-23599.pdf*, p. 51128.

burden, HHS assumes that 10 State Exchanges, including State Exchanges that newly transitioned to being State Exchanges by the time of this rulemaking, will incur the highest level of implementation cost detailed earlier in this proposed rule ($1 million in one-time implementation burden per State Exchange) for a total estimated impact of $10,000,000 in the 2024 benefit year across all State Exchanges. HHS seeks comment on the estimated costs and benefits described in this section.

10. Special Enrollment Periods—Special Enrollment Period Verification (§ 155.420)

We are proposing to amend § 155.420 to add new paragraph (g) to state that Exchanges may conduct pre-enrollment verification of eligibility for special enrollment periods, at the option of the Exchange, and that Exchanges may provide an exception to pre-enrollment special enrollment period verification for special circumstances. Exchanges on the Federal platform would conduct pre-enrollment special enrollment period eligibility verification for new consumers who attest to losing minimum essential coverage.

We do not anticipate that revisions to § 155.420 would impose regulatory burden or costs on the Exchanges on the Federal platform because these Exchanges will decrease the number of special enrollment period types that require pre-enrollment verification to only include special enrollment periods for new consumers who attest to losing minimum essential coverage. The provisions proposed in this rule would decrease the scope of pre-enrollment special enrollment period verification in all states with Exchanges served by the Federal platform. We anticipate that this would result in 194,000 fewer individuals having their enrollment delayed or ''pended'' annually until eligibility verification is completed, which would result in a $5,150,700 decrease in annual ongoing costs to the federal government.

There may be State Exchanges that also decide to reduce the scope of their current pre-enrollment special enrollment period verification, which would also decrease annual ongoing costs for State Exchanges. State Exchanges that are currently conducting pre-enrollment verification of eligibility for more special enrollment period types than those that the Exchanges on the Federal platform would be verifying under this proposal could experience a decrease in burden and costs if they choose to align their approaches with the Exchanges on the Federal platform. State Exchanges that are currently conducting pre-enrollment verification of eligibility for fewer types of special enrollment periods than the proposed special enrollment period that the Exchanges on the Federal platform would be verifying under this proposal could experience an increase in burden and costs if they choose to align with the Exchanges on the Federal platform, but State Exchanges will not be required to align with the Exchanges on the Federal platform.

We do not anticipate that this would increase administrative costs on QHP issuers. Additionally, our data suggests that SEP documentation deters younger, likely healthier individuals from enrolling, but there could be an increase in claims costs to QHP issuers since the Exchanges on the Federal platform will be requiring document submission prior to enrollment for fewer special enrollment period types.

We seek comment on the potential costs, benefits, and transfers associated with this proposal.

11. General Program Integrity and Oversight Requirements (§ 155.1200)

We propose to add new § 155.1200(e) to permit a State Exchange to meet the requirement to conduct an annual independent external programmatic audit, as described at § 155.1200(c), by completing the annual, required SEIPM program process. As a result, we estimate that there would be a general reduction in reporting and contracting costs to State Exchanges related to meeting auditing requirements under § 155.1200. We anticipate the combined cost in contracting and reporting would result in an average annual reduction of approximately $90,624.62 for each State Exchange beginning in benefit year 2024. The total cost annual reduction across 18 State Exchanges would be approximately $1,631,243.16. Any new costs, burdens, and benefits to State Exchanges of meeting requirements for the SEIPM program are described later in this proposed rule.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

12. State Exchange Improper Payment Measurement Program (§§ 155.1500 Through 155.1540)

The implementation of the SEIPM program could have the direct effect of reducing improper payments. Measuring the error rate of State Exchange Premium Tax Credit payments will reveal vulnerable processes to be corrected. Recordkeeping costs of $3.0 million annually will begin in 2023.

We seek comment on the estimated costs and benefits and potential transfers associated with this provision.

13. FFE and SBE–FP User Fees (§ 156.50)

We are proposing an FFE user fee rate of 2.75 percent of monthly premiums for the 2023 benefit year, which is the same as the 2.75 percent FFE user fee rate finalized in part 3 of the 2022 Payment Notice.[400] We also propose an SBE–FP user fee rate of 2.25 percent for the 2023 benefit year, which is the same as the 2.25 percent SBE–FP user fee rate finalized in part 3 of the 2022 Payment Notice. Therefore, we do not believe that these proposed user fee rates will have any additional impact on premiums compared to the 2022 benefit year. We also propose to amend § 156.50 to conform the user fee regulations with the repeal of the Exchange DE option finalized in part 3 of the 2022 Payment Notice.[401] As this proposal does not alter existing policy, we do not expect that it will have any additional regulatory impact.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

14. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

We are proposing to eliminate the requirement at § 156.111(d) and (f) to require states to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any state-required benefits applicable to QHPs in the individual or small group market that are considered to be in addition to EHB in accordance with § 155.170(a)(3) and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination.

Under this proposal, states would no longer be required to submit an annual report that complies with each requirement listed at § 156.111(f)(1) through (6), nor would HHS identify which benefits are in addition to EHB for the applicable PY in the state if a state does not submit an annual reporting package.

The 2021 Payment Notice acknowledged that requiring states to annually report to HHS would require that states submit additional paperwork to HHS on an annual basis but noted that, as states are already required under § 155.170 to identify which state-required benefits are in addition to EHB and to defray the cost of those benefits,

[400] 86 FR 53412 at 53445.

[401] 86 FR 53412.

any such burden experienced by states would be minimal.[402] The 2021 Payment Notice also stated that this reporting requirement would be complementary to the process the state should already have in place for tracking and analyzing state-required benefits. The 2021 Payment Notice further explained that states may opt not to report this information and instead let HHS make this determination for them. In the 2021 Payment Notice, we also discussed that any state burden associated with this policy would be limited to the completion of the HHS templates, validation of that information, and submission of the templates to HHS. Repealing the annual reporting requirement would remove the burden associated with that policy, detailed in 2021 Payment Notice and summarized previously in the Collection of Information Requirements section in this proposed rule.

Although this proposal would relieve states of the annual reporting requirements and any associated burden with submission and validation of the information on the annual reporting templates, it would not pend or otherwise impact the defrayal requirements under section 1311(d)(3)(B) of the ACA, as implemented at § 155.170. Under this proposal, states remain responsible for making payments to defray the cost of additional required benefits and issuers are still responsible for quantifying the cost of these benefits and reporting the cost to the state. We also note that the obligation for a state to defray the cost of QHP coverage of state-required benefits in addition to EHB is an independent statutory requirement from the annual reporting policy finalized at § 156.111(d) and (f).

We seek comment on the potential costs, benefits, and transfers associated with this provision.

15. Levels of Coverage (Actuarial Value) (§ 156.140, 156.200, 156.400)

We are proposing to change the de minimis range for levels of coverage at § 156.140(c) to a variation of +2/−2 percentage points for all standard bronze plans, gold plans, platinum plans, individual market off-Exchange silver plans, and all small group market silver plans (on- and off-Exchange), as well as proposing to change the de minimis for expanded bronze plans to +5/−2, that are required to comply with AV standards for PYs beginning in 2023. In addition, we are proposing to change the de minimis under § 156.200 to +2/0 percentage points for individual market silver QHPs and for the income-based silver CSR plan variations under § 156.400 to +1/0.

In the 2017 Market Stabilization rule,[403] we acknowledged that in the short run, expanding the standard de minimis range to +2/−4 would generate a transfer of costs from consumers to issuers in the form of decreased APTC and increased premiums, but stated our belief that the additional flexibility for issuers would have positive effects for consumers over the longer term as premiums stabilized, issuer participation increased, and coverage options at the silver level and above increased, which would attract more young and healthy enrollees into such plans. As discussed above, since we finalized the expanded de minimis ranges, we have observed decreased enrollment in silver plans (from 963,241 enrollees in PY 2018 to 424,345 enrollees in PY 2021), despite the number of standard silver plans available on *HealthCare.gov* steadily increasing from 811 silver plans in PY 2018 to 1,386 silver plans in PY 2021. Thus, we cannot justify the decreased APTC with evidence of increased enrollment of younger and healthier enrollees in silver plans.

Changing the de minimis ranges for standard metal level plans would generate a transfer of costs from the government and issuers to consumers in the form of increased APTC and decreased premiums, because narrowing the de minimis range for silver plans can affect the generosity of the SLCSP. The SLCSP is the benchmark plan used to determine an individual's PTC. A subsidized enrollee in any county that has a SLCSP that is currently below 70 percent AV would see the generosity of their current SLCSP increase, resulting in an increase in PTC. Not all counties would see the SLCSP change as a result of this proposal. In states using *HealthCare.gov,* approximately 87 percent of counties across 23 states have a SLCSP that is below 70 percent AV.

For this proposal, the CMS Office of the Actuary estimates a nationwide increase in PTCs through PY 2032, as shown in Table 26:

TABLE 26: PTC Impact of +2/0 Silver, +1/0 CSR De Minimis Plan AVs, 2023-2032

Calendar Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
PTC Impact ($ Billions)	0.73	0.77	0.77	0.76	0.77	0.78	0.82	0.83	0.87	0.92
Fiscal Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
PTC Impact ($ Billions)	0.55	0.76	0.77	0.76	0.77	0.78	0.81	0.83	0.86	0.91

This proposal would impact those consumers currently enrolled in standard silver plans that are currently in the −4 to −0.01 percent de minimis range that would be out of compliance under this proposal, as well as consumers currently enrolled in individual market silver QHPs that are currently in the −4 to −0.01 percent de minimis range and associated income-based CSR silver plan variations currently enrolled in the −1 to −0.01 percent de minimis range. Of the plans on *HealthCare.gov,* we estimate that there are approximately 150,000 enrollees in gold plans below 78 percent AV, and 3,500 enrollees in platinum plans below 88 percent AV.[404] Additionally, we estimate there are approximately 248,000 enrollees in *HealthCare.gov* silver QHPs below 70 percent AV, with approximately 4.2 million enrollees in corresponding income-based CSR plan variations. Under these proposals, those enrollees would need to select a different plan for PY 2023 if the issuer chooses to discontinue the plan rather than revise the plan's cost sharing. Additionally, these proposals would similarly affect enrollees in such plans that are not available on *HealthCare.gov,* such as plans sold on state Exchanges, for which

[402] 85 FR 29164, 29252.

[403] Patient Protection and Affordable Care Act; Market Stabilization, 82 FR 18346 (April 18, 2017). Available at *https://www.govinfo.gov/content/pkg/FR-2017-04-18/pdf/2017-07712.pdf.*

[404] There are no enrollees in bronze plans below 58% AV.

we do not have data to make an informed estimate.

We estimate the premiums for these plans would increase approximately 2 percent on average because of benefit changes required for plans to meet a +2/0 de minimis threshold. However, for Exchange enrollees, we expect this premium increase to be substantially offset by the corresponding increase in PTC because of the proposal's impact on the SLCSP. Similarly, the proposal to change the de minimis range for CSR variants to +1/0 would lead to improved cost-sharing due to the higher relative AV compared to the current +1/−1 range, along with increased gross premiums that would be substantially offset by increased PTC payments. After implementation of the ARP enhanced financial subsidies, subsidized enrollees make up the majority of *HealthCare.gov* silver QHP enrollees—only 91,000 of approximately 248,000 individual market silver QHP enrollees in plans with AV between 66.00 and 69.99 percent plan AV remain unsubsidized. By comparison, enrollment within the corresponding income-based silver CSR variations of the above silver QHPs has increased to approximately 4.2 million. We expect the increased PTC payments due to the premium increase to incentivize healthier subsidy-eligible enrollees to participate in the Marketplace, and that the improved risk pool as a result of increased healthier enrollees would mitigate the net cost burden of covering a decreasing population of unsubsidized enrollees.

In addition, changing the de minimis range for standard silver plans would impact ICHRAs, which use the Lowest Cost Silver Plan (LCSP) as the benchmark to determine whether an ICHRA is considered affordable to an employee. Under this proposal, as silver plans become more generous and premiums increase, an employer would have to contribute more to an ICHRA to have it be considered affordable. This change could discourage large employer use of ICHRAs because large employers need to offer affordable coverage to satisfy the employer shared responsibility provisions.[405] Additionally, if coverage is considered unaffordable to the employee, the employee can opt out of the ICHRA and instead purchase coverage on the Exchange with APTC, if otherwise eligible; and increasing the LCSP premiums could make employer-sponsored coverage unaffordable to more employees. We estimate silver plans with an AV below 70 percent will see premiums increase approximately 2 percent on average due to more generous benefits. We do not believe this will have a significant impact on the number of employers willing to offer ICHRAs or whether an ICHRA is considered affordable to most employees, but invite comment to refute or refine this understanding on these issues in particular.

We seek comment on the estimated costs, benefits, and transfers associated with this provision.

16. Standardized Options (§ 156.201)

Section 156.201 would require QHP issuers to offer standardized QHP options. Though these proposed requirements would necessitate the creation of new plans, HHS believes the burden imposed on issuers would be minimal because these new plans' benefits, networks, and formularies would not differ substantially from the benefits, networks, and formularies of plans that issuers currently offer and because HHS is specifying the cost sharing parameters, MOOPs, and deductibles for these new plans. Additionally, HHS would design these standardized options to resemble the most popular QHPs in the individual market FFEs and SBE–FPs in PY 2021, making these standardized options comparable to plans that the majority of issuers already offer. Furthermore, since HHS proposes to require QHP issuers to offer standardized options at every product network type, metal level, and throughout every service area that they also offer non-standardized QHPs (but not at different product network types, metal levels, and service areas that they do not also offer non-standardized QHPs), issuers would not be required to extend plan offerings beyond their existing service areas.

Additionally, since HHS does not propose to limit the number of non-standardized QHP options that issuers can offer in PY 2023, HHS believes the majority of enrollees will remain enrolled in their current non-standardized options. Moreover, since HHS does not propose to require issuers to offer a higher number of QHPs than what they currently offer, issuers would still be able to determine how many QHPs they wish to offer. As a result, HHS does not expect the total number of plans that issuers will offer to change substantially subsequent to the imposition of requirement. Thus, though these new plans would have to be submitted for approval, certification, and display, we expect that the overall burden for issuers and states alike would not substantially increase because we do not expect the number of overall plan offerings to substantially increase—due in part to issuers discontinuing some old plans.

As noted earlier in the preamble, HHS is considering resuming the differential display of standardized options per the existing authority at § 155.205(b)(1). HHS would assume burden for the differential display of standardized options on *HealthCare.gov,* meaning FFE and SBE–FP issuers would not be subject to this burden. In addition, as noted above in the preamble, HHS is considering resuming enforcement of the standardized options display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively.

HHS believes that resuming enforcement of these differential display requirements will not require significant modification of these entities' platforms and non-Exchange websites. Further, since HHS would continue to allow these entities to submit requests to deviate from the manner in which standardized options are differentially displayed on *HealthCare.gov,* potential burden for these for these entities would be further reduced. HHS also intends to provide access to information on standardized options to web-brokers through the Health Insurance Marketplace PUFs and QHP Landscape file to further minimize burden. The specific burden estimates for these requirements can be found in the corresponding ICR sections for §§ 155.220 and 156.265.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

17. Network Adequacy (§ 156.230)

Section 156.230(a)(2) currently requires a QHP issuer to maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorders, to ensure that all services will be accessible without unreasonable delay. In this proposed rule, HHS proposes for PY 2023 and future PYs that all QHPs or QHP candidates that use a provider network must comply with network adequacy standards.

HHS proposes to conduct prospective quantitative network adequacy reviews for all FFEs in all FFE states except in states performing plan management functions that adhere to a standard as stringent as the federal standard, conduct reviews prospectively, and choose to conduct their own reviews.

[405] See section 4980H of the Code; 26 CFR 54.4980H–1—26 CFR 54.4980H–6.

HHS proposes for PY 2023 and future PYs to adopt time and distance standards to assess whether FFE QHPs or QHP candidates fulfill network standards based on numbers and types of providers and providers' geographic locations. Time and distance standards would be calculated at the county level using information from the ECP/NA template. HHS also proposes to adopt appointment wait time standards to assess whether FFE QHPs or QHP candidates fulfill network adequacy standards. For PY 2023, issuers would attest to meeting the appointment wait time standards. Issuers that are unable to meet the specified standards for time and distance or appointment wait times must submit a justification to account for such variances.

HHS proposes that, for plans that use tiered networks to count toward the issuer's satisfaction of the network adequacy standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers would be counted towards network adequacy standards.

Finally, HHS proposes to collect information about providers who offer telehealth services via the ECP/NA template to inform network adequacy and provider access standards for future PYs. As discussed previously in the Collection of Information Requirements section, this may increase related administrative costs for issuers who do not already possess this data, though many issuers already collect and submit this information for network adequacy submissions in other markets. While we anticipate that increased burden related to telehealth data collection would be minimal for many issuers, the increased burden could ultimately lead to an increase in premiums for consumers. As noted previously, we believe that the potential benefits of obtaining telehealth information and using it to inform future network adequacy standards are in the best interests of both QHP enrollees and QHP issuers. As such, we anticipate that the additional burden would be mitigated by the expected benefits.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

18. Essential Community Providers (§ 156.235)

Section 156.235(a)(2)(i) provides that a plan has a sufficient number and geographic distribution of ECPs if the issuer demonstrates, among other things, that a QHP or QHP candidate provides access to a network of providers that includes at least a minimum percentage of ECPs, as specified by HHS.

For PY 2023 and future PYs, HHS proposes to raise the ECP threshold applicable to QHPs and QHP candidates from 20 percent to 35 percent. For this increased threshold, HHS would consider issuers to have satisfied the regulatory threshold requirement if the issuer contracts with at least 35 percent of available ECPs in each plan's service area to participate in the plan's provider network.

We note that in PYs 2015–2017, all FFE QHP issuers satisfied the 30 percent threshold with minimal reliance on ECP write-ins and justifications. In PYs 2018 through 2021, when the ECP threshold was 20 percent, all QHP issuers satisfied the lower threshold with ease and very little reliance on ECP write-ins and justifications.

Consequently, HHS anticipates that issuers can meet the proposed 35 percent threshold using ECP write-ins and justifications as needed. We believe that increasing the ECP threshold would lead to greater ECP access for low-income and medically underserved individuals. HHS anticipates that costs may not increase since HHS' data analysis shows most issuers could easily meet this standard or use the justification process. HHS expects that administrative cost changes would likely be minimal for most issuers.

HHS proposes that, for plans that use tiered networks to count toward the issuer's satisfaction of ECP standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers would be counted towards ECP standards.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

19. Standards for Delegated and Downstream Entities (§ 156.340)

We propose to amend and add language to § 156.340, to extend its applicability to QHP issuers on all Exchange models. The proposed changes capture the delegated and downstream entity standards that would apply to QHP issuers on State Exchanges and State Exchange SHOPs, as well as QHP issuers providing coverage on Exchange models that use the Federal platform, including, but not limited to, FFEs, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs. HHS also proposes to add a requirement that all agreements between QHP issuers and their downstream and delegated entities include language stating that the relevant Exchange authority, including State Exchanges, may demand and receive a delegated and downstream entity's records related to the QHP issuer's obligations in accordance with the minimum Federal standards related to Exchanges. These proposed amendments are intended to hold QHP issuers in all Exchange models responsible for their downstream and delegated entities' compliance with applicable Exchange standards, and to make their oversight obligations, and the obligations of their downstream and delegated entities, explicit. We also propose conforming amendments to the title of subpart D of 45 CFR part 156 from ''Standards for Qualified Health Plan Issuers on Federally Facilitated Exchanges and State-Based Exchanges on the Federal platform'' to ''Standards for Qualified Health Plan Issuers on Specific Types of Exchanges''.

We anticipate these proposals will impose a minimal burden on QHP issuers and Exchange authorities impacted by them. HHS expects some QHP issuers may need to make changes to existing record retention policies and their agreements with delegated and downstream entities. If finalized as proposed, the conforming amendments will become applicable to all books, contracts, computers, or other electronic systems, including medical records and documentation relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period, as of the effective date of the final rule. State Exchange authorities will retain primary enforcement authority and would be responsible for ensuring QHP issuers in State Exchanges and State Exchange SHOPs maintain oversight over downstream and delegated entities.

We seek comment on the potential costs, benefits, and transfers associated with this provision.

20. Payment for Cost-Sharing Reductions (§ 156.430)

We propose to amend § 156.430 to clarify that the CSR data submission process is mandatory only for those issuers that received CSR payments from HHS for any part of the benefit year as a result of a valid appropriation to make CSR payments, and voluntary for other issuers. In the event HHS has not made CSR payments to issuers

because there is no appropriation to do so, HHS will continue to provide those issuers that have not received CSR payments from HHS for any part of the benefit year the option to submit CSR data, but issuers will not be required to do so. We do not expect any of these provisions to increase burden on issuers, as this amendment would codify existing practices.

We seek comment on any potential costs, benefits, and transfers associated with this provision.

21. Quality Improvement Strategy (§ 156.1130)

We propose that beginning in 2023, a QHP issuer would be required to address reducing health and health care disparities as one of their QIS topic areas in addition to at least one other topic area outlined in section 1311(g)(1) of the ACA, including improving health outcomes of plan enrollees, preventing hospital readmissions, improving patient safety and reducing medical errors, and promoting wellness and health. We are not proposing any changes to regulatory text. We do not estimate additional costs or burdens as a result of this proposal.

We seek comment on any potential costs, benefits, and transfers associated with this proposal.

22. Medical Loss Ratio (§§ 158.140, 158.150, 158.170)

We propose to amend § 158.140(b)(2)(iii) to clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. To the extent some issuers currently include in incurred claims payments to providers that significantly reduce or eliminate rebates while providing no value to consumers, the proposed clarification would result in transfers from such issuers to enrollees in the form of higher rebates or lower premiums. Although we do not know how many issuers currently engage in such reporting practices or the amounts improperly included in MLR calculations, we estimate the impact of the proposed clarification by assuming that provider incentive and bonus payments of 1.06 percent or more of paid claims (the top 5 percent of such observations) may represent incentives based on MLR or similar metrics. Based on this assumption and the MLR data for 2019, the proposed clarification would increase rebates paid by issuers to consumers or reduce premiums collected by issuers from consumers by approximately $ 12 million per year.

We also propose to amend § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes. This proposed change would result in transfers from issuers that currently include indirect expenses in QIA to enrollees in the form of higher rebates or lower premiums. Although we do not know how many issuers include indirect expenses in QIA, we estimate the impact of the proposed change by assuming that indirect expenses inflate QIA by 41.5 percent (the midpoint of the 33 percent- to 50 percent range we have observed during MLR examinations) for half of the issuers that report QIA expenses (based on the frequency of QIA-related findings in MLR examinations). Based on these assumptions and the MLR data for 2020, the proposed clarification would increase rebates paid by issuers to consumers or reduce premiums collected by issuers from consumers by approximately $ 49.8 million per year.

We also propose to make a technical amendment to § 158.170(b) to correct an oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8), a provision that was vacated by the United States District Court for the District of Maryland in *City of Columbus, et al.* v. *Cochran,*[406] and thus deleted in part 2 of the 2022 Payment Notice final rule. We do not anticipate any impact on rebates or premiums as a result of this change. We seek comment on any potential costs, benefits, and transfers associated with these provisions.

D. Regulatory Alternatives Considered

In developing the policies contained in this proposed rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

As described in prior rulemakings and the 2021 RA Technical Paper, we considered a variety of alternatives to the proposed model specifications and updated enrollment duration factors for the HHS risk adjustment models.[407] For example, we considered adding a non-linear term or HCC counts terms for all enrollees in the adult and child risk adjustment models. As detailed in the proposed 2022 Payment Notice and the 2021 RA Technical Paper, we found that non-linear model specifications often failed to converge, preventing us from testing the impact of the non-linear model specifications on the magnitude of transfers.[408] In addition, the non-linear model specifications would significantly overhaul the current linear models, increasing the administrative burden on issuers and HHS. We also found that the HCC counts terms approach posed gaming concerns, which would violate principle six of the HHS-operated risk adjustment program by rewarding coding proliferation.

In addition to the non-linear and HCC counts model specifications, we also considered variations to the interacted HCC counts factors and the two-stage weighted model specifications. Specifically, we tested various alternative caps for the weights based on the distribution of costs, but found the proposed caps resulted in better prediction on average. For the prediction weights, we tested various alternative forms of weights, including reciprocals of the square root of prediction, log of prediction, and residuals from the first-step estimation, but the reciprocal of the capped predictions resulted in better PRs for low-cost enrollees compared to any of the other weights.

For the interacted HCC counts factors, we tested several HCCs and considered adding and removing certain HCCs from the proposed list in Table 3. We chose the list of HCCs in Table 3 because including these HCCs most improved prediction for enrollees with the highest costs, multiple HCCs, and with these specific HCCs. We also considered various alternatives to structure the interacted HCC counts, such as applying individual interacted HCC count factors (between 1–10 based on the number of HCCs an enrollee has) to each of the selected HCCs included in the models, instead of combining all of the selected HCCs into two severe and transplant indicator groups. We chose the proposed model specification because it would add fewer additional factors to the models, which minimizes the increased burden on issuers and HHS without sacrificing any significant predictive accuracy.

For the enrollment duration factors in the adult models, we propose to replace the enrollment duration factors with monthly duration factors of up to 6 months for enrollees with HCCs. The purpose of this proposed change is to

[406] 523 F. Supp. 3d 731 (D. Md. 2021).

[407] 85 FR 78572 at 78583–78586; See the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[408] Ibid.

address the underprediction of plan liability for partial-year adult enrollees with HCCs. As part of this assessment, we considered whether enrollment duration factors by type of partial-year enrollment (enrolling through a special enrollment period versus enrolling during the annual open enrollment period and dropping enrollment partway through the year), by market type (individual versus small group market), or by specific HCC (as well as by type of HCC—acute versus chronic) may be warranted. As previously noted, varying enrollment duration factors by partial-year enrollment type or by market produced factors that were generally very similar between partial- and full-year enrollees, which indicates they would add little value to the models while increasing complexity.[409] We chose the proposed enrollment duration factors, contingent on the presence of at least one HCC, because these factors improve predictive accuracy for partial-year enrollees and simplify the adult risk adjustment models compared to the current models.[410]

Relative to the other considered alternatives, our proposed model specification changes would improve the current models' predictive accuracy and minimize burden on issuers and HHS by avoiding unnecessary complexity.

With respect to the proposed changes to § 153.320(d), we considered repealing risk adjustment state flexibility for the individual catastrophic and non-catastrophic market risk pools, while retaining risk adjustment state flexibility for the small group market risk pool. Consistent with the directive in E.O. 14009[411] to prioritize protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals, we considered whether this approach is inconsistent with policies described in Sections 1 and 3 of E.O. 14009. In prior rulemakings, we received comments stating that risk adjustment state flexibility in any market may result in risk selection, market destabilization, increased premiums, smaller networks, and worse plan options. we believe that generally retaining state flexibility could introduce unnecessary risk of undermining the stated goals of the risk adjustment program.

We also considered whether to adopt an exception for states that previously requested reductions under § 153.320(d) to the risk adjustment transfers calculated by HHS under the state payment transfer formula. In the one state that has requested to reduce transfers under this policy, it has stabilized market participation and impacts issuers who receive risk adjustment payments by less than 1 percent of premiums.[412] Although allowing state flexibility may undermine the efficacy of risk adjustment by not fully compensating higher-risk plans for their enrollees, we believe the benefit of maintaining participation in markets that might otherwise only have a single issuer offering coverage outweighs the potential harm of not fully compensating the higher-risk plan for its enrollees when there is a *de minimis* (less than 1 percent) impact on premiums. Additionally, under the proposal in this rulemaking, if a prior participant seeks a future reduction to risk adjustment transfers in the 2024 benefit year or beyond, the state would need to demonstrate that it meets the de minimis regulatory criteria, meaning no issuer would need to increase its premiums by more than 1 percent as a result of the reduced risk adjustment payments.

With regard to the proposed changes to § 155.320, we considered taking no action to modify the requirement that when an Exchange does not reasonably expect to obtain sufficient verification data related to enrollment in or eligibility for employer sponsored coverage, the Exchange must select a random sample of applicants and attempt to verify their attestation with the employer listed on their Exchange application. However, based on HHS' experience conducting sampling, this manual verification process requires significant resources for a low return on investment, as using this method HHS identified only a small population of applicants who received APTC/CSR payments inappropriately. We believe the proposed change discussed earlier in the preamble to design a process to verify enrollment in or eligibility for an employer sponsored plan, informed by a risk assessment, is reasonably designed to ensure the accuracy of data, and is based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's own enrollment data. We also believe the proposed change would protect the integrity of the individual market by allowing all Exchanges to proactively identify applicants with the greatest incentive to forego enrolling in an employer sponsored plan in favor of Exchange coverage with APTC/CSRs that they may not be eligible to receive, thereby potentially adding high health risk to the individual market risk pool that should be covered by the group health market, for example.

We considered several alternatives to specifying in § 155.420 that Exchanges may conduct pre-enrollment verification of eligibility for special enrollment periods, at the option of the Exchange, including requiring Exchanges to verify a certain percentage of special enrollment period enrollments and designating specific special enrollment period types for which eligibility must be verified by the Exchange. However, we believed that imposing any requirements for pre-enrollment special enrollment period verification would increase burden on consumers and Exchanges and decrease implementation flexibility to decide the best way to conduct special enrollment period verification based on Exchange type, population characteristics, and trends.

HHS considered multiple options for measuring the improper payment amounts and rates for State Exchanges to comply with its statutory mandate in the PIIA. HHS developed and pilot tested the proposed methodology with extensive collaboration from participating Exchanges during a multi-year research and demonstration period. HHS considered the following alternatives while developing this proposed rule:

1. Conducting No Reviews

HHS might take no preventive efforts to detect improper payments. We would wait passively until third-party investigators, private whistleblowers, qui tam relators, disgruntled relatives, or others report speculation through Inspector General channels. Advanced statistical analysis could estimate the odds of third-party prosecution and project the improper payment amount and rate for each State Exchange (with wide confidence intervals). This low intervention strategy may not fully comply with statutory intent.

2. Placing More Responsibility on State Exchanges To Conduct Reviews

HHS could require that each State Exchange determine its own improper payment rate with broad discretion on

[409] See, for example, 85 FR 78572 at 78585–78586 and Sections 3.3.1 and 3.3.2 of the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes, available at *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[410] As detailed above, these new proposed factors would only apply to partial-year adult enrollees with up to 6 months of enrollment and at least one payment HCC.

[411] Executive Order 14009; 86 FR 7793 (Feb. 2, 2021).

[412] See, for example, the 2019, 2020, and 2021 Unified Rate Review Public Use Files, available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/ratereview.*

the methodology. This option would maximize regulatory flexibility while still complying with PIIA 2019 requirements. However, diverse methodology would make the State Exchanges' results difficult to compare and of variable validity. In addition, the costs resulting from higher error rates are borne by the federal government in the form of increased APTC and CSRs, giving State Exchanges' minimal incentive to aggressively reduce improper payments.

3. Placing More Responsibility on State Exchanges To Engage Third-Party Reviewers

HHS could require that State Exchanges engage third-party reviewers to determine the improper payment rate. As with financial reporting, the State Exchange could select among competing vendors to obtain its preferred combination of methodology, service, quality, and price. However, this approach would require more work and resources from both State Exchanges and HHS than the proposed methodology would require. The third party would need to obtain personally identifiable information from both state and federal data systems. These processes suffer from potential record matching and data security issues. In addition, competing vendors might offer incompatible methodologies, producing non-comparable improper payment rates.

4. Conducting a Random Sample Across All State Exchanges

HHS could annually sample from the population of all State Exchange enrollees, rather than within each State Exchange. Thus, more cases would come from larger State Exchanges. This design would increase the efficiency and decrease the variance for the national estimate, but it would not provide an estimate for each State Exchange. It also would not reduce the burden on each State Exchange and may not comply with statutory intent.

With respect to standardized options, we considered a range of options for our proposed policy approach at § 156.201. On one end of this range, we considered resuming standardized options as reflected in the 2017 and 2018 Payment Notices. This approach would have allowed issuers to voluntarily offer standardized options and have the Exchanges on the Federal platform, web-brokers, and Classic DE and EDE Pathways differentially display these plans. We also considered gradually limiting the number of non-standardized options per issuer, product network type, metal level, and service area over the course of several PYs. We also considered preferentially displaying standardized options over non-standardized options. We also considered requiring issuers to offer exclusively standardized options in FFEs and SBE–FPs. We believe the approach we have chosen for standardized options in which we propose to require issuers to offer standardized options and do not propose to limit the number of non-standardized offerings in PY 2023 strikes the greatest balance between simplifying the plan selection process, combatting discriminatory benefit designs, and advancing health equity, all while promoting a smooth transition to the introduction of standardized options.

For our proposal in §§ 155.240(e), 155.305(f)(5), and 155.340 on prorating the calculation and administration of premium and APTC, HHS considered an alternative form of implementation in which HHS would perform the proration on behalf of each State Exchange which does not already implement proration according to the proposed methodology. This approach would lessen concern regarding the burden of implementing a new proration methodology among State Exchanges. HHS already has the structures in place to prorate APTC and premium amounts in accordance with the proposed methodology and has already implemented proration in the FFEs and SBE–FPs.[413] Under this alternative, HHS would assume responsibility for prorating the amount of APTC due to each State Exchange based on the methodology HHS proposes in § 155.340 which states that when an enrollee is enrolled in a particular policy for less than the full coverage month (including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month) the amount of APTC paid to the issuer of the policy will be calculated as the product of (1) the APTC applied on the policy for one month of coverage divided by the number of days in the month, and (2) the number of days for which coverage is provided during the applicable month. However, this alternative would require State Exchanges to agree to allow HHS to use the data on the monthly SBMI to calculate the prorated amount. This would require State Exchanges to review payment reports to ensure the correct calculation of APTC and premium is reflected on each applicable State Exchanges' 1095–A. HHS expects that this alternative would produce additional burden of $4,500 in contract labor to update each State Exchange's SBMI and would necessitate increased data sharing and coordination back and forth between HHS and the applicable State Exchanges. In order to streamline the process of proration and allow State Exchanges greater control in the administration of APTC, HHS determined that it would propose that each State Exchange would prorate their own APTC and premium amounts for the applicable enrollees in their state. HHS seeks comment on the alternative proposals considered.

Additionally, for the proposal to prorate APTC amounts with amendments to §§ 155.240, 155.305(f)(5) and 155.340, we considered proposing to implement this requirement for the 2023 benefit year. However, after analyzing the potential burden on State Exchanges to achieve operational readiness, we concluded that 2023 may not provide sufficient time. Therefore, we propose 2024 benefit year implementation and request comment on the feasibility of 2023 benefit year implementation.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this proposed rule, we propose standards for the risk adjustment and HHS–RADV programs, which are intended to stabilize premiums and reduce incentives for issuers to avoid higher-risk enrollees. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for ''small entities'' established by the SBA, we do not believe that an initial regulatory

[413] Under the SBE–FP agreement, the same method also applies in the SBE–FPs, as they rely on the Federal platform, which calculates applicable premiums in those Exchanges.

flexibility analysis is required for such firms.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $41.5 million or less would be considered small entities for these NAICS codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $35 million or less.[414] We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report submissions for the 2019 MLR reporting year, approximately 77 out of 479 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less.[415] This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 72 percent of these small issuers belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $41.5 million. Only 10 of these 90 potentially small entities, three of them part of larger holding groups, are estimated to experience a change in rebates under the proposed amendments to the MLR provisions of this proposed rule in part 158. Therefore, we do not expect the proposed MLR provisions of this rule to affect a substantial number of small entities.

The proposals related to SEIPM at §§ 155.1500–155.1540 will affect only State Exchanges. As state governments do not constitute small entities under the statutory definition, and as all State Exchanges have revenues exceeding $5 million, an impact analysis for these provisions is not required under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule under title XVIII, title XIX, or part B of title 42 of the Social Security Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, we have determined that This proposed rule would not affect small rural hospitals. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. Although we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector does not meet the UMRA definition of unfunded mandate.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications.

In compliance with the requirement of E.O. 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the states, we 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 an individual basis.

While developing this rule, we attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, we complied with the requirements of E.O. 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For states that elected previously to operate an Exchange, those states had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the state. Current State Exchanges charge user fees to issuers.

In our view, while this proposed rule would not impose substantial direct requirement costs on state and local governments, this regulation has federalism implications due to potential direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. For example, the repeal of the risk adjustment state flexibility policy may have federalism implications, but they are mitigated because states have the option to operate their own Exchange and risk adjustment program if they believe the HHS risk adjustment methodology does not account for state-specific factors unique to the state's markets.

In addition, we believe this proposed regulation has federalism implications due to our proposal for Exchanges to design a new risk-based verification process for enrollment in or eligibility for employer sponsored plan coverage that meets minimum value standards, that is based on the Exchange's assessment of risk for inappropriate APTC/CSR payments. However, the federalism implications are mitigated because the proposed requirement provides Exchanges with the flexibility to determine the best process to verify employer sponsored coverage and may choose not to implement such a risk-based verification process.

As previously noted, the proposals in this rule related to SEIPM would impose a minimal unfunded mandate on State Exchanges to supply data for the improper payment calculation. Accordingly, E.O. 13132 does not apply to this section of the proposed rule. In addition, statute requires HHS to determine the amount and rate of improper payments. Finally, states have the option to choose an FFE or SBE–FP, each of which place different federal burdens on the state. As the SEIPM section of the proposed rule should not conflict with state law, HHS does not anticipate any preemption of state law. We invite State Exchanges to submit comments on this section of the proposed rule if they believe it would conflict with state law.

[414] *https://www.sba.gov/document/support--table-size-standards.*

[415] Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 15, 2021.

List of Subjects

45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below.

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 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.

§ 144.103 [Amended]

■ 2. Amend § 144.103 in the definition of ''large group market'' by removing the phrase '', unless otherwise provided under State law.''

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 3. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

■ 4. Amend § 147.104 by—
■ a. Revising paragraph (e);
■ b. Redesignating paragraph (i) as paragraph (j); and
■ c. Adding a new paragraph (i).

The revision and addition read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(e) *Marketing.* A health insurance issuer and its officials, employees, agents, and representatives must comply with any applicable State laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, sexual orientation, gender identity, expected length of life, degree of medical dependency, quality of life, or other health conditions.

* * * * *

(i) *Coverage denials for failure to pay premiums for prior coverage.* A health insurance issuer that denies coverage to an individual or employer due to the individual's or employer's failure to pay premium owed under a prior policy, certificate, or contract of insurance, including by attributing payment of premium for a new policy, certificate, or contract of insurance to the prior policy, certificate, or contract of insurance, violates paragraph (a) of this section.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 5. The authority citation for part 153 continues to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

■ 6. Amend § 153.320 by—
■ a. Revising paragraphs (d) introductory text and (d)(1)(iii);
■ b. Adding paragraph (d)((1)(iv);
■ c. Revising paragraphs (d)(4)(i)(A) and (B); and
■ d. Adding paragraph (d)(5).

The revisions and additions read as follows:

§ 153.320 Federally certified risk adjustment methodology.

* * * * *

(d) *State flexibility to request reductions to transfers.* For the 2020 through 2023 benefit years, States can request to reduce risk adjustment transfers in the State's individual catastrophic, individual non-catastrophic, small group, or merged markets risk pools by up to 50 percent in States where HHS operates the risk adjustment program. Beginning with the 2024 benefit year, only prior participants, as defined in paragraph (d)(5) of this section, may request to reduce risk adjustment transfers in the State's individual catastrophic, individual non-catastrophic, small group, or merged markets risk pools by up to 50 percent in States where HHS operates the risk adjustment program.

(1) * * *

(iii) For the 2020 through 2023 benefit years, a justification for the reduction requested demonstrating the State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool, or demonstrating the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments; or

(iv) Beginning with the 2024 benefit year, a justification for the reduction requested demonstrating the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers

that would receive reduced transfer payments.

* * * * *

(4) * * *

(i) * * *

(A) For the 2020 through 2023 benefit years, that State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and support the percentage reduction to risk adjustment transfers requested; or State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(B) Beginning with the 2024 benefit year that the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

* * * * *

(5) *Exception for prior participants.* As used in paragraph (d) of this section, prior participants mean States that submitted a State reduction request in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool in the 2020, 2021, 2022, or 2023 benefit year.

■ 7. Amend § 153.710 by—

■ a. Revising paragraphs (h)(1) introductory text and (h)(1)(iii) and (iv);

■ b. Adding paragraph (h)(1)(v); and

■ c. Revising paragraphs (h)(2) and (3).

The revisions and addition read as follows:

§ 153.710 Data requirements.

* * * * *

(h) * * *

(1) Notwithstanding any discrepancy report made under paragraph (d)(2) of this section, any discrepancy filed under § 153.630(d)(2), or any request for reconsideration under § 156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; reinsurance payment; cost-sharing reduction payment or charge; or risk corridors payment or charge, unless the dispute has been resolved, an issuer must report, for purposes of the risk corridors and MLR programs:

* * * * *

(iii) A cost-sharing reduction amount equal to the actual amount of cost-sharing reductions for the benefit year as calculated under § 156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service;

(iv) For medical loss ratio reporting only, the risk corridors payment to be made or charge assessed by HHS under § 153.510; and

(v) The risk adjustment data validation adjustment calculated by HHS in the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers.

(2) An issuer must report during the current MLR and risk corridors reporting year any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge before August 15, or the next applicable business day, of the current MLR and risk corridors reporting year unless instructed otherwise by HHS. An issuer must report any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge where such adjustment has not been accounted for in a prior MLR and Risk Corridor Annual Reporting Form, in the MLR and Risk Corridors Annual Reporting Form for the following reporting year.

(3) In cases where HHS reasonably determines that the reporting instructions in paragraph (h)(1) or (2) of this section would lead to unfair or misleading financial reporting, issuers must correct their data submissions in a form and manner to be specified by HHS.

■ 8. Revise § 153.730 to read as follows:

§ 153.730 Deadline for submission of data.

A risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must submit data to be considered for risk adjustment payments and charges and reinsurance payments for the applicable benefit year by April 30 of the year following the applicable benefit year or, if such date is not a business day, the next applicable business day.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 9. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

§ 155.120 [Amended]

■ 10. Amend § 155.120 in paragraph (c)(1)(ii) by removing the phrase ''age, or sex'' and adding in its place the phrase ''age, sex, sexual orientation, or gender identity''.

§ 155.206 [Amended]

■ 11. Amend § 155.206 in paragraph (i) by removing the phrase ''$100 for each day for each'' and adding in its place the phrase ''$100 for each day, as adjusted annually under 45 CFR part 102, for each''.

■ 12. Amend § 155.220 by—

■ a. Revising paragraphs (c)(3)(i)(A) and (L);

■ b. Adding paragraph (c)(3)(i)(M);

■ c. In paragraph (j)(2)(i) by removing the phrase ''age, or sex'' and adding in its place the phrase ''age, sex, sexual orientation, or gender identity'';

■ d. Revising paragraphs (j)(2)(ii);

■ e. In paragraph (j)(2)(iv), by removing the phrase ''described in § 155.260(b)(2); and'' and adding in its place the phrase ''described in § 155.260(b)(2);''; and

■ f. Adding paragraphs (j)(2)(vi) through (viii).

The revisions and additions read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(A) Disclose and display the following QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(c), and to the extent that enrollment support for a QHP is not available using the web-broker's website, prominently display a standardized disclaimer provided by HHS stating that enrollment support for the QHP is available on the Exchange website, and provide a Web link to the Exchange website:

(*1*) Premium and cost-sharing information;

(*2*) The summary of benefits and coverage established under section 2715 of the PHS Act;

(*3*) Identification of whether the QHP is a bronze, silver, gold, or platinum

level plan as defined by section 1302(d) of the Affordable Care Act, or a catastrophic plan as defined by section 1302(e) of the Affordable Care Act;

(*4*) The results of the enrollee satisfaction survey, as described in section 1311(c)(4) of the Affordable Care Act;

(*5*) Quality ratings assigned in accordance with section 1311(c)(3) of the Affordable Care Act; and

(*6*) The provider directory made available to the Exchange in accordance with § 156.230 of this subchapter.

* * * * *

(L) Not display QHP advertisements or recommendations, or otherwise provide favored or preferred placement in the display of QHPs, based on compensation the agent, broker, or web-broker receives from QHP issuers; and

(M) Prominently display a clear explanation of the rationale for QHP recommendations and the methodology for its default display of QHPs.

* * * * *

(j) * * *

(2) * * *

(ii) Provide the federally-facilitated Exchanges with correct information under section 1411(b) of the Affordable Care Act, including, but not limited to:

(A) Only entering an email address on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost sharing reductions for QHPs that is secure, not disposable, and belongs to the consumer or the consumer's authorized representative designated in compliance with § 155.227. A consumer's email address may only be entered on an Exchange application with the consent of the consumer or the consumer's authorized representative. Properly entered email addresses must adhere to the following guidelines:

(*1*) The email address may not have domains that remove email from an inbox after a set period of time;

(*2*) The email address must be accessible by the consumer, or the consumer's authorized representative designated in compliance with § 155.227, and may not be accessible by the agent, broker, or web-broker assisting the consumer; and

(*3*) The email address may not have domains that belong to the agent, broker, or web-broker or their business or agency.

(B) Only entering a telephone number on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost sharing reductions for QHPs that belongs to the consumer or their authorized representative designated in compliance with § 155.227. Telephone numbers entered on Exchange applications may not be the personal number or business number of the agent, broker, or web-broker assisting the consumer, or their business or agency, unless the telephone number is actually that of the consumer or their authorized representative.

(C) Only entering a mailing address on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost sharing reductions for QHPs that belongs to, or is primarily accessible by, the consumer or their authorized representative designated in compliance with § 155.227, is not for the exclusive or convenient use of the agent, broker, or web-broker, and is an actual residence or a secure location where the consumer or their authorized representative may receive correspondence, such as a P.O. Box or homeless shelter. Mailing addresses entered on Exchange applications may not be that of the agent, broker, or web-broker assisting the consumer, or their business or agency, unless the address is the actual residence of the consumer or their authorized representative.

(D) When submitting household income projections used by the Exchange to determine a tax filer's eligibility for advance payments of the premium tax credit in accordance with § 155.305(f) or cost-sharing reductions in accordance with § 155.305(g), only entering a consumer's household income projection that the consumer or the consumer's authorized representative designated in compliance with § 155.227 has knowingly authorized and confirmed as accurate. Household income projections on Exchange applications must be calculated and attested to by the consumer. The agent, broker, or web-broker assisting the consumer may answer questions posed by the consumer related to household income projection, such as helping the consumer determine what qualifies as income.

* * * * *

(vi) Not engage in scripting and other automation of interactions with CMS Systems or the Direct Enrollment Pathways, unless approved in advance in writing by CMS.

(vii) Only use an identity that belongs to the consumer when identity proofing the consumer's account on *HealthCare.gov*.

(viii) When providing information to federally-facilitated Exchanges that may result in a determination of eligibility for a special enrollment period in accordance with § 155.420, obtain authorization from the consumer to submit the request for a determination of eligibility for a special enrollment period and make the consumer aware of the specific triggering event and special enrollment period for which the agent, broker, or web-broker will be submitting an eligibility determination request on the consumer's behalf.

* * * * *

■ 13. Amend § 155.240 by adding paragraph (e)(2) to read as follows:

§ 155.240 Payment of premiums.

* * * * *

(e) * * *

(2) For plan years 2024 and beyond, in each Exchange, the premium for a policy in which an enrollee is enrolled for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, must equal the product of:

(i) The premium for 1 month of coverage divided by the number of days in the month; and

(ii) The number of days for which coverage is being provided in the month described in paragraph (e)(1)(i) of this section.

■ 14. Amend § 155.305 by revising paragraph (f)(1)(i) to read as follows:

§ 155.305 Eligibility standards.

* * * * *

(f) * * *

(1) * * *

(i) He or she is expected to have a household income that will qualify the tax filer as an applicable taxpayer according to 26 CFR 1.36B–2(b) for the benefit year for which coverage is requested; and

* * * * *

■ 15. Amend § 155.320 by—

■ a. Revising paragraphs (d)(4) introductory text, (d)(4)(i) introductory text, and (d)(4)(i)(A);

■ b. Removing paragraph (d)(4)(i)(D).

■ c. Redesignating paragraph (d)(4)(i)(E) as paragraph (d)(4)(i)(D).

■ d. Removing paragraph (d)(4)(i)(F);

■ e. Redesignating paragraph (d)(4)(i)(G) as paragraph (d)(4)(i)(E) and revising it; and

■ f. Removing and reserving paragraph (d)(4)(ii).

The revisions read as follows:

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(d) * * *

(4) *Alternate procedures.* For any benefit year for which it does not reasonably expect to obtain sufficient

verification data as described in paragraphs (d)(2)(i) through (iii) of this section, the Exchange may follow the procedures specified in paragraph (d)(4)(i) of this section, or the Exchange may follow the procedures specified in paragraph (d)(4)(ii) of this section. For purposes of this paragraph (d)(4), the Exchange reasonably expects to obtain sufficient verification data for any benefit year when, for the benefit year, the Exchange is able to obtain data about enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan from at least one electronic data source that is available to the Exchange and that has been approved by HHS, based on evidence showing that the data source is sufficiently current, accurate, and minimizes administrative burden, as described under paragraphs (d)(2)(i) of this section.

(i) Based on the Exchange's assessment of risk for inappropriate payment of advance payments of the premium tax credit or cost-sharing reductions, implement a verification process that is reasonably designed to ensure the accuracy of the data and is based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's own enrollment data, for enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan, as appropriate.

(A) If, as part of the verification process described under paragraph (d)(4)(i) of this section, the Exchange will be contacting any employer identified on the application for the applicant and the members of his or her family, as defined in 26 CFR 1.36B–1(d), to verify whether the applicant is enrolled in an eligible employer sponsored plan or is eligible for qualifying coverage in an eligible employer sponsored plan for the benefit year for which coverage is requested, the Exchange must provide notice to the applicant;

* * * * *

(E) To carry out the process described in paragraph (d)(4)(iii) of this section, the Exchange must only disclose an individual's information to an employer to the extent necessary for the employer to identify the employee.

* * * * *

■ 16. Amend § 155.340 by adding paragraph (i) to read as follows:

§ 155.340 Administration of advance payments of the premium tax credit and cost-sharing reductions.

* * * * *

(i) *Calculation of advance payments of the premium tax credit when policy coverage lasts less than the full coverage month.* (1) For plan years beginning in 2024 and beyond, when the Exchange determines that an individual is eligible for advance payments of the premium tax credit and the enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, the amount of the advance payment of the premium tax credit paid to the issuer of the policy must equal the product of—

(i) The advance payments of the premium tax credit applied to the policy for one month of coverage divided by the number of days in the month; and

(ii) The number of days for which coverage is being provided in the month under the policy described in paragraph (i)(1)(i) of this section.

(2) [Reserved]

■ 17. Amend § 155.420 by adding paragraph (g) to read as follows:

§ 155.420 Special enrollment periods.

* * * * *

(g) *Pre-enrollment special enrollment period verification.* At the option of the Exchange, an Exchange may verify prior to processing a qualified individual's plan selection that the qualified individual is eligible for a special enrollment period under this section. In special circumstances where the Exchange determines that such pre-enrollment special enrollment period verification may cause undue burden on qualified individuals, the Exchange may provide an exception to the pre-enrollment special enrollment period verification process, provided it does so in a manner that is not based on a prohibited discriminatory basis. Exchanges on the Federal platform will conduct pre-enrollment special enrollment verification of eligibility only for special enrollment periods under paragraph (d)(1) of this section.

■ 18. Amend § 155.1200—

■ a. In paragraph (c) introductory text by removing the phrase ''HHS for review'' and adding in its place the phrase, ''HHS for review, unless a State Exchange is meeting its programmatic audit requirement for a given benefit year under paragraph (e) of this section''; and

■ b. By adding paragraph (e).

The addition reads as follows.

§ 155.1200 General program integrity and oversight requirements.

* * * * *

(e) *State Exchange Improper Payment Measurement (SEIPM) program.* For a given benefit year, a State Exchange may meet the independent external programmatic audit requirement outlined in paragraph (c) of this section by completing the required SEIPM program process, established through 45 CFR part 155, subpart P.

■ 19. Add subpart P to read as follows:

Subpart P—State Exchange Improper Payment Measurement Program

Sec.
155.1500 Purpose and definitions.
155.1505 Program notification and planning process.
155.1510 Data collection.
155.1515 Review process and improper payment rate determination.
155.1520 Error findings decisions.
155.1525 Redetermination of error findings decisions.
155.1530 Appeal of redetermination decision.
155.1535 Corrective action plan.
155.1540 Failure to comply.

Subpart P—State Exchange Improper Payment Measurement Program

§ 155.1500 Purpose and definitions.

(a) *Purpose.* This subpart sets forth the requirements of the State Exchange Improper Payment Measurement program.

(b) *Definition*s. As used in this subpart—

Appeal of redetermination decision (or appeal decision) means the HHS appeal decision resulting from a State Exchange's appeal of the HHS' redetermination decision.

Corrective action plan (CAP) means the plan a State Exchange develops in order to correct errors resulting in improper payments.

Error means a finding by HHS that a State Exchange did not correctly apply a requirement in subparts D and E of this part regarding eligibility for and enrollment in a qualified health plan; advance payments of the premium tax credit, including the calculation of advance payments of the premium tax credit; redeterminations of eligibility determinations during a benefit year; or annual eligibility redeterminations, which have a payment impact.

Error findings decision means the enumeration of errors made by a State Exchange, including a determination of how the enumerated errors inform improper payment estimation and reporting requirements.

Redetermination of an error findings decision (or redetermination decision) means HHS' decision resulting from a State Exchange's request for a redetermination of an error findings decision.

Review means the process of analyzing and assessing data submitted by a State Exchange to HHS in order to determine a State Exchange's

compliance with subparts D and E of this part as it relates to improper payments.

State Exchange Improper Payment Measurement (SEIPM) program means the process for determining estimated improper payments and other information required under the Payment Integrity Information Act of 2019, and implementing guidance, for advance payments of the premium tax credit, which includes a review of a State Exchange's determinations regarding eligibility for and enrollment in a qualified health plan; the calculation of advance payments of the premium tax credit; redeterminations of eligibility determinations during a benefit year; and annual eligibility redeterminations.

§ 155.1505 Program notification and planning process.

(a) *Annual program notification.* Beginning no earlier than in 2023, prior to the start of the measurement year, HHS will annually issue a notification to State Exchanges concerning information related to the SEIPM program and the program's upcoming measurement cycle, which may include but would not be limited to review criteria; key changes from prior measurement cycles, where applicable; or other modifications regarding specific SEIPM activities.

(b) *Issuance of annual program schedule.* Beginning no earlier than 2023, prior to the start of the measurement year, HHS will annually issue a schedule that prescribes the timeline for the data requests in accordance with § 155.1510.

(c) *Notification of changes.* In response to the annual program notification, the State Exchange must provide HHS with operational and policy information required to perform the SEIPM review process, as well as any operational, policy, or other changes that may impact the SEIPM review process within the deadline prescribed in the annual program schedule.

§ 155.1510 Data collection.

(a) *Requirements.* For purposes of the SEIPM program, a State Exchange must annually submit the following eligibility and enrollment information, in a manner specified by HHS.

(1) Pre-sampling data.

(2) Sampled unit data.

(b) *Timing.* The State Exchange must submit the data specified in paragraph (a) of this section within the timelines specified in the annual program schedule described in § 155.1505(c). HHS will consider requests for extension when extreme circumstances hinder the ability of a State Exchange to submit data in accordance with the requirements of this section.

(c) *Compliance.* Failure to timely provide the information in accordance with paragraph (a) or (b) of this section may result in one or more error findings during the review based upon insufficient data to support that the State was in compliance with subparts D and E of this part as it relates to advance payments of premium tax credits.

§ 155.1515 Review process and improper payment rate determination.

(a) *Receipt of data.* HHS will maintain a record of status of receipt for the information that is requested from each State Exchange for a minimum of 10 years.

(b) *Review of records.* For each sampled record, HHS will review the information provided by the State Exchange. The review will determine whether any errors were made in a State Exchange's determinations regarding eligibility for and enrollment in a qualified health plan; advance payments of the premium tax credit, including the calculation of advance payments of the premium tax credit; redeterminations of eligibility determinations during a benefit year; and annual eligibility redeterminations.

(c) *Improper payment rate.* HHS will notify each State Exchange of HHS' error findings decisions for that State Exchange and HHS' estimate of that State Exchange's improper payment rate.

§ 155.1520 Error findings decisions.

(a) *Issuance of error findings decisions.* Upon completion of the review, HHS will issue the error findings decision to the State Exchange.

(b) *Content of error findings decision.* The error findings decisions at a minimum will include:

(1) The review findings regarding any errors made by the State Exchange.

(2) Information regarding the State Exchange's right to request a redetermination of the error findings decision in accordance with § 155.1525.

§ 155.1525 Redetermination of error findings decisions.

(a) *Request for redetermination.* A State Exchange may request a redetermination of error findings decision within the deadline prescribed by the annual program schedule. During the period for a State Exchange to request a redetermination of the error findings decision, HHS will consider a request for an extension in extreme circumstances, which includes but is not limited to situations such as natural disasters, interruptions in business operations such as major system failures, or other extreme circumstances. At a minimum, the request for redetermination must include:

(1) The error(s) for which the State Exchange is requesting a redetermination;

(2) All data and information that supports the State Exchange's request for a redetermination; and

(3) An explanation of how the data and information pertains to the error(s) specified in (a)(1).

(b) *Issuance of redetermination decision.* The redetermination of an error findings decision will be issued within the deadline prescribed by the annual program schedule. A State Exchange will be notified of any delays in the issuance in the redetermination of an error findings decision.

(c) *Content of redetermination decision.* HHS' redetermination of an error findings decision, at a minimum, will include:

(1) HHS' findings regarding the impact of the additional data and information provided by the State Exchange on the error(s) for which the State Exchange requested a redetermination,

(2) Information regarding the State Exchange's right to request an appeal of the redetermination of the error findings decision in accordance with § 155.1530.

§ 155.1530 Appeal of redetermination decision.

(a) *Request for appeal.* A State Exchange may request an appeal of a redetermination decision within the deadline prescribed by the annual program schedule. The request for appeal must indicate the specific error(s) identified in the redetermination decision for which the State Exchange is requesting an appeal.

(b) *On-the-record review.* Additional data or information, beyond that submitted during the redetermination request, will not be considered in rendering the appeal decision.

(c) *Issuance of appeal decision.* The appeal decision will be issued within the deadline prescribed in the annual program schedule unless there is a delay. A State Exchange will be notified of any delays in the issuance of the appeal decision.

(d) *Content of appeal decision.* HHS' appeal decision will include:

(1) The findings regarding the error(s) for which an appeal was requested. The findings will be limited to those error(s) identified in the request for an appeal.

(2) The final disposition of the appeal request.

(e) *Final report.* Upon completion of the review and the closure of all appeals, HHS may issue a report containing the error findings and the estimated improper payment rate.

§ 155.1535 Corrective action plan.

(a) *Corrective action plan.* Based on a State Exchange's error rate for a given benefit year, HHS, in its reasonable discretion, may require the State Exchange to develop and submit a corrective action plan to correct errors resulting in improper payments.

(b) *Content of proposed corrective action plan.* A State Exchange's corrective action plan must be developed in accordance with Appendix C to Office of Management and Budget Circular No. A–123.

(c) *Implementation and evaluation of corrective action plan.* A State Exchange must develop an implementation schedule for its corrective action plan, implement the plan in accordance with that schedule, and regularly evaluate whether the initiatives are effective at reducing or eliminating error causes.

(d) *Failure to submit.* If a State Exchange does not submit a corrective action plan when required, HHS may take actions consistent with § 155.1540(a)(1) and (2).

§ 155.1540 Failure to comply.

(a) *Failure to comply.* If a State Exchange fails to substantially comply with the data collection requirements or the CAP provisions contained in this subpart, and HHS finds that such failures undermine or prohibit HHS's efficient administration of Exchange improper payment measurement activities, HHS may implement measures or procedures in relation to the State Exchange that:

(1) HHS determines are appropriate to secure the State Exchange's compliance with the data collection requirements or the CAP provisions contained in subpart P, and to detect, prevent or reduce abuses in the administration of advance payments of the premium tax credit under title I of the ACA; and

(2) the Secretary has authority to implement under title I of the Affordable Care Act or any other Federal law.

(b) [Reserved]

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 20. The authority citation for part 156 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 21. Amend § 156.50 by—

■ a. Removing paragraph (c)(3); and

■ b. Revising paragraphs (d)(1) introductory text, (d)(2)(i)(A) and (B), (d)(2)(ii), (d)(2)(iii)(B), (d)(3) introductory text, (d)(4) and (6), and (d)(7) introductory text.

The revisions read as follows:

§ 156.50 Financial support.

* * * * *

(d) * * *

(1) A participating issuer offering a plan through a federally-facilitated Exchange or State Exchange on the Federal platform may qualify for an adjustment of the federally-facilitated Exchange user fee specified in paragraph (c)(1) of this section or the State Exchange on the Federal platform user fee specified in paragraph (c)(2) of this section, to the extent that the participating issuer—

* * * * *

(2) * * *

(i) * * *

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, whether or not the participating issuer was the entity that made the payments for contraceptive services;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable; and

* * * * *

(ii) Each third party administrator that intends to seek an adjustment on behalf of a participating issuer of the federally-facilitated Exchange user fee or the State-based Exchange on the Federal platform user fee based on payments for contraceptive services, must submit to HHS a notification of such intent, in a manner specified by HHS, by the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4).

(iii) * * *

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable;

* * * * *

(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, equal in value to the sum of the following:

* * * * *

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

* * * * *

(6) A participating issuer that receives an adjustment in the user fee specified in paragraph (c)(1) or (2) of this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator of a plan with respect to which an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

* * * * *

■ 22. Amend § 156.111 by—

■ a. Revising the section heading;

■ b. Revising paragraph (d) and paragraph (e) introductory text; and

■ c. Removing paragraph (f).

The revisions read as follows:

§ 156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020.

* * * * *

(d) A State must notify HHS of the selection of a new EHB-benchmark plan by the first Wednesday in May that is 2 years before the effective date of the new EHB-benchmark plan.

(1) If the State does not make a selection by the first Wednesday in May that is 2 years before the effective date of the new EHB-benchmark plan, or its benchmark plan selection does not meet the requirements of this section and section 1302 of the ACA, the State's EHB-benchmark plan for the applicable plan year will be that State's EHB-benchmark plan applicable for the prior year.

(2) [Reserved]

* * * * *

(e) A State changing its EHB-benchmark plan under this section must submit documents in a format and manner specified by HHS by the first Wednesday in May that is 2 years before the effective date of the new EHB-benchmark plan. These must include:

* * * * *

■ 23. Amend § 156.115 by revising paragraph (b)(2) to read as follows:

§ 156.115 Provision of EHB.

* * * * *

(b) * * *

(2) An issuer may substitute a benefit within the same EHB category, unless prohibited by applicable State requirements. Substitution of benefits between EHB categories is not permitted.

* * * * *

■ 24. Amend § 156.125 by revising paragraph (a) to read as follows:

§ 156.125 Prohibition on discrimination.

(a) An issuer does not provide EHB if its benefit design, or the implementation of its benefits design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. A non-discriminatory benefit design that provides EHB is one that is clinically-based, incorporates evidence-based guidelines into coverage and programmatic decisions, and relies on current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources.

* * * * *

■ 25. Amend § 156.140 by revising paragraph (c) to read as follows:

§ 156.140 Levels of coverage.

* * * * *

(c) *De minimis variation.* (1) For plan years beginning on or after January 1, 2018 through December 31, 2022, the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is −4 percentage points and +2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, in which case the allowable variation in AV for such plan is −4 percentage points and +5 percentage points.

(2) For plan years beginning on or after January 1, 2023, the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is −2 percentage points and +2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, in which case the allowable variation in AV for such plan is −2 percentage points and +5 percentage points.

■ 26. Amend § 156.200—

■ a. By revising paragraph (b)(3); and

■ b. In paragraph (e) by removing the phrase ''age, or sex'' and adding in its place the phrase ''age, sex, sexual orientation, or gender identity''.

The revision read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(b) * * *

(3) Ensure that each QHP complies with benefit design standards, as defined in § 156.20, except that individual market silver QHPs must have an AV of 70 percent, with a de minimis allowable AV variation of −0 percentage points and +2 percentage points;

* * * * *

■ 27. Add § 156.201 to read as follows:

§ 156.201 Standardized options.

For plan year 2023 and subsequent plan years, a QHP issuer in a federally-facilitated Exchange or a State-based Exchange on the Federal platform, other than an issuer that is already required to offer standardized options under state action taking place on or before January 1, 2020, must offer at least one standardized QHP option, defined at § 155.20 of this subchapter, at every product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, metal level, and throughout every service area that it also offers non-standardized QHP options, including, for silver plans, for the income-based cost-sharing reduction plan variations, as provided for at § 156.420(a), but not for the zero and limited cost sharing plan variations, as provided for at § 156.420(b).

■ 28. Amend § 156.230 by—

■ a. Revising paragraphs (a)(1) through (3); and,

■ b. Removing paragraph (f).

The revisions read as follows:

§ 156.230 Network adequacy standards.

(a) * * *

(1) Each QHP issuer that uses a provider network must ensure that the provider network consisting of in-network providers, and, for plans with more than one tier of network, specifically the provider network consisting of in-network providers in the tier for which the plan imposes the lowest cost-sharing obligation, as available to all enrollees, meets the following standards:

(i) Includes essential community providers in accordance with § 156.235;

(ii) Maintains a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance abuse services, to ensure that all services will be accessible without unreasonable delay; and

(iii) Is consistent with the rules for network plans of section 2702(c) of the PHS Act.

(2)(i) *Standards.* For plan years beginning on or after January 1, 2023, a QHP issuer on a federally-facilitated Exchange must comply with the requirement in paragraph (a)(1)(ii) of this section by:

(A) Meeting time and distance standards established by the federally-facilitated Exchange. Such time and distance standards will be developed for consistency with industry standards and published in guidance.

(B) Meeting appointment wait time standards established by the federally-facilitated Exchange. Such appointment wait time standards will be developed for consistency with industry standards and published in guidance.

(ii) *Written justification.* If a plan applying for QHP certification to be offered through a federally-facilitated

Exchanges does not satisfy the network adequacy standards described in paragraphs (a)(2)(i)(A) and (B) of this section, the issuer must include as part of its QHP application a justification describing how the plan's provider network provides an adequate level of service for enrollees and how the plan's provider network will be strengthened and brought closer to compliance with the network adequacy standards prior to the start of the plan year. The issuer must provide information as requested by the FFE to support this justification.

(3) The federally-facilitated Exchange may grant an exception to the requirements in paragraph (a)(2)(i)(A) of this section if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates.

* * * * *

■ 29. Amend § 156.235 by revising paragraphs (a)(2)(i) and (b)(2)(i) to read as follows:

§ 156.235 Essential community providers.

(a) * * *

(2) * * *

(i) The network includes as participating providers at least a minimum percentage, as specified by HHS, of available essential community providers in each plan's service area. Multiple providers at a single location will count as a single essential community provider toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the essential community provider standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers will be counted towards essential community provider standards; and

* * * * *

(b) * * *

(2 * * *

(i) The number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal poverty level satisfies a minimum percentage, specified by HHS, of available essential community providers in the plan's service area. Multiple providers at a single location will count as a single essential community provider toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the essential community provider standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers would be counted towards essential community provider standards; and

* * * * *

Subpart D—Standards for Qualified Health Plan Issuers for Specific Types of Exchanges

■ 30. Revise the subpart D heading to read as set forth above.

■ 31. Amend § 156.340 by revising paragraphs (a) and (b)(4) and (5) to read as follows:

§ 156.340 Standards for downstream and delegated entities.

(a) *General requirement.* Effective October 1, 2013, notwithstanding any relationship(s) that a QHP issuer may have with delegated and downstream entities, a QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities with all applicable Federal standards related to Exchanges. The applicable standards depend on the Exchange model type in which the QHP is offered, as described in paragraph (a)(1) and (2) of this section.

(1) QHP issuers participating in Exchange models that do not use the Federal platform, including State Exchanges and State Exchange SHOPs. QHP issuers maintain responsibility for ensuring their downstream and delegated entities comply with the Federal standards related to Exchanges, including the standards in of subpart C of this part with respect to each of its QHPs on an ongoing basis, as well as the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 and, in the small group market, §§ 155.705 and 155.706 of this subchapter, unless the standard is specifically applicable to a federally-facilitated Exchange or FF–SHOP;

(2) QHP issuers participating in Exchanges that use the Federal platform, including federally-facilitated Exchanges, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs. QHP issuers maintain responsibility for ensuring their downstream and delegated entities comply with Federal standards related to Exchanges, including the standards in subpart C of part 156 with respect to each of its QHPs on an ongoing basis, as well as the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 of this subchapter and, in the small group market, §§ 155.705 and 155.706 of this subchapter if applicable to the Exchange type in which the QHP issuer is operating. QHP issuers are also responsible for their downstream and delegated entities' compliance with the standards of § 155.220 of this subchapter with respect to assisting with enrollment in QHPs, and to the standards of §§ 156.705 and 156.715 of this subchapter for maintenance of records and compliance reviews if applicable to the Exchange type in which the QHP issuer is operating.

(b) * * *

(4) Specify that the delegated or downstream entity must permit access by the Secretary and the OIG or their designees in connection with their right to evaluate through audit, inspection, or other means, to the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period;

(5) All agreements between issuers offering QHPs through an Exchange and delegated or downstream entities the issuers engage to support the issuer's activities on an Exchange must include text under which the language stating that the relevant Exchange authority may demand and receive the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period.

■ 32. Amend § 156.400 by revising the definition of ''De minimis variation for a silver plan variation'' to read as follows:

§ 156.400 Definitions.

* * * * *

De minimis variation for a silver plan variation means a −0 percentage point

and +1 percentage point allowable AV variation.

* * * * *

■ 33. Amend § 156.430 by revising paragraphs (b)(1), (d) introductory text, (e) introductory text, and (e)(1) to read as follows:

§ 156.430 Payment for cost-sharing reductions.

* * * * *

(b) * * *

(1) When there is an appropriation to make cost-sharing reduction payments to QHP issuers, a QHP issuer will receive periodic advance payments from HHS to the extent permitted by the appropriation and calculated in accordance with § 155.1030(b)(3) of this subchapter.

* * * * *

(d) *Cost-sharing reductions data submissions.* HHS will periodically provide a submission window for issuers to submit cost-sharing reduction data documenting cost-sharing reduction amounts issuers paid, as specified in paragraphs (d)(1) and (2) of this section, in a form and manner specified by HHS in guidance, calculated in accordance with paragraph (c) of this section. When HHS makes cost-sharing reduction payments to QHP issuers, HHS will notify QHP issuers that the submission of the cost-sharing data is mandatory for those issuers having received cost-sharing reduction payments for any part of the benefit year and voluntary for other issuers, and HHS will use the data to reconcile advance cost-sharing reduction payments to issuers against the actual amounts of cost-sharing reductions QHP issuers provided, as determined by HHS based on amounts specified in paragraphs (d)(1) and (2) of this section, as calculated in accordance with paragraph (c) of this section. In the absence of an appropriation to make cost-sharing reduction payments to issuers, HHS will notify QHP issuers that the submission of the cost-sharing data is voluntary. The cost-sharing data that must be submitted in either a voluntary or mandatory submission includes:

* * * * *

(e) *Cost-sharing reductions payments and charges.* If the actual amounts of cost-sharing reductions determined by HHS based on amounts described in paragraphs (d)(1) and (2) of this section are—

(1) More than the amount of advance payments HHS provided, and the QHP issuer has timely provided the data of actual amounts of cost-sharing reductions as required under paragraph (c) of this section, if an appropriation is available to make cost-sharing payments to QHP issuers, HHS will make a payment to the QHP issuer for the difference; or

* * * * *

§ 156.1230 [Amended]

■ 34. Amend § 156.1230 in paragraph (b)(2) by removing the phrase ''age, or sex'' and adding in its place the phrase ''age, sex, sexual orientation, or gender identity''.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 35. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg–18.

■ 36. Amend § 158.140 by revising paragraph (b)(2)(iii) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(2) * * *

(iii) The amount of incentive and bonus payments made to providers that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.

* * * * *

■ 37. Amend § 158.150 by revising paragraph (a) to read as follows:

§ 158.150 Activities that improve health care quality.

(a) *General requirements.* The report required in § 158.110 must include expenditures directly related to activities that improve health care quality, as such activities are described in this section.

* * * * *

■ 38. Amend § 158.170 by revising paragraph (b) introductory text to read as follows:

§ 158.170 Allocation of expenses.

* * * * *

(b) *Description of the methods used to allocate expenses.* The report required in § 158.110 must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

* * * * *

Dated: December 23, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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