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

CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Part 1003

Home Mortgage Disclosure (Regulation C) Adjustment to Asset-Size Exemption Threshold

AGENCY: Consumer Financial Protection Bureau.

ACTION: Final rule; official interpretation.

SUMMARY: The Consumer Financial Protection Bureau (CFPB) is amending the official commentary that interprets the requirements of the CFPB's Regulation C (Home Mortgage Disclosure) to reflect the asset-size exemption threshold for banks, savings associations, and credit unions based on the annual percentage change in the average of the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W). Based on the 4.1 percent increase in the average of the CPI–W for the 12-month period ending in November 2023, the exemption threshold is adjusted to $56 million from $54 million. Therefore, banks, savings associations, and credit unions with assets of $56 million or less as of December 31, 2023, are exempt from collecting data in 2024.

DATES: This rule is effective on January 1, 2024.

FOR FURTHER INFORMATION CONTACT: Anna Boadwee and Adrien Fernandez, Attorney-Advisors, Office of Regulations, at (202) 435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION: The CFPB is amending Regulation C, which implements the Home Mortgage Disclosure Act of 1975 (HMDA) asset thresholds, to establish the asset-sized exemption threshold for depository financial institution for 2024. The asset threshold will be $56 million for 2024.

I. Background

HMDA requires most mortgage lenders located in metropolitan areas to collect data about their housing-related lending activity.[1] Annually, lenders must report their data to the appropriate Federal agencies and make the data available to the public. The CFPB's Regulation C implements HMDA.[2]

Prior to 1997, HMDA exempted certain depository institutions as defined in HMDA (*i.e.,* banks, savings associations, and credit unions) with assets totaling $10 million or less as of the preceding year-end. In 1996, HMDA was amended to expand the asset-size exemption for these depository institutions.[3] The amendment increased the dollar amount of the asset-size exemption threshold by requiring a one-time adjustment of the $10 million figure based on the percentage by which the CPI–W for 1996 exceeded the CPI–W for 1975, and it provided for annual adjustments thereafter based on the annual percentage increase in the CPI–W, rounded to the nearest multiple of $1 million.

The definition of ''financial institution'' in § 1003.2(g) provides that the CFPB will adjust the asset threshold based on the year-to-year change in the average of the CPI–W, not seasonally adjusted, for each 12-month period ending in November, rounded to the nearest $1 million. For 2023, the threshold was $54 million. During the 12-month period ending in November 2023, the average of the CPI–W increased by 4.1 percent. As a result, the exemption threshold is increased to $56 million for 2024. Thus, banks, savings associations, and credit unions with assets of $56 million or less as of December 31, 2023, are exempt from collecting data in 2024. An institution's exemption from collecting data in 2024 does not affect its responsibility to report data it was required to collect in 2023.

II. Procedural Requirements

A. Administrative Procedure Act

Under the Administrative Procedure Act (APA), notice and opportunity for public comment are not required if the CFPB finds that notice and opportunity for public comment are impracticable, unnecessary, or contrary to the public interest.[4] Pursuant to this final rule, comment 2(g)–2 in Regulation C, supplement I, is amended to update the exemption threshold. The amendment in this final rule is technical and non-discretionary, and it merely applies the formula established by Regulation C for determining any adjustments to the exemption threshold. For these reasons, the CFPB has determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. Therefore, the amendment is adopted in final form.

Section 553(d) of the APA generally requires publication of a final rule not less than 30 days before its effective date, except in the case of (1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretive rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule.[5] At a minimum, the CFPB has determined that the amendments fall under the third exception to section 553(d). The CFPB finds that there is good cause to make the amendments effective on January 1, 2024. The amendment in this final rule is technical and non-discretionary, and it applies the method previously established in the agency's regulations for determining adjustments to the threshold.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[6] As noted previously, the CFPB has determined that it is unnecessary to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirement relating to an initial and final regulatory flexibility analysis does not apply.

C. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,[7] the CFPB reviewed this final rule. The CFPB has determined that this rule does not create any new information collections or

[1] 12 U.S.C. 2801–2810.
[2] 12 CFR part 1003.
[3] 12 U.S.C. 2808(b).
[4] 5 U.S.C. 553(b)(B).
[5] 5 U.S.C. 553(d).
[6] 5 U.S.C. 603(a), 604(a).
[7] 44 U.S.C. 3506; 5 CFR part 1320.

substantially revise any existing collections.

D. Congressional Review Act

Pursuant to the Congressional Review Act, the CFPB will submit a report containing this rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to the rule taking effect.[8] The Office of Information and Regulatory Affairs (OIRA) has designated this rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 12 CFR Part 1003

Banks, banking, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations.

Authority and Issuance

For the reasons set forth above, the CFPB amends Regulation C, 12 CFR part 1003, as set forth below:

PART 1003—HOME MORTGAGE DISCLOSURE (REGULATION C)

■ 1. The authority citation for part 1003 continues to read as follows:

Authority: 12 U.S.C. 2803, 2804, 2805, 5512, 5581.

■ 2. Supplement I to part 1003 is amended under the heading *Section 1003.2—Definitions* by revising paragraph 2(g) Financial Institution to read as follows:

Supplement I to Part 1003—Official Interpretations

* * * * *

Section 1003.2—Definitions

* * * * *

2(g) Financial Institution

1. *Preceding calendar year and preceding December 31.* The definition of financial institution refers both to the preceding calendar year and the preceding December 31. These terms refer to the calendar year and the December 31 preceding the current calendar year. For example, in 2019, the preceding calendar year is 2018 and the preceding December 31 is December 31, 2018. Accordingly, in 2019, Financial Institution A satisfies the asset-size threshold described in § 1003.2(g)(1)(i) if its assets exceeded the threshold specified in comment 2(g)–2 on December 31, 2018. Likewise, in 2020, Financial Institution A does not meet the loan-volume test described in § 1003.2(g)(1)(v)(A) if it originated fewer than 25 closed-end mortgage loans during either 2018 or 2019.

2. *Adjustment of exemption threshold for banks, savings associations, and credit unions.* For data collection in 2024, the asset-size exemption threshold is $56 million. Banks, savings associations, and credit unions with assets at or below $56 million as of December 31, 2023, are exempt from collecting data for 2024.

3. Merger or acquisition—coverage of surviving or newly formed institution. After a merger or acquisition, the surviving or newly formed institution is a financial institution under § 1003.2(g) if it, considering the combined assets, location, and lending activity of the surviving or newly formed institution and the merged or acquired institutions or acquired branches, satisfies the criteria included in § 1003.2(g). For example, A and B merge. The surviving or newly formed institution meets the loan threshold described in § 1003.2(g)(1)(v)(B) if the surviving or newly formed institution, A, and B originated a combined total of at least 200 open-end lines of credit in each of the two preceding calendar years. Likewise, the surviving or newly formed institution meets the asset-size threshold in § 1003.2(g)(1)(i) if its assets and the combined assets of A and B on December 31 of the preceding calendar year exceeded the threshold described in § 1003.2(g)(1)(i). Comment 2(g)–4 discusses a financial institution's responsibilities during the calendar year of a merger.

4. Merger or acquisition—coverage for calendar year of merger or acquisition. The scenarios described below illustrate a financial institution's responsibilities for the calendar year of a merger or acquisition. For purposes of these illustrations, a ''covered institution'' means a financial institution, as defined in § 1003.2(g), that is not exempt from reporting under § 1003.3(a), and ''an institution that is not covered'' means either an institution that is not a financial institution, as defined in § 1003.2(g), or an institution that is exempt from reporting under § 1003.3(a).

i. Two institutions that are not covered merge. The surviving or newly formed institution meets all of the requirements necessary to be a covered institution. No data collection is required for the calendar year of the merger (even though the merger creates an institution that meets all of the requirements necessary to be a covered institution). When a branch office of an institution that is not covered is acquired by another institution that is not covered, and the acquisition results in a covered institution, no data collection is required for the calendar year of the acquisition.

ii. A covered institution and an institution that is not covered merge. The covered institution is the surviving institution, or a new covered institution is formed. For the calendar year of the merger, data collection is required for covered loans and applications handled in the offices of the merged institution that was previously covered and is optional for covered loans and applications handled in offices of the merged institution that was previously not covered. When a covered institution acquires a branch office of an institution that is not covered, data collection is optional for covered loans and applications handled by the acquired branch office for the calendar year of the acquisition.

iii. A covered institution and an institution that is not covered merge. The institution that is not covered is the surviving institution, or a new institution that is not covered is formed. For the calendar year of the merger, data collection is required for covered loans and applications handled in offices of the previously covered institution that took place prior to the merger. After the merger date, data collection is optional for covered loans and applications handled in the offices of the institution that was previously covered. When an institution remains not covered after acquiring a branch office of a covered institution, data collection is required for transactions of the acquired branch office that take place prior to the acquisition. Data collection by the acquired branch office is optional for transactions taking place in the remainder of the calendar year after the acquisition.

iv. Two covered institutions merge. The surviving or newly formed institution is a covered institution. Data collection is required for the entire calendar year of the merger. The surviving or newly formed institution files either a consolidated submission or separate submissions for that calendar year. When a covered institution acquires a branch office of a covered institution, data collection is required for the entire calendar year of the merger. Data for the acquired branch office may be submitted by either institution.

5. Originations. Whether an institution is a financial institution depends in part on whether the institution originated at least 25 closed-end mortgage loans in each of the two preceding calendar years or at least 200 open-end lines of credit in each of the two preceding calendar years.

[8] 5 U.S.C. 801 *et seq.*

Comments 4(a)–2 through –4 discuss whether activities with respect to a particular closed-end mortgage loan or open-end line of credit constitute an origination for purposes of § 1003.2(g).

6. Branches of foreign banks—treated as banks. A Federal branch or a State-licensed or insured branch of a foreign bank that meets the definition of a ''bank'' under section 3(a)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1813(a)) is a bank for the purposes of § 1003.2(g).

7. Branches and offices of foreign banks and other entities—treated as nondepository financial institutions. A Federal agency, State-licensed agency, State-licensed uninsured branch of a foreign bank, commercial lending company owned or controlled by a foreign bank, or entity operating under section 25 or 25A of the Federal Reserve Act, 12 U.S.C. 601 and 611 (Edge Act and agreement corporations) may not meet the definition of ''bank'' under the Federal Deposit Insurance Act and may thereby fail to satisfy the definition of a depository financial institution under § 1003.2(g)(1). An entity is nonetheless a financial institution if it meets the definition of nondepository financial institution under § 1003.2(g)(2).

* * * * *

Brian Shearer,

Senior Advisor, Consumer Financial Protection Bureau.

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CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Part 1026

Truth in Lending Act (Regulation Z) Adjustment to Asset-Size Exemption Threshold

AGENCY: Consumer Financial Protection Bureau.

ACTION: Final rule; official interpretation.

SUMMARY: The Consumer Financial Protection Bureau (CFPB) is amending the official commentary to its Regulation Z in order to make annual adjustments to the asset-size thresholds exempting certain creditors from the requirement to establish an escrow account for a higher-priced mortgage loan (HPML). These changes reflect updates to the exemption from the escrow requirement in the Truth in Lending Act (TILA) for creditors that, together with their affiliates that regularly extended covered transactions secured by first liens, had total assets of less than $2 billion (adjusted annually for inflation). They also reflect updates to the exemption the CFPB added, by implementing section 108 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA), for certain insured depository institutions and insured credit unions with assets of $10 billion or less (adjusted annually for inflation). These amendments are based on the annual percentage change in the average of the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W). Based on the 4.1 percent increase in the average of the CPI–W for the 12-month period ending in November 2023, the exemption threshold for creditors and their affiliates that regularly extended covered transactions secured by first liens is adjusted to $2.640 billion from $2.537 billion and the exemption threshold for certain insured depository institutions and insured credit unions with assets of $10 billion or less is adjusted to $11.835 billion from $11.374 billion.

DATES: This rule is effective on January 1, 2024.

FOR FURTHER INFORMATION CONTACT: Anna Boadwee and Adrien Fernandez, Attorney-Advisors, Office of Regulations, at (202) 435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 129D of TILA generally requires creditors to establish escrow accounts for certain first-lien higher-priced mortgage loan transactions. However, TILA section 129D also permits the CFPB to exempt creditors from this higher-priced mortgage loan escrow requirement if they meet certain requirements, including any asset-size threshold that the CFPB may establish.

In the 2013 Escrows Final Rule,[1] the CFPB established an asset-size threshold of $2 billion, which would adjust automatically each year, based on the year-to-year change in the average of the CPI–W for each 12-month period ending in November, with rounding to the nearest million dollars.[2] In 2015, the CFPB revised the asset-size threshold for small creditors and how it applies. The CFPB included in the calculation of the asset-size threshold the assets of the creditor's affiliates that regularly extended covered transactions secured by first liens during the applicable period and added a grace period to allow an otherwise eligible creditor that exceeded the asset limit in the preceding calendar year (but not in the calendar year before the preceding year) to continue to operate as a small creditor with respect to transactions with applications received before April 1 of the current calendar year.[3] For 2023, the threshold was $2.537 billion.

During the 12-month period ending in November 2023, the average of the CPI–W increased by 4.1 percent. As a result, the exemption threshold is increased to $2.640 billion for 2024.[4] Thus, if the creditor's assets together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2023 are less than $2.640 billion on December 31, 2023, and it meets the other requirements of § 1026.35(b)(2)(iii), the creditor will be exempt from the escrow-accounts requirement for higher-priced mortgage loans in 2024 and will also be exempt from the escrow-accounts requirement for higher-priced mortgage loans for purposes of any loan consummated in 2025 with applications received before April 1, 2025. The adjustment to the escrows asset-size exemption threshold also will increase the threshold for small-creditor portfolio and balloon-payment qualified mortgages under Regulation Z. The requirements for small-creditor portfolio qualified mortgages at § 1026.43(e)(5)(i)(D) reference the asset threshold in § 1026.35(b)(2)(iii)(C). Likewise, the requirements for balloon-payment qualified mortgages at § 1026.43(f)(1)(vi) reference the asset threshold in § 1026.35(b)(2)(iii)(C). Under § 1026.32(d)(1)(ii)(C), balloon-payment qualified mortgages that satisfy all applicable criteria in § 1026.43(f)(1)(i) through (vi) and (f)(2), including being made by creditors that have (together with certain affiliates) total assets below the threshold in § 1026.35(b)(2)(iii)(C), are also excepted from the prohibition on balloon payments for high-cost mortgages.

In the 2018 Economic Growth, Regulatory Relief, and Consumer

[1] 78 FR 4726 (Jan. 22, 2013).

[2] *See* 12 CFR 1026.35(b)(2)(iii)(C).

[3] *See* 80 FR 59943, 59951 (Oct. 2, 2015). The CFPB also issued an interim final rule in March 2016 to revise certain provisions in Regulation Z to effectuate the Helping Expand Lending Practices in Rural Communities Act's amendments to TILA (Pub. L. 114–94, sec. 89003, 129 Stat. 1312, 1800–01 (2015)). The rule broadened the cohort of creditors that may be eligible under TILA for the special provisions allowing origination of balloon-payment qualified mortgages and balloon-payment high-cost mortgages, as well as for the escrow exemption. *See* 81 FR 16074 (Mar. 25, 2016).

[4] Numbers may not multiply to totals shown because of rounding.

Protection Act (EGRRCPA),[5] Congress directed the CFPB to issue regulations to add a new exemption from TILA's escrow requirement that exempts transactions by certain insured depository institutions and insured credit unions.[6] In 2021, the CFPB issued a final rule implementing this exemption in § 1026.35(b)(2)(vi) (2021 Escrows Rule).[7] The final rule exempted from the Regulation Z HPML escrow requirement any loan made by an insured depository institution or insured credit union and secured by a first lien on the principal dwelling of a consumer if: (1) the institution has assets of $10 billion or less; (2) the institution and its affiliates originated 1,000 or fewer loans secured by a first lien on a principal dwelling during the preceding calendar year; and (3) certain of the existing HPML escrow exemption criteria are met. In the 2021 Escrows Rule, the CFPB established an asset-size threshold of $10 billion or less in § 1026.35(b)(2)(vi)(A), which will adjust automatically each year, based on the year-to-year change in the average of the CPI–W, not seasonally adjusted, for each 12-month period ending in November, with rounding to the nearest million dollars. Unlike the asset threshold in § 1026.35(b)(2)(iii) and the other thresholds in § 1026.35(b)(2)(vi), affiliates are not considered in calculating compliance with this asset threshold. For calendar year 2023, the asset threshold was $11.374 billion.

During the 12-month period ending in November 2023, the average of the CPI–W increased by 4.1 percent. As a result, the exemption threshold is increased to $11.835 billion for 2024.[8] Thus, a creditor that is an insured depository institution or insured credit union that during calendar year 2023 had assets of $11.835 billion or less on December 31, 2023, satisfies this criterion for purposes of any loan consummated in 2024 and for purposes of any loan secured by a first lien on a principal dwelling of a consumer consummated in 2025 for which the application was received before April 1, 2025.

II. Procedural Requirements

A. Administrative Procedure Act

Under the Administrative Procedure Act (APA), notice and opportunity for public comment are not required if the CFPB finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(B). Pursuant to this final rule, comment 35(b)(2)(iii)–1 in Regulation Z is amended to update the exemption threshold in § 1026.35(b)(2)(iii) and comment 35(b)(2)(vi)(A)–1 in Regulation Z is amended to update the exemption threshold in § 1026.35(b)(2)(vi). The amendments in this final rule are technical and merely apply the formulae previously established in Regulation Z for determining any adjustments to the exemption thresholds. For these reasons, the CFPB has determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. Therefore, the amendments are adopted in final form.

Section 553(d) of the APA generally requires publication of a final rule not less than 30 days before its effective date, except (1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretive rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule. 5 U.S.C. 553(d). At a minimum, the CFPB has determined the amendments fall under the third exception to section 553(d). The CFPB finds that there is good cause to make the amendments effective on January 1, 2024. The amendment in this final rule is technical and non-discretionary, and it merely applies the method previously established in the agency's regulations for automatic adjustments to the threshold.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[9] As noted previously, the CFPB has determined that it is unnecessary to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirement relating to an initial and final regulatory flexibility analysis does not apply.

C. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,[10] the CFPB reviewed this final rule. The CFPB has determined that this rule does not create any new information collections or substantially revise any existing collections.

D. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the CFPB will submit a report containing this rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to the rule taking effect. The Office of Information and Regulatory Affairs (OIRA) has designated this rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 12 CFR Part 1026

Advertising, Banks, banking, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth-in-lending.

Authority and Issuance

For the reasons set forth above, the CFPB amends Regulation Z, 12 CFR part 1026, as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 1. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

■ 2. In supplement I to part 1026, under *§ 1026.35—Requirements for Higher-Priced Mortgage Loans, 35(b)(2) Exemptions,* paragraphs 35(b)(2)(iii) and (b)(2)(vi)(A) are revised to read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Subpart E—Special Rules for Certain Home Mortgage Transactions

* * * * *

Section 1026.35—Requirements for Higher-Priced Mortgage Loans

* * * * *

35(b)(2) Exemptions.

* * * * *

Paragraph 35(b)(2)(iii).

1. *Requirements for exemption.* Under § 1026.35(b)(2)(iii), except as provided in § 1026.35(b)(2)(v), a creditor need not establish an escrow account for taxes and insurance for a higher-priced mortgage loan, provided the following four conditions are satisfied when the higher-priced mortgage loan is consummated:

i. During the preceding calendar year, or during either of the two preceding calendar years if the application for the

[5] Public Law 115–174, 132 Stat. 1296 (2018).

[6] EGRRCPA sec. 108, 132 Stat. 1304–05; 15 U.S.C. 1639d(c)(2).

[7] 86 FR 9840 (Feb. 17, 2021).

[8] Numbers may not multiply to totals shown because of rounding.

[9] 5 U.S.C. 603(a), 604(a).

[10] 44 U.S.C. 3506; 5 CFR part 1320.

loan was received before April 1 of the current calendar year, a creditor extended a first-lien covered transaction, as defined in § 1026.43(b)(1), secured by a property located in an area that is either ''rural'' or ''underserved,'' as set forth in § 1026.35(b)(2)(iv).

A. In general, whether the rural-or-underserved test is satisfied depends on the creditor's activity during the preceding calendar year. However, if the application for the loan in question was received before April 1 of the current calendar year, the creditor may instead meet the rural-or-underserved test based on its activity during the next-to-last calendar year. This provides creditors with a grace period if their activity meets the rural-or-underserved test (in § 1026.35(b)(2)(iii)(A)) in one calendar year but fails to meet it in the next calendar year.

B. A creditor meets the rural-or-underserved test for any higher-priced mortgage loan consummated during a calendar year if it extended a first-lien covered transaction in the preceding calendar year secured by a property located in a rural-or-underserved area. If the creditor does not meet the rural-or-underserved test in the preceding calendar year, the creditor meets this condition for a higher-priced mortgage loan consummated during the current calendar year only if the application for the loan was received before April 1 of the current calendar year and the creditor extended a first-lien covered transaction during the next-to-last calendar year that is secured by a property located in a rural or underserved area. The following examples are illustrative:

1. Assume that a creditor extended during 2016 a first-lien covered transaction that is secured by a property located in a rural or underserved area. Because the creditor extended a first-lien covered transaction during 2016 that is secured by a property located in a rural or underserved area, the creditor can meet this condition for exemption for any higher-priced mortgage loan consummated during 2017.

2. Assume that a creditor did not extend during 2016 a first-lien covered transaction secured by a property that is located in a rural or underserved area. Assume further that the same creditor extended during 2015 a first-lien covered transaction that is located in a rural or underserved area. Assume further that the creditor consummates a higher-priced mortgage loan in 2017 for which the application was received in November 2017. Because the creditor did not extend during 2016 a first-lien covered transaction secured by a property that is located in a rural or underserved area, and the application was received on or after April 1, 2017, the creditor does not meet this condition for exemption. However, assume instead that the creditor consummates a higher-priced mortgage loan in 2017 based on an application received in February 2017. The creditor meets this condition for exemption for this loan because the application was received before April 1, 2017, and the creditor extended during 2015 a first-lien covered transaction that is located in a rural or underserved area.

ii. The creditor and its affiliates together extended no more than 2,000 covered transactions, as defined in § 1026.43(b)(1), secured by first liens, that were sold, assigned, or otherwise transferred by the creditor or its affiliates to another person, or that were subject at the time of consummation to a commitment to be acquired by another person, during the preceding calendar year or during either of the two preceding calendar years if the application for the loan was received before April 1 of the current calendar year. For purposes of § 1026.35(b)(2)(iii)(B), a transfer of a first-lien covered transaction to ''another person'' includes a transfer by a creditor to its affiliate.

A. In general, whether this condition is satisfied depends on the creditor's activity during the preceding calendar year. However, if the application for the loan in question is received before April 1 of the current calendar year, the creditor may instead meet this condition based on activity during the next-to-last calendar year. This provides creditors with a grace period if their activity falls at or below the threshold in one calendar year but exceeds it in the next calendar year.

B. For example, assume that in 2015 a creditor and its affiliates together extended 1,500 loans that were sold, assigned, or otherwise transferred by the creditor or its affiliates to another person, or that were subject at the time of consummation to a commitment to be acquired by another person, and 2,500 such loans in 2016. Because the 2016 transaction activity exceeds the threshold but the 2015 transaction activity does not, the creditor satisfies this condition for exemption for a higher-priced mortgage loan consummated during 2017 if the creditor received the application for the loan before April 1, 2017, but does not satisfy this condition for a higher-priced mortgage loan consummated during 2017 if the application for the loan was received on or after April 1, 2017.

C. For purposes of § 1026.35(b)(2)(iii)(B), extensions of first-lien covered transactions, during the applicable time period, by all of a creditor's affiliates, as ''affiliate'' is defined in § 1026.32(b)(5), are counted toward the threshold in this section. ''Affiliate'' is defined in § 1026.32(b)(5) as ''any company that controls, is controlled by, or is under common control with another company, as set forth in the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*).'' Under the Bank Holding Company Act, a company has control over a bank or another company if it directly or indirectly or acting through one or more persons owns, controls, or has power to vote 25 per centum or more of any class of voting securities of the bank or company; it controls in any manner the election of a majority of the directors or trustees of the bank or company; or the Federal Reserve Board determines, after notice and opportunity for hearing, that the company directly or indirectly exercises a controlling influence over the management or policies of the bank or company. 12 U.S.C. 1841(a)(2).

iii. As of the end of the preceding calendar year, or as of the end of either of the two preceding calendar years if the application for the loan was received before April 1 of the current calendar year, the creditor and its affiliates that regularly extended covered transactions secured by first liens, together, had total assets that are less than the applicable annual asset threshold.

A. For purposes of § 1026.35(b)(2)(iii)(C), in addition to the creditor's assets, only the assets of a creditor's ''affiliate'' (as defined by § 1026.32(b)(5)) that regularly extended covered transactions (as defined by § 1026.43(b)(1)) secured by first liens, are counted toward the applicable annual asset threshold. *See* comment 35(b)(2)(iii)–1.ii.C for discussion of definition of ''affiliate.''

B. Only the assets of a creditor's affiliate that regularly extended first-lien covered transactions during the applicable period are included in calculating the creditor's assets. The meaning of ''regularly extended'' is based on the number of times a person extends consumer credit for purposes of the definition of ''creditor'' in § 1026.2(a)(17). Because covered transactions are ''transactions secured by a dwelling,'' consistent with § 1026.2(a)(17)(v), an affiliate regularly extended covered transactions if it extended more than five covered transactions in a calendar year. Also consistent with § 1026.2(a)(17)(v), because a covered transaction may be a

high-cost mortgage subject to § 1026.32, an affiliate regularly extends covered transactions if, in any 12-month period, it extends more than one covered transaction that is subject to the requirements of § 1026.32 or one or more such transactions through a mortgage broker. Thus, if a creditor's affiliate regularly extended first-lien covered transactions during the preceding calendar year, the creditor's assets as of the end of the preceding calendar year, for purposes of the asset limit, take into account the assets of that affiliate. If the creditor, together with its affiliates that regularly extended first-lien covered transactions, exceeded the asset limit in the preceding calendar year—to be eligible to operate as a small creditor for transactions with applications received before April 1 of the current calendar year—the assets of the creditor's affiliates that regularly extended covered transactions in the year before the preceding calendar year are included in calculating the creditor's assets.

C. If multiple creditors share ownership of a company that regularly extended first-lien covered transactions, the assets of the company count toward the asset limit for a co-owner creditor if the company is an ''affiliate,'' as defined in § 1026.32(b)(5), of the co-owner creditor. Assuming the company is not an affiliate of the co-owner creditor by virtue of any other aspect of the definition (such as by the company and co-owner creditor being under common control), the company's assets are included toward the asset limit of the co-owner creditor only if the company is controlled by the co-owner creditor, ''as set forth in the Bank Holding Company Act.'' If the co-owner creditor and the company are affiliates (by virtue of any aspect of the definition), the co-owner creditor counts all of the company's assets toward the asset limit, regardless of the co-owner creditor's ownership share. Further, because the co-owner and the company are mutual affiliates the company also would count all of the co-owner's assets towards its own asset limit. *See* comment 35(b)(2)(iii)–1.ii.C for discussion of the definition of ''affiliate.''

D. A creditor satisfies the criterion in § 1026.35(b)(2)(iii)(C) for purposes of any higher-priced mortgage loan consummated during 2016, for example, if the creditor (together with its affiliates that regularly extended first-lien covered transactions) had total assets of less than the applicable asset threshold on December 31, 2015. A creditor that (together with its affiliates that regularly extended first-lien covered transactions) did not meet the applicable asset threshold on December 31, 2015, satisfies this criterion for a higher-priced mortgage loan consummated during 2016 if the application for the loan was received before April 1, 2016, and the creditor (together with its affiliates that regularly extended first-lien covered transactions) had total assets of less than the applicable asset threshold on December 31, 2014.

E. Under § 1026.35(b)(2)(iii)(C), the $2,000,000,000 asset threshold adjusts automatically each year based on the year-to-year change in the average of the Consumer Price Index for Urban Wage Earners and Clerical Workers, not seasonally adjusted, for each 12-month period ending in November, with rounding to the nearest million dollars. The Bureau will publish notice of the asset threshold each year by amending this comment. For calendar year 2024, the asset threshold is $2,640,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2023 has total assets of less than $2,640,000,000 on December 31, 2023, satisfies this criterion for purposes of any loan consummated in 2024 and for purposes of any loan consummated in 2025 for which the application was received before April 1, 2025. For historical purposes:

1. For calendar year 2013, the asset threshold was $2,000,000,000. Creditors that had total assets of less than $2,000,000,000 on December 31, 2012, satisfied this criterion for purposes of the exemption during 2013.

2. For calendar year 2014, the asset threshold was $2,028,000,000. Creditors that had total assets of less than $2,028,000,000 on December 31, 2013, satisfied this criterion for purposes of the exemption during 2014.

3. For calendar year 2015, the asset threshold was $2,060,000,000. Creditors that had total assets of less than $2,060,000,000 on December 31, 2014, satisfied this criterion for purposes of any loan consummated in 2015 and, if the creditor's assets together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2014 were less than that amount, for purposes of any loan consummated in 2016 for which the application was received before April 1, 2016.

4. For calendar year 2016, the asset threshold was $2,052,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2015 had total assets of less than $2,052,000,000 on December 31, 2015, satisfied this criterion for purposes of any loan consummated in 2016 and for purposes of any loan consummated in 2017 for which the application was received before April 1, 2017.

5. For calendar year 2017, the asset threshold was $2,069,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2016 had total assets of less than $2,069,000,000 on December 31, 2016, satisfied this criterion for purposes of any loan consummated in 2017 and for purposes of any loan consummated in 2018 for which the application was received before April 1, 2018.

6. For calendar year 2018, the asset threshold was $2,112,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2017 had total assets of less than $2,112,000,000 on December 31, 2017, satisfied this criterion for purposes of any loan consummated in 2018 and for purposes of any loan consummated in 2019 for which the application was received before April 1, 2019.

7. For calendar year 2019, the asset threshold was $2,167,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2018 had total assets of less than $2,167,000,000 on December 31, 2018, satisfied this criterion for purposes of any loan consummated in 2019 and for purposes of any loan consummated in 2020 for which the application was received before April 1, 2020.

8. For calendar year 2020, the asset threshold was $2,202,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2019 had total assets of less than $2,202,000,000 on December 31, 2019, satisfied this criterion for purposes of any loan consummated in 2020 and for purposes of any loan consummated in 2021 for which the application was received before April 1, 2021.

9. For calendar year 2021, the asset threshold was $2,230,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2020 had total assets of less than $2,230,000,000 on December 31, 2020, satisfied this criterion for purposes of any loan consummated in 2021 and for purposes of any loan consummated in 2022 for which the application was received before April 1, 2022.

10. For calendar year 2022, the asset threshold was $2,336,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2021 had total assets of less than $2,336,000,000 on December 31, 2021, satisfied this criterion for purposes of any loan consummated in 2022 and for purposes of any loan consummated in 2023 for which the application was received before April 1, 2023.

11. For calendar year 2023, the asset threshold was $2,537,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2022 had total assets of less than $2,537,000,000 on December 31, 2022, satisfied this criterion for purposes of any loan consummated in 2023 and for purposes of any loan consummated in 2024 for which the application was received before April 1, 2024.

iv. The creditor and its affiliates do not maintain an escrow account for any mortgage transaction being serviced by the creditor or its affiliate at the time the transaction is consummated, except as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*). Thus, the exemption applies, provided the other conditions of § 1026.35(b)(2)(iii) (or, if applicable, the conditions for the exemption in § 1026.35(b)(2)(vi)) are satisfied, even if the creditor previously maintained escrow accounts for mortgage loans, provided it no longer maintains any such accounts except as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*). Once a creditor or its affiliate begins escrowing for loans currently serviced other than those addressed in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*), however, the creditor and its affiliate become ineligible for the exemption in § 1026.35(b)(2)(iii) and (vi) on higher-priced mortgage loans they make while such escrowing continues. Thus, as long as a creditor (or its affiliate) services and maintains escrow accounts for any mortgage loans, other than as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*), the creditor will not be eligible for the exemption for any higher-priced mortgage loan it may make. For purposes of § 1026.35(b)(2)(iii) and (vi), a creditor or its affiliate ''maintains'' an escrow account only if it services a mortgage loan for which an escrow account has been established at least through the due date of the second periodic payment under the terms of the legal obligation.

* * * * *

Paragraph 35(b)(2)(vi)(A).

1. The asset threshold in § 1026.35(b)(2)(vi)(A) will adjust automatically each year, based on the year-to-year change in the average of the Consumer Price Index for Urban Wage Earners and Clerical Workers, not seasonally adjusted, for each 12-month period ending in November, with rounding to the nearest million dollars. Unlike the asset threshold in § 1026.35(b)(2)(iii) and the other thresholds in § 1026.35(b)(2)(vi), affiliates are not considered in calculating compliance with this threshold. The Bureau will publish notice of the asset threshold each year by amending this comment. For calendar year 2024, the asset threshold is $11,835,000,000. A creditor that is an insured depository institution or insured credit union that during calendar year 2023 had assets of $11,835,000,000 or less on December 31, 2023, satisfies this criterion for purposes of any loan consummated in 2024 and for purposes of any loan secured by a first lien on a principal dwelling of a consumer consummated in 2025 for which the application was received before April 1, 2025. For historical purposes:

1. For calendar year 2021, the asset threshold was $10,000,000,000. Creditors that had total assets of 10,000,000,000 or less on December 31, 2020, satisfied this criterion for purposes of any loan consummated in 2021 and for purposes of any loan secured by a first lien on a principal dwelling of a consumer consummated in 2022 for which the application was received before April 1, 2022.

2. For calendar year 2022, the asset threshold was $10,473,000,000. Creditors that had total assets of $10,473,000,000 or less on December 31, 2021, satisfied this criterion for purposes of any loan consummated in 2022 and for purposes of any loan secured by a first lien on a principal dwelling of a consumer consummated in 2023 for which the application was received before April 1, 2023.

3. For calendar year 2023, the asset threshold is $11,374,000,000. A creditor that is an insured depository institution or insured credit union that during calendar year 2022 had assets of $11,374,000,000 or less on December 31, 2022, satisfied this criterion for purposes of any loan consummated in 2023 and for purposes of any loan secured by a first lien on a principal dwelling of a consumer consummated in 2024 for which the application was received before April 1, 2024.

* * * * *

Brian Shearer,

Senior Advisor, Consumer Financial Protection Bureau.

[FR Doc. 2023–28076 Filed 12–20–23; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2023–2220; Airspace Docket No. 23–AWP–59]

RIN 2120–AA66

Amendment of Restricted Area R–2512 Holtville, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction; withdrawal.

SUMMARY: This action withdraws the final rule correction published in the **Federal Register** on December 6, 2023. That action incorrectly stated that the action would be incorporated by reference. The FAA has determined that withdrawal of the final rule correction is warranted since the action is not incorporated by reference.

DATES: As of date 0901 UTC, December 21, 2023, the final rule correction published December 6, 2023 (88 FR 84695), is withdrawn.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** for Docket No. FAA–2023–2220 (88 FR 78636, November 16, 2023) that amended restricted area R–2512 in the vicinity of Holtville, CA. The section of 14 CFR part 73 to be amended by the final rule was inadvertently stated as § 73.22. The correct section of 14 CFR part 73 to be amended is § 73.25.

Subsequently, the FAA published a final rule correction in the **Federal Register** for Docket No. FAA–2023–2220 (88 FR 84695, December 6, 2023) that amended restricted area R–2512 in the vicinity of Holtville, CA, correcting the section of 14 CFR part 73 to be amended. That action incorrectly stated

that the action is incorporated by reference under 1 CFR part 51. As a result, the final rule correction is being withdrawn.

Lists of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Withdrawal

■ The FAA determined that the final rule correction published in the **Federal Register** on December 6, 2023 (88 FR 84695) contains incorrect references. Therefore, the FAA withdraws that final rule correction.

Issued in Washington, DC, on December 15, 2023.

Brian Konie,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023–28032 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50, 312, and 812

[Docket No. FDA–2018–N–2727]

RIN 0910–AH52

Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations to implement a provision of the 21st Century Cures Act (Cures Act). This final rule allows an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The final rule permits an institutional review board (IRB) to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations.

DATES: This rule is effective January 22, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Lauren Milner, Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5514, *lauren.milner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

This final rule implements the statutory changes made to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Cures Act to allow for a waiver or alteration of informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The rule will permit an IRB to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain minimal risk clinical investigations.

B. Summary of the Major Provisions of the Final Rule

The final rule amends FDA's regulations to allow IRBs responsible for the review, approval, and continuing review of clinical investigations to approve an informed consent procedure that does not include or that alters certain informed consent elements, or to waive the requirement to obtain informed consent, for certain minimal risk clinical investigations. For an IRB to approve a waiver or alteration of informed consent requirements for minimal risk clinical investigations, the rule requires an IRB to find and document five criteria that are consistent with the revised rule entitled ''Federal Policy for the Protection of Human Subjects'' (the revised Common Rule (January 19, 2017)). FDA believes the amendment provides appropriate safeguards to protect the rights, safety, and welfare of the human subjects participating in such clinical investigations. We are also making conforming amendments to FDA's regulations.

C. Legal Authority

Sections 505(i)(4) and 520(g)(3) of the FD&C Act, as amended by the Cures Act, in conjunction with FDA's general rulemaking authority in section 701(a) of the FD&C Act, serve as FDA's principal legal authority for this rule. In addition, the Cures Act directs the Secretary of the Department of Health and Human Services (HHS) to ''harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations,'' to the extent practicable and consistent with other statutory provisions.

D. Costs and Benefits

This rule will help enable the conduct of certain minimal risk clinical investigations for which the requirement to obtain informed consent is waived or for which certain elements of informed consent are waived or altered.

We expect costs in the form of affected IRBs, as well as investigators and sponsors of clinical investigations, reading and learning the rule. We also expect costs in the form of drafting new

waiver or alteration requests and additional recordkeeping burdens associated with reviewing and documenting IRB decisions on waiver or alteration requests. The net present value of the estimated costs of the rule are approximately $10.1 million, with a lower bound of approximately $8.1 million and an upper bound of approximately $14.0 million, discounted at 3 percent over 10 years. At a 7 percent discount rate, the estimated costs of the rule are approximately $9.1 million, with a lower bound of approximately $7.5 million and an upper bound of approximately $12.4 million. The estimated annualized costs of the rule are approximately $1.2 million, with a lower bound of approximately $0.9 million and an upper bound of approximately $1.6 million, discounted at 3 percent over 10 years. At a 7 percent discount rate, the estimated annualized costs of the rule are approximately $1.3 million, with a lower bound of approximately $1.1 million and an upper bound of approximately $1.8 million.

We expect that there will be cost savings to IRBs from harmonization of FDA's informed consent regulations with the provision for waiver or alteration of informed consent for certain minimal risk research in the Common Rule. The estimated net present value of the cost savings of the rule are approximately $1.7 million, with a lower bound of approximately $0.9 million and an upper bound of approximately $3.5 million, discounted at 3 percent over 10 years. At a 7 percent discount rate, the estimated cost savings of the rule are approximately $1.4 million, with a lower bound of approximately $0.7 million and an upper bound of approximately $2.8 million. The estimated annualized cost savings of the rule are approximately $0.2 million, with a lower bound of approximately $0.1 million and an upper bound of approximately $0.4 million, discounted at 3 percent over 10 years. At a 7 percent discount rate, the estimated annualized costs savings of the rule are approximately $0.2 million, with a lower bound of approximately $0.1 million and an upper bound of approximately $0.4 million.

We also expect benefits in the form of healthcare advances from minimal risk clinical investigations that would not be performed without a waiver or alteration of informed consent. We cannot quantify all benefits that might arise from such studies because of the lack of relevant data available regarding the focus of these types of studies that will support regulatory submissions to FDA.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation	What it means
Cures Act	21st Century Cures Act (Pub. L. 114–255).
FDA or the Agency	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
HHS	U.S. Department of Health and Human Services.
HIPAA Privacy Rule	Health Insurance Portability and Accountability Act Privacy Rule (45 CFR Part 160 and 45 CFR Part 164, Subparts A and E).
IDE	Investigational Device Exemption.
IRB	Institutional Review Board.
IVD	In Vitro Diagnostic.
LAR	Legally Authorized Representative.
OHRP	Office for Human Research Protections.
OMB	U.S. Office of Management and Budget.
PHI	Protected Health Information.
PRA	Paperwork Reduction Act of 1995.
RWD	Real-world data.
SACHRP	Secretary's Advisory Committee on Human Research Protections.

III. Background

A. Need for the Regulation/History of This Rulemaking

In the **Federal Register** of November 15, 2018 (83 FR 57378), FDA issued a proposed rule to revise our informed consent regulations at part 50 (21 CFR part 50) to permit an IRB to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations. As described in the proposed rule, FDA's current regulations governing the protection of human subjects (parts 50 and 56 (21 CFR parts 50 and 56)) require that a human subject, or the subject's legally authorized representative (LAR), provide informed consent before the subject participates in a clinical investigation, and only allow exception from the general requirements of informed consent in certain life-threatening situations or by Presidential waiver for certain military operations when specific conditions are met (§ 50.23 (21 CFR 50.23)) or when the requirements for emergency research are met (§ 50.24 (21 CFR 50.24)).

On December 13, 2016, the Cures Act (Pub. L. 114–255) was signed into law. Section 3024 of the Cures Act amended sections 505(i)(4) and 520(g)(3) of the FD&C Act (21 U.S.C. 355(i)(4) and 360j(g)(3)) to provide FDA with the authority to permit an exception from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject. This rule implements the statutory change by allowing an additional exception from the general requirements of informed consent for certain FDA-regulated clinical investigations.

In addition, section 3023 of the Cures Act directs the Secretary of the Department of Health and Human Services (HHS) to ''harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations,'' to the extent practicable and consistent with other statutory provisions. This rule harmonizes [1] FDA's requirements for waiver or alteration of informed consent for minimal risk clinical investigations with the revised Common Rule's requirements under 45 CFR 46.116(f)(3). The Common Rule has included four criteria for waiver or alteration of informed consent for minimal risk research since it was originally issued in

[1] The term ''harmonize,'' as used in this proposed rule means, ''harmonize to the extent practicable and consistent with other statutory provisions,'' consistent with section 3023 of the Cures Act.

1991 (56 FR 28001, June 18, 1991). When the Common Rule was revised (82 FR 7149, January 19, 2017),[2] a fifth criterion was added, *i.e.,* ''[i]f the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format'' (45 CFR 46.116(f)(3)(iii)). FDA proposed to adopt the four criteria from the 1991 version of the Common Rule and solicited comment on whether to adopt the fifth criterion (83 FR 57378, November 15, 2018).

On July 25, 2017, FDA issued a guidance document entitled ''IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects'' (IRB Waiver or Alteration of Informed Consent Guidance) (82 FR 34535). This guidance informs sponsors, investigators, and IRBs that FDA does not intend to object to an IRB waiving or altering informed consent requirements, as described in the guidance, for certain minimal risk clinical investigations. In addition, the guidance informs sponsors, investigators, and IRBs that FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described in the guidance. FDA intends to withdraw the guidance after the regulations in this rule become effective.

FDA is issuing this final rule to permit an IRB waiver or alteration of informed consent in limited circumstances, consistent with the Cures Act. We believe that this rule will both safeguard the rights, safety, and welfare of human subjects and enable minimal risk clinical investigations that may facilitate medical advances and promote public health. In addition, because some clinical research is subject to FDA and other federal requirements under the Common Rule, harmonization of this waiver provision should also provide clarity for and reduce burden on the research community.

[2] For the purposes of this final rule, the phrase ''revised Common Rule'' refers to the final rule (82 FR 7149, January 19, 2017), modified by the interim final rule that delayed the effective and general compliance date (83 FR 2885, January 22, 2018) and the final rule that further delayed the general compliance date, while allowing use of three burden-reducing provisions for certain research during the delay period (83 FR 28497, June 19, 2018).

B. Summary of Comments to the Proposed Rule

We received fewer than 50 comment letters to the proposed rule from academia, IRBs, public advocacy groups, industry, trade organizations, public health organizations, individuals, and other organizations. FDA received comments on topics that included the following: (1) general support or opposition to the rule; (2) definitions and descriptions of the criteria listed in the rule; (3) adopting the fifth criterion from the revised Common Rule; (4) secondary research involving biospecimens; (5) examples of clinical investigations that might meet the proposed waiver criteria; (6) requests for specific and/or additional guidance on the rule; (7) the expedited review list and IRB continuing review; (8) cost savings of the proposed rule; and (9) the proposed effective date of the rule.

C. General Overview of the Final Rule

In this rulemaking, FDA is finalizing its proposal to add new § 50.22, ''Exception from informed consent requirements for minimal risk clinical investigations'' to part 50 and make three conforming amendments to §§ 50.20, 312.60, and 812.2 (21 CFR 50.20, 312.60, and 812.2) of our current regulations to reflect the exception from informed consent for certain minimal risk clinical investigations. In addition, based on comments received on the proposed rule, FDA is adding the criterion at § 50.22(c), which addresses clinical investigations involving identifiable private information or identifiable biospecimens. As described below, FDA changed the order of the criteria in § 50.22 to match the order of the revised Common Rule's requirements for general waiver or alteration of consent (45 CFR 46.116(f)(3)). FDA also made minor organizational and editorial changes to § 50.22 to increase clarity and consistency with the regulatory text of the revised Common Rule.

- FDA made a minor editorial change to the introductory text to § 50.22 for clarity. Specifically, we revised the text ''or that waives'' to read ''or may waive.'' The regulation permits the IRB responsible for the review, approval, and continuing review of the clinical investigation to approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent in § 50.25(a) and (b) of FDA's current regulations, or to waive the requirement to obtain informed consent, provided that the IRB finds and documents five criteria under § 50.22(a) through (e).
- In § 50.22(a), FDA finalizes the criterion as proposed that the clinical investigation involves no more than minimal risk to the subjects.
- In § 50.22(b), FDA adopts the criterion that was proposed at § 50.22(c) and adds the word ''requested'' for clarity and to harmonize with the text of the revised Common Rule at 45 CFR 46.116(f)(3)(ii) (*i.e.,* the clinical investigation could not practicably be carried out without the requested waiver or alteration).
- Based on comments received on the proposed rule (see section V.D. of this final rule), FDA is finalizing this rule with the additional criterion at § 50.22(c) that states that if the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format.
- In § 50.22(d), FDA adopts the criterion that was proposed at § 50.22(b) that states that the waiver or alteration will not adversely affect the rights and welfare of the subjects.
- In § 50.22(e), FDA adopts the criterion that was proposed at § 50.22(d) and adds ''or legally authorized representatives'' to the criterion (*i.e.,* whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation) to align with the revised Common Rule and to make clear to whom additional information may be provided.
- Three conforming amendments to §§ 50.20, 312.60, and 812.2 of our current regulations are finalized as proposed. FDA received no public comments on these three proposed conforming amendments. The introductory clause of § 50.20, General requirements for informed consent, is revised to include reference to § 50.22 as one of the limited exceptions to the general requirements for informed consent. The second sentence in § 312.60, General responsibilities of investigators, is revised to reference part 50 generally rather than list each specific exception to the informed consent requirements in part 50. This simplifies the regulatory text and makes it clear that the investigator is responsible for obtaining the informed consent of each human subject to whom the drug is administered in accordance with part 50, which includes § 50.22. Similarly, in part 812, Investigational Device Exemptions (IDEs), § 812.2(b)(1)(iii) is revised to make clear that the investigator must obtain informed consent in accordance with part 50, which includes § 50.22. In

addition, to simplify the current regulatory text, we removed the reference to documentation being waived under § 56.109(c) (21 CFR 56.109(c)), as the relevant section of the regulations in part 50 (*i.e.,* § 50.27 (21 CFR 50.27)) refers to § 56.109(c) and need not be repeated.

IV. Legal Authority

Title III, section 3024 of the Cures Act amended sections 505(i)(4) and 520(g)(3) of the FD&C Act to provide FDA with the authority to permit an exception from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject. This statutory amendment was signed into law and became effective on December 13, 2016. These regulations reflect these statutory changes to the FD&C Act, including appropriate human subject protection safeguards. Thus, sections 505(i)(4) and 520(g)(3) of the FD&C Act, as amended by section 3024 of the Cures Act, in conjunction with FDA's general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)), serve as our principal legal authority for this rule. In addition, Title III, section 3023 of the Cures Act provides that the Secretary of Health and Human Services shall ''harmonize differences between HHS Human Subject Regulations and FDA Human Subject Regulations'' to the extent practicable and consistent with other statutory provisions.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received fewer than 50 comment letters on the proposed rule by the close of the comment period. We received comments from academia, IRBs, public advocacy groups, industry, trade organizations, public health organizations, individuals, and other organizations.

We describe and respond to the comments below. Comment summaries are numbered, with similar comments grouped together under the same number. In some cases, different issues discussed in the same comment letter were designated as distinct comments for purposes of our responses. The number assigned to each comment summary or comment topic is purely for organizational purposes and does not signify the comment's value or importance, or the order in which comments were received.

B. Description of General Comments and FDA Response

FDA proposed to amend its regulations to allow the IRB responsible for the review, approval, and continuing review of FDA-regulated clinical investigations to approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent set forth in § 50.25(a) and (b), or that waives the requirement to obtain informed consent, provided that the IRB finds and documents that four criteria are met. FDA also solicited public comment on the inclusion of a fifth criterion and asked for comment on the types of FDA-regulated minimal risk clinical investigations for which sponsors would anticipate requesting a waiver or alteration of informed consent from the IRB.

(Comment 1) A majority of general comments favor the Agency's efforts to harmonize FDA's human subject protection regulations with the revised Common Rule. These comments generally support the proposed rule because it would reduce administrative burdens on IRBs and researchers, reduce research costs, facilitate valuable research, or address public health concerns without compromising subjects' rights, safety, or welfare.

Several comments express support for harmonization with the revised Common Rule's provision for waiver or alteration of informed consent to reduce burdens related to conducting certain types of research, including some cluster randomized or pragmatic trials, and enabling learning health systems, in which clinicians continually learn from data collected at the point of care. One comment indicates that such research has the potential to contribute in important ways to the evidence base regarding drug and device efficacy, while another suggests that finalizing the proposal would result in more and better data regarding the risks and benefits of drugs and devices in real-world settings. An additional comment argues that a waiver of informed consent may be necessary and ethically justifiable for certain types of clinical investigations that are critical for medical advancement, patient care, and safety.

Other comments support the proposal because certain minimal risk investigations are difficult or impossible to carry out if consent is required, such as certain secondary research involving biospecimens that may lead to important medical advances toward personalized medicine; research involving retrospective records reviews; and research involving no more than minimal risk to subjects that would not qualify for an exception from informed consent under § 50.24 of FDA's current regulations because participation would not hold out a prospect of direct benefit to the subjects. The comments point out that current FDA regulations permit waivers from the requirement to obtain informed consent only under limited circumstances.

(Response 1) FDA agrees that this rule will facilitate investigators' ability to conduct certain minimal risk clinical investigations that could lead to healthcare advances through development of products to diagnose or treat diseases or other conditions, without compromising subjects' rights, safety, or welfare. To the extent that the studies described in the comments would constitute FDA-regulated clinical investigations that could not be carried out under our current regulations, we agree that this final rule may help enable such research and that a waiver of informed consent is ethically justifiable for certain types of investigations.

In addition, FDA expects that this final rule will reduce administrative burdens on IRBs and researchers and reduce research costs. For example, harmonization with the revised Common Rule's general provision for waiver or alteration of informed consent will allow IRBs that review minimal risk clinical research subject to both FDA's regulations and the revised Common Rule to use the same criteria for reviewing a request for a waiver or alteration of informed consent for a clinical investigation. This should minimize the need for separate processes for review of such requests.

(Comment 2) Of the comments that oppose the proposed rule, two oppose it because they assert that waiving consent conflicts with existing ethical and international standards, such as the Belmont Report, the Nuremberg Code, the Declaration of Helsinki, and the International Covenant on Civil and Political Rights (ICCPR). Two other comments suggest that FDA withdraw the proposal because the underlying law and revised Common Rule are defective and ''against the spirit'' of human subject protection.

(Response 2) FDA disagrees with the comments opposing the rule. We believe that the rule upholds the principles underlying existing ethical standards, while accounting for advances in the conduct of FDA-regulated clinical investigations. It is also consistent with the obligations of the ICCPR and the U.S.' reservations, declarations, and understandings to the Covenant (see,

e.g., Ref. 1). The standards referenced in the comments emphasize the importance of voluntary informed consent for research participants. As stated in the proposed rule, obtaining informed consent from those who volunteer to participate in research is a fundamentally important principle of human subject protection. However, there are some situations in which important research cannot practicably be conducted if informed consent is required. This rule permits a waiver of consent in limited circumstances, consistent with the statutory amendments Congress made in section 3024 of the Cures Act. The waiver is only permitted in circumstances where the risks posed to subjects by the research are minimal and where an IRB has reviewed the research and determined, among other things, that the waiver or alteration will not adversely affect the rights and welfare of subjects. If research can be practicably carried out without a waiver of informed consent, investigators cannot obtain a waiver under this rule.

Additionally, the ethical principles identified in many of the national and international guidelines for research conduct, such as the three ethical principles described in the Belmont Report (respect for persons, beneficence, and justice), should be considered and weighed within the context of a particular clinical investigation, as the consideration of each principle depends on multiple factors associated with the investigation, such as research methodologies or participant populations. This rule permits a waiver or alteration of consent only in limited circumstances where the risks posed to subjects by the research are very low. We believe that with the protections in place under this rule (including the requirement for an IRB to find and document that the waiver or alteration will not adversely affect the rights and welfare of subjects), the balance between respect for persons and beneficence should come out in favor of facilitating research that satisfies the criteria in § 50.22 by permitting waiver or alteration of informed consent requirements to advance the public health. Additionally, although informed consent is a critical element of FDA's regulations that reflects the principle of respect for persons through the exercise of autonomy, we believe that the criteria provided in this rule also reflect the principle of respect for persons. For example, in a minimal risk clinical investigation for which an IRB waives consent, ensuring that the rights and welfare of subjects are not adversely affected by the waiver demonstrates respect for persons, as does providing additional pertinent information about the investigation to subjects whenever appropriate (Ref. 2).

Finally, FDA declines to withdraw the proposed rule in response to the comments that disagree with section 3024 of the Cures Act and the revised Common Rule. The Common Rule's provisions for waiver or alteration of informed consent for minimal risk research have been in effect for over 30 years and have provided appropriate safeguards to protect the rights and welfare of human subjects. As noted above, FDA believes that this rule provides an important mechanism for conducting clinical investigations that will both appropriately safeguard human subjects and potentially lead to medical advances that serve the public health.

(Comment 3) Some comments suggest that conducting research without informed consent would violate the U.S. Constitution or weaken constitutionally guaranteed rights. One comment argues that ''invasive procedures, interventions or intrusions'' into a person's ''body, cognition, or otherwise'' without consent is a violation or a potential violation of the Fourth, Fifth, Eighth, and Fourteenth Amendments. A second comment asserts that waiving consent for research involving physical interventions would violate the Fourth and Fifth Amendments and requested clarification that Constitutional rights are among the rights at issue when considering whether the proposed criteria for waiver of consent are satisfied. Another comment indicates that a waiver of informed consent would constitute an unwanted bodily invasion and that individuals have a constitutional right to privacy that protects them against such invasions. Other comments make general statements questioning the constitutionality of a waiver of informed consent.

(Response 3) We disagree with comments suggesting that the rule is unconstitutional. With respect to the comments that make only a general assertion that the rule may violate the Constitution or weaken constitutional rights, the lack of additional detail regarding the grounds for this assertion makes it impossible to provide a further substantive response. One comment cites a Federal district court case, *Merriken* v. *Cressman,* 364 F. Supp. 913 (E.D. Pa. 1973), for the general proposition that Federal courts have applied a requirement for fully voluntary informed consent grounded in constitutional law to social, behavioral, and biomedical research. Contrary to the comment's assertion, however, the court did not decide in *Merriken* whether informed consent is required for participation in all research as a general matter. The case involved a program designed to help a school district identify potential drug abusers. *Id.* at 914. The court found that part of this program represented an invasion of an individual constitutional right to privacy that was not outweighed by the government's public need for the information. *Id.* at 918, 921. The court then went on to address the standard for and adequacy of consent to waive a constitutional right to privacy involving an invasion of the parent-child relationship, rather than consent to participate in FDA-regulated minimal risk research. *Merriken* does not prevent FDA from finalizing this rule.

Of those comments that identify particular constitutional Amendments or rights, none provides specific facts or a legal basis for their claims that the rule would violate those provisions or rights. We are thus unable to provide a specific response to those comments. However, we note that the rule does not require an IRB to waive or alter informed consent, nor does it require any entity, including a government entity, to conduct or support any research. Therefore, to the extent that conducting a particular clinical investigation with a waiver or alteration of informed consent could be viewed as interfering with a constitutional right, this rule does not require an IRB to grant such a waiver or alteration or require that the research be conducted. In addition, we are clarifying, as requested by one comment, that constitutional rights are among the rights that may be appropriate for an IRB to consider when determining if the criterion in § 50.22(d) of the final rule (which requires the IRB to find that ''[t]he waiver or alteration will not adversely affect the rights and welfare of the subjects'') is satisfied.

Finally, we note that some of the comments that question the constitutionality of the rule appear to be concerned about potential waivers of informed consent for research involving ''invasive procedures.'' It is important to emphasize that the provision for a waiver or alteration of informed consent being finalized in this rule is available only for clinical investigations that involve no more than minimal risk to the subjects and meet the other criteria in § 50.22. In general, we do not believe that a study involving an invasive procedure being used for research

purposes would qualify as presenting no more than minimal risk to subjects.[3]

(Comment 4) A few comments oppose the proposal because it would not restrict or prohibit waiver of consent for classified research, citing President Clinton's Memorandum of 1997 regarding classified research (''Clinton Memorandum,'' Ref. 3).

(Response 4) We do not believe it is necessary to address classified research in this rulemaking. As noted in some of these comments, the Clinton Memorandum is directed to Agencies that may conduct or support classified research subject to the 1991 Common Rule. FDA's informed consent regulations apply to all clinical investigations, as defined in § 50.3(c) (21 CFR 50.3(c)), involving FDA-regulated articles. FDA does not regulate research on the basis that it is federally conducted or supported. To the extent a Federal Agency conducts or supports classified research and prohibits waiver of informed consent for such research, FDA's new waiver provision at § 50.22 does not require any IRB to waive informed consent and thus would not conflict with the prohibition.

(Comment 5) Several comments argue that waivers of informed consent weaken human subject protections and would allow IRBs to retreat from their human subject protection responsibilities. These comments also express concern that the proposal might decrease public trust in both research and healthcare providers. One comment states that no third parties, including IRBs, should be allowed to make decisions for study subjects as to what constitutes ''minimal risk.''

(Response 5) We do not agree that providing a waiver or alteration of informed consent under the limited circumstances described in the rule would allow IRBs to retreat from their human subject protection responsibilities or that such waivers or alterations will decrease public trust in research and healthcare providers. IRBs have been making similar waiver and alteration decisions for research subject to the Common Rule since its issuance in 1991, and the comments do not provide evidence that such decisions have decreased overall public trust in either research or healthcare providers. As noted above, this rule provides appropriate safeguards to protect the rights, safety, and welfare of human subjects when consent is waived and thus waivers granted in accordance with § 50.22 should not weaken public trust.

We also disagree with the comment stating that IRBs should not be allowed to make decisions as to what research constitutes ''minimal risk.'' IRBs have considerable experience making ''minimal risk'' determinations under FDA regulations (see response to Comment 10). For example, IRBs have been making minimal risk determinations for decades to decide whether expedited review procedures may be used for certain categories of research (see § 56.110(b)(1) (21 CFR 56.110(b)(1)); 63 FR 60353, November 9, 1998) and when reviewing clinical investigations involving children as subjects (see part 50, subpart D). In light of this experience, we believe that IRBs are generally well-positioned to determine what constitutes ''minimal risk'' to subjects when considering the details of a particular clinical investigation.

(Comment 6) Several comments criticize the proposal as too vague and subjective. These comments recommend adding definitions or providing further description of the criteria in § 50.22. They also recommend clarifying or providing examples of research for which a waiver or alteration would be allowed under the proposal in order to reduce the potential for inconsistency and variability in IRBs' decision making.

(Response 6) We do not agree with the comments stating that this rule is too vague and subjective. The five criteria in § 50.22 for a waiver or alteration of informed consent for minimal risk clinical investigations are harmonized with the revised Common Rule's criteria in 45 CFR 46.116(f)(3). We note that four of these criteria have been included in the Common Rule and have been successfully applied since the Common Rule was originally issued in 1991. The revised Common Rule added a fifth criterion (45 CFR 46.116(f)(3)(iii)), which corresponds to § 50.22(c) in this rule. That fifth criterion was modeled on a comparable criterion in the HIPAA Privacy Rule, which requires, as a condition of waiver of the requirement to obtain an individual's authorization, that the research could not practicably be conducted without access to and use of protected health information (PHI) (see 82 FR 7149 at 7224).[4] We believe that alignment between the HIPAA Privacy Rule, the revised Common Rule, and part 50 will support consistent application of the criterion in § 50.22(c) by the research community.

In response to the comments recommending additional definitions or criteria descriptions, we note that throughout this document (for example, see FDA responses to comments 10, 12, 13, and 16) we address comments requesting the addition of specific definitions or further clarification for each of the criteria described in § 50.22. FDA intends to issue further guidance to assist IRBs in applying these criteria to clinical investigations with additional information on the types of clinical investigations that may qualify for a waiver or alteration of consent under § 50.22.

(Comment 7) Some comments address implementation-related aspects of the proposed waiver or alteration provision. One comment, noting that subjects may already be giving consent to undergo non-research related patient care, questions why it would not also be appropriate to obtain their consent for research-related interventions at the same time. Another comment questions how a person reviewing hospital records would know a subject agreed to be in the study if consent had been waived.

(Response 7) With respect to the comment that questions why consent would need to be waived if informed consent to participate in research could be obtained at the same time that non-research related consent for patient care was being obtained, FDA notes that that the investigation would need to be impracticable to perform without a waiver in order to qualify for a waiver under this final rule. As stated in the preamble to the proposed rule, if scientifically sound research can practicably be carried out using only consenting subjects, we believe it should be carried out without involving nonconsenting subjects (83 FR 57378 at 57382). Waivers or alterations of informed consent under § 50.22 are intended for situations where it is impracticable to carry out the clinical investigation, as designed, without the waiver or alteration. There may be certain cases in which getting consent from a subset of individuals in the target study population may be possible, but the study may still be considered impracticable without a waiver because of obstacles[5] to obtaining consent from a sufficient number of the subjects needed to carry out the study as designed.

[3] Certain procedures, such as blood sampling that involves simple venipuncture, are considered noninvasive for purposes of FDA's IDE regulations (§ 812.3(k) (21 CFR 812.3(k)), and research involving such procedures may be considered no more than minimal risk for the purpose of expedited review (63 FR 60353 at 60355, November 9, 1998) (see response to Comment 20).

[4] See also 45 CFR 164.512 (Uses and disclosures for which an authorization or opportunity to agree or object is not required).

[5] Please refer to FDA's response to comment 13 for more information on FDA's interpretation of the term ''practicably.''

With respect to the comment that questions how a person reviewing hospital records would know a subject agreed to be in the study if consent had been waived, any person reviewing the data for purposes of the study would be themselves an investigator or otherwise involved in the investigation, and should therefore be aware that an IRB had approved the study, found the criteria under § 50.22 were met, and granted a waiver of the requirement to obtain informed consent. This would provide that person with assurance that the subject's rights, safety, and welfare are protected. Additionally, in the event of concerns about including a particular subject or group of subjects in a clinical investigation for which informed consent has been waived in accordance with § 50.22, the investigator or member of the study team could consult appropriate parties, such as the sponsor or the IRB, to address those concerns.

(Comment 8) Two comments suggest additional requirements for studies in which consent is waived. One comment cites a research paper that assesses the legitimacy of waivers of consent for research, which the authors posit is ''predicated on the reasonable belief that potential subjects would agree if they were asked and capable of consent.'' The paper includes a literature review and qualitative assessment of studies examining participation and refusal rates in human subjects research (Ref. 4). From this review, the authors conclude that there is reason to believe that many potential participants would not want to be enrolled in a study for which informed consent is waived, if asked. The paper concludes that waivers of informed consent should be rare, and that IRBs and researchers must find out if a study is acceptable to the target population and in the community where the proposed research takes place. The comment states that ''waivers of informed consent may be granted for a population based on general characteristics of the population that make getting consent from everyone impracticable, with express acknowledgement that securing consent from some members of the population may be quite feasible and practicable, and in those cases consent must be secured.'' The comment notes that this approach is modeled on the exception from informed consent in FDA's emergency research regulations at § 50.24, and states that § 50.24 is legally and ethically superior to the waiver provision in the proposed rule. Finally, the comment recommends that an additional requirement be added to the proposed regulations requiring that consent should be secured from individuals or their LARs ''when practicable.''

A second comment suggests that, for any research for which the requirement to obtain informed consent would be waived under the provision in the proposed rule, FDA require the drafting of an ''as if'' consent form in language geared toward the subject's viewpoint before the research begins. This comment argues a precedent for this approach under § 50.24(a)(6). It also asserts that this exercise would prevent practitioners from being deprived of a description of research interventions and would describe the intervention in language geared toward the viewpoint of the human subject, which may enhance human subject protections and promote an atmosphere of appropriate respect and empathy for non-consenting human subjects.

(Response 8) With regard to the points outlined in the cited research paper, we agree that the acceptability of the research to potential participants is an important consideration for an IRB when determining whether to grant a waiver or alteration of informed consent under the final rule. FDA stated in the preamble of the proposed rule that, to make the finding that the waiver or alteration will not adversely affect the rights and welfare of the subjects, IRBs may consider, for example, whether the subject population in general would be likely to object to a waiver or alteration being granted for the research in question (83 FR 57378 at 57381 to 57382). However, individual decisions to participate in research often depend on different factors, such as the recruitment method used (Ref. 5) and health literacy (Ref. 6). Additionally, an individual's trust (or distrust) in their healthcare provider and/or in the institution conducting the research may also contribute to their willingness to participate (Ref. 7). Requiring IRBs to determine and researchers to establish that an ''appropriate majority'' of the target study population would choose to participate before granting a waiver of consent, as the article suggests, would involve accounting for the individualized factors underlying such decisions. This would be unduly burdensome and could create significant limitations or delays for minimal risk investigations that § 50.22 is intended to facilitate. Given the complexities and unknowns surrounding individual reasons for participation or refusal to participate in minimal risk research, we believe that this rule strikes an appropriate balance between enabling important research to proceed while safeguarding the rights, safety, and welfare of subjects such that consent (or elements of consent) can be appropriately waived.

FDA declines to adopt the commenter's suggestion to include in the final rule a requirement to obtain consent from individual potential subjects or their LARs ''when practicable.'' FDA's provision for exceptions from informed consent for emergency research requires, among other things, an investigator commitment to attempt to contact an LAR for each subject within the therapeutic window and, if feasible, to ask the LAR for consent within that window (§ 52.24(a)(5)). However, we disagree with the commenter's conclusion that because of this requirement, § 50.24 is ''superior'' to the requirements for a waiver under § 50.22. Each of these provisions was developed to address significantly different types of clinical investigations. The criteria listed in § 50.24 are intended for research involving a study population with no capacity to consent, in a setting where the emergency circumstances require prompt action and generally provide insufficient time and opportunity to locate and obtain consent from each subject's legally authorized representative. Specifically, for research to qualify to be conducted under § 50.24 certain conditions, including the following, must be satisfied: the subject is in a life-threatening situation; available treatments are unproven or unsatisfactory; participation in the research holds out the prospect of direct benefit to the subject; obtaining informed consent from the subject is not feasible because the subject cannot provide consent due to their medical condition; and the intervention must be administered before consent can be obtained from the subject's LAR. In contrast, the criteria for waiver or alteration of consent in § 50.22 are intended for research in which the risk to participants is minimal and are not focused on research where subjects are in a life-threatening situation. We, therefore, conclude that revising § 50.22 in this final rule to include a requirement similar to that found in § 50.24(a)(5) is not appropriate for the minimal risk research that would otherwise qualify for a waiver or alteration of informed consent under this final rule. In addition, the comment's suggestion that FDA require informed consent to be obtained from individual subjects or their LARs ''when practicable'' could cause confusion, given that the criterion at § 50.22(b) requires an IRB to find that the research could not practicably be carried out

without the requested waiver or alteration of consent. Including such a requirement would also be an unnecessary difference from the corresponding provision under the Common Rule at 45 CFR 46.116(f)(3), contrary to the harmonization goals of this rulemaking. Because §§ 50.24 and 50.22 are intended for different types of research with different ethical considerations, we believe that differences between these provisions are appropriate and that both provisions protect the rights, safety, and welfare of study subjects through the requirements that must be met for approval by an IRB.

We also decline the suggestion to require the drafting of an ''as if'' informed consent form (*i.e.,* a form that would not actually be used to obtain consent) if an IRB waives the informed consent requirement for a clinical investigation that meets the § 50.22 criteria. Although the commenter points to § 50.24(a)(6) as precedent, that provision requires IRB approval of informed consent procedures and an informed consent document that are to be used to obtain consent from a subject or LAR, when feasible. This requirement recognizes that some emergency research conducted under § 50.24 ''may include a limited number of subjects for whom a representative is able to provide surrogate consent for the subject, and the treatment window may be such to permit such consent to be obtained.'' (60 FR 49086 at 49095, September 21, 1995.) As explained above, FDA is not including a requirement in § 50.22 that the investigator obtain consent from subjects or LARs if feasible similar to the requirement in § 50.24(a)(5). Development of an ''as-if'' informed consent form that would not be used would impose additional burdens on IRBs and investigators without a clear benefit. For investigations in which informed consent is waived, we have no evidence that an ''as if'' consent document would provide practitioners with additional information or understanding of the research beyond what is available in the research protocol, or that this additional document would foster additional empathy or respect for subjects whose consent is waived. Additionally, we disagree that an ''as if'' informed consent form would increase human subject protections beyond the requirements listed in § 50.22, such as the requirement that the waiver or alteration not adversely affect the rights and welfare of subjects, as well as the requirement that, whenever appropriate, the subjects or their LARs are provided with additional pertinent information after participation.

(Comment 9) Two comments suggest tracking the cumulative effects of minimal risk studies on subjects who have participated in more than one such study and suggest establishing a centralized registry containing the names of all human subjects who are involved in research or clinical investigations, the names of the sponsor and researcher, whether the research is classified, and whether informed consent was waived or altered.

(Response 9) We decline to adopt the suggested requirement that all participants in minimal risk studies be tracked and the suggestion to establish a centralized registry of participants in clinical investigations because, among other issues (*e.g.,* the time and resources needed to establish and maintain a registry with appropriate procedures for the collection, use, and disclosure of identifiable information), such a registry might present additional risks regarding privacy and confidentiality of participant data (*e.g.,* data leak of private health information, creating links between individual data that otherwise would not exist, increased chance of stigmatization through identification of individual data collected in the registry).

C. Comments on the Proposed Waiver or Alteration Criteria

FDA proposed that, to permit a waiver or alteration of the informed consent requirements, the IRB must find and document that the following four criteria are met: (1) the clinical investigation involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the clinical investigation could not practicably be carried out without the waiver or alteration; and, (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

1. The Clinical Investigation Involves No More Than Minimal Risk to the Subjects (Proposed § 50.22(a))

The proposed rule included, as the first criterion, that the clinical investigation involves no more than minimal risk to the subjects. ''Minimal risk'' is defined in § 50.3(k) to mean that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(Comment 10) Fewer than half of the comments reference proposed § 50.22(a) or mention the minimal risk criterion. The majority of these comments support an IRB's ability to approve informed consent procedures that do not include or that alter some of the elements of informed consent, or to waive consent entirely, for minimal risk research. Some of these comments support the ability to waive or alter informed consent requirements for specific types of research they identify as minimal risk, including research involving clinical record reviews or secondary use of biospecimens, and certain cluster randomized trials. One comment expresses trust in IRBs' abilities to know when informed consent is required.

Conversely, some comments oppose or express reservations about allowing waiver or alteration of consent for minimal risk studies, suggesting that the term ''minimal risk'' is vague, ambiguous, or subjective, or express other confusion about its meaning. One comment indicates concern that the vagueness of the term ''minimal risk'' would precipitate misuse of the rule. Other comments suggest that the rule clarify the meaning of specific terms in the definition of minimal risk (*e.g.,* ''routine physical or psychological examinations or tests''). These comments also suggest that FDA clarify that the ''daily life'' risk standard in the current definition so that IRBs would know how to interpret the standard to avoid allowing populations that encounter higher risks in daily life (*e.g.,* live in a dangerous region) to be exploited. Another comment raises concerns regarding the subjective nature of the definition of ''minimal harm'' and the potential for variability in IRB decisions on requests for waivers of informed consent.

Several comments assert that IRBs should not be entrusted to make minimal risk determinations. A few comments suggest that determinations of risk are subjective and that only the individual subject can make a meaningful decision about degrees of risk and whether a particular risk in a study is actually minimal. Some comments express concern that IRBs might inappropriately grant waivers for clinical investigations that are greater than minimal risk, or that they may fail to appreciate both the nature and risks of procedures in the research studies that are submitted to them for review. Other comments caution that IRB members may have conflicts of interest that could affect their interpretation of the term. To support their concerns and opposition, these comments cite past instances in which researchers had

reportedly misled subjects or inappropriately conducted research without obtaining informed consent.

Other comments suggest that additional oversight or clarification regarding IRB processes is needed with regard to granting waivers of informed consent and the determination of minimal risk. One comment urges that, if waivers are allowed, the Agency revise the proposal to address the following: clarify the process to determine whether to grant and approve waivers of informed consent, require ongoing review of waivers to determine whether IRBs are properly defining the studies as minimal risk, immediately terminate any research in which medical interventions are withheld or are too aggressive, and provide a ''whistleblower form'' for individuals involved in a research study to anonymously submit a complaint about that study to HHS. Another comment requests that FDA provide details about the practical application of the proposal, that is, how an IRB's process of determining whether to grant waivers of informed consent might work to remove the risk of variability in when and how such waivers are granted.

Some comments express concern that studies involving records or data are often labeled as minimal risk, even though IRBs struggle to make determinations about the magnitude of the risks posed by such studies and whether the risks are indeed minimal. One of these comments notes that the ability to link various sources of personal data may create additional risks for study subjects. One comment indicates concern that, in research involving real-world data (RWD) or review of health records that is categorized as ''minimal risk,'' hacking or inadvertent sharing could put the subjects' information at risk or cause subjects to be at risk for losing healthcare coverage.

(Response 10) FDA is not revising the definition of minimal risk in this rule. Retaining the current definition of minimal risk will avoid confusion in the research community and maintain harmonization with the revised Common Rule. The Common Rule and FDA regulations have shared the same definition of minimal risk since 1991,[6] and the definition of minimal risk was not changed in the revised Common Rule. Because of the longstanding consistency in the definitions of minimal risk provided in both FDA regulations and the Common Rule, IRBs have experience in applying the term ''minimal risk'' to research involving human subjects, including determining when a clinical investigation involves no more than minimal risk. Without additional detail, it is not possible to determine whether the specific types of studies the comments identify as minimal risk would involve no more than minimal risk to the subjects (see also response to Comment 19). However, we agree with these comments' support for waiving or altering informed consent to facilitate minimal risk research that meets the requirements of § 50.22.

In response to comments suggesting that IRB members might have conflicts of interest that could affect their interpretation of the term ''minimal risk,'' we note that IRBs are subject to the requirements under § 56.107 (21 CFR 56.107), including the requirements prohibiting participation in IRB review by a member with a conflict of interest, except to provide information requested by the IRB, under § 56.107(e).

With respect to the comment that recommends revising the rule to clarify the process of an IRB waiver determination and require ongoing review for waivers to determine the adequacy of IRBs' interpretation of ''minimal risk,'' we note that IRBs are required to prepare and follow written procedures for conducting reviews of FDA-regulated clinical investigations (see 21 CFR 56.108(a) and 56.115(a)(6)). These written procedures should include an IRB's processes for reviewing requests to waive or alter informed consent and documenting that the criteria in § 50.22 are satisfied. We also note that FDA inspects IRBs to determine whether they are reviewing and approving research in accordance with FDA regulations and with the IRBs' written procedures. We do not believe it is necessary to prescribe a particular process or procedure that IRBs must follow when making and documenting a waiver or alteration decision for a research study, or that such a process would result in more consistent decision making. FDA regulations provide for flexibility in terms of the specific contents of IRB written procedures, which gives IRBs the ability to establish procedures best suited to their own operations. Written procedures, including the processes IRBs follow for making certain determinations, may vary among institutions and IRBs because of differences in the way organizations are structured, the type of research studies reviewed by the IRB, institutional policy or administrative practices, the number of IRBs at the institution, affiliation with an institution, or local and State laws and regulations (Ref. 8).

FDA also declines the commenter's suggestion to add to the rule a requirement that research be terminated that withholds or provides for aggressive medical intervention. Although the comment does not elaborate on the meaning of an ''aggressive'' medical intervention, it does not appear that the types of research studies the comment describes would qualify for a waiver or alteration under § 50.22. In addition, if changes are proposed to a study for which a waiver or alteration has been granted under § 50.22, and those changes include the addition of an investigational intervention or other protocol amendment that involves more than minimal risk to subjects, then the study, with the change, would no longer qualify for the waiver or alteration.[7] With regard to the comment encouraging a process for HHS to receive anonymous complaints from individuals involved in a research study, FDA notes these processes are already in place for both FDA [8] and HHS.[9]

Regarding the comment suggesting that hacking or inadvertent sharing of health information can create risks for subjects, such as losing healthcare coverage, we note that § 56.111(a)(7) (21 CFR 56.111(a)(7)) of FDA's regulations requires IRBs to determine that, where appropriate, adequate provisions to protect subjects' privacy and maintain the confidentiality of data are in place in order to approve FDA-regulated research. This would include research for which the IRB grants a waiver or alteration of consent under § 50.22.

As previously noted, FDA plans to publish guidance to assist IRBs in applying the criteria for waiver or alteration of informed consent requirements in § 50.22 to FDA-regulated clinical investigations. In that guidance, we intend to include additional information on the types of research activities that may involve no

[6] 83 FR 57378 at 53781.

[7] While outside the scope of this rulemaking, FDA's existing IRB regulations at 21 CFR 56.113 provide for termination of IRB approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

[8] Complaints related to FDA-regulated clinical investigations should be reported to the Center responsible for the product involved. Additional information and contact information for each Center is available at: *https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/reporting-complaints-related-fda-regulated-clinical-trials.*

[9] Complaints related to research subject to HHS regulations may be emailed to OHRP's Director of the Division of Compliance Oversight at *complaints.ohrp@hhs.gov*. More information is available at: *https://www.hhs.gov/ohrp/compliance-and-reporting/submitting-a-complaint/index.html.*

more than minimal risk to the subjects and therefore might qualify for a waiver or alteration of informed consent.

(Comment 11) One comment, focused on device studies, warns about the potential for confusion and inconsistent interpretation across IRBs when applying the concept of ''minimal risk'' to studies of ''non-significant risk'' devices.

(Response 11) FDA addressed the difference between ''non-significant risk'' and ''minimal risk'' in a 2006 guidance for IRBs, clinical investigators, and sponsors entitled ''Significant Risk and Nonsignificant Risk Medical Device Studies'' (SR/NSR Guidance; Ref. 9). In the SR/NSR Guidance, FDA explains that ''non-significant risk'' and ''minimal risk'' determinations are distinct and involve different considerations. IRBs that review device investigations have experience applying FDA's regulations at parts 50, 56, and 812, and the SR/NSR Guidance has been in place for many years as a resource. As a result, IRBs should be aware that ''non-significant risk'' and ''minimal risk'' are different concepts that serve different regulatory purposes. Given this experience, we do not believe that IRBs will encounter difficulty applying the concept of ''minimal risk'' in § 50.22 to clinical investigations involving ''non-significant risk'' devices.

2. The Waiver or Alteration Will Not Adversely Affect the Rights and Welfare of the Subjects (Proposed § 50.22(b))

The proposed rule included, as the second criterion, that the waiver or alteration will not adversely affect the rights and welfare of the subjects.[10] FDA stated in the preamble of the proposed rule that, to make this finding, IRBs may consider, for example, whether the waiver or alteration has the potential to negatively affect the subjects' well-being or whether the subject population in general would likely object to a waiver or alteration being granted for the research in question (83 FR 57378 at 57381 to 57382). It would not be necessary for an IRB to find that obtaining informed consent would be harmful or contrary to the best interests of subjects in order to satisfy this criterion.

(Comment 12) Several comments mention the effects of the proposed rule on subjects' rights and welfare. Some comments oppose the idea of a waiver of consent, stating that the absence or omission of informed consent affects the rights of subjects. Two comments assert that a waiver of informed consent would be unethical and in violation of subjects' trust because subjects would be prevented from knowing who is seeing or using their records, and the waiver would take away the subjects' choice and ability to specify how their data will be used. An additional comment mirrors this concern and notes the importance of protecting personal data.

Two comments object to waiving consent on the grounds that doing so would deny subjects necessary information about the research (*e.g.,* the name of the sponsor, a description of the research or research protocol, a description of subjects' rights, who to contact in the event of injury) and would deny subjects the right to object to participation in the research, the right to withdraw from the research, and the right to recourse and remedy in the event of issues or wrongdoing. Finally, one comment objects to the rule based, in part, on a lack of definitions for the term ''welfare'' and the phrase ''welfare of the subjects.''

(Response 12) FDA does not agree with the comments suggesting that allowing for a waiver of informed consent for minimal risk clinical investigations in the circumstances described in § 50.22, including the criterion in proposed § 50.22(b), adversely affects the rights of subjects or is unethical or in violation of subjects' trust. We note that provisions relating to safeguarding the rights and welfare of subjects in clinical investigations have been included in FDA's regulations for decades. Section 56.107(a) of our regulations on IRB membership requires that each IRB be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. We believe that an IRB responsible for the review, approval, and continuing review of a minimal risk clinical investigation that meets these membership requirements is capable of finding and documenting, as appropriate, that the waiver or alteration will not adversely affect the rights and welfare of subjects participating in the research. Additionally, we note that to approve a clinical investigation, including a clinical investigation for which informed consent is waived or altered under this rule, an IRB must find that, where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (§ 56.111(a)(7)).

We believe that the safeguards in § 50.22 also help to alleviate the comments' concerns regarding subjects' access to information about the research, as we anticipate that IRBs will consider if any study information falling within the elements listed in § 50.25(a) or (b) should be provided to subjects. If so, the IRB may conclude, for example, that an alteration of certain informed consent elements is appropriate rather than a waiver, or that it is appropriate for the subjects or their LARs to be provided with additional pertinent information after participation (see § 50.22(e) in this rule).

In response to the comments objecting to the waiver provision as unethical or adversely affecting subjects' rights, we also point to our response to comment 2 for discussion regarding the ethical principles associated with clinical research (*e.g.,* autonomy, beneficence, justice) in the context of this rule. For those FDA-regulated clinical investigations that would meet the criteria for waiver or alteration of consent under § 50.22, we believe that the protections in place under this rule are appropriate to protect the rights, safety, and welfare of human subjects while facilitating research to advance public health.

Finally, FDA declines to include a definition of ''welfare'' or ''welfare of the subjects'' in the final rule. We note that the language of ''rights and welfare of human subjects'' has a long history of inclusion in both FDA regulations for human subject protections and the Common Rule. This and similar language are also used in other well-established guidelines on human subject research (Refs. 10 and 11). Given this history, FDA believes that IRBs are accustomed to applying the term ''welfare'' to different types of research, including minimal risk research.

FDA notes that there are resources available to IRBs and the research community more broadly when considering human subject welfare in minimal risk research. For example, the Secretary's Advisory Committee on Human Research Protections (SACHRP), through its Subcommittee on Subpart A, developed several recommendations regarding the interpretation of the Common Rule criteria for a waiver or alteration of informed consent, including the criterion regarding the ''rights and welfare'' of subjects (Ref. 2).

3. The Clinical Investigation Could Not Practicably Be Carried Out Without the Waiver or Alteration (Proposed § 50.22(c))

The proposed rule included, as the third criterion, that the clinical investigation could not practicably be carried out without the waiver or

[10] We note that, in the final rule, proposed § 50.22(b) is now § 50.22(d).

alteration.[11] In the preamble to the proposed rule, FDA stated that, if scientifically sound research can practicably be carried out using only consenting subjects, FDA believes it should be carried out without involving nonconsenting subjects. FDA also provided an example of what practicable means (*i.e.,* (1) that recruitment of consenting subjects does not bias the science and the science is no less rigorous as a result of restricting it to consenting subjects or (2) that the research is not unduly delayed by restricting it to consenting subjects) (83 FR 57378 at 57382). As noted in our response to comment 7, the emphasis is on situations where it is impracticable to carry out the clinical investigation, as designed, without the waiver or alteration, rather than on situations where it is not feasible to obtain informed consent from subjects.

(Comment 13) Several comments on the proposal make reference to proposed § 50.22(c) or commented on the term ''practicably'' in this criterion. Several of the comments ask for clarification or additional guidance about the meaning of the term ''practicably'' in the proposed criterion.

One comment asserts that there is wide variation in the way IRBs interpret the practicability standard. The comment continues that some IRBs interpret impracticable to mean that the research is impossible to do with consent, while other IRBs might accept investigator resistance to obtaining informed consent as meeting the impracticability threshold. This comment also recommends that practicability determinations be made in the context of understanding the value or importance of the research, and that ''impracticable'' should be understood to mean that the burdens of getting consent are too high, given the benefit, or value, promised by the research. This comment is one of two recommending that FDA revise its interpretation of ''practicable'' to align with recommendations made by SACHRP in 2008 related to waiver of informed consent and interpretation of minimal risk under the Common Rule (Ref. 2).

Another comment seeks reassurance that one of the objectives of § 50.22 is to provide IRBs with the latitude to allow a sponsor to have access to and utilize data and/or biospecimens that have already been collected without having to obtain informed consent. The comment encourages the inclusion of examples of minimal risk investigations to help IRBs understand that they have the flexibility to make real-world assessments of whether the research would be rendered impracticable because of the unavailability of subjects to give new individual consent.

A final comment asks that FDA clarify the meaning of the phrase ''unduly delayed'' in its description of the term ''practicable.'' This comment states that more effort should be put into finding an alternative to conducting research without subjects' consent.

(Response 13) With respect to the interpretation of the term ''practicably,'' we reiterate that the emphasis is on situations where it is impracticable—not necessarily impossible—to carry out the clinical investigation, as designed, without the waiver or alteration. Practicability should be assessed on a case-by-case basis considering the unique factors associated with the clinical investigation, such as its aims, its population(s), and the impact on its scientific validity if informed consent were required (*e.g.,* introduction of bias). The relevant considerations, and the weight given to each consideration, should reflect the unique circumstances of the clinical investigation for which a waiver or alteration of informed consent is being sought.

If an IRB finds that a clinical investigation can be practicably carried out using only consenting subjects, then FDA believes it should be carried out without involving nonconsenting subjects. However, we agree that, under this final rule, an IRB can approve a clinical investigation falling within the scope of part 50 in which investigators will have access to and utilize data and/or biospecimens that have already been collected without having to obtain informed consent, provided the IRB finds and documents that the criteria under § 50.22 are met.

In addition, we agree that IRBs may find under § 50.22(b) (§ 50.22(c) in the proposed rule) that a clinical investigation could not practicably be carried out without a waiver or alteration of informed consent based on the unavailability of certain subjects in an investigation to give consent for a new investigation (*e.g.,* subjects lost to followup), when restricting the research to the subjects available to provide consent would compromise the scientific or ethical integrity, or cause undue delay of, the investigation.

As some comments point out, SACHRP made recommendations in 2008 related to waivers of informed consent and the interpretation of minimal risk under the Common Rule, including the Common Rule waiver criterion that corresponds to § 50.22(b). In its recommendations, SACHRP emphasized that the criterion ''states that the research could not practicably be carried out without the waiver or alteration. Put another way, it would not be practicable to perform the research (as it has been defined in the protocol by its specific aims and objectives) if consent was required'' (Ref. 2). SACHRP also offered the following concepts to help an IRB determine whether the research could not be practicably carried out without the waiver or alteration of consent: (1) the scientific validity of the research would be compromised if consent were required; (2) ethical concerns would be raised if consent were required; (3) there is a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained; and (4) practicability should not be determined solely by considerations of convenience, cost, or speed.

Although SACHRP's recommendations regarding the ''practicably'' waiver criterion were developed for research that is regulated under the Common Rule, they are consistent with FDA's interpretation of the corresponding waiver criterion in this rule (*i.e.,* § 50.22(b)). It thus may be appropriate for an IRB to find that a clinical investigation could not practicably be carried out without a waiver or alteration of informed consent on the grounds that ethical concerns would be raised if consent were required (*e.g.,* an investigation using previously collected biospecimens where obtaining subjects' consent for secondary research use of the biospecimens may expose individuals to new privacy risks by linking the biospecimens with nominal identifiers in order to contact the individuals to seek consent). In some cases, these ethical concerns could justify a finding of impracticability under § 50.22(b) even if the scientific validity of the clinical investigation would not be compromised by asking the individuals to provide informed consent.

In addition, as stated in the preamble to the proposed rule, FDA interprets the term ''practicably'' in § 50.22(b) to mean, for example, that the research is not unduly delayed by restricting it to consenting subjects (83 FR 57378 at 57382). The phrase ''unduly delayed'' refers to more than just considerations of speed. By ''unduly delayed,'' we mean a delay in the initiation of a clinical investigation that is so lengthy as to raise ethical or scientific concerns given the benefit, or value, potentially gained by the research (*e.g.,* delaying the initiation of an investigation of a rare disease treatment by several years in

[11] We note that, in the final rule, proposed § 50.22(c) is now § 50.22(b).

order to allow for collection of new biospecimens from consenting subjects with the rare disease, when biospecimens from individuals with the disease are available from a repository but the biospecimens have no accompanying current contact information). Accordingly, an IRB may make a finding that the research could not practicably be carried out without the requested waiver or alteration because requiring consent would unduly delay the research.

We note that it would be inappropriate for an IRB to find that a clinical investigation could not practicably be carried out without a waiver or alteration of informed consent based solely on a clinical investigator being resistant to obtaining informed consent. We do not consider investigator resistance to obtaining informed consent to be a scientifically or ethically valid reason for finding under § 50.22(b) that a clinical investigation could not practicably be carried out without a requested waiver or alteration of informed consent.

4. Whenever Appropriate, the Subjects Will Be Provided With Additional Pertinent Information After Participation (Proposed § 50.22(d))

As the fourth criterion, FDA proposed that, whenever appropriate, the subjects will be provided with additional pertinent information after participation.[12] For example, an IRB may find that information that had been previously withheld about the clinical investigation to prevent bias must be provided to subjects following their participation.

(Comment 14) FDA received a few comments about proposed § 50.22(d). Two comments cite a lack of clarity about the phrase ''whenever appropriate'' and one asks ''when and why'' it would not be appropriate to provide a subject with pertinent information after the research has ended. One comment recommends that definitions for § 50.22(d) be included, without providing further specificity on the definitions to be included.

(Response 14) For this criterion, the phrase ''whenever appropriate'' means that, when evaluating whether this criterion is met, the reviewing IRB considers factors relevant to the specific clinical investigation and population of the study under review to determine whether an investigator should provide information to the subjects of the minimal risk clinical investigation or to their LARs after participation (Ref. 2). One example where providing additional pertinent information after participation may be appropriate is in the case where some aspects of the study are not fully disclosed upfront because full disclosure may interfere with the purpose of the study (*e.g.,* full knowledge might cause subjects to act differently than they naturally would during the study). In that case, withholding full information upfront helps to ensure subject responses are not biased. Providing subjects with additional pertinent information about the study after participation may be appropriate.

FDA declines the recommendation that definitions in § 50.22(d) be included, as we do not have additional information from the commenter regarding what specific definitions should be described. As noted in our responses to comments 6 and 10, we believe that IRBs are equipped to consider the criteria outlined in the rule, as IRBs have experience applying the criteria in the corresponding Common Rule provision for waiver or alteration of informed consent. IRBs also have resources available to draw upon when considering a waiver or alteration of informed consent for minimal risk research (Ref. 2).

D. Comments on Adopting the Revised Common Rule's Fifth Criterion for Waiver or Alteration of Informed Consent

In the proposed rule, FDA explained that the revised Common Rule retained the same four criteria for IRB waiver or alteration of informed consent as were included in the 1991 version of the Common Rule, but added a fifth criterion, *i.e.,* ''if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format'' (45 CFR 46.116(f)(3)(iii)). FDA proposed to adopt the four criteria from the 1991 version of the Common Rule but did not propose to adopt the fifth criterion at that time. Instead, FDA invited public comment on whether to include the fifth criterion in FDA regulations.

(Comment 15) Several comments support including the fifth criterion in the final rule because it would harmonize FDA's criteria in § 50.22 for a waiver or alteration of informed consent for minimal risk clinical investigations with the revised Common Rule's criteria in 45 CFR 46.116(f)(3) and would support the continued protection of human subjects by addressing identifiable private information and biospecimens. Some comments also note that adopting the fifth criterion is consistent with the goal of reducing administrative burden. One comment expresses the concern that less than complete harmonization would do nothing to reduce the time and effort spent training staff and developing multiple sets of forms and processes for review of research under different standards.

Some comments maintain that inclusion of the fifth criterion is helpful because research involving biospecimens is an area of confusion and controversy and including the fifth criterion provides clarification of FDA's policy. One comment asserts that omission of the fifth criterion would contribute to the mistaken belief that FDA's regulations do not permit a waiver or alteration of informed consent for minimal risk research involving identifiable biospecimens.

Two comments request FDA's rationale for not promulgating the fifth criterion if the criterion is not adopted in the final rule. Another comment recommends that FDA revise the definition of human subject at § 50.3(g) to clarify the applicability of part 50 to private information and biospecimens. This comment also recommends that, given that ''identifiability is more fluid than the term implies, and technology is rapidly changing how data can be identified,'' FDA adopt a provision, similar to the revised Common Rule at 45 CFR 46.102(e)(7), requiring the Agency to periodically reevaluate the meaning of ''identifiable'' and what technologies or techniques generate identifiable information or specimens.

(Response 15) FDA is adopting the fifth criterion in this final rule. To match the structure of the revised Common Rule's general waiver provision (*i.e.,* 45 CFR 46.116(f)), the fifth criterion has been incorporated into the codified text at § 50.22(c).

In adopting the fifth criterion, we are harmonizing the waiver criteria set forth in § 50.22 with those set forth in the revised Common Rule's general waiver provision (45 CFR 46.116(f)(3)). As discussed in our response to comment 1, we expect that this harmonization will reduce administrative burdens on IRBs and researchers and reduce research costs. We also agree with comments noting that inclusion of the fifth criterion in the codified text will help avoid confusion regarding the applicability of § 50.22 to minimal risk clinical investigations involving the use of private information or biospecimens in an identifiable format. The fifth criterion makes it clear that § 50.22 applies to minimal risk clinical investigations involving the use of

[12] We note that, in the final rule, proposed § 50.22(d), as revised, is now § 50.22(e).

identifiable private information or identifiable biospecimens and that IRBs are permitted to waive or alter informed consent for such investigations, provided the IRB finds and documents that the other criteria in § 50.22 are met and that the investigation could not practicably be carried out without using such information or biospecimens in an identifiable format.

We decline the recommendation to revise the definition of ''human subject'' in § 50.3(g), as changes to the definition of ''human subject'' could have unintended effects on other sections in part 50 beyond the scope of this rule. We also decline to adopt a provision that would require FDA to periodically reexamine the definitions of ''identifiable private information'' or ''identifiable biospecimen.'' We note that definitions of ''identifiable private information'' and ''identifiable biospecimen'' are included in FDA's proposed rule to amend part 50, Protection of Human Subjects, and part 56, Institutional Review Boards (87 FR 58733, September 28, 2022). Additionally, the revised Common Rule includes provisions at 45 CFR 46.102(e)(7)(i) and 46.102(e)(7)(ii) that require Federal departments and Agencies implementing the revised Common Rule, regularly and upon consultation with appropriate experts, to (i) reexamine the meaning of ''identifiable private information'' and ''identifiable biospecimen'' [13] and (ii) assess whether there are analytic technologies or techniques that should be considered to generate identifiable private information or identifiable biospecimens. FDA intends to participate in these efforts with HHS and the other Federal departments and Agencies, providing input on FDA-regulated research and promoting consistent and appropriate interpretation of these terms across HHS and FDA human subject research regulations. Including a new requirement in FDA's regulations for FDA to consider issues relating to the meaning of ''identifiable,'' on a periodic basis and in light of evolving technology, is thus unnecessary and could result in duplicative efforts and additional burden on the Agency without added benefit.

(Comment 16) A few comments oppose adopting the fifth criterion. Two comments observe that FDA did not propose to establish a regulatory definition for ''identifiable.'' These comments assert that the definitions of the terms ''identifiable private information'' and ''identifiable biospecimen'' in the revised Common Rule must be periodically reevaluated under 45 CFR 46.102(e)(7) and may change in the future, which could impact research involving identifiable biospecimens and identifiable private information in unknown ways. In addition, these comments maintain that the fifth criterion could lead to unintended negative consequences, such as investigators being reluctant to retain identifiers needed for quality control purposes and for the verification of data that may be required for FDA submissions, applications, and approvals. The comments also express concern that IRBs may be reluctant to grant waivers for research with identifiable biospecimens and data. Additional comments contend that the fifth criterion is unnecessary because it does not provide additional human subject protections beyond those provided by the other criteria in proposed § 50.22, or because certain types of research (*i.e.,* on biospecimens) fall outside the scope of FDA-regulated clinical investigations because the research does not include a ''human subject.'' Finally, one comment asserts that informed consent should never be waived for research involving identifiable private information or biospecimens.

(Response 16) FDA declines to add a definition for ''identifiable'' in this rule. As noted in our response to comment 15, we include definitions of ''identifiable private information'' and ''identifiable biospecimen'' as part of our proposed rule to amend part 50, Protection of Human Subjects, and part 56, Institutional Review Boards. In that rule, the proposed definitions of ''identifiable private information'' and ''identifiable biospecimen'' harmonize with the revised Common Rule's definitions of these terms (45 CFR 46.102(e)(5) and (6)).

With respect to the revised Common Rule definitions for ''identifiable private information'' and ''identifiable biospecimen,'' we acknowledge that the meaning of these terms must be periodically reexamined pursuant to 45 CFR 46.102(e)(7) and that they may be interpreted differently by the Common Rule departments and Agencies in the future. However, we believe the commenters' concerns regarding the potential impact on FDA-regulated research of such periodic reexaminations can be addressed through FDA's involvement in the consultation process described in the revised Common Rule, as discussed in the response to comment 15. Additionally, these comments do not provide a basis for us to conclude that adoption of the fifth criterion will have unintended negative consequences for investigator retention of identifiers. We fully expect clinical investigators to retain the identifiers for private information and biospecimens when it is necessary to do so for quality control purposes. A failure to preserve the identifiers could compromise the integrity of an investigation's results. We do not believe clinical investigators will risk compromising an investigation to avoid triggering the fifth criterion in any research involving private information or biospecimens. Nor are we aware of evidence that IRBs will be reluctant to waive or alter informed consent for clinical investigations involving private information or biospecimens in an identifiable format when the waiver criteria are met, or that IRBs are more reluctant to waive informed consent for research involving identifiable private information or biospecimens since the fifth criterion has been adopted in the revised Common Rule. FDA expects IRBs to evaluate carefully each request and grant a waiver or alteration of informed consent only when adequately justified.

We disagree with the contention that the fifth criterion is unnecessary because it does not provide additional human subject protections beyond what the other criteria provide. The fifth criterion respects subjects' interests in protecting the confidentiality of their information and biospecimens by embodying the principle that nonidentifiable private information and nonidentifiable biospecimens should be used whenever possible in clinical investigations for which informed consent is not obtained.[14] Although some IRBs might consider these privacy interests as a part of analyzing other criteria in § 50.22, the fifth criterion requires that all IRBs consider these interests when determining whether to grant a waiver or alteration of informed consent under § 50.22 for a clinical investigation involving identifiable

[13] The provision in 45 CFR 46.102(e)(7)(i) further provides that, if appropriate and permitted by law, these Federal departments and Agencies may alter the interpretation of these terms, including through the use of guidance.

[14] In adopting this criterion, the preamble to the revised Common Rule stated: ''This criterion was modeled on the comparable criterion in the HIPAA Privacy Rule, which requires as a condition of waiver of the requirement to obtain an individual's authorization that the research could not practicably be conducted without access to and use of protected health information. The principle embodied in this additional proposed criterion was that nonidentified information should be used whenever possible in order to respect subjects' interests in protecting the confidentiality of their data and biospecimens'' (see 82 FR 7149 at 7224).

private information or identifiable biospecimens.

In response to the comment suggesting that the fifth criterion is unnecessary because ''biospecimen research'' does not involve a human subject and thus does not meet the definition of ''clinical investigation,'' we disagree. The comment points to FDA's definition of ''human subject'' in § 50.3(g) (''*Human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.''). We note that FDA's existing IDE regulations (§ 812.3(p)) refer specifically to specimens in the definition of ''subject'' (*i.e.,* ''*Subject* means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.''). FDA's IDE regulations cross-reference part 50 with respect to requirements for obtaining informed consent (see, *e.g.,* §§ 812.2(b)(1)(iii) and 812.100), and the Agency's longstanding position is that FDA-regulated device investigations using biospecimens are subject to informed consent requirements under part 50 (Refs. 12 and 13). Additionally, as the comment itself subsequently points out, the inclusion of this criterion may be helpful to biospecimen research by providing clarity on this issue.

We also do not agree that informed consent should never be waived for clinical investigations involving private information or biospecimens in an identifiable format. Such research plays an important role in the discovery and development of innovative medical products, and it may not be practicable to perform the research if investigators are required to obtain informed consent from the individuals associated with the private information or biospecimens. Without the possibility of a waiver of informed consent, scientific progress in many therapeutic areas could be slowed. We believe that the criteria for obtaining a waiver or alteration of informed consent in § 50.22 (including, for example, that ''[t]he waiver or alteration will not adversely affect the rights and welfare of the subjects''), in conjunction with the requirement in § 56.111(a)(7) that requires IRBs, in order to approve research, to determine that ''[w]here appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data,'' adequately protect the privacy of individuals while not unduly inhibiting research that could benefit the public health.

E. Comments on Secondary Research Involving Leftover Biospecimens

A few public comments address the applicability of § 50.22 to secondary research involving previously collected human biospecimens.

(Comment 17) One comment points out that FDA has an existing policy, the ''Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable'' (Leftover Specimen Guidance; Ref. 12), that addresses the use, without informed consent, of nonidentifiable leftover human specimens in certain in vitro diagnostic (IVD) device investigations. This comment recommends incorporating key elements of section IV of the Leftover Specimen Guidance into § 50.22(a) to clarify when IRBs may waive informed consent for IVD device investigations that use nonidentifiable leftover human specimens. The comment specifically proposes adding a new paragraph to § 50.22(a) that would identify IVD device investigations meeting these key elements as examples of clinical investigations that involve no more than minimal risk to subjects.

(Response 17) We decline the commenter's suggestion to add a new paragraph to § 50.22(a) that would include key elements of section IV of the Leftover Specimen Guidance as examples of clinical investigations that involve no more than minimal risk to the subjects because such a change would create unnecessary differences between the revised Common Rule's general waiver provision (*i.e.,* 45 CFR 46.116(f)) and § 50.22. Such differences could cause confusion for IRBs that review and approve clinical research under both sets of regulations.

We believe that most IVD device investigations falling within the scope of the policy described in section IV of the Leftover Specimen Guidance will satisfy the criteria at § 50.22. However, to the extent that there are IVD device investigations that fall within the scope of the Leftover Specimen Guidance but do not satisfy the waiver criteria in § 50.22, FDA is retaining the Leftover Specimen Guidance at this time to help avoid potential disruption to IVD device investigations as IRBs gain experience implementing the new waiver provision in § 50.22 for FDA-regulated clinical investigations.

(Comment 18) Two comments support the proposal, noting that it would facilitate research on residual biospecimens (*e.g.,* archived pathology biospecimens) that is critical for developing new biomarkers for use in diagnosing and measuring the progress of disease in a patient. These comments remark that seeking informed consent retrospectively from the patients from whom the biospecimens and related clinical data were obtained during the course of routine care or for other research purposes may be very difficult or even impossible because, for example, the patients cannot be located. Both comments note that FDA recognized the challenges that obtaining informed consent can pose for secondary biospecimen research in the Leftover Specimen Guidance, which indicates that FDA intends to exercise enforcement discretion with regard to the use, without informed consent, of leftover biospecimens in IVD device studies in certain circumstances. However, the comments assert that the guidance does not go far enough because it is only guidance and it does not apply to minimal risk secondary research use of biospecimens that are individually identifiable.

(Response 18) FDA agrees that clinical investigations involving the use, without informed consent, of previously collected biospecimens and related clinical data can play an important role in the development of new medical products, provided that the rights, safety, and welfare of the subjects from whom the data and/or biospecimens were obtained are adequately protected. For example, leftover biospecimens are frequently used in feasibility studies and studies to characterize the performance of new IVD devices. In addition, banked leftover biospecimens can be a source for unique and possibly rare specimens in sufficient quantity to permit the rapid completion of IVD device investigations that would be very difficult to conduct in a reasonable timeframe without these specimens. This rule addresses the minimal risk secondary research use of biospecimens that are individually identifiable by permitting IRBs to waive or alter informed consent for a clinical investigation involving the use of such specimens if they find and document that the waiver criteria in § 50.22 have been satisfied.

F. Comments on Examples of Clinical Investigations That Would Meet the Waiver Criteria

In the proposed rule, FDA solicited additional public input on the types of FDA-regulated clinical investigations for which sponsors would anticipate requesting a waiver or alteration of informed consent from the IRB. Several respondents provide examples of the types of studies for which sponsors would anticipate requesting a waiver or alteration of informed consent.

(Comment 19) Several comments provide the example of secondary research on biospecimens, *e.g.,* studies using leftover identifiable and/or non-identifiable human biospecimens, as the type of minimal risk clinical investigations for which sponsors would anticipate requesting a waiver or alteration of informed consent from the IRB.

One comment provides the hypothetical example of an investigator who wants to use archived prostate cancer biospecimens and clinical data for a study of a new molecular marker of response to treatment for which the investigator anticipates submitting an application to FDA. The comment includes the caveat that the investigator could use the archived biospecimens with 10 years of clinical data but for the ability to obtain informed consent from patients. The comment concludes that, while this kind of research would offer tremendous potential to advance medical care, it would not be possible under the existing FDA regulations. The comment cites this study as an example of the type of study that would be appropriate for a waiver of informed consent under the proposed rule.

Several comments suggest that studies including RWD would exemplify of the type of studies that would benefit from the proposed regulations. One comment describes several examples of minimal risk research including RWD, such as: (1) minimal risk studies that involve previously collected biospecimens and/or data from prior studies, with the safeguard that subjects' personal data must remain protected from public disclosure; retrospective or prospective use of de-identified subject data collected in registries (*e.g.,* nested studies supplementing registry data); (2) use of de-identified electronic health record, claims, or provider data in analyses of RWD; and (3) studies using residual de-identified biospecimens collected during routine clinical practice. This comment also suggests that FDA state that consent can be waived or modified in postapproval studies (including registries) where the only research activity is the collection of anonymized standard-of-care data from subjects' medical records.

One comment provides an example of ''minimal risk emergency research'' that does not hold out the prospect of direct benefit to the subjects as a type of study where requesting a waiver or alteration of informed consent would be anticipated. The comment suggests that sponsors may want to study FDA-approved products where the use of the product is no more than minimal risk. As an example, this comment cites a clinical investigation for a new indication for an approved diagnostic device utilizing ultrasound for the diagnosis of lower extremity venous thromboses being studied for the detection of cerebral thromboses in an acute, pre-hospital setting, *i.e.,* immediately after head injury. The comment suggests that an approved ultrasound device could be deployed in the field (provided its use would not delay transport or adversely affect emergency care), and the data from the ultrasound device would not be used to guide clinical management of injured individuals, who would undergo definitive and proven diagnostic testing for cerebral blood clots after arrival in the hospital. The comment concludes that results from the ultrasound device could be compared to the definitive scan at a later time to determine its effectiveness in diagnosing cerebral thromboses.

Finally, several comments request that FDA provide specific examples of the types of clinical investigations intended to be covered by the rule, while one comment argues that instances in which informed consent is difficult or impossible to obtain in minimal risk clinical investigations would be rare and that many common examples used to illustrate minimal risk research are unlikely to qualify as clinical investigations.

(Response 19) FDA appreciates the efforts of those commenters responding to our request for examples of FDA-regulated clinical investigations for which sponsors would anticipate requesting a waiver or alteration of informed consent from the IRB. To the extent that the studies described in the comments would be considered FDA-regulated clinical investigations, we agree that some of the examples appear to be of the type for which we would anticipate sponsors might request a waiver or alteration of informed consent (*e.g.,* research involving previously collected data and biospecimens, certain studies involving FDA-approved or cleared products). However, we decline to state that certain types of clinical investigations will necessarily meet the criteria under § 50.22 for a waiver or alteration of informed consent. It is the responsibility of the reviewing IRB to determine, on a case-by-case basis considering the unique factors associated with the clinical investigation for which a waiver or alteration of informed consent is being sought, whether the criteria under § 50.22 are met. As previously noted, FDA plans to issue guidance with additional information on the types of FDA-regulated clinical investigations that may qualify for a waiver or alteration of informed consent under § 50.22.

(Comment 20) Several comments generally support the proposed rule, but ask FDA to place additional restrictions on, or limit the types of studies eligible for, such a waiver or alteration. Some comments suggest that the Agency place limitations on waivers or alterations of informed consent, such as limiting the duration of the research to 1 year or less or limiting the number of occurrences in which a waiver of consent can be used for any individual to one. Some of these comments also recommend precluding waivers or alterations of consent for a variety of research activities, including research involving interventions or invasive procedures, behavior modifications, the introduction of energy into the human body, and data collection from an individual's body or behavior in a private space. Two comments suggest that a notice be published in the **Federal Register** identifying the conditions under which the waiver or alteration would be applied, as well as additional information about the research such as the intended duration and number of human subjects in the study, a justification for why the waiver is appropriate for the research, a description of how the criteria in proposed § 50.22 were satisfied, and how the decision is consistent with the principles of the Belmont Report. Another comment asks that FDA limit the minimal risk research that could be considered for a waiver or alteration of informed consent to observational studies only. This comment also requests that, in order to protect the interests of participants, FDA require that notice be provided to study participants, either on an individual basis or publicly where the research is conducted, outlining the period the study was conducted, the purpose of the study, and the potential benefits of the study.

Other comments oppose permitting a waiver of informed consent for certain types of research, such as studies involving RWD and those being conducted in learning healthcare systems, use of specimens without consent, or studies in certain research populations, such as children or adults of diminished capacity.

A final comment states that waivers or alterations of informed consent should never be permitted for interventions on human subjects.

(Response 20) FDA does not agree with the comments suggesting that we limit the duration or number of studies that may be eligible for a waiver or

alteration of consent under § 50.22. Similarly, we decline to include additional restrictions in § 50.22 with respect to a waiver or alteration of informed consent for specific categories of research (*e.g.,* research involving behavior modifications or research involving RWD). We do not believe imposing such limitations or restrictions would provide additional protections for the rights, safety, and welfare of human subjects beyond those provided by the criteria listed in this rule and believe that these restrictions may serve to stifle innovation and advancements in research.

We also do not agree with the comments stating that individual or public notice should be required for every minimal risk clinical investigation conducted with a waiver of informed consent. While FDA regulations provide for community consultation and public disclosure in the context of the exception from informed consent requirements for emergency research (see § 50.24), FDA does not believe minimal risk research that is reviewed by an IRB and found to meet the criteria in § 50.22 necessitates these additional protections. However, under § 50.22(e), IRBs may find that additional pertinent information must be provided to subjects or their LARs after participation for the clinical investigation to qualify for a waiver or alteration of informed consent under § 50.22.

With regard to excluding children and adults with diminished capacity from the types of studies that may be conducted under § 50.22, we believe it is appropriate for studies with child subjects to qualify for a waiver or alteration under § 50.22 when the IRB finds and documents that the criteria in § 50.22 are satisfied. In addition to the requirements of § 50.22, other requirements in FDA's regulations are intended to ensure that the rights and welfare of child subjects are adequately protected. For example, to approve a clinical investigation involving children as subjects, the IRB must determine that the clinical investigation meets the requirements of part 50, subpart D, Additional Safeguards for Children in Clinical Investigations (see 21 CFR 50.50 and 56.109(h)). Similarly, FDA regulations at § 56.111(b) require that additional safeguards be included in studies to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence. Further, § 56.111(a)(3) requires IRBs to make an assessment that the selection of subjects for any clinical investigation is equitable, including that the IRB ''should be particularly cognizant of the special problems of research involving vulnerable populations.''

FDA believes that IRBs can appropriately determine whether the criteria in § 50.22 are satisfied for research involving vulnerable populations, including children and adults with diminished capacity. FDA encourages IRBs to carefully consider the anticipated risks of the investigation as they might specifically affect vulnerable populations included in the proposed research when making findings regarding the ''minimal risk'' criterion in § 50.22(a).

Finally, we do not agree that a waiver or alteration of informed consent should never be allowed for interventions on human subjects as part of a minimal risk clinical investigation. We note that the definition of minimal risk included in FDA's regulations at § 50.3(k) is identical to the definition of minimal risk found in the revised Common Rule at 46 CFR 46.102(j). The current definition of minimal risk in both FDA regulations and in the revised Common Rule states that minimal risk means ''the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or *during the performance of routine physical or psychological examinations or tests*'' (emphasis added, § 50.3(k) and 45 CFR 46.102(j)). Under both FDA's regulations and the revised Common Rule, minimal risk studies that may be reviewed by an IRB through an expedited review procedure can include studies that require the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture under certain conditions.[15] Thus, both the revised Common Rule and FDA's regulations allow for some interventions to the human body as part of minimal risk research; nothing in this rule changes the current paradigm. In instances where minimal risk research involves interventions to the human body, we think this rule strikes an appropriate balance between respect for persons and facilitating research.

G. Comments on Requests for Guidance

Several comments specifically request that FDA issue guidance on topics related to the proposed rule.

(Comment 21) A few comments request clarification and guidance to ensure that IRBs apply the criteria in § 50.22 appropriately and consistently. As noted above, several commenters request additional guidance to clarify the terms ''minimal risk'' and ''practicability.'' Others specifically ask for guidance on the applicability of a waiver for studies comparing the effectiveness of FDA-approved products to help IRBs understand and apply the criteria consistently.

One comment requests that detailed guidance on the types of clinical investigations that would and would not qualify for the waiver of informed consent be issued simultaneously with the final rule. This comment expresses the concern that clinical investigators will inappropriately seek, and IRBs inappropriately will grant, waivers of informed consent for clinical investigations that involve greater than minimal risk to subjects after FDA finalizes the proposed rule. The comment cites studies that, according to the comment, were inappropriately characterized as minimal risk by researchers and states that researchers have often mischaracterized the nature of their studies involving human subjects and minimized the risks of the procedures involved in the research in an effort to avoid the requirements for obtaining and documenting the informed consent of the human subjects.

One comment requests guidance on the relationship and interplay between the new waiver criterion (*i.e.,* the fifth criterion) and the minimal risk criterion and on what kind of information IRBs should seek to make the determination that research, if carried out with identifiable private information or biospecimens, qualifies as minimal risk.

(Response 21) Throughout this document we provide clarification of specific terms and phrases that are used in this rule. As discussed in section V.C, many of the terms used in § 50.22 have longstanding definitions in both the Common Rule and FDA's regulations (*e.g.,* ''minimal risk''). Therefore, FDA is not making further modifications to these terms and definitions in the final rule. We plan to issue guidance to assist IRBs in applying the criteria for waiver or alteration of informed consent requirements in § 50.22 to FDA-regulated clinical investigations. In that guidance, we intend to provide additional information on the types of FDA-regulated minimal risk clinical investigations that we anticipate would satisfy the criteria for a waiver or alteration of informed consent under § 50.22.

FDA believes that the structure of § 50.22, requiring IRBs to find and document that applicable criteria are met, provides appropriate safeguards to protect the rights, safety, and welfare of human subjects. We note that § 50.22 requires that the IRB responsible for the review, approval, and continuing review of a minimal risk clinical investigation

[15] See 63 FR 60353 at 60355.

find and document that the applicable criteria are met, not the researcher or sponsor of the clinical investigation. FDA believes that IRBs understand their obligations to review research to ensure the protection of the rights and welfare of human subjects and are capable of appropriately applying these criteria to minimal risk clinical investigations.

(Comment 22) One comment requests that FDA provide clarification or advisory text for sponsors, investigators, and IRBs to carefully consider the specific data elements to be collected as part of research to determine the applicability of the HIPAA Privacy Rule requirements.[16] This comment suggests that, although retrospective collection of anonymized data or research on anonymized biospecimens obtained in a previous research study would not typically require consent under the HIPAA Privacy Rule, many low-risk, retrospective, postmarket clinical followup studies may require collection of PHI and, therefore, may still require subject authorization under the HIPAA Privacy Rule. This comment recommends that FDA and HHS work together to determine the potential impact of the multiple consent requirements in the Common Rule, part 50, and the HIPAA Privacy Rule on the collection and use of RWD, and consider developing guidance on when privacy requirements apply.

(Response 22) FDA agrees that the protection of human subjects' privacy when participating in clinical investigations is important, including when the investigation uses data collected as part of clinical care. We note that the criteria for IRB approval of research in our current regulations at § 56.111(a)(7) require that, to approve research, IRBs determine that ''[w]here appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.'' This provision requires IRBs to review clinical investigations to ensure that appropriate privacy safeguards are in place to protect human subjects involved in FDA-regulated clinical investigations.

Applicability of the HIPAA Privacy Rule to clinical investigations covered by § 50.22 is outside the scope of this rulemaking. However, we note that the standards laid out in both the HIPAA Privacy Rule and the Common Rule have coexisted for many years. Accordingly, FDA believes that IRBs have experience considering both rules when reviewing minimal risk research. By harmonizing the waiver criteria set forth in § 50.22 with those set forth in the revised Common Rule's general waiver provision, we are promoting consistency in the application of such requirements across Common Rule Agencies and minimizing burden to IRBs tasked with applying the criteria described in this rule to FDA-regulated research.

H. Comments on the Expedited Review List and IRB Continuing Review

(Comment 23) Some comments question the interpretation of ''minimal risk'' in the proposed rule in relation to the list of categories of research that may be reviewed by the IRB through an expedited review procedure (''expedited review list,'' Ref. 14). One comment disagrees with categories of research included on the expedited review list. Another comment notes that, while the expedited review list categories could provide some benchmarks for the types of research that are minimal risk, these applications are limited and there may be research that qualifies as ''minimal risk,'' that would not qualify for the expedited review procedure.

Similarly, some comments express concern that the proposed rule did not address how FDA intends to harmonize with the revised Common Rule with respect to expedited review procedures and IRB continuing review. A few comments cite SACHRP's recommendations on the expedited review list (Ref. 15) and note concern about FDA and HHS adopting them. These comments assert that if FDA and HHS adopt the SACHRP recommendations and FDA harmonizes with changes made in the revised Common Rule regarding expedited review (*e.g.,* by permitting expedited review of research activities appearing on the expedited review list, unless the IRB reviewer determines that the studies involve more than minimal risk) would weaken human subject protections. Other comments state that human subject protections would be weakened if FDA adopts the revised Common Rule's requirement that eliminates IRB continuing review for studies that are eligible for review under an expedited review procedure. These comments urge that minimal risk studies for which an IRB waives informed consent remain subject to IRB continuing review.

(Response 23) FDA agrees with the comments to the extent they emphasize the importance of ensuring that waivers or alterations of informed consent under this rule are granted only for research that presents no more than minimal risk to the subjects. However, we do not agree that it is necessary to address how FDA intends to harmonize with the revised Common Rule's expedited and continuing review requirements as part of this rulemaking, which finalizes our proposal to permit an IRB to approve an informed consent procedure that waives or alters certain informed consent elements, or to waive the requirement to obtain informed consent, for certain minimal risk investigations. FDA issued a separate proposed rule to amend its regulations at parts 50 and 56, including with respect to expedited and continuing review (87 FR 58733), and will consider all timely comments received as part of that rulemaking, including those related to expedited review and/or continuing review. We address below the more specific concerns raised by the comments in relation to expedited or continuing review.

Some of the comments appear concerned that any changes to the FDA expedited review requirements intended to harmonize with the revised Common Rule could be perceived by the research community as broadening what qualifies as minimal risk or discourage determinations that a study presents more than minimal risk. As an initial matter, the revised Common Rule did not modify the current definition of ''minimal risk'' that is found in HHS regulations (45 CFR 46.102(j)), so FDA regulations (§ 50.3(k)) remain consistent with the definition of ''minimal risk'' provided in the revised Common Rule. In addition, under FDA's regulations at § 56.110(b)(1), for research to qualify for expedited review, a determination must be made by an IRB that the proposed research involves no more than minimal risk to human subjects. In other words, under current FDA regulations, the categories of activities appearing on the expedited review list are not presumed to be minimal risk. FDA's proposed rule to amend parts 50 and 56 (87 FR 58733) does not propose to change this. In addition, the revised Common Rule did not modify the 1998 expedited review list (63 FR 60364), so HHS and FDA (63 FR 60353) maintain identical lists of categories of research activities that may be reviewed by an IRB through the expedited review procedure. As described in the revised Common Rule, an IRB may use the expedited review procedure to review studies that involve activities appearing on the expedited review list, unless the IRB reviewer determines that the studies involve more than minimal risk (see 45 CFR 46.110(b)(1)(i)). However, OHRP has clarified that, until a new expedited review list is finalized, the entire 1998 HHS expedited review list, including the ''Applicability'' section, remains in

[16] See 45 CFR parts 160 and 164, subparts A and E.

effect for studies subject to the revised Common Rule (Ref. 16). Under the current wording of the ''Applicability'' section, to be eligible for expedited review, research must present no more than minimal risk to subjects. Therefore, for research to qualify for expedited review under the revised Common Rule, a determination must still be made by an IRB that the specific circumstances of the proposed research involve no more than minimal risk to human subjects. Under § 50.22, as finalized in this rule, an IRB must find and document that the clinical investigation involves no more than minimal risk to subjects, regardless of whether the study falls within a category on the expedited review list, to waive or alter informed consent.

As noted in comments, the revised Common Rule provision at 45 CFR 46.109(f)(1)(i) eliminates the requirement for an IRB to conduct continuing review of research that is eligible for expedited review in accordance with 45 CFR 46.110, unless the IRB determines otherwise. FDA's IRB continuing review requirements are not being revised in this rule. As explained above, FDA is engaged in separate rulemaking to amend parts 50 and 56 to harmonize with the revised Common Rule in accordance with section 3023 of the Cures Act. As part of that effort, FDA proposed changes to eliminate the requirement for an IRB to conduct continuing review of research, unless an IRB determines otherwise, that has progressed to the point that it involves only data analysis, including analysis of identifiable private information or identifiable biospecimens, and/or accessing followup clinical data from procedures that subjects would undergo as part of clinical care. However, FDA's proposed rule to amend parts 50 and 56 (87 FR 58733) does not propose to eliminate continuing review of all research eligible for expedited review, unless the IRB determines otherwise, for the reasons described in the preamble to that proposed rule. FDA will take into account the comments urging that minimal risk studies for which an IRB waives informed consent remain subject to IRB continuing review as part of finalizing any changes to continuing review requirements in that separate rulemaking.

As HHS evaluates and amends, as appropriate, its current expedited review list as required under 45 CFR 46.110(a), FDA intends to participate in the process and will update our own expedited review list, as appropriate, and will consider if any related changes to our regulations are necessary.

I. Comments on the Cost Savings of the Proposed Rule

(Comment 24) Some comments describe support for the rule because it will reduce administrative burden and result in cost savings. Other comments express the view that the proposed cost savings of the rule are low and may not outweigh the negative impact of waiving informed consent for certain minimal risk studies. One comment states that, although the potential benefits cannot be fully quantified, the analysis should focus on some of the drawbacks of this rule.

(Response 24) As discussed in section VII, FDA believes that this rule will reduce administrative burden and that any costs incurred are outweighed by non-quantifiable benefits in the form of healthcare advances resulting from research performed using a waiver or alteration of informed consent, as well as a reduction in burden for the research community arising from the harmonization of FDA's informed consent regulations with the revised Common Rule's provision for waiver or alteration of informed consent for certain minimal risk research.

However, as part of developing a response to this comment, we reanalyzed the proposed rule to consider potential additional costs associated with the rulemaking. Based on that review, we determined that there are some one-time costs associated with reading and implementing the rule, which we anticipate to be small because the final rule is harmonized with Common Rule provisions with which the clinical research community is already familiar. We also determined that there are some annual costs associated with drafting and reviewing requests for a waiver or alteration of consent. In this final rule, we include a revised analysis of cost and cost savings in the Economic Analysis of Impacts (section VII). We also determined that some of these costs are associated with collections of information subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). For further information, see section IX.

J. Comments on the Proposed Effective Date

(Comment 25) We proposed that any final rule issued based on the proposed rule would become effective 30 days after its date of publication in the **Federal Register**. One comment requests clarification on the application of the effective date. Specifically, the comment asks whether the rule would apply only to clinical investigations that receive initial IRB approval on or after the effective date, or if it would apply to IRB review at any stage of the clinical investigation (*e.g.,* initial IRB approval or amendments) conducted on or after that date.

(Response 25) In response to this comment, we note that the rule will apply to IRB review at any stage of an FDA-regulated clinical investigation conducted on or after the effective date, including initial IRB approval or review of any changes to a previously approved clinical investigation.

VI. Effective Date

This rule is effective 30 days after the date of its publication in the **Federal Register**.

VII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

A rule is ''major'' under the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act if it has resulted or is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act (5 U.S.C. 804(2)). OIRA has determined that this

final rule is not a major rule under the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule is unlikely to impose a substantial burden on the affected small entities, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated impacts, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs, Cost Savings, and Benefits

We expect costs in the form of affected IRBs, as well as investigators and sponsors of clinical investigations, reading and learning the rule. We also expect costs in the form of drafting new waiver or alteration requests, and additional recordkeeping burdens associated with reviewing and documenting IRB decisions on waiver or alteration requests. The net present value of the estimated costs of the rule are approximately $10.1 million, with a lower bound of approximately $8.1 million and an upper bound of approximately $14.0 million, discounted at 3 percent over 10 years. At a 7 percent discount rate, the estimated costs of the rule are approximately $9.1 million, with a lower bound of approximately $7.5 million and an upper bound of approximately $12.4 million. The estimated annualized costs of the rule are approximately $1.2 million, with a lower bound of approximately $0.9 million and an upper bound of approximately $1.6 million, discounted at 3 percent over 10 years. At a 7 percent discount rate, the estimated annualized costs of the rule are approximately $1.3 million, with a lower bound of approximately $1.1 million and an upper bound of approximately $1.8 million.

We also expect that there will be cost savings to IRBs because the time burdens of reviewing waiver or alterations requests would be reduced from harmonization of FDA's informed consent regulations with the provision for waiver or alteration of informed consent for certain minimal risk research in the Common Rule. The estimated net present value of the cost savings of the rule are approximately $1.7 million, with a lower bound of approximately $0.9 million and an upper bound of approximately $3.5 million, discounted at 3 percent over 10 years. At a 7 percent discount rate, the estimated cost savings of the rule are approximately $1.4 million, with a lower bound of approximately $0.7 million and an upper bound of approximately $2.8 million. The estimated annualized cost savings of the rule are approximately $0.2 million, with a lower bound of approximately $0.1 million and an upper bound of approximately $0.4 million, discounted at 3 percent over 10 years. At a 7 percent discount rate, the estimated annualized costs savings of the rule are approximately $0.2 million, with a lower bound of approximately $0.1 million and an upper bound of approximately $0.4 million.

We expect benefits in the form of healthcare advances from minimal risk clinical investigations for which the requirements for informed consent are waived or altered under the final rule and that otherwise would not be conducted. We cannot quantify all benefits that might arise from such studies because of the lack of relevant data available regarding the focus of these types of studies that will support regulatory submissions to the Agency. The costs and cost savings of the rule are summarized in table 1.

TABLE 1—SUMMARY OF COSTS, COSTS SAVINGS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

[Millions $]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Costs:							
Annualized Monetized millions/year							
Annualized Quantified	$1.3	$1.1	$1.8	2020	7	10	
	1.2	0.9	1.6	2020	3	10	
Qualitative							
Annualized Monetized millions/year							
Annualized	0.2	0.1	0.4	2020	7	10	
Quantified	0.2	0.1	0.4	2020	3	10	
Qualitative	Healthcare advances stemming from minimal risk clinical investigations that can proceed using a waiver or alteration of informed consent and that otherwise would not have been conducted.						
Transfers:							
Federal Annualized							
Monetized $millions/year							
	From:			To:			
Other Annualized							
Monetized $millions/year							
	From:			To:			
Effects:							
State, Local or Tribal Government:							

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Docket No. FDA–2018–N–2727) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

In the proposed rule, FDA stated, ''This proposed rule refers to previously approved collections of information found in FDA regulations. . . . Therefore, FDA tentatively concludes the requirements in this document are not subject to additional review by OMB.'' In developing the final rule, FDA determined that there are information collections contained in the rule that are subject to review by OMB under the PRA (44 U.S.C. 3501–3521). Specifically, the final rule adds § 50.22 to part 50 to allow IRBs responsible for the review, approval, and continuing review of clinical investigations to approve an informed consent procedure that does not include or that alters certain informed consent elements, or to waive the requirement to obtain informed consent, for certain minimal risk clinical investigations, provided the IRB finds and documents the criteria set forth in § 50.22(a)–(e). The information collections associated with part 50 have been approved in accordance with the PRA under OMB control number 0910–0130, but the additional provision at § 50.22 will modify this information collection. We estimate the rulemaking will result in an annual burden increase of 1,102 responses and 1,102 hours from recordkeeping and disclosure activity relating to the revised regulations in 21 CFR part 50.

With this exception, we conclude that the other provisions of this rule do not require substantive revisions to information collections already approved under the PRA. Provisions in part 312 (21 CFR part 312) of FDA's regulations set forth procedures for the conduct of clinical investigations of drugs and provide for the protection of human subjects involved in such investigations. Existing regulations at § 312.60 describe the general responsibilities of investigators with regard to study conduct, including ensuring the rights, safety, and welfare of human subjects. As part of these responsibilities, the current regulations require that investigators obtain informed consent, except as provided in exceptions from general requirements (§ 50.23) and exception from informed consent requirements for emergency research (§ 50.24). This final rule, as noted above, adds an additional exception to include waiver or alteration of informed consent for minimal risk clinical investigations under § 50.22. Therefore, FDA made a conforming revision to § 312.60 to cross-reference part 50 generally, rather than list each specific exception to the informed consent requirements, for simplicity and for accuracy of the cross-references in the regulatory text. FDA does not expect changes to the collections of information approved under OMB control number 0910–0014 as a result of this final rule. In addition, FDA's existing regulations at § 812.2 describe abbreviated requirements for IDEs, which require that investigators obtain and document informed consent under part 50, unless documentation is waived under IRB regulations at § 56.109(c). This final rule amends § 812.2(b)(1)(iii) to clarify that the investigator must obtain informed consent in accordance with part 50, which includes the new provision for waiver or alteration in § 50.22. The final rule also simplifies the regulatory text at § 812.2(b)(1)(iii) by removing the cross-reference to waiver of documentation of informed consent under § 56.109(c). The relevant section of the regulations in part 50 (*i.e.,* § 50.27) already refers to § 56.109(c), so the cross-reference to § 56.109(c) need not be repeated. FDA does not expect any changes to the collections of information collection approved under OMB control number 0910–0078 as a result of this final rule.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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List of Subjects

21 CFR Part 50

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 50, 312, and 812 are amended as follows:

PART 50—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for part 50 is revised to read as follows:

Authority: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262.

■ 2. In § 50.20 revise the first sentence to read as follows:

§ 50.20 General requirements for informed consent.

Except as provided in §§ 50.22, 50.23, and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. * * *

■ 3. Add § 50.22 to subpart B to read as follows:

§ 50.22 Exception from informed consent requirements for minimal risk clinical investigations.

The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent set forth in § 50.25(a) and (b), or may waive the requirement to obtain informed consent, provided the IRB finds and documents the following:

(a) The clinical investigation involves no more than minimal risk to the subjects;

(b) The clinical investigation could not practicably be carried out without the requested waiver or alteration;

(c) If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;

(d) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(e) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 4. The authority citation for part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

■ 5. Revise § 312.60 to read as follows:

§ 312.60 General responsibilities of investigators.

An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation. An

investigator shall obtain the informed consent of each human subject to whom the drug is administered, in accordance with part 50 of this chapter. Additional specific responsibilities of clinical investigators are set forth in this part and in parts 50 and 56 of this chapter.

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 6. The authority citation for part 812 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360hh–360pp, 360rr–360ss, 360bbb–8b, 371, 372, 374, 379e, 381, 382; 42 U.S.C. 216, 241, 262.

■ 7. Revise § 812.2 (b)(1)(iii) to read as follows:

§ 812.2 Applicability.

* * * * *

(b) * * *

(1) * * *

(iii) Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent in accordance with part 50 of this chapter.

* * * * *

Dated: December 1, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023–27935 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 3, 100, 165

[Docket Number USCG–2023–0970]

RIN 1625–AA00

Coast Guard Sector Sault Sainte Marie; Sector Name Conforming Amendment

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The rule makes non-substantive changes to Coast Guard regulations in association with a change in the Coast Guard's internal organization. The purpose of this rule is to reflect that U.S. Coast Guard Sector Sault Sainte Marie has been renamed U.S. Coast Guard Sector Northern Great Lakes. This rule will have no substantive effect on the regulated public.

DATES: This rule is effective without actual notice December 21, 2023. For the purposes of enforcement, actual notice will be used from December 1, 2023, until December 21, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0970 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Chief Warrant Officer Charles Palmer, U.S. Coast Guard; telephone 906–253–2462, email *Charles.b.palmer@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

AOR Area of responsibility
CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
OCMI Officer in Charge of Marine Inspections
OFCO Operating Facility Change Order
SAR Search and Rescue
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

For the last several years, the Coast Guard has sought to better align the names of its assets to correspond to the area of responsibility which they serve. Review of the missions and engagements within the northern Great Lakes region highlighted that ''Sector Sault Sainte Marie'' alone did not adequately capture the breadth and range of Coast Guard operations and relationships throughout the region. The Coast Guard has approved the name change to U.S. Coast Guard Sector Northern Great Lakes to acknowledge the long-standing commitment to all communities of the region and to reaffirm the multi-mission support that the Coast Guard provides to ensure safety at sea and enhanced maritime governance. The geographic boundaries of Sector Northern Great Lakes are not changing, and its office is not moving from Sault Sainte Marie, MI.

We did not publish a notice of proposed rulemaking (NPRM) before this final rule. The Coast Guard finds that this rule is exempt from notice and comment rulemaking requirements under 5 U.S.C. 553(b)(A) because the changes it makes are conforming amendments involving agency organization. The Coast Guard also finds good cause exists under 5 U.S.C. 553(b)(B) for not publishing an NPRM because the changes will have no substantive effect on the public and notice and comment are therefore unnecessary. For the same reasons, the Coast Guard finds good cause exists under 5 U.S.C. 553(d)(3) to make the rule effective fewer than 30 days after publication in the **Federal Register**.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 14 U.S.C. 504(a)(2), as delegated at 33 CFR 1.05–1(h), to issue regulations necessary to implement technical, organizational, and conforming amendments and corrections to rules, regulations, and notices.

On November 06, 2023, the Coast Guard issued Operating Facility Change Order (OFCO) No. 037–23 which changed the official unit name of U.S. Coast Guard Sector Sault Sainte Marie to U.S. Coast Guard Sector Northern Great Lakes. The previous name of Sector Sault Sainte Marie is described and reflected in regulations, which also contain contact details and other references to Sector Sault Sainte Marie. These conforming amendments update those regulations so that they contain current information.

Under 14 U.S.C. 504(a)(2), the Commandant of the Coast Guard has the authority to establish and prescribe the purpose of Coast Guard Shore establishments. This authority has been delegated to the Chief of the Coast Guard's Office of Regulations and Administrative Law under 33 CFR 1.05–1(h).

IV. Discussion of the Rule

OFCO No. 037–23, issued November 06, 2023, changed the official unit name of U.S. Coast Guard Sector Sault Sainte Marie to U.S. Coast Guard Sector Northern Great Lakes. The November 2023 OFCO did not change the area of responsibility (AOR). The AOR of U.S. Coast Guard Sector Northern Great Lakes is identical to that of what was U.S. Coast Guard Sector Sault Sainte Marie. All authorities and responsibilities previously assigned to Commander, U.S. Coast Guard Sector Sault Sainte Marie have been assigned to Commander, U.S. Coast Guard Sector Northern Great Lakes. Additionally, all authorities that were vested in the Commander, U.S. Coast Guard Sector Sault Sainte Marie as it pertains to the COTP, the OCMI, the Federal On Scene Coordinator, the Federal Maritime Security Coordinator, and the Search and Rescue Coordinator, have been assigned to Commander, U.S. Coast Guard Sector Northern Great Lakes. This rule does not change any sector, OCMI, or COTP zone boundary lines, nor does

it have any substantive impact on existing regulated navigation area, safety zone, or security zone regulation, or any naval vessel protection zones.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the finding that the name change will have no substantive effect on the public.

B. Impact on Small Entities

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

For the reasons stated in section V.A. above, this rule will not have a significant economic impact on any member of the public, including ''small entities.''

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule consists only of an organizational amendment. It is categorically excluded from further review under paragraph L3 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1, Implementation of the National Environmental Policy Act.

List of Subjects

33 CFR Part 3

Organization and functions (Government agencies).

33 CFR Part 100

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

33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR parts 3, 100, and 165 as follows:

PART 3—COAST GUARD AREAS, DISTRICTS, SECTORS, MARINE INSPECTION ZONES, AND CAPTAIN OF THE PORT ZONES

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

Authority: 14 U.S.C. 501, 504; Pub. L. 107–296, 116 Stat. 2135; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

§ 3.45–45 [Amended]

■ 2. Amend § 3.45–45 by removing the words ''Sector Sault Ste. Marie'' and adding in their place the words ''Sector Northern Great Lakes'' in the section heading and removing the words ''Sector Sault Ste. Marie's'' and adding in their place the words ''Sector Northern Great Lakes' '' in the introductory text and paragraph (a).

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

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

§ 100.901 [Amended]

■ 4. Amend § 100.901 in table 1 by removing the words ''Sector Sault Ste. Marie'' and adding in their place the words ''Sector Northern Great Lakes'' in the center heading above the entry ''(1) Bridgefest Regatta Sponsor: Bridgefest Committee''.

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

§ 165.918 [Amended]

■ 6. Amend § 165.918 by removing the words ''Port Sault Sainte Marie'' and adding in their place the words ''Port Northern Great Lakes'' in the section heading and wherever they appear in paragraphs (a)(1) through (3), (b), (d), and (e).

§ 165.928 [Amended]

■ 7. Amend § 165.928 in paragraph (g) by removing the words ''Sault Ste. Marie'' and adding in their place the words ''Northern Great Lakes''.

§ 165.944 [Amended]

■ 8. Amend § 165.944 in paragraphs (d)(1) and (e) by removing the words ''Sault Sainte Marie'' and adding in their place the words ''Northern Great Lakes''.

Dated: December 18, 2023.

Michael T. Cunningham,

Chief, Office of Regulations and Administrative Law.

[FR Doc. 2023–28103 Filed 12–20–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2023–0934]

RIN 1625–AA09

Drawbridge Operation Regulation; Turner Cut, Near Stockton, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary interim rule and request for comments

SUMMARY: The Coast Guard is temporarily modifying the operating schedule that governs the draw of the Zuckerman Brothers (McDonald Island) bridge, mile 2.3, across Turner Cut, near Stockton, CA. This action is necessary to allow the bridge owner, Reclamation District 2030 (RD2030), to complete design plans and conduct repairs to the bridge to bring it back to its normal operating status.

DATES: This temporary interim rule is effective from December 21, 2023 through 5 p.m. on September 30, 2024.

Comments and related material must reach the Coast Guard on or before January 22, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov.* Type the docket number (USCG–2023–0934) in the ''SEARCH'' box and click ''SEARCH''. In the Document Type column, select ''Supporting & Related Material''.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary interim rule, call or email Carl Hausner, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email *Carl.T.Hausner@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
NOTD Notice of Temporary Deviation
PG&E Pacific Gas and Electric
Pub. L. Public Law
RD2030 Reclamation District 2030
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary interim rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. This bridge is secured closed and will be secured closed until design plans are finalized, coordination of construction schedule can be made with landowners and PG&E, contractor hired, and repairs completed.

On June 21, 2023, RD2030 notified the Coast Guard that the Zuckerman Brothers (McDonald Island) retractable span bridge should not open for the passage of vessels. The cause was the gradual movement which squeezed the abutments towards the center movable steel section. The span cannot be opened without the risk of it being stuck in the open-to-navigation position. The Zuckerman Brothers (McDonald Island) bridge is the only road in and out of McDonald Island, which includes farms and a PG&E station and wells. The Coast Guard granted a Notice of Temporary Deviation (NOTD) from the operating schedule of the bridge, allowing the span to be secured in the closed position until repairs can be made. The NOTD will expire at 7 a.m. on December 18, 2023. The design, coordination of work with affected parties, and repair is delayed. The retractable span will not be operational at the expiration of the NOTD. The Coast Guard received the report of these delays on November 17, 2023. Therefore, there is insufficient time to provide a reasonable comment period and then consider those comments before issuing the modification.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective in less than 30 days after publication in the **Federal Register**. For reasons presented above, delaying the effective date of this rule would be impracticable and contrary to the public interest because the retractable span of the bridge is currently secured closed and cannot be operated until repairs are completed.

We are soliciting comments on this rulemaking. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this temporary interim rule under authority in 33 U.S.C. 499. The Coast Guard is modifying the operating schedule that governs the Zuckerman Brothers (McDonald Island) bridge, mile 2.3, across Turner Cut, near Stockton, CA. The Zuckerman Brothers (McDonald Island) bridge has a vertical clearance, in the closed position, of 16 feet at mean high water and unlimited vertical clearance when opened.

The existing drawbridge regulation, 33 CFR 117.5, states that the draw of the Zuckerman Brothers (McDonald Island) bridge must open for vessels if a signal is given to do so. RD2030, the bridge owner, has requested this modification as additional time is required to complete bridge repairs.

Drawtender logs from January 2022 through June 2023 indicate the span opened on average, 2 times in January; 1 time in February; 1 time in March; 3 times in April; 11 times in May; 8 times in June; 18 times in July; 6 times in August; 7 times in September; 4 times in October; 2 times in November; and 3 times in December. No complaints have been received from mariners since the

retractable span was secured closed on June 21, 2023.

IV. Discussion of the Rule

The Coast Guard is issuing this rule, which permits a temporary deviation from the operating schedule that governs the Zuckerman Brothers (McDonald Island) bridge, mile 2.3, across Turner Cut, near Stockton, CA. This rule allows the bridge to be secured in the closed-to-navigation position through 5 p.m. on September 30, 2024.

RD2030 hired an engineering firm as part of the design, planning and repairs of the bridge. RD2030 and the engineers are working to finalize the plans for the repairs. RD2030 is also coordinating construction time windows with landowners on McDonald Island. PG&E is currently conducting major well rehabilitation on the island and have limited windows where their access to McDonald Island across the bridge can be interrupted. These elements contributed to the delay in the repairs to the retractable span. Currently, the retractable span is secured closed until repairs are complete. The anticipated completion of the repairs is September 30, 2024.

V. Regulatory Analyses

We developed this temporary interim rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, it has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the fact that little or no commercial or recreational vessel traffic will be impacted by this rule. Furthermore, the retractable span of the bridge, as of date of the publication of this rule, should not be operated for fear of becoming non-operational in the partially open position until repairs can be made.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Government

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 177.T200 to read as follows:

§ 117.T200 Turner Cut.

The draw of the Zuckerman Brothers (McDonald Island) bridge, mile 2.3, near Stockton need not open for the passage of vessels.

Dated: December 15, 2023.

Andrew M. Sugimoto,

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

[FR Doc. 2023–28146 Filed 12–20–23; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 380

[Docket No. 19–CRB–0005–WR (2021–2025) COLA (2024)

Cost of Living Adjustment to Royalty Rates for Webcaster Statutory License; Correction

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Final rule; correction.

SUMMARY: On November 30, 2023, the Copyright Royalty Judges amended regulations governing royalty rates that commercial and noncommercial noninteractive webcasters pay for eligible transmissions pursuant to the statutory licenses for the public performance of and for the making of ephemeral reproductions of sound recordings. That document contained an incorrect reference to a rate. This document corrects that reference.

DATES:

Effective date: This correction is effective December 20, 2023.

Applicability dates: The adjusted rates as published on November 30, 2023, are applicable to the period January 1, 2024, through December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Anita Brown, (202) 707–7658, *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: On November 30, 2023, at 88 FR 83508, the Copyright Royalty Judges published a rule that contained an incorrect reference to a rate in the **SUPPLEMENTARY INFORMATION** section. This document corrects that reference.

Correction

In the **Federal Register** of Thursday, November 30, 2023, in FR Rule Doc. 2023–26221, appearing on page 83508, make the following correction:

1. On page 85309, in the first column, in the fourth paragraph, correct ''$0.20025'' to read ''$0.0025''.

Dated: December 15, 2023.

David P. Shaw,

Chief Copyright Royalty Judge.

[FR Doc. 2023–28098 Filed 12–20–23; 8:45 am]

BILLING CODE 1410–72–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 385

[Docket No. 23–CRB–0014–PR–COLA (2024)]

Cost of Living Adjustment to Royalty Rates and Terms for Making and Distributing Phonorecords; Correction

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Correcting amendments; cost of living adjustment.

SUMMARY: On December 12, 2023, the Copyright Royalty Judges amended regulations governing royalty rates for making and distributing physical phonorecords and Permanent Downloads of nondramatic musical works pursuant to statutory license. That document inadvertently omitted figures related to calculation of the adjusted rates and listed an incorrect per-minute rate.

DATES:

Effective date: December 21, 2023.

Applicability date: These rates and terms are applicable during the period from January 1, 2024, through December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Anita Brown, Program Specialist, (202) 707–7658, *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: This document provides an amplification of the information in the **SUPPLEMENTARY INFORMATION** section and a correction to a rate in the Final Regulations in the final rule/cost of living adjustment document published in the **Federal Register** on December 12, 2023 (88 FR 86058).

Section 115 of the Copyright Act, title 17 of the United States Code, creates a statutory license for making and distributing phonorecords of nondramatic musical works. On December 16, 2022, the Copyright Royalty Judges (Judges) adopted final regulations governing the rates and terms of copyright royalty payments under that license for the license period 2024–2027 for making and distributing phonorecords of nondramatic musical works. *See* 87 FR 76942.

Pursuant to those regulations, at least 25 days before January 1 of each year, the Judges shall publish in the **Federal Register** notice of a cost of living adjustment (COLA) applicable to the royalty fees for making and distributing physical phonorecords and Permanent Downloads. *See* 37 CFR 385.11.

The adjustment in the royalty fee shall be based on a calculation of the percentage increase in the Consumer Price Index for All Urban Consumers (CPI–U) published in November 2022 (298.012) [1] (''base rate'') according to the formulas: for the per-work rate, (1 + (Cy − 298.012 [2])/298.012) × 12¢, rounded to the nearest tenth of a cent; for the per-minute rate, (1 + (Cy − 298.012)/298.012) × 2.31¢, rounded to the nearest hundredth of a cent; where Cy is the CPI–U published by the Secretary of Labor before December 1 of the preceding year. 37 CFR 385.11(a)(2). The CPI–U published by the Secretary of Labor from the most recent index published before December 1, 2023, is 307.671.[3] Applying the formulas in 37 CFR 385.11(a)(2) results in an increase in the rates for 2024.

The adjusted rates for 2024 are 12.4 cents for the per-work rate and 2.38 cents for the per-minute rate.

Details of the required calculations were inadvertently omitted from the document published in the **Federal Register** on December 12, 2023 (88 FR 86058). This document provides, in the **SUPPLEMENTARY INFORMATION** section herein, additional details of and results of the calculations, and corrects the amount for the per-minute rate in the Final Regulations herein.

List of Subjects in 37 CFR Part 385

Copyright, Phonorecords, Recordings.

Final Regulations

In consideration of the foregoing, the Judges correct part 385 of title 37 of the Code of Federal Regulations by making the following correcting amendment:

PART 385—RATES AND TERMS FOR USE OF NONDRAMATIC MUSICAL WORKS IN THE MAKING AND DISTRIBUTING OF PHYSICAL AND DIGITAL PHONORECORDS

■ 1. The authority citation for part 385 continues to read as follows:

Authority: 17 U.S.C. 115, 801(b)(1), 804(b)(4).

[1] The CPI–U published in November 2022 is available at *https://www.bls.gov/news.release/archives/cpi_11102022.htm* at Table 1.

[2] Base rate.

[3] The CPI–U announced on November 14, 2023, by the Bureau of Labor Statistics in its *Consumer Price Index News Release—Consumer Price Index,* is available at *https://www.bls.gov/news.release/archives/cpi_11142023.htm* at Table 1.

■ 2. Section 385.11 is amended by revising paragraph (a)(1) to read as follows:

§ 385.11 Royalty rates.

(a) * * *

(1) *2024 rate.* For the year 2024 for every physical phonorecord and Permanent Download the Licensee makes and distributes or authorizes to be made and distributed, the royalty rate payable for each work embodied in the phonorecord or Permanent Download shall be either 12.4 cents or 2.38 cents per minute of playing time or fraction thereof, whichever amount is larger.

* * * * *

Dated: December 15, 2023.

David P. Shaw,

Chief Copyright Royalty Judge.

[FR Doc. 2023–28075 Filed 12–20–23; 8:45 am]

BILLING CODE 1410–72–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0157; FRL–10778–02–R9]

Air Plan Approval; California; San Diego County Air Pollution Control District; Oxides of Nitrogen

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the San Diego County Air Pollution Control District (SDCAPCD) portion of the California State Implementation Plan (SIP). This revision concerns emissions of oxides of nitrogen (NO_X) from small boilers, process heaters, steam generators, and large water heaters. We are approving a local rule that regulates these emission sources under the Clean Air Act (CAA or ''the Act'').

DATES: This rule is effective January 22, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2023–0157. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Alina Batool, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; by phone at (415) 972–3345 or by email at *batool.alina@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Proposed Action
II. Public Comments and EPA Responses
III. EPA Action
IV. Incorporation by Reference
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I. Proposed Action

On July 26, 2023 (88 FR 48150), the EPA proposed to approve the following rule into the California SIP.

Local agency	Rule No.	Rule title	Adopted	Submitted
SDCAPCD	69.2.1	Small Boilers, Process Heaters, Steam Generators, and Large Water Heaters	[a] 07/08/20	09/21/20
SDCAPCD	69.2.1	Small Boilers, Process Heaters, Steam Generators, and Large Water Heaters	[a] 07/08/20	09/21/20

[a] SDCAPCD locally adopted Rule 69.2.1 on March 25, 2009, and locally revised the rule on July 8, 2020. CARB submitted the version of the rule that SDCAPCD revised on July 8, 2020, for inclusion in the California SIP. Note that, in terms of the use of the word ''revised'' or ''amended'' in the description of this rule, the supporting materials in SDCAPCD's submission refer to the rule as an ''amended rule,'' but the submitted rule text uses the abbreviation, ''rev,'' for ''revision.'' For purposes of consistency in incorporating by reference, we are substituting the word ''revised'' for ''amended,'' because the two terms are used interchangeably but the rule text uses the term ''revision.''

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

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received one comment that was supportive of the proposed action.

III. EPA Action

No comments were submitted that change our assessment of the rule as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving this rule into the California SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of Rule 69.2.1, ''Small Boilers, Process Heaters, Steam Generators, and Large Water Heaters,'' revised on July 8, 2020, which regulates NO_X emissions from small boilers, process heaters, steam generators, and large water heaters with a heat input rating from 75,000 British thermal units (Btu) per hour to 2 million Btu per hour that are manufactured, sold, offered for sale or distribution, or installed for use within San Diego County, California. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to

approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

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

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The State did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 20, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Reporting and recordkeeping requirements.

Dated: December 14, 2023.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by revising the introductory text of paragraph (c)(557) and adding paragraph (c)(557)(i)(B)(*2*) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(557) The following rules were submitted on September 21, 2020, by the Governor's designee as an attachment to a letter dated September 18, 2020.

(i) * * *

(B) * * *

(2) Rule 69.2.1, ''Small Boilers, Process Heaters, Steam Generators, and Large Water Heaters,'' revised on July 8, 2020.

* * * * *

[FR Doc. 2023–27876 Filed 12–20–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0925; FRL–10943–02–R9]

Air Quality Implementation Plan; California; Great Basin Unified Air Pollution Control District; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing a revision to the Great Basin Unified Air Pollution Control District's (GBUAPCD or ''District'') portion of the California State Implementation Plan (SIP). This revision governs the District's issuance of permits for stationary sources, and focuses on the preconstruction review and permitting of major sources and major modifications under part D of title I of the Clean Air Act (CAA or ''the Act'').

DATES: This rule is effective January 22, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket No. EPA–R09–OAR–2022–0925. All

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

FOR FURTHER INFORMATION CONTACT: Nidia Trejo, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; by phone: (415) 972–3968, or by email at *trejo.nidia@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, the terms ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Proposed Action
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I. Proposed Action

On August 28, 2023,[1] the EPA proposed to approve the rule listed in Table 1 into the California SIP.

TABLE 1—SUBMITTED RULE

Local agency	Rule No.	Rule title	Adopted	Submitted
GBUAPCD	Rule 222	NSR Requirements for New and Modified Major Sources in Nonattainment Areas.	01/06/22	07/05/22

For areas designated nonattainment for one or more National Ambient Air Quality Standards (NAAQS), the applicable SIP must include preconstruction review and permitting requirements for new or modified major stationary sources of such nonattainment pollutant(s) under part D of title I of the Act, commonly referred to as Nonattainment New Source Review (NNSR). The rule listed in Table 1 contains the GBUAPCD's NNSR permit program applicable to new and modified major sources located in the District. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received one comment, which was supportive of our proposal.

III. EPA Action

We received one comment that was supportive of our proposed action and did not change our findings regarding Rule 222. We continue to find that Rule 222 satisfies the relevant requirements for a CAA NNSR program for PM_{10}, as well as the associated visibility requirements for sources subject to review under such a program in accordance with 40 CFR 51.307. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving the submitted rule. This action incorporates the submitted rule into the California SIP. In conjunction with the EPA's SIP approval of the District's visibility program for sources subject to the NNSR program, this action also revises the scope of the visibility Federal Implementation Plan (FIP) at 40 CFR 52.281 for California so that this FIP no longer applies to sources located in the GBUAPCD nonattainment areas that are subject to the District's visibility program.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is incorporating by reference Great Basin Unified Air Pollution Control District's Rule 222 as described in Section I of this preamble. Rule 222 governs the District's issuance of permits for stationary sources, and focuses on the preconstruction review and permitting of major sources and major modifications under part D of title I of the Clean Air Act (CAA or ''the Act''). The EPA has made, and will continue to make, these materials available through *https://www.regulations.gov* and in hard copy at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it proposes to approve a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land

[1] 88 FR 58538.

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

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The District did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goals of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and indigenous peoples.

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 20, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate Matter, Reporting and recordkeeping requirements.

Dated: December 14, 2023.

Martha Guzman Aceves,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(607) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(607) The following regulations were submitted on July 5, 2022, by the Governor's designee.

(ii) *Incorporation by reference.* (A) Great Basin Unified Air Pollution Control District.

(ii) Rule 222, ''New Source Review Requirements for New and Modified Major Sources in Nonattainment Areas,'' adopted on January 6, 2022.

(*2*) [Reserved]

(B) [Reserved]

(ii) [Reserved]

■ 3. Section 52.281 is amended by adding paragraph (d)(13) to read as follows:

§ 52.281 Visibility protection.

* * * * *

(d) * * *

(13) Great Basin Unified Air Pollution Control District.

* * * * *

[FR Doc. 2023–27889 Filed 12–20–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket Nos. 03–123, 10–51, 13–24 and WC Docket No. 12–375; FCC 22–51; FCC 22–76; FR ID 191657]

VRS and IP CTS—Commencement of Pending User Registration; Rates for Interstate Inmate Calling Services

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective and compliance dates.

SUMMARY: In this document, the Federal Communications Commission (FCC or Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection associated with certain rules adopted in the Commission's documents *Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities et al.,* Report and Order, FCC 22–51, and *Rates for Interstate Inmate Calling Services,* Fourth Report and Order, FCC 22–76. This document is consistent with the Report and Orders, which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of those rules.

DATES:

Effective date: The amendments to §§ 64.611(k)(1)(i) through (iii) (amendatory instruction 6), 64.6040(c) (amendatory instruction 11), and 64.6060(a)(5) through (7) (amendatory instruction 12), published at 87 FR 75496, December 9, 2022, are effective December 21, 2023.

Compliance dates: Compliance with § 64.6040(b)(2), published at 87 FR 75496, December 9, 2022, is required by January 1, 2024. Compliance with §§ 64.611(a)(4)(iii) and (iv) and 64.615(a)(6)(v) and (vi), published at 87 FR 57645, September 21, 2022, for providers of video relay service (VRS), is required on December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Michael Scott, Disability Rights Office, Consumer and Governmental Affairs Bureau, at (202) 418–1264, or email: *Michael.Scott@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that, on December 5, 2023, and December 13, 2023, OMB approved, for a period of three years, the information collection requirements contained in the Commission's Report and Order, FCC 22–51, published at 87 FR 57645, September 21, 2022, and

Report and Order FCC 22–76, published at 87 FR 75496, December 9, 2022. The OMB Control Numbers are 3060–1053 and 3060–1089. The Commission publishes this document as an announcement of the effective and compliance dates of the rules. On March 8, 2023, the Commission published an effective date notification, at 88 FR 14251, for the programmatic changes adopted in FCC 22–51 that apply to the provision of Internet Protocol captioned telephone relay service (IP CTS), specifically 47 CFR 64.611 (amendatory instruction 3) and 64.615 (amendatory instruction 4). If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, via email: *Cathy.Willilams@fcc.gov.* Please include the OMB Control Numbers, 3060–1053 or 3060–1089, in your correspondence. The Commission will also accept your comments via the internet if you send them to *PRA@fcc.gov.*

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 and Governmental Affairs Bureau at (202) 418–0530 (voice).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on December 5, 2023, and December 13, 2023, for the information collection requirements contained in the Commission's documents FCC 22–51 and FCC 22–76.

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Numbers are 3060–1053 and 3060–1089.

The foregoing notification is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1053.

OMB Approval Date: December 13, 2023.

OMB Expiration Date: December 31, 2026.

Title: Misuse of Internet Protocol Captioned Telephone Service (IP CTS); Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CG Docket Nos. 13–24 and 03–123.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 187,173 respondents; 673,980 responses.

Estimated Time per Response: 0.1 hours (6 minutes) to 40 hours.

Frequency of Response: Annual, every five years, monthly, and ongoing reporting requirements; Recordkeeping requirements; Third party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is found at sec. 225 [47 U.S.C. 225] Telecommunications Services for Hearing-Impaired Individuals; The Americans with Disabilities Act of 1990, (ADA), Public Law 101–336, 104 Stat. 327, 366–69, enacted on July 26, 1990.

Total Annual Burden: 342,103 hours.

Total Annual Cost: $72,000.

Needs and Uses:

On August 1, 2003, the Commission released *Telecommunication Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CC Docket No. 98–67, Declaratory Ruling, 68 FR 55898, September 28, 2003, clarifying that one-line captioned telephone voice carry over (VCO) service is a type of telecommunications relay service (TRS) and that eligible providers of such services are eligible to recover their costs from the Interstate TRS Fund (Fund) in accordance with section 225 of the Communications Act.

On July 19, 2005, the Commission released *Telecommunication Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CC Docket No. 98–67 and CG Docket No. 03–123, Order, 70 FR 54294, September 14, 2005, clarifying that two-line captioned telephone VCO service, like one-line captioned telephone VCO service, is a type of TRS eligible for compensation from the Fund.

On January 11, 2007, the Commission released *Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket No. 03–123, Declaratory Ruling, 72 FR 6960, February 14, 2007, granting a request for clarification that Internet Protocol captioned telephone relay service is a type of TRS eligible for compensation from the Fund.

On August 26, 2013, the Commission issued *Misuse of Internet Protocol Captioned Telephone Service; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket Nos. 13–24 and 03–123, Report and Order, 78 FR 53684, August 30, 2013, to regulate practices relating to the marketing of IP CTS, impose certain requirements for the provision of this service, and mandate registration and certification of IP CTS users.

On June 8, 2018, the Commission issued *Misuse of Internet Protocol Captioned Telephone Service; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket Nos. 13–24 and 03–123, Report and Order and Declaratory Ruling, 83 FR 30082, June 27, 2018 (*2018 IP CTS Modernization Order*), to facilitate the Commission's efforts to reduce waste, fraud, and abuse and improve its ability to efficiently manage the IP CTS program through regulating practices related to the marketing of IP CTS, generally prohibiting the provision of IP CTS to consumers who do not genuinely need the service, permitting the provision of IP CTS in emergency shelters, and approving the use of automatic speech recognition to generate captions without the assistance of a communications assistant.

On February 15, 2019, the Commission issued *Misuse of Internet Protocol Captioned Telephone Service; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket Nos. 13–24 and 03–123, Report and Order and Order, 84 FR 8457, March 8, 2019 (*2019 IP CTS Program Management Order*), requiring the submission of IP CTS user registration information to the telecommunications relay service (TRS) User Registration Database (Database) so that the Database administrator can verify IP CTS users to reduce the risk of waste, fraud, and abuse in the IP CTS program.

On June 30, 2022, the Commission issued *Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities; Structure and Practices of the Video Relay Service Program; Misuse of Internet Protocol Captioned Telephone Service,* CG Docket Nos. 03–123, 10–51, and 13–24, Report and

Order, published at 87 FR 57645, September 21, 2022 (*Registration Grace Period Order*), allowing IP CTS and Video Relay Service (VRS) providers to provide compensable service to a new user for up to two weeks after submitting the user's information to the Database if the user's identity is verified within that period, in order to offer more efficient service to IP CTS and VRS users without risk of waste, fraud, and abuse to the Fund.

On September 30, 2022, the Commission released *Rates for Interstate Inmate Calling Services,* FCC 22–76, published at 87 FR 75496, December 9, 2022 (*Accessible Carceral Communications Order*). To improve access to communications services for incarcerated people with communications disabilities, the Commission adopted modifications to the user registration and verification requirements applicable to the provision of IP CTS and VRS for use of internet-based TRS in correctional facilities.

OMB Control No.: 3060–1089.

OMB Approval Date: December 5, 2023.

OMB Expiration Date: December 31, 2026.

Title: Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CG Docket Nos. 10–51 & 03–123.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Individuals or households;

Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 187,019 respondents; 1,836,456 responses.

Estimated Time per Response: 0.05 hours (3 minutes) to 300 hours.

Frequency of Response: Annual, monthly, on occasion, on-going, one-time, and quarterly reporting requirements; recordkeeping requirement; and third-party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for the collection is contained in section 225 of the Communications Act, 47 U.S.C. 225. The law was enacted on July 26, 1990, as title IV of the Americans with Disabilities Act of 1990 (ADA), Public Law 101–336, 104 Stat. 327, 366–69, and amended by the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, 103(a), 124 Stat. 2751, 2755 (2010) (CVAA); Public Law 111–265 (technical amendments to CVAA).

Total Annual Burden: 320,484 hours.

Annual Cost Burden: $280,200.

Needs and Uses:

The telecommunications relay service (TRS) program enables access to the nation's telephone network by persons with hearing and speech disabilities. In 1991, as required by the Americans with Disabilities Act and codified at 47 U.S.C. 225, the Commission adopted rules governing the telecommunications relay services (TRS) program and procedures for each state TRS program to apply for initial Commission certification and renewal of Commission certification of each state program. *Telecommunications Services for Individuals with Hearing and Speech Disabilities, and the Americans with Disabilities Act of 1990,* Report and Order and Request for Comments, document FCC 91–213, published at 56 FR 36729, August 1, 1991 (*1991 TRS Implementation Order*).

Between 2008 and 2011, to integrate internet-based TRS into the North American Numbering plan and facilitate interoperability, universal calling, and 911 emergency services, the Commission adopted rules in three separate orders related to the telephone numbering system and enhanced 911 (E911) services for users of two forms of internet-based TRS: Video Relay Service (VRS) and Internet Protocol Relay service (IP Relay). *See* document FCC 08–151, *Report and Order,* published at 73 FR 41286, July 18, 2008 (*First Numbering Order*); document FCC 08–275, *Second Report and Order and Order on Reconsideration,* published at 73 FR 79683, December 30, 2008 (*Second Numbering Order*); and document FCC 11–123, *Report and Order,* published at 76 FR 59551, September 27, 2011 (*internet-based TRS Toll Free Order*).

The rules adopted in these three orders have information collection requirements that include requiring VRS and IP Relay providers to: register each user who selects the provider as his or her default provider, including obtaining a self-certification from each user; verify the accuracy of each user's registration information; provision and maintain their registered users' routing information to the TRS Numbering Directory; place their users' Registered Location and certain callback information in Automatic Location Information (ALI) databases across the country and provide a means for their users to update their Registered Locations; include advisories on their websites and in any promotional materials addressing numbering and E911 services for VRS or IP Relay; verify in the TRS Numbering Directory whether each dial-around user is registered with another provider; and if they provide equipment to a consumer, make available to other VRS providers enough information about that equipment to enable another VRS provider selected as the consumer's default provider to perform all of the functions of a default provider.

On July 28, 2011, the Commission released *Structure and Practices of the Video Relay Service Program,* document FCC 11–118, published at 76 FR 47469, August 5, 2011, and at 76 FR 47476, August 5, 2011 (*VRS Certification Order*), adopting final and interim rules—designed to help prevent waste, fraud, and abuse, and ensure quality service, in the provision of internet-based forms of TRS. On October 17, 2011, the Commission released *Structure and Practices of the Video Relay Service Program,* Memorandum Opinion and Order and Order, document FCC 11–155, published at 76 FR 67070, October 31, 2011 (*VRS Certification Reconsideration Order*), modifying two aspects of information collection requirements contained in the *VRS Certification Order.*

On June 10, 2013, the Commission made permanent the interim rules adopted in the *VRS Certification Order. Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* Report and Order, document FCC 13–82, published at 78 FR 40582, July 5, 2013 (*2013 VRS Reform Order*).

The *VRS Certification Order* as modified by the *VRS Certification Reconsideration Order* and, as applicable, made permanent by the *2013 VRS Reform Order,* amended the Commission's process for certifying internet-based TRS providers as eligible for payment from the Interstate TRS Fund (Fund) for their provision of internet-based TRS to ensure that internet-based TRS providers receiving certification are qualified to provide internet-based TRS in compliance with the Commission's rules and to eliminate waste, fraud and abuse through improved oversight of such providers. They contain information collection requirements including: submission of detailed information in an application for certification that shows the applicant's ability to comply with the Commission's rules; submission of annual reports that include updates to

the provider's information on file with the Commission or a certification that there are no changes to the information; requirements for a senior executive of an applicant for internet-based TRS certification or an internet-based TRS provider, when submitting an annual compliance report, to certify under penalty of perjury to its accuracy and completeness; requirements for VRS providers to obtain prior authorization from the Commission for planned interruptions of service, to report to the Commission unforeseen interruptions of service, and to provide notification of temporary service outages, including updates, to consumers on their websites; and requirements for internet-based TRS providers that will no longer be providing service to give their customers notice at least 30-days in advance.

In the *2013 VRS Reform Order,* the Commission adopted further measures to improve the structure, efficiency, and quality of the VRS program, reducing the noted inefficiencies in the program, as well as reducing the risk of waste, fraud, and abuse, and ensuring that the program makes full use of advances in commercially-available technology. The Commission required reporting of unauthorized and unnecessary use of VRS; established a central TRS user registration database (TRS–URD) for VRS, which incorporates a centralized eligibility verification requirement to ensure accurate registration and verification of users, as well as per-call validation, to achieve more effective prevention of waste, fraud, and abuse; established procedures to prevent unauthorized changes of a user's default TRS provider; and established procedures to protect TRS users' customer proprietary network information (CPNI) from disclosure.

On March 23, 2017, the Commission released *Structure and Practices of the Video Relay Services Program et al.,* FCC 17–26, published at 82 FR 17754, April 13, 2017 (*2017 VRS Improvements Order*), which among other things, allows VRS providers to assign TRS Numbering Directory 10-digit telephone numbers to hearing individuals for the limited purpose of making point-to-point video calls, and gives VRS providers the option to participate in an at-home call handling pilot program, subject to certain limitations, as well as recordkeeping and reporting requirements.

On May 15, 2019, the Commission released *Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* FCC 19–39, published at 84 FR 26364, June 6, 2019 (*2019 VRS Program Management Order*). The Commission further improved the structure, efficiency, and quality of the VRS program, reduced the risk of waste, fraud, and abuse, and ensured that the program makes full use of advances in commercially-available technology. These improvements include information collection requirements, including: the establishment of procedures to register enterprise and public videophones to the TRS–URD; and permitting Qualified Direct Video Calling (DVC) Entities to access the TRS Numbering Directory and establishing an application procedure to authorize such access, including rules governing DVC entities and entry of information in the TRS Numbering Directory and the TRS–URD.

On August 2, 2019, the Commission released *Implementing Kari's Law and Section 506 of RAY BAUM's Act; Inquiry Concerning 911 Access, Routing, and Location in Enterprise Communications Systems; Amending the Definition of Interconnected VoIP Service in Section 9.3 of the Commission's Rules,* FCC 19–76, published at 84 FR 66716, December 5, 2019 (*MLTS 911 and Dispatchable Location Order*). The Commission amended its rules to ensure that the dispatchable location is conveyed to a Public Safety Answering Point (PSAP) with a 911 call, regardless of the technological platform used. Based on the directive in section 506 of RAY BAUM'S Act, the Commission adopted dispatchable location requirements that in effect modified the existing information collection requirements applicable to VRS, IP Relay, and covered internet Protocol captioned telephone service by improving the options for providing accurate location information to PSAPs as part of 911 calls.

Fixed internet-based TRS devices must provide automated dispatchable location. For non-fixed devices, when dispatchable location is not technically feasible, internet-based TRS providers may fall back to Registered Location or provide alternative location information. As a last resort, internet-based providers may route calls to Emergency Relay Calling Centers after making a good faith effort to obtain location data from all available alternative location sources. Dispatchable location means a location delivered to the PSAP with a 911 call that consists of the validated street address of the calling party, plus additional information such as suite, apartment, or similar information necessary to adequately identify the location of the calling party. Automated dispatchable location means automatic generation of dispatchable location. Alternative location information is location information (which may be coordinate-based) sufficient to identify the caller's civic address and approximate in-building location, including floor level, in large buildings.

On January 31, 2020, the Commission released *Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* FCC 20–7, 85 FR 27309, May 8, 2020 (*VRS At-Home Call Handling Order*). The Commission amended its rules to convert the VRS at-home call handling pilot program into a permanent one, thereby allowing CAs to work from home. To ensure user privacy and call confidentiality and to help prevent waste, fraud, and abuse, the modified information collections include requirements for VRS providers to apply for certification to allow their communications assistants to handle calls while working at home; monitoring and oversight requirements; and reporting requirements.

On June 30, 2022, the Commission released *Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities; Structure and Practices of the Video Relay Service Program; Misuse of internet Protocol Captioned Telephone Service,* FCC 22–51, published at 87 FR 57645, September 21, 2022 (*Registration Grace Period Order*). To offer more efficient service to VRS and IP CTS users without risk of waste, fraud, and abuse to the TRS Fund, the Commission amended its rules to allow VRS and IP CTS providers to provide compensable service to a new user for up to two weeks after submitting the user's information to the TRS URD if the user's identity is verified within that period.

On September 30, 2022, the Commission released *Rates for Interstate Inmate Calling Services,* FCC 22–76, published at 87 FR 75496, December 9, 2022 (*Accessible Carceral Communications Order*). To improve access to communications services for incarcerated people with communications disabilities, the Commission adopted modifications to the user registration and verification requirements applicable to the provision of IP CTS and VRS for use of internet-based TRS in correctional facilities.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–28007 Filed 12–20–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket Nos. 22–238, 11–42, 21–450; FCC 23–96, FR ID 190866]

Supporting Survivors of Domestic and Sexual Violence; Lifeline and Link Up Reform Modernization

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: The Federal Communications Commission (Commission) is correcting a final rule that appeared in the **Federal Register** on December 5, 2023. The document issued final rules implementing the Safe Connections Act of 2022 (Safe Connections Act or SCA), taking significant steps to improve access to communications services for survivors of domestic abuse and related crimes.

DATES:

Effective date: This correction is effective January 14, 2024.

Compliance date: Compliance with the revisions to 47 CFR 64.2010 is delayed indefinitely. The FCC will publish a document in the **Federal Register** announcing the compliance date for that section.

FOR FURTHER INFORMATION CONTACT: For further information, contact Melissa Kirkel at *melissa.kirkel@fcc.gov* or 202–418–7958.

SUPPLEMENTARY INFORMATION: The Commission is correcting a final rule that appeared in the **Federal Register** on December 5, 2023, at 88 FR 84406, which issued final rules implementing the SCA, taking significant steps to improve access to communications services for survivors of domestic abuse and related crimes. A subsequent rule published on December 8, 2023, at 88 FR 85814, also added a paragraph (h) to § 64.2010. This document corrects the December 5 rule's addition of § 64.2010(h) by redesignating it as paragraph (i) and revising it to account for a reference within.

Correction

Accordingly, in FR Rule Doc. No. 2023–26605 appearing on page 84406 in the issue of Tuesday, December 5, 2023, make the following correction:

■ 1. On page 84448, in the first column, correct amendatory instruction 10 amending § 64.2010, redesignate paragraph (h) as paragraph (i), and revise newly redesignated paragraph (i) to read as follows:

■ 10. Amend § 64.2010 by revising paragraph (f) and adding paragraph (i) to read as follows:

§ 64.2010 [Corrected]

* * * * *

(i) *Compliance date.* Compliance with the provision in paragraph (f) of this section applicable to line separation requests under 47 U.S.C. 345 and subpart II of this part will not be required until this paragraph (i) is removed or contains a compliance date, which will not occur until the later of July 15, 2024; or after OMB completes review of any information collection requirements in subpart II of this part that the Wireline Competition Bureau determines is required under the Paperwork Reduction Act or the Wireline Competition Bureau determines that such review is not required. The Commission directs the Wireline Competition Bureau to announce a compliance date for the requirements of paragraph (f) by subsequent Public Notice and notification in the **Federal Register** and to cause this section to be revised accordingly.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2023–27840 Filed 12–20–23; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

48 CFR Part 1252

RIN 2105–AF22

Solicitation Provisions and Contract Clauses

AGENCY: Department of Transportation.

ACTION: Final rule.

SUMMARY: This final rule amends the Transportation Acquisition Regulation (TAR) to provide needed editorial changes. DOT is publishing a technical amendment to make a minor administrative correction to a TAR clause citation.

DATES: This rule is effective on December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. LaWanda Morton-Chunn, Procurement Analyst, Acquisition Policy, Oversight & Business Strategies (M–61), Office of the Senior Procurement Executive (OSPE), Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 366–2267. This is not a toll-free telephone number.

SUPPLEMENTARY INFORMATION:

Background

The purpose of this rule is to make a minor administrative correction to the clause at 1252.239–92, Information and Communication Technology Accessibility Notice, paragraph (b). This revision corrects an erroneous reference to a separate TAR clause.

Discussion and Analysis

TAR part 1252, 1252.239–92, Information and Communication Technology Accessibility Notice, paragraph (b), is revised to correct a typographical error to a reference to another TAR clause. The reference in paragraph (b) to the clause at 1252.239–81, Information and Communication Technology Accessibility, is revised to reference the clause at 1252.239–93, Information and Communication Technology Accessibility. The clause at 1252.239–81 is titled Cloud Identification and Authentication (Organizational Users) Multi-Factor Authentication, which is not the correct reference. The clause at 1252.239–93 is titled Information and Communication Technology Accessibility. The clause at 1252.239–93 is the clause that paragraph (b) of 1252.239–92 intended to reference.

Notice and Comment

This rule makes administrative changes that do not require prior notice and an opportunity for comment or a delayed effective date, consistent with 41 U.S.C. 1707, 48 CFR 1.301, and 48 CFR 1.501–3.

The statutes at 41 U.S.C. 1707(a) specifies a required comment period for procurement policies, regulations, procedures and forms. Specifically, a procurement policy, regulation, procedure, or form may not take effect until 60 days after it is published for public comment if it relates to the expenditure of funds and either (i) has a significant effect beyond the internal operating procedures of the agency issuing the action; or (ii) has a significant cost or administrative impact on contractors or offerors. An exception can be made if there are compelling circumstances for an earlier effective date. The statutes at 41 U.S.C. 1707(b) also requires agencies to publish proposed procurement regulations in the **Federal Register** for a comment period of at least 30 days unless the agency waives those requirements pursuant to 41 U.S.C. 1707(d). This

provision specifies that an agency may waive the publication and comment requirements only if urgent and compelling circumstances make compliance impracticable. Section 1.501–3 of the Federal Acquisition Regulation (FAR) further provides that proposed agency acquisition regulations need not be published for comment when the rule does not constitute a significant revision, and FAR 1.301 requires publication of proposed changes to agency acquisition regulations for public comment in conformance with FAR subpart 1.5 (including FAR 1.501–3) and 41 U.S.C. 1707.

The Department has determined that publication of this rule for notice and comment is not required pursuant to these authorities. The correction of the erroneous cross reference is an administrative change that will not have a significant effect on any party. The correction will not impose a significant cost, or have a significant administrative impact, on contractors or offerors. This final rule merely updates 1252.239–92 to reference the correct TAR clause.

Executive Orders 12866 and 13563

The Office of Management and Budget (OMB) has determined that this rule is not a significant regulatory action under Executive Order 12866. Therefore, OMB did not review the final rule.

Regulatory Flexibility Act

The Secretary hereby certifies that this final 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). The factual basis for this certification follows. This rulemaking does not change DOT's policy regarding small businesses, does not have an economic impact on individual businesses, and does not impose any increased or decreased costs on small business entities. Instead, it is merely an administrative correction to an erroneous cross reference. Therefore, pursuant to 5 U.S.C. 605(b), a regulatory flexibility analysis is not required.

Paperwork Reduction Act

This final rule does not contain any information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Congressional Review Act

This rule has not been designated by the Office of Information and Regulatory Affairs as a major rule pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.;* see 5 U.S.C. 804(2)).

List of Subjects in 48 CFR Part 1252

Government procurement, Reporting and recordkeeping requirements.

Signing Authority

Signed under authority provided by 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304; 1.501–3, and 49 CFR 1.38 in Washington, DC, on December 14, 2023.

Philip A. McNamara,

Assistant Secretary for Administration, U.S. Department of Transportation.

For the reasons set out in the preamble, DOT amends 48 CFR part 1252 as set forth below.

PART 1252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for part 1252 continues to read as follows:

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1252.2—Text of Provisions and Clauses

1252.239–92 [Amended]

■ 2. Amend section 1252.239–92 in paragraph (b) of the provision by removing ''1252.239–81, Information and Communication Technology Accessibility'' and adding in its place ''1252.239–93, Information and Communication Technology Accessibility''.

[FR Doc. 2023–27890 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 231214–0303]

RIN 0648–BF98

Approach Regulations for Humpback Whales in Waters Surrounding the Hawaiian Islands Under the Marine Mammal Protection Act

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

ACTION: Final rule.

SUMMARY: NMFS issues this final rule ''Approach Regulations for Humpback Whales in Waters Surrounding the Islands of Hawaii under the Marine Mammal Protection Act'' under the Marine Mammal Protection Act (MMPA). This rule prohibits the ''take'' of humpback whales (*Megaptera novaeangliae*), which means ''to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal,'' within 200 nautical miles (nmi) (370.4 kilometers (km)) of the islands of Hawaii from the detrimental effects resulting from approach by humans.

DATES: This rule is effective January 22, 2024.

ADDRESSES: Public comments and other supporting materials are available at *www.regulations.gov* identified by docket number NOAA–NMFS–2016–0046 or by submitting a request to the Protected Resources Division, National Marine Fisheries Service, Pacific Islands Regional Office, 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818, Attn: Humpback Whale Approach Regulations.

FOR FURTHER INFORMATION CONTACT: Elena Duke, NMFS, Pacific Islands Regional Office, *elena.duke@noaa.gov;* 808–725–5085.

SUPPLEMENTARY INFORMATION:

Background

Protections for humpback whales in Hawaii were initially promulgated under the ESA, after NMFS determined that guidelines published in 1979 as a ''Notice of Interpretation of 'Taking by Harassment' in Regard to Humpback Whales in the Hawaiian Islands Area'' (44 FR 1113; January 4, 1979) proved ineffective in protecting humpback whales in Hawaii from tour vessel operators approaching closer than the recommended viewing guidelines. The ESA rule that protected humpback whales in Hawaii was published on November 23, 1987 as an interim final rule (52 FR 44912), and then was finalized on January 19, 1995 (60 FR 3775). That rule made it unlawful to operate an aircraft within 1,000 feet (ft), approach by any means within 100 yards (yds), cause a vessel or another object to approach within 100 yds, or disrupt the normal behavior or prior activity of a humpback whale by any other act or omission. Regulations regarding the implementation of the ESA were then reorganized on March 23, 1999, with the section containing the approach regulations for humpback whales in Hawaii, changed from 50 CFR 222.31 to 50 CFR 224.103 (64 FR 14052).

NMFS published a final ESA listing rule on September 8, 2016 (81 FR 62259) that revised the species-wide

listing and separated humpback whales into 14 DPSs. In that rule, the humpback whales that use the waters surrounding Hawaii as their breeding grounds are identified as the ''Hawaii DPS,'' which is not listed under the ESA as endangered or threatened and, therefore, is no longer protected under the ESA. Humpback whales in Hawaii would have continued to be protected by approach regulations only within the boundaries of the Hawaiian Islands Humpback Whale National Marine Sanctuary (HIHWNMS) under the National Marine Sanctuaries Act (15 CFR 922.184(a)(1) and (2) and (b)).

However, NMFS determined that, although unpermitted take is prohibited by the MMPA for humpback whales or any marine mammals in any location, specific regulations were warranted to address approach and human interactions that result in the take of humpback whales in Hawaii. These specific regulations were warranted because: (1) humpback whales are charismatic and sought out by local community members and tourists; (2) commercial and recreational whale watchers and other tour operators are expected to pursue humpback whales for close encounters absent any protections; (3) increasing numbers of both humpback whales and humans using Hawaiian waters raises the likelihood of human-whale interactions; and (4) approaching whales during the breeding, calving, and nursing season is likely to cause a disturbance that could adversely affect reproduction and development of individuals.

Therefore, an interim final rule was published on September 8, 2016, to ensure that there was no lapse in protection for humpback whales in Hawaii once the final ESA listing rule became effective on October 11, 2016. The interim final rule prohibited operating an aircraft within 1,000 ft (304.8 meters (m)) of a humpback whale, approaching within 100 yds (91.4 m) of a humpback whale by any means, causing a vessel, person or another object to approach within 100 yds (91.4 m) of a humpback whale, or approaching a humpback whale by interception (*i.e.,* placing an aircraft, vessel, person, or another object in the path of a humpback whale so that the whale approaches within a restricted distance). The regulations also prohibited the disruption of normal behavior or prior activity of a humpback whale by any act or omission. Certain vessels and activities were exempted from the prohibition.

This final rule serves to clarify the interim final rule by amending regulatory language in paragraphs (a)(5) and (b) of 50 CFR 216.19. The changes to 50 CFR 216.19 include a punctuation correction in paragraph (a)(5), a word change in paragraph (b)(3), and further clarification of exception 1, described in paragraph (b)(1). This final rule also amends the regulatory language in 50 CFR 216.19(b)(4) to clarify the scope of NMFS-permitted or authorized activities that may fall under that exemption. The exemption under 50 CFR 216.19(b)(4) in the interim final rule reads ''vessels or persons authorized under permit or authorization issued by NMFS to conduct scientific research or response efforts that may result in taking of humpback whales.'' However, the exemption as worded in the interim rule leaves out other potentially permitted or authorized activities. The intent of the rule was not to preclude the issuance of permits or authorizations for purposes of scientific research, enhancement, educational or commercial photography, or during emergency response of stranded or entangled marine mammals, or persons authorized to incidentally take humpback whales consistent with the requirements of the MMPA. Therefore, NMFS is amending 50 CFR 216.19(b)(4) to read, ''Activities authorized through a permit or authorization issued by the National Marine Fisheries Service to take humpback whales.''

Scope and Applicability

Applications to All Humpback Whales

Under the MMPA, the regulations apply to all humpback whales found in the action area, as described below.

Geographic Action Area

The action area for this rule is limited to the waters within 200 nmi (370.4 km) from the shore of the islands of Hawaii. The islands of Hawaii consist of the entire Hawaiian Archipelago, including the main Hawaiian Islands (Hawai'i, Maui, Kaho'olawe, Lāna'i, Moloka'i, O'ahu, Kaua'i, and Ni'ihau) and the Northwestern Hawaiian Islands.

Applications to All Forms of Approach

The regulations apply to all forms of approach in water and air. Forms of approaching humpback whales include, but are not limited to, operating a manned or unmanned motorized, non-motorized, self-propelled, human-powered, or submersible vessel; operating a manned aircraft; operating an unmanned aircraft system (UAS) or drone; and swimming at the water surface or underwater (*i.e.,* SCUBA or free diving). UASs are, at minimum, objects, and therefore UASs are not to approach humpback whales within 100 yds (91.4 m) without a permit. NMFS may change this determination in the future if scientific information becomes available showing humpback whales react to UASs within or beyond 100 yds.

Approach Prohibitions

The regulations prohibit people from operating aircraft within 1,000 ft (304.8 m) or approaching by any means within 100 yds (91.4 m) of humpback whales within the action area described above (see *Geographic Action Area*). This includes an approach by interception (*i.e.,* placing an aircraft, vessel, person, or another object in the path of a humpback whale so that the whale approaches within the restricted distance), also known as ''leapfrogging.'' The regulations also prohibit disrupting the normal behavior or prior activity of a humpback whale. Disruption of normal behavior can include, but is not limited to, a rapid change in direction or speed; escape tactics such as prolonged diving, underwater course changes, underwater exhalation, or evasive swimming patterns; interruptions of breeding, nursing, or resting activities; attempts by a whale to shield a calf from a vessel or human observer by tail swishing or by other protective movements; or the abandonment of a previously frequented area.

Exceptions

The following specific categories are exempt from the regulations:

(1) Federal, State, or local government vessels, aircraft, personnel, and assets, when necessary, in the course of performing official duties;

(2) Vessel operations necessary to avoid an imminent and serious threat to a person, vessel, or the environment;

(3) Vessels restricted in their ability to maneuver that, because of this restriction, are not able to comply with approach restrictions; or

(4) Activities authorized through a permit or authorization issued by the National Marine Fisheries Service to take humpback whales.

Comments and Responses

NMFS solicited public comments on the interim final rule and received 10 comments. Several comments contained similar recommendations and/or questions and are consolidated. In response to comments, NMFS concurred with comments of support and clarified why NMFS is taking this action specific to humpback whales and not all cetaceans. NMFS provided rationale for not including regulations on speed, approach angle, and engine operating procedures in this rule making. NMFS

provided clarification regarding enforcement of this regulation, provided information on the classification of UAS systems, and prohibitions of using UAS within 100 yards of humpback whales. Responses to comments addressing significant issues are summarized below.

Comment 1: Four commenters expressed support for the interim final rule, with two of these commenters specifically stating support for making 100 yds (91.4 m) the regulatory approach distance.

Response: NMFS concurs.

Comment 2: One commenter requested clarification on how NMFS will enforce this approach regulation, how enforcement will contend with efforts by restricted groups to adjust their services/methodologies to conform to the rules of exemption, and how NMFS will manage those situations where an innocent party unwittingly violates the restrictions.

Response: Enforcement will be accomplished via all available means, including through land and sea patrols conducted by the NOAA Office of Law Enforcement, the United States Coast Guard, and State partners who work with NMFS on outreach and enforcement under a cooperative joint enforcement agreement (*i.e.,* State of Hawaii's Division of Conservation and Resources Enforcement (DOCARE), as well as through cases developed through evidence submitted by citizens observing violations.

Regarding exceptions or exemptions to this rule, for exceptions to apply, a person must be a Federal, State, or local government official operating in the course of their official duties; avoiding an imminent and serious threat to a person, vessel, or the environment; authorized under permit or other authorization issued by NMFS; or operating a vessel restricted in its ability to maneuver. Additional details regarding exceptions to these regulations are provided in the final rule below in (b) Exceptions. Any person claiming the benefit of any exemption, exception, or permit has the burden of proving that the exemption or exception is applicable. Enforcement officials will consider and collect, as part of the normal investigative process, all available evidence, including evidence tending to support a party's claim to be exempt from the rule.

Regarding intent, the MMPA is a strict liability statute, meaning the intention of a party violating a regulation issued under the MMPA is not relevant for purposes of liability. Nonetheless, the Agency does consider the individual circumstances of each violation in deciding on an appropriate enforcement response and assessing any penalties. Under the Agency's penalty policy, available to the public at *http://www.gc.noaa.gov/enforce-office3.html,* any penalties assessed for unintentional violations are assessed at a lower level than penalties assessed for intentional violations.

Comment 3: NMFS should extend this 100-yd approach regulation to all cetaceans protected by the MMPA.

Response: We appreciate your concern for all cetaceans. In general, the MMPA prohibits the take of marine mammals with section 3(13) (16 U.S.C. 1362(13)) of the MMPA defining the term ''take'' as ''to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal.'' These approach regulations are specific to humpback whales in Hawaii because of geographic and species-specific factors, including, but not limited to, (1) the fact that humpback whales are sought out for encounters by the local community and tourists; (2) safety concerns for both whales and humans created by a desire of whale watch and other tour operators, as well as individuals, to get as close as possible to the whales; (3) the importance of the habitat around the Hawaiian Islands for breeding, calving, and nurturing young; and (4) the increasing numbers of both humpback whales and humans that use Hawaiian waters. In short, while unpermitted take of marine mammals continues to be prohibited by the MMPA, NMFS believes that specific regulations aimed at approach and human interactions that result in the take of humpback whales in Hawaii are warranted.

Comment 4: Several commenters expressed concern regarding how this regulation will affect the collection of up-close photos and video footage if such activities are regulated at distances closer than 100 yds. Specifically, these commenters suggested that UASs or drones could be allowed to collect up-close footage while posing minimal risk to the humpback whales being observed. Two of these commenters noted that the sound of boat engines even at over 100 yds away can produce more vibrations and are far louder than some UASs, which generate noise that is very low and of a frequency that would not penetrate the water to any significant depth.

Response: As described in the interim final rule, research suggests that close human interaction poses a significant threat to the health and social structure of humpback whales. These threats can include collisions, noise, visual, and other effects from interactions with vessels, aircraft, persons, or objects. While some UASs create less noise than vessels, there are situations in which noise and visual effects have the potential to disturb the whales because of the UASs use within 100 yds of humpback whales. Examples of some situations include the use of multiple UASs around a single whale or groups of whales and the use of UASs by inexperienced users. As a result, NMFS has determined that UASs are, at a minimum, ''objects'' and therefore are not permitted to approach humpback whales within 100 yds in Hawaiian waters (within 200 nmi of the islands of Hawaii).

Specifically, regarding the acquisition of up-close footage of whales, the regulations include exceptions to the 100-yd approach regulations for humpback whales in Hawaii, including an exception for vessels or persons authorized under permit or authorization issued by NMFS to take humpback whales for purposes of scientific research, enhancement educational or commercial photography, or during emergency response of stranded or entangled marine mammals; or persons authorized to incidentally take humpback whales.

Comment 5: NMFS should consider a drone or UAS to be an aircraft, rather than an object, therefore prohibiting their use within 1,000 ft of humpback whales.

Response: NMFS understands that UASs are considered ''aircraft'' by Federal agencies, such as the Federal Aviation Administration. UASs, at least in their current form, are relatively small and generate little noise and are therefore unlikely to disturb humpback whales if kept at a distance of 100 yds from the whales. In the context of this rule and, considering available data regarding the effects of UASs on humpback whales and other marine mammals (see the National Environmental Policy Act (NEPA) Environmental Assessment (EA) prepared for the interim final rule), NMFS has determined that UASs are, at a minimum, considered ''objects'' and therefore are not to approach humpback whales within 100 yds without a permit. NMFS may change this determination in the future if scientific information becomes available showing whales react to UASs within or beyond 100 yds.

Comment 6: The approach regulations for humpback whales should specify vessel operating procedures such as the guidance developed for the HIHWNMS and whale-watching guidance developed by NMFS for humpback whales in the northeastern United States. The operating procedures should

include guidance on vessel speed limits depending on the distance from a humpback whale, the angles at which a vessel can approach and depart from a humpback whale, and engine operating procedures within various distances.

Response: The guidelines referenced in this comment contain various measures that are designed to protect humpback whales and other marine mammals. NMFS agrees that all of the guidelines can be useful in protecting humpback whales and other large whale species. However, NMFS did not include in the regulations any provisions regarding speed, approach angle, and engine operating procedures within various distances because the specifics of such provisions vary according to different situations. Therefore, these provisions are more appropriate as guidelines rather than regulations, which must be followed at all times except in limited situations (*i.e.,* the exceptions to the rule). These general guidelines may be used to supplement the minimum approach regulations, but the regulations must be complied with at all times unless an exception applies.

Classification

National Environmental Policy Act (NEPA)

NMFS prepared an EA pursuant to NEPA (42 U.S.C. 4321, *et seq.*) to support the interim final rule published on September 8, 2016. NMFS also provided an opportunity for public comment on the EA; however, no public comments were received. The EA contains an analysis of two no-action alternatives and two action alternatives. Several elements were common to both of the action alternatives analyzed, including the preferred alternative described in the interim final rule, and several exceptions that would apply to the alternatives. Because the preferred alternative in the interim final rule is the same as in this final rule, an updated NEPA document is unnecessary. The EA with the Finding of No Significant Impact is available for download on the NMFS Pacific Islands Region website *https://www.fisheries.noaa.gov/species/humpback-whale.*

Executive Order 12866

This final rule has been determined to be not significant for purposes of Executive Order (E.O.) 12866.

Paperwork Reduction Act

The purpose of the Paperwork Reduction Act is to minimize the paperwork burden for individuals, small businesses, educational and nonprofit institutions, and other persons resulting from the collection of information by or for the Federal government. The final rule includes no new collection of information, so further analysis is not required.

Coastal Zone Management Act

NMFS determined that the interim final rule would be implemented in a manner consistent, to the maximum extent practicable, with the enforceable policies of the approved coastal zone management program of the State of Hawaii. The State of Hawaii's Coastal Zone Management Program (the responsible State agency under section 307(c)(1) of the Federal Coastal Zone Management Act (CZMA) of 1972) provided a letter, dated May 13, 2016, concurring with NMFS's federal consistency determination. Because the interim final rule is substantively the same as this final rule, no updated CZMA documentation is necessary.

Executive Order 13132, Federalism

E.O. 13132 requires agencies to take into account any federalism impacts of regulations under development. It includes specific directives for consultation in situations in which a regulation will preempt State law or impose substantial direct compliance costs on State and local governments (unless required by statute). Neither of those circumstances applies to this final rule; therefore, this action does not have federalism implications as that term is defined in E.O. 13132.

Information Quality Act

Pursuant to section 515 of Public Law 106–554 (the Information Quality Act), this information product has undergone a pre-dissemination review by NMFS. The signed Pre-dissemination Review and Documentation Form is on file with the NMFS Pacific Islands Regional Office (see **ADDRESSES**).

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, whenever an agency publishes a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a Regulatory Flexibility Analysis describing the effects of the rule on small entities, *i.e.,* small businesses, small organizations, and small government jurisdictions. The final regulations are exempt from the requirements of the Regulatory Flexibility Act because NMFS determined that notice and public comment when publishing the interim final rule would have been impracticable and against the public interest.

List of Subjects in 50 CFR Part 216

Administrative practice and procedure, Marine mammals.

Dated: December 14, 2023.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS amends 50 CFR part 216 as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for 50 CFR part 216 continues to read as follows:

Authority: 16 U.S.C. 1361, *et seq.,* unless otherwise noted.

■ 2. In § 216.19, revise paragraphs (a)(5) and (b) to read as follows:

§ 216.19 Special restrictions for humpback whales in waters surrounding the islands of Hawaii.

(a) * * *

(5) Disrupt the normal behavior or prior activity of a whale by any other act or omission. A disruption of normal behavior may be manifested by, among other actions on the part of the whale, a rapid change in direction or speed; escape tactics such as prolonged diving, underwater course changes, underwater exhalation, or evasive swimming patterns; interruptions of breeding, nursing, or resting activities; attempts by a whale to shield a calf from a vessel or human observer by tail swishing or by other protective movements; or the abandonment of a previously frequented area.

(b) *Exceptions.* The prohibitions of paragraph (a) of this section do not apply to:

(1) Federal, State, or local government vessels, personnel, and assets, when necessary, in the course of performing official duties;

(2) Vessel operations necessary to avoid an imminent and serious threat to a person, vessel, or the environment;

(3) Vessels restricted in their ability to maneuver that, because of this restriction, are not able to comply with approach restrictions; or

(4) Activities authorized through a permit or authorization issued by the National Marine Fisheries Service to take humpback whales.

* * * * *

[FR Doc. 2023–28091 Filed 12–20–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 231215–0305]

RIN 0648–BM59

Fisheries of the Northeastern United States; 2024 and Projected 2025 Specifications for the Summer Flounder and Scup Fisheries, and 2024 Specifications for the Black Sea Bass Fishery

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

ACTION: Final rule.

SUMMARY: NMFS announces 2024 specifications for the summer flounder, scup, and black sea bass fisheries, and projected 2025 specifications for summer flounder and scup. The implementing regulations for the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan require us to publish specifications for the upcoming fishing year for each of these species and to respond to public comments received during the public comment period. This action is intended to inform the public of the specifications for the start of the 2024 fishing year for summer flounder, scup, and black sea bass. A Supplemental Information Report (SIR) was prepared for the 2024 black sea bass specifications. An Environmental Assessment (EA) was prepared for the 2024 and projected 2025 summer flounder and scup specifications.

DATES: This rule is effective January 1, 2024.

ADDRESSES: Copies of the SIR and EA are available on request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. The SIR and EA are also accessible via the internet at *https://www.mafmc.org/supporting-documents.*

FOR FURTHER INFORMATION CONTACT: Emily Keiley, Fishery Policy Analyst, (978) 281–9116, or *emily.keiley@noaa.gov.*

SUPPLEMENTARY INFORMATION:

General Background

The Mid-Atlantic Fishery Management Council (Council) and the Atlantic States Marine Fisheries Commission (Commission) cooperatively manage the summer flounder, scup, and black sea bass fisheries. The Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) outlines the Council's process for establishing specifications. The FMP requires NMFS to set an acceptable biological catch (ABC), annual catch limit (ACL), annual catch targets (ACT), commercial quotas, recreational harvest limits (RHL), and other management measures, for 1 to 3 years at a time. This action establishes the 2024 ABCs, as well as the recreational and commercial ACLs, ACTs, commercial quotas, and RHLs for all three species, consistent with the recommendations made by the Commission's Summer Flounder, Scup, and Black Sea Bass Board (Board) and the Council at their joint August 2023 meeting. This action also sets projected 2025 ABCs and corresponding specifications for summer flounder and scup.

Final 2024 and Projected 2025 Specifications

Summer Flounder Specifications

This action approves the Council- and Board-recommended 2024 and projected 2025 summer flounder specifications as shown in table 1. The recommendations are based on the averaged 2024–2025 ABCs recommended by the Council's Science and Statistical Committee (SSC). This approach allows for constant catch and landings limits across both years. The ABCs are based on the overfishing limit (OFL) and the Council's risk policy, resulting in a 32- to 38-percent probability of overfishing. For summer flounder, this results in a 42-percent decrease in the recommended 2024 and 2025 ABC relative to the 2023 ABC. The 2024–2025 commercial quota represents a 42-percent decrease compared to the 2023 quota, and an approximately 30-percent reduction compared to 2022 reported landings. The 2024–2025 RHL is a 40-percent decrease compared to the 2023 RHL.

TABLE 1—SUMMARY OF FINAL 2024 AND PROJECTED 2025 SUMMER FLOUNDER FISHERY SPECIFICATIONS

Specifications	million pounds (lb)	metric tons (mt)
OFL	22.98 (2024) 24.97 (2025)	10,422 (2024) 11,325 (2025)
ABC	19.32	8,761
Commercial ACL = ACT	10.62	4,819
Commercial Quota	8.79	3,987
Recreational ACL = ACT	8.69	3,942
Recreational Harvest Limit	6.35	2,879

The final state summer flounder commercial quotas take into account any overages that occurred during the 2022 fishing year and the current fishing year, through October 31, 2023, as described at 50 CFR 648.103(b)(2). The final 2024 state-by-state summer flounder commercial quotas are provided in table 2.

TABLE 2—FINAL 2024 SUMMER FLOUNDER STATE-BY-STATE QUOTAS

State	Final 2024 quotas (lb)	Final 2024 quotas (mt)
ME	4,180	1.90
NH	40	0.02
MA	599,507	271.93
RI	1,378,507	625.28
CT	198,394	89.99
NY	672,157	304.89

TABLE 2—FINAL 2024 SUMMER FLOUNDER STATE-BY-STATE QUOTAS—Continued

State	Final 2024 quotas (lb)	Final 2024 quotas (mt)
NJ	1,470,098	666.83
DE	1,564	0.71
MD	179,233	81.30
VA	1,873,707	849.90
NC	2,412,443	1,094.27
Total	8,789,830	3,987.02

This action makes no changes to the current commercial management measures, including the minimum fish size (14-inch (36-centimeter (cm)) total length), gear requirements, and possession limits. Changes to 2024 recreational management measures (bag limits, size limits, and seasons) will be considered through a separate action.

Black Sea Bass Specifications

This action approves the Council- and Board-recommended 2024 black sea bass specifications as shown in table 3. No updated stock assessment information is available for black sea bass this year; therefore, the SSC decided to set the 2024 ABC equal to the 2023 ABC. The Council and Board made no changes to the ACLs or ACTs compared to 2023. They approved a 2024 commercial quota of 6 million lb (2,721 mt) (25-percent increase from 2023) and a 2024 RHL of 6.27 million lb (2,845 mt) (5-percent decrease from 2023). While these values are based on the same methodology used to set the 2023 measures, updated dead-discard projections for each sector led to a change in the quota and RHL. An updated management track stock assessment is anticipated to be available in 2024 for setting future specifications.

TABLE 3—FINAL 2024 BLACK SEA BASS CATCH AND LANDINGS LIMITS

Specifications	2024	
	million lb	mt
OFL	17.01	7,716
ABC	16.66	7,557
Expected Commercial Discards	1.50	680
Expected Recreational Discards	2.89	1,311
Commercial ACL = ACT	7.50	3,401
Commercial Quota	6.00	2,721
Recreational ACL = ACT	9.16	4,156
RHL	6.27	2,845

This action implements no changes to the 2024 commercial management measures for black sea bass, including the commercial minimum fish size (11-inch (27.94-cm) total length) and gear requirements.

On August 2, 2023, NMFS partially approved Amendment 23 to the Summer Flounder, Scup, and Black Sea Bass FMP. The approved measures change the Federal coastwide commercial in-season accountability measure such that the commercial fishery will now close when the quota plus an additional buffer of up to 5-percent is projected to be landed. The intent of this buffer is to minimize negative economic impacts when the coastwide quota is reached before all states have fully harvested their allocations due to overages in individual states. Each year, through the specification process, the Council and Board will recommend a buffer from 0- to 5-percent. For 2024, the Council and Board have recommended a 5-percent commercial in-season closure buffer. The final rule implementing Amendment 23 has not been published, so the buffer cannot be implemented through this action. Implementation of the 5-percent buffer recommended for 2024 will be considered through the Amendment 23 final rule.

Scup Specifications

This action approves the Council- and Board-recommended 2024 scup specifications as shown in table 4. The SSC-recommended 2024–2025 ABCs are based on the OFL and the Council's risk policy for a stock above 1.5 times the biomass target, with an associated 49-percent probability of overfishing. To ensure that the probability of overfishing remained below 50-percent in each year, the SSC recommended annually varying ABCs for 2024 and 2025. This results in a 2024 ABC that is 49-percent higher than the 2023 ABC; and a projected 2025 ABC that is 35-percent higher than the 2023 ABC. The scup commercial quota for 2024 is 52-percent higher than the 2023 commercial quota. The 2024 RHL is 43-percent higher than the 2023 RHL.

TABLE 4—2024–2025 SCUP CATCH AND LANDING LIMITS *

Specifications	2024		2025	
	million lb	mt	million lb	mt
OFL	44.74	20,295	40.58	18,393
ABC	43.82	19,876	39.74	18,028

TABLE 4—2024–2025 SCUP CATCH AND LANDING LIMITS *—Continued

Specifications	2024		2025	
	million lb	mt	million lb	mt
Expected Commercial Discards	7.33	3,327	7.04	3,192
Expected Recreational Discards	2.15	977	2.07	937
Commercial ACL = ACT	28.48	12,919	25.83	11,718
Commercial Quota	21.15	9,592	18.80	8,526
Recreational ACL = ACT	15.34	6,957	13.91	6,310
RHL	13.18	5,980	11.84	5,373

* Some of the values in table 4 have been updated since the proposed rule (88 FR 80263, November 17, 2023) due to a minor calculation error.

The commercial scup quota is divided into three commercial fishery quota periods, as outlined in table 5.

TABLE 5—COMMERCIAL SCUP QUOTA ALLOCATIONS FOR 2024 BY QUOTA PERIOD

Quota period	Percent Share	lb	mt
Winter I	45.11	9,539,294	4,327
Summer	38.95	8,236,655	3,736
Winter II	15.94	3,370,790	1,529
Total	100.0	21,146,740	9,592

The current quota period possession limits are not changed by this action and are outlined in table 6.

TABLE 6—COMMERCIAL SCUP POSSESSION LIMITS BY QUOTA PERIOD

Quota period	Percent share	Federal possession limits (per trip)	
		lb	kg
Winter I	45.11	50,000	22,680
Summer	38.95	N/A	N/A
Winter II	15.94	12,000	5,443
Total	100.0	N/A	N/A

The Winter I scup commercial possession limit will drop to 1,000 lb (454 kg) when 80-percent of that period's allocation is landed. If the Winter I quota is not fully harvested, the remaining quota is transferred to Winter II. The Winter II possession limit may be adjusted (in association with a transfer of unused Winter I quota to the Winter II period) via notification in the **Federal Register**. The regulations specify that the Winter II possession limit increases consistent with the increase in the quota, as described in table 7.

TABLE 7—POTENTIAL INCREASE IN WINTER II POSSESSION LIMITS BASED ON THE AMOUNT OF UNUSED SCUP ROLLED OVER FROM WINTER I TO WINTER II

Initial Winter II possession limit		Rollover from Winter I to Winter II		Increase ininitial Winter II possession limit		Final Winter II possession limit after rollover from Winter I to Winter II	
lb	kg	lb	kg	lb	kg	lb	kg
12,000	5,443	0–499,999	0–226,796	0	0	12,000	5,443
12,000	5,443	500,000–999,999.	226,796–453,592.	1,500	680	13,500	6,123
12,000	5,443	1,000,000–1,499,999.	453,592–680,388.	3,000	1,361	15,000	6,804
12,000	5,443	1,500,000–1,999,999.	680,389–907,184.	4,500	2,041	16,500	7,484

TABLE 7—POTENTIAL INCREASE IN WINTER II POSSESSION LIMITS BASED ON THE AMOUNT OF UNUSED SCUP ROLLED OVER FROM WINTER I TO WINTER II—Continued

Initial Winter II possession limit		Rollover from Winter I to Winter II		Increase ininitial Winter II possession limit		Final Winter II possession limit after rollover from Winter I to Winter II	
lb	kg	lb	kg	lb	kg	lb	kg
12,000	5,443	*2,000,000–2,500,000.	907,185–1,133,981.	6,000	2,722	18,000	8,165

*This process of increasing the possession limit in 1,500 lb (680 kg) increments would continue past 2,500,000 lb (1,122,981 kg), but we end here for the purpose of this example.

This action makes no changes to the 2024 commercial management measures for scup, including the minimum fish size (9-inch (22.9-cm) total length), gear requirements, and quota period possession limits.

Federal Recreational Scup Closure

Through this action, we are removing the January 1–April 30 Federal recreational scup closure. Because of the timing of the recreational management measures discussions and rulemaking, it would not be possible to remove this closure prior to the January 1, 2024, start date of the closure outside of this rulemaking. At the December 2023 meeting, the Council and Board approved a 10-percent reduction in recreational scup harvest in 2024 and 2025. State waters measures, in addition to the 40-fish possession limit and 10-inch minimum size in Federal waters, will be developed to achieve the full reduction required. The Federal closure will not be needed to achieve the required reduction. Additionally, preliminary data on recreational scup harvest indicate that 2023 harvest is trending lower than 2022. Estimated scup harvest in waves 1 to 4 is 9.46 million lb (4,291 mt), which is 31-percent lower than scup harvest during the same time period in 2022. For these reasons, we have determined that the January 1–April 30 Federal recreational fishery closure can be removed through this action.

Comments and Responses

We received two comments on the proposed rule (88 FR 80263, November 17, 2023). One comment was not applicable to the proposed measures.

Comment 1: One comment supported the removal of the January–April 30 Federal recreational scup closure, citing a preference for changes in the possession limit or size limit instead of closed seasons.

Response: This action removes the Federal recreational scup closure.

Changes From the Proposed Rule

Table 4 in the proposed rule has been updated as several of the values were incorrect. The corrected numbers are shown in table 4 of this rule.

Classification

Pursuant to section 304(b)(3) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator has determined that this final rule is consistent with the Summer Flounder, Scup, and Black Sea Bass FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

The Assistant Administrator for Fisheries finds that the need to implement these measures in a timely manner constitutes good cause, under the authority contained in 5 U.S.C. 553(d)(3), to waive the 30-day delay in effective date of this action. This action implements 2024 specifications for the summer flounder, scup, and black sea bass fisheries. These specifications should be effective by the start of the fishing year on January 1, 2024, and must be published on or before December 31, 2023.

This rule is being issued at the earliest possible date. Preparation of the final rule is dependent on the analysis of commercial summer flounder landings for the prior fishing year (2022) and the current fishing year through October 31, 2023, to determine whether any overages have occurred and adjustments are needed to the final state quotas. This process is codified in the summer flounder regulations and, therefore, cannot be performed earlier. A proposed rule was published on November 17, 2023, with a public comment period through December 2, 2023. This final rule is being published as soon as possible. Annual publication of the summer flounder quotas prior to the start of the fishing year, by December 31, is required by Court Order in *North Carolina Fisheries Association* v. *Daley.*

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

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

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: December 15, 2023.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS amends 50 CFR part 648 as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. Revise § 648.127 to read as follows:

§ 648.127 Scup recreational fishing season.

Fishermen and vessels that are not eligible for a scup moratorium permit under § 648.4(a)(6), may possess scup from January 1 through December 31, subject to the possession limit specified in § 648.128(a). The recreational fishing season may be adjusted pursuant to the procedures in § 648.122. Should the recreational fishing season be modified, non-federally permitted scup vessels abiding by state regulations may transit with scup harvested from state waters on board through the Block Island Sound Transit Area following the provisions outlined in § 648.131.

[FR Doc. 2023–28090 Filed 12–20–23; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 88, No. 244
Thursday, December 21, 2023

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2395; Project Identifier AD–2023–00767–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–08–12, which applies to all The Boeing Company Model 757 airplanes. AD 2022–08–12 requires repetitive inspections for skin cracking and shim migration at the upper link drag fittings, diagonal brace cracking, and fastener looseness; and applicable on-condition actions. Since the FAA issued AD 2022–08–12, it was determined that certain drag fittings may be made of alternate materials, which could result in reduced structural integrity of the engine strut, and that additional inspections and revised compliance times are needed. This proposed AD would retain the requirements of AD 2022–08–12 with revised compliance times for certain actions and would add inspections for existing repairs and applicable on-condition actions. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by February 5, 2024.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–2395; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* by searching for and locating Docket No. FAA–2023–2395.

FOR FURTHER INFORMATION CONTACT: Wayne Ha, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 562–627–5238; email *wayne.ha@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–2395; Project Identifier AD–2023–00767–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Wayne Ha, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 562–627–5238; email *wayne.ha@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2022–08–12, Amendment 39–22015 (87 FR 26964, May 6, 2022) (AD 2022–08–12), for all The Boeing Company Model 757 airplanes. AD 2022–08–12 was prompted by reports of bolt rotation in the engine drag fitting joint and fastener heads and cracks found in the skin of the fastener holes, and the need to reduce the compliance time for certain groups. AD 2022–08–12 requires repetitive inspections for skin cracking and shim migration at the upper link drag fittings, diagonal brace cracking, and fastener looseness; and applicable on-condition actions. The FAA issued AD 2022–08–12 to address cracking in the wing upper skin and forward drag fittings, which could lead to a compromised upper link and reduced structural integrity of the engine strut, and possible separation of a strut and engine from the airplane during flight.

Actions Since AD 2022–08–12 Was Issued

Since the FAA issued AD 2022–08–12, it was determined that drag fittings made of alternate materials have possibly been installed on some configurations, which could result in reduced structural integrity of the engine strut. The FAA has determined that additional inspections and revised compliance times are needed to maintain structural integrity.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023. This service information specifies procedures for a general visual inspection or records check of the wing upper skin at the drag fitting attachment holes for any existing repair; repetitive general visual and detailed inspections for loose fasteners, skin cracking, and shim migration at the upper link drag fittings, and for cracking in the diagonal brace and diagonal brace fittings; repetitive open-hole high frequency eddy current (HFEC) inspections for cracking of the fastener holes and loose bolt holes; and applicable on-condition actions. On-condition actions include performing an ultrasonic inspection for cracks at any repaired upper wing skin location; installing the upper link and upper link pins; replacing drag fittings; installing bolts, washers, and nuts; performing a torque check of fasteners on the affected shims; trimming affected shims and applying chemical conversion coating on the shims, fillet seal, and drag fittings; and repairing cracks, migrated shims, mistorqued bolts, and loose fasteners.

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

Proposed AD Requirements in This NPRM

Although this proposed AD does not explicitly restate the requirements of AD 2022–08–12, this proposed AD would retain all of the requirements of AD 2022–08–12. Those requirements are referenced in the service information identified previously, which, in turn, is referenced in paragraph (g) of this proposed AD.

This proposed AD would require accomplishing the actions specified in the service information already described except for any differences identified as exceptions in the regulatory text of this proposed AD. For information on the procedures and compliance times, see this service information at *regulations.gov* under Docket No. FAA–2023–2395.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 496 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive HFEC inspections (retained actions from AD 2022-08-12).	85 work-hours × $85 per hour = $7,225 per inspection cycle.	$0	$7,225 per inspection cycle	$3,583,600 per inspection cycle.
New proposed actions	Up to 4 work-hours × $85 per hour = Up to $340.	0	Up to $340	Up to $168,640.

The FAA has received no definitive data on which to base the cost estimates for the on-condition actions specified in this proposed AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–08–12, Amendment 39–22015 (87 FR 26964, May 6, 2022), and

■ b. Adding the following new AD:

The Boeing Company: Docket No. FAA–2023–2395; Project Identifier AD–2023–00767–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by February 5, 2024.

(b) Affected ADs

This AD replaces AD 2022–08–12, Amendment 39–22015 (87 FR 26964, May 6, 2022) (AD 2022–08–12).

(c) Applicability

This AD applies to all The Boeing Company Model 757–200, 200PF, –200CB, and –300 series airplanes, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of bolt rotation in the engine drag fitting joint and fastener heads and cracks found in the skin of the fastener holes, a determination that certain drag fittings may be made of alternate materials, which could result in reduced structural integrity of the engine strut, and a determination that additional inspections and revised compliance times are needed. The FAA is issuing this AD to address cracking in the wing upper skin and forward drag fittings, which could lead to a compromised upper link and reduced structural integrity of the engine strut, and possible separation of a strut and engine from the airplane during flight.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 757–57A0073, Revision 3, dated May 5, 2023, which is referred to in Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023.

(h) Exceptions to Service Information Specifications

(1) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023, use the phrase ''the Original Issue date of Requirements Bulletin 757–57A0073 RB,'' this AD requires using ''September 10, 2018 (the effective date of AD 2018–16–05, Amendment 39–19345 (83 FR 38250, August 6, 2018))'' (AD 2018–16–05).

(2) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023, use the phrase ''the Revision 1 date of Requirements Bulletin 757–57A0073 RB,'' this AD requires using ''January 14, 2021 (the effective date of AD 2020–21–17, Amendment 39–21290 (85 FR 79418, December 10, 2020))'' (AD 2020–21–17).

(3) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023, use the phrase ''the Revision 2 date of Requirements Bulletin 757–57A0073 RB,'' this AD requires using ''June 10, 2022 (the effective date of AD 2022–08–12).''

(4) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023, use the phrase ''the Revision 3 date of Requirements Bulletin 757–57A0073 RB,'' this AD requires using the effective date of this AD.

(5) Where Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023, specifies contacting Boeing for repair instructions or for alternative inspections: This AD requires doing the repair, or doing the alternative inspections and applicable on-condition actions using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Credit for Previous Actions

(1) This paragraph provides credit for the actions specified in paragraph (g) of this AD, except for the open-hole high frequency eddy current inspections at fastener locations 11–18, if those actions were performed before January 14, 2021 (the effective date of AD 2020–21–17) using Boeing Alert Requirements Bulletin 757–57A0073 RB, dated July 14, 2017.

(2) This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before June 10, 2022 (the effective date of AD 2022–08–12) using Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 1, dated August 1, 2019.

(3) This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved for AD 2022–08–12 are approved as AMOCs for the corresponding provisions of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023, that are required by paragraph (g) of this AD, except for AMOCs approved for locations at the wing skin and drag fittings at the upper link drag fittings (fasteners 1–18).

(5) AMOCs approved for AD 2020–21–17 are approved as AMOCs for the corresponding provisions of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023, that are required by paragraph (g) of this AD, except for AMOCs approved for locations at the wing skin and drag fittings at the upper link drag fittings (fasteners 1–18).

(6) AMOCs approved for AD 2018–16–05 are approved as AMOCs for the corresponding provisions of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023, that are required by paragraph (g) of this AD, except for AMOCs approved for locations at the wing skin and drag fittings at the upper link drag fittings (fasteners 1–18).

(k) Related Information

(1) For more information about this AD, contact Wayne Ha, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 562–627–5238; email *wayne.ha@faa.gov.*

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

(l) Material Incorporated by Reference

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

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

(i) Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 3, dated May 5, 2023.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the

availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on December 14, 2023.

Victor Wicklund,

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

[FR Doc. 2023–28004 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2244; Project Identifier MCAI–2023–00972–R]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Leonardo S.p.a Model AW169 helicopters. This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the airworthiness limitations section (ALS) of the existing helicopter maintenance manual or instructions for continued airworthiness (ICA) for your helicopter and the existing approved maintenance or inspection program for your helicopter, as applicable, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by February 5, 2024.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–2244; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material that is proposed for incorporation by reference in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. The EASA material is also available at *regulations.gov* under Docket No. FAA–2023–2244.

Other Related Service Information: For Leonardo Helicopters service information identified in this NPRM, contact Leonardo S.p.A., Emanuele Bufano, Head of Airworthiness, Viale G. Agusta 520, 21017 C. Costa di Samarate (Va) Italy; telephone (+39) 0331–225074; fax (+39) 0331–229046; or at *customerportal.leonardocompany.com/en-US/.* You may also view this service information at the FAA contact information under *Material Incorporated by Reference* above.

FOR FURTHER INFORMATION CONTACT: Sungmo Cho, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (781) 238–7241; email: *Sungmo.D.Cho@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–2244; Project Identifier MCAI–2023–00972–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Sungmo Cho, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (781) 238–7241; email: *Sungmo.D.Cho@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, issued a series of ADs with the most recent being EASA AD 2023–0160, dated August 16, 2023 (EASA AD 2023–0160), to correct an unsafe condition for Leonardo S.p.A. Model AW169 helicopters.

This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is proposing this AD to address fatigue cracking, damage, and corrosion in principal structural elements.

You may examine the EASA AD in the AD docket at *regulations.gov* under Docket No. FAA–2023–2244.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0160 requires replacing components before exceeding their life limits and accomplishing maintenance tasks within thresholds

and intervals specified in the applicable ALS as defined in EASA AD 2023–0160. Depending on the results of the maintenance tasks, EASA AD 2023–0160 requires accomplishing corrective action(s) or contacting Leonardo [Leonardo S.p.a.] for approved instructions and accomplishing those instructions. EASA AD 2023–0160 also requires revising the Aircraft Maintenance Programme (AMP) by incorporating the limitations, tasks, and associated thresholds and intervals described in the specified ALS as applicable to the helicopter model and configuration. Revising the AMP constitutes terminating action for the requirement to record accomplishment of the actions of replacing components before exceeding their life limits and accomplishing maintenance tasks within the thresholds and intervals specified in the applicable ALS as required by EASA AD 2023–0160 for demonstration of AD compliance on a continued basis.

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

Other Related Service Information

The FAA also reviewed AW169 Air vehicle maintenance planning information, 69–A–AMPI–00–P, Chapter 04, ALS, Issue 21, dated July 7, 2023. This service information specifies airworthiness limitations, tasks, and associated thresholds and intervals for various parts, and specifies new or more restrictive airworthiness limitations for certain components installed on the tail rotor system.

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2023–0160, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between this Proposed AD and the EASA AD.''

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2023–0160 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2023–0160 through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2023–0160 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2023–0160. Service information referenced in EASA AD 2023–0160 for compliance will be available at *regulations.gov* under Docket No. FAA–2023–2244 after the FAA final rule is published.

Differences Between This Proposed AD and the EASA AD

EASA AD 2023–0160 requires replacing certain components before exceeding applicable life limits, accomplishing certain maintenance tasks within thresholds and intervals as specified in the ALS, as defined within, and depending on the results, accomplishing corrective action within the compliance time specified in that ALS. EASA AD 2023–0160 also requires revising the approved AMP to incorporate the limitations, tasks, and associated thresholds and intervals described in that ALS within 12 months after its effective date. Whereas, this proposed AD would require revising existing documents and programs within 30 days to incorporate the limitations, tasks, and associated thresholds and intervals described in that ALS, and clarifies that if an incorporated limitation or threshold therein is reached before 30 days after the effective date of the final rule of this proposed AD, you still have up to 30 days after the effective date of the final rule of this proposed AD to accomplish the corresponding task.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 10 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 proposed AD.

Revising the ALS of the existing helicopter maintenance manual or ICA for your helicopter and the existing approved maintenance or inspection program for your helicopter, as applicable, would take about 2 work-hours for an estimated cost of $170 per helicopter and $1,700 for the U.S. fleet.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Leonardo S.p.a.: Docket No. FAA–2023–2244; Project Identifier MCAI–2023–00972–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by February 5, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model AW169 helicopters, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6400, Tail rotor system.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address fatigue cracking, damage, and corrosion in principle structural elements. The unsafe condition, if not addressed, could result in failure of a part and loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0160, dated August 16, 2023 (EASA AD 2023–0160).

(h) Exceptions to EASA AD 2023–0160

(1) Where EASA AD 2023–0160 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the requirements specified in paragraphs (1), (2), (4), and (5) of EASA AD 2023–0160.

(3) Where paragraph (3) of EASA AD 2023–0160 specifies ''Within 12 months after the effective date of this AD, revise the approved AMP,'' this AD requires replacing those words with ''Within 30 days after the effective date of this AD, revise the airworthiness limitations section of your existing helicopter maintenance manual or instructions for continued airworthiness and your existing approved maintenance or inspection program, as applicable.''

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2023–0160 is on or before the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2023–0160, or within 30 days after the effective date of this AD, whichever occurs later.

(5) This AD does not adopt the Remarks paragraph of EASA AD 2023–0160.

(i) Provisions for Alternative Actions, Thresholds, and Intervals, Including Life Limits

No alternative actions and associated thresholds and intervals, including life limits, are allowed for compliance with paragraph (g) of this AD unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2023–0160.

(j) Special Flight Permit

Special flight permits are prohibited.

(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) 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

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (781) 238–7241; email: *Sungmo.D.Cho@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2023–0160, dated August 16, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0160, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*

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

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email: *fr.inspection@nara.gov.*

Issued on December 14, 2023.

Victor Wicklund,

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

[FR Doc. 2023–28037 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2245; Project Identifier MCAI–2023–00973–R]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Leonardo S.p.a Model AW189 helicopters. This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the airworthiness limitations section (ALS) of the existing helicopter maintenance manual or instructions for continued airworthiness (ICA) for your helicopter and the existing approved maintenance or inspection program for your helicopter, as applicable, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by February 5, 2024.

ADDRESSES: You may send comments, using the procedures found in 14 CFR

11.43 and 11.45, by any of the following methods:

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–2245; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material identified in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu*; internet *easa.europa.eu*. You may find the EASA material on the EASA website at *ad.easa.europa.eu*.
- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. The EASA material is also available at *regulations.gov* under Docket No. FAA–2023–2245.

Other Related Service Information: For Leonardo Helicopters service information identified in this NPRM, contact Leonardo S.p.A., Emanuele Bufano, Head of Airworthiness, Viale G. Agusta 520, 21017 C. Costa di Samarate (Va) Italy; telephone (+39) 0331–225074; fax (+39) 0331–229046; or at *customerportal.leonardocompany.com/en-US/*. You may also view this service information at the FAA contact information under *Material Incorporated by Reference* above.

FOR FURTHER INFORMATION CONTACT: Sungmo Cho, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (781) 238–7241; email: *Sungmo.D.Cho@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–2245; Project Identifier MCAI–2023–00973–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Sungmo Cho, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (781) 238–7241; email: *Sungmo.D.Cho@faa.gov*. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued a series of ADs with the most recent being EASA AD 2023–0161, dated August 16, 2023 (EASA AD 2023–0161), to correct an unsafe condition on Leonardo S.p.A. Model AW189 helicopters.

This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is proposing this AD to address fatigue cracking, damage, and corrosion in principal structural elements.

You may examine the EASA AD in the AD docket at regulations.gov under Docket No. FAA–2023–2245.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0161 requires replacing components before exceeding their life limits and accomplishing maintenance tasks within thresholds and intervals specified in the applicable ALS as defined in EASA AD 2023–0161. Depending on the results of the maintenance tasks, EASA AD 2023–0161 requires accomplishing corrective action(s) or contacting Leonardo [Leonardo S.p.a.] for approved instructions and accomplishing those instructions. EASA AD 2023–0161 also requires revising the Aircraft Maintenance Programme (AMP) by incorporating the limitations, tasks, and associated thresholds and intervals described in the specified ALS as applicable to the helicopter model and configuration. Revising the AMP constitutes terminating action for the requirement to record accomplishment of the actions of replacing components before exceeding their life limits and accomplishing maintenance tasks within the thresholds and intervals specified in the applicable ALS as required by EASA AD 2023–0161 for demonstration of AD compliance on a continued basis.

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

Other Related Service Information

The FAA also reviewed Leonardo AW189 document 89–A–AMPI–00–P, Air Vehicle Maintenance Planning Information, Chapter 4, Airworthiness Limitations, Issue 25, dated July 5, 2023, for helicopters equipped with General Electric CT7–2E1 engines. This service information specifies procedures for airworthiness limitations, tasks, and associated thresholds and intervals for various parts; including a new or more restrictive airworthiness limitation for a certain component installed in the main rotor gearbox.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all

known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2023–0161, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between this Proposed AD and the EASA AD.''

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2023–0161 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2023–0161 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2023–0161 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2023–0161. Service information referenced in EASA AD 2023–0161 for compliance will be available at regulations.gov under Docket No. FAA–2023–2245 after the FAA final rule is published.

Differences Between This Proposed AD and the EASA AD

EASA AD 2023–0161 requires replacing certain components before exceeding applicable life limits, accomplishing certain maintenance tasks within thresholds and intervals as specified in the ALS, as defined within, and depending on the results, accomplishing corrective action within the compliance time specified in that ALS. EASA AD 2023–0161 also requires revising the approved AMP to incorporate the limitations, tasks, and associated thresholds and intervals described in that ALS within 12 months after its effective date. Whereas, this proposed AD would require revising existing documents and programs within 30 days to incorporate the limitations, tasks, and associated thresholds and intervals described in that ALS, and clarifies that if an incorporated limitation or threshold therein is reached before 30 days after the effective date of the final rule of this proposed AD, you still have up to 30 days after the effective date of the final rule of this proposed AD to accomplish the corresponding task.

Additionally, EASA AD 2023–0161 requires using 89–E–AMPI–00–P Air Vehicle Maintenance Planning Information, Chapter 04, ALS Issue 09, dated July 5, 2023, for revising the ALS. This service information is applicable for helicopters equipped with SAFRAN ANETO–1K engines. This proposed AD would not allow this service information because that engine has not been FAA type-certificated for Model AW189 helicopters.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 4 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 proposed AD.

Revising the ALS of the existing helicopter maintenance manual or instructions for ICA for your helicopter and the existing approved maintenance or inspection program for your helicopter, as applicable, would take about 2 work-hours for an estimated cost of $170 per helicopter and $680 for the U.S. fleet.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Leonardo S.p.a.: Docket No. FAA–2023–2245; Project Identifier MCAI–2023–00973–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by February 5, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Leonardo S.p.a. Model AW189 helicopters, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6320, Main rotor gearbox.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address fatigue cracking, damage, and corrosion in principle structural elements. The unsafe condition, if not addressed, could result in failure of a part and loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0161, dated August 16, 2023 (EASA AD 2023–0161).

(h) Exceptions to EASA AD 2023–0161

(1) Where EASA AD 2023–0161 defines ''the ALS'' as ''Leonardo AW189 document 89–A–AMPI–00–P (Air Vehicle Maintenance Planning Information), Chapter 04, Airworthiness Limitations Section (ALS) Issue 025, applicable for helicopters equipped with General Electric (GE) CT7–2E1 engines; or document 89–E–AMPI–00–P (Air Vehicle Maintenance Planning Information), Chapter 04, ALS Issue 09, applicable for helicopters equipped with SAFRAN ANETO–1K engines.;'' for this AD, replace that definition with ''Leonardo AW189 document 89–A–AMPI–00–P, Air Vehicle Maintenance Planning Information, Chapter 4, Airworthiness Limitations, Issue 25, dated July 5, 2023 (for helicopters equipped with General Electric CT7–2E1 engines).''

(2) Where EASA AD 2023–0161 refers to its effective date, this AD requires using the effective date of this AD.

(3) This AD does not adopt the requirements specified in paragraphs (1), (2), (4), and (5) of EASA AD 2023–0161.

(4) Where paragraph (3) of EASA AD 2023–0161 specifies ''Within 12 months after the effective date of this AD, revise the approved AMP,'' this AD requires replacing those words with ''Within 30 days after the effective date of this AD, revise the airworthiness limitations section of your existing helicopter maintenance manual or instructions for continued airworthiness and your existing approved maintenance or inspection program, as applicable.''

(5) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2023–0161 is on or before the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2023–0161, or within 30 days after the effective date of this AD, whichever occurs later.

(6) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0161.

(i) Provisions for Alternative Actions, Thresholds, and Intervals, Including Life Limits

No alternative actions and associated thresholds and intervals, including life limits, are allowed for compliance with paragraph (g) of this AD unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2023–0161.

(j) Special Flight Permit

Special flight permits are prohibited.

(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) 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

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (781) 238–7241; email: *Sungmo.D.Cho@faa.gov*.

(m) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2023–0161, dated August 16, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0161, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu*; internet *easa.europa.eu*. You may find the EASA material on the EASA website at *ad.easa.europa.eu*.

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

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email: *fr.inspection@nara.gov*.

Issued on December 14, 2023.

Victor Wicklund,

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

[FR Doc. 2023–28034 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2431; Airspace Docket No. 23–AEA–26]

RIN 2120–AA66

Amendment of Class E Airspace; Ebensburg, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Ebensburg, PA. The FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the Revloc very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operating Network (MON) Program. This action will bring the airspace into compliance with FAA orders to support instrument flight rule (IFR) operations.

DATES: Comments must be received on or before February 5, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2431 and Airspace Docket No. 23–AEA–26 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instruction for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/*

publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it received on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or dely. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice (DOT/ALL–14FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing to amend 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface to within an 8.1-mile (increased from a 6.4-mile) radius of Ebensburg Airport, Ebensburg, PA; adding an extension within 4 miles each side of the 237° bearing from the airport extending from the 8.1-mile radius to 11.3 miles west of the airport; removing the exclusion area as it is no longer required; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the Revloc VOR as part of the VOR MON Program, to bring the airspace into compliance with current FAA orders, and to support IFR operations at this airport.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting

Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

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

* * * * *

AEA PA E5 Ebensburg, PA [Amended]

Ebensburg Airport, PA
(Lat. 40°27′41″ N, long. 78°46′31″ W)

That airspace extending upward from 700 feet above the surface within a 8.1-mile radius of Ebensburg Airport; and within 4 miles each side of the 237° bearing from the airport extending from the 8.1-mile radius to 11.3 miles west of the airport.

* * * * *

Issued in Fort Worth, Texas, on December 14, 2023.

Martin A. Skinner,

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

[FR Doc. 2023–27869 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2363 Airspace Docket No. 22–AAL–33]

RIN 2120–AA66

Revocation of Colored Federal Airway Amber 15 and Amendment of Alaskan Very High Frequency Omnidirectional Range Federal Airway V–428 in Alaska

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revoke Colored Federal airway Amber 15 (A–15) within United States (U.S.) airspace due to the pending decommissioning of the Nabesna, Sumner Strait, Haines, and Nichols Nondirectional Radio Beacons (NDB) in Alaska. Additionally, this action proposes to amend Alaskan Very High Frequency Omnidirectional Range (VOR) Federal Airway V–428 due to the pending decommissioning of the Haines NDB.

DATES: Comments must be received on or before February 5, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2363 and Airspace Docket No. 22–AAL–33 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/*. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific segment of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy*.

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Western Service Center, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Incorporation by Reference

Colored Federal airways are published in paragraph 6009 and Alaskan VOR Federal airways are published in paragraph 6010 of FAA

Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

In 2003, Congress enacted the Vision 100-Century of Aviation Reauthorization Act (Pub. L. 108–176), which established a joint planning and development office in the FAA to manage the work related to the Next Generation Air Transportation System (NextGen). Today, NextGen is an ongoing FAA-led modernization of the nation's air transportation system to make flying safer, more efficient, and more predictable.

In support of NextGen, this proposal is part of an ongoing, large, and comprehensive T-route modernization project in the state of Alaska. The project mission statement states: ''To modernize Alaska's Air Traffic Service route structure using satellite-based navigation development of new T-routes and optimization of existing T-routes will enhance safety, increase efficiency and access, and will provide en route continuity that is not subject to the restrictions associated with ground-based airway navigation.'' As part of this project, the FAA evaluated the existing Colored Airway structure for: (a) direct replacement (*i.e.,* overlay) with a T-route that offers a similar or lower Minimum En route Altitude (MEA) or Global Navigation Satellite System (GNSS) MEA; (b) the replacement of the colored airway with a T-route in an optimized but similar geographic area, while retaining similar or lower MEA; or (c) removal with no route structure (T-route) restored in that area because the value was determined to be insignificant.

The aviation industry/users have indicated a desire for the FAA to transition the Alaskan en route navigation structure away from dependency on NDBs and move to develop and improve the United States Area Navigation (RNAV) route structure.

Colored Federal airway A–15 extends between the Ethelda, British Columbia (BC), Canada, NDB and the Delta Junction, AK, NDB, excluding the airspace within Canada.

The decommissioning of the Nichols, Sumner Strait, and Haines NDBs in Alaska would render the segment of A–15 within U.S. airspace between the United Sates/Canadian border south of the Nichols NDB and the United States/Canadian border north of Haines NDB unusable. Mitigations to the loss of this segment are a combination of conventional airways and RNAV routes. Alternatives to the segment of A–15 between the United Sates/Canadian border and the Nichols NDB are nearby V–317 and V–309. Alternative routing between the Nichols NDB and the United States/Canadian border north of the Haines NDB, are V–317, T–266, and T–481. T–266 was developed for routing from the Nichols NDB to the Haines NDB and T–481 was developed for routing from Haines to the United States/Canadian border. T–266 and T–481 were developed to provide alternate routing in this area that avoids mountainous terrain and its associated weather by following the water channels along the Lynn Canal and Stephens Passage. This routing adds some mileage to the route but avoids the higher minimum enroute altitudes (MEA) and the dangers associated with overflying the mountain terrain.

The decommissioning of the Nabesna, AK, NDB, would render the northern segment of A–15 within U.S. airspace between the United States/Canadian border and the Delta Junction NDB unusable. The loss of this segment is mitigated by the existence of V–444, T–232, and T–372.

Alaskan VOR Federal Airway V–428 extends between the Biorka Island, AK, Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC) and Whitehorse, Yukon Territory (YT), Canada, VOR/distance measuring equipment (VOR/DME), excluding the airspace within Canada. With the decommissioning of the Haines NDB, a segment of V–428 would become unusable. The FAA is proposing to revoke the segment of V–428 between the Sisters Island, AK, VORTAC and Whitehorse, YT, Canada, VOR/DME within United States airspace. The loss of this airway is mitigated by an existing RNAV route, T–481, between the Sisters Island VORTAC and the Haines NDB, and T–266 between the Haines NDB and the United States/Canadian border.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to revoke Colored Federal airway A–15 in its entirety and amend Alaskan VOR Federal Airway V–428 due to the pending decommissioning of supporting Navigational Aids (NAVAID).

Colored Federal airway A–15 extends between the Ethelda, BC, Canada, NDB and the Delta Junction, AK, NDB, excluding the airspace within Canada. The FAA proposes to revoke Colored Federal airway A–15 in its entirety.

Alaskan VOR Federal Airway V–428 extends between the Biorka Island, AK, VORTAC and the Whitehorse, YT, Canada, VOR/DME, excluding the airspace within Canada. The FAA is proposing to revoke the segment of V–428 within U.S. airspace between the Sisters Island, AK, VORTAC and Whitehorse, YT, Canada, VOR/DME. As amended, V–428 would extend between the Biorka Island VORTAC and the Sisters Island VORTAC.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6009(c) Amber Federal Airways.

* * * * *

A–15 [Removed]

* * * * *

Paragraph 6010(b) Alaskan VOR Federal Airways.

* * * * *

V–428 [Amended]

From Biorka Island, AK; to Sisters Island, AK.

* * * * *

Issued in Washington, DC, on December 15, 2023.

Brian Konie,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023–28029 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2346 Airspace Docket No. 22–AAL–31]

RIN 2120–AA66

Revocation of Colored Federal Airway Amber 1 (A–1) in Alaska

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revoke Colored Federal airway Amber 1 (A–1) in Alaska due to the pending decommissioning of the navigational aids (NAVAID) that support the airway.

DATES: Comments must be received on or before February 5, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2346 and Airspace Docket No. 22–AAL–31 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/*. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy*.

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Western Service Center, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Incorporation by Reference

Colored Federal airways are published in paragraph 6009 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This

document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

In 2003, Congress enacted the Vision 100-Century of Aviation Reauthorization Act (Pub. L. 108–176), which established a joint planning and development office in the FAA to manage the work related to the Next Generation Air Transportation System (NextGen). Today, NextGen is an ongoing FAA-led modernization of the nation's air transportation system to make flying safer, more efficient, and more predictable.

In support of NextGen, this proposal is part of an ongoing, large, and comprehensive T-route modernization project in the state of Alaska. The project mission statement states: ''To modernize Alaska's Air Traffic Service route structure using satellite-based navigation development of new T-routes and optimization of existing T-routes will enhance safety, increase efficiency and access, and will provide en route continuity that is not subject to the restrictions associated with ground-based airway navigation.'' As part of this project, the FAA evaluated the existing Colored Airway structure for: (a) direct replacement (*i.e.,* overlay) with a T-route that offers a similar or lower Minimum En route Altitude (MEA) or Global Navigation Satellite System (GNSS) MEA; (b) the replacement of the colored airway with a T-route in an optimized but similar geographic area, while retaining similar or lower MEA; or (c) removal with no route structure (T-route) restored in that area because the value was determined to be insignificant.

The aviation industry/users have indicated a desire for the FAA to transition the Alaskan en route navigation structure away from dependency on Nondirectional Radio Beacons (NDB) and move to develop and improve the United States Area Navigation (RNAV) route structure.

Colored Federal airway A–1 extends between the Abbotsford, British Columbia (BC), Canada and Orca Bay, AK, NDBs; and between the Takotna River, AK, and Fort Davis, AK, NDBs, excluding the airspace within Canada. The Orca Bay, Ocean Cape, Sitka, Takotna River, North River, and Fort Davis NDBs are scheduled for decommissioning. The FAA is proposing to revoke Colored Federal airway A–1 in its entirety due to its supporting NAVAIDs being decommissioned.

The loss of the segment extending between the Abbotsford and Orca Bay NDBs is mitigated by Area Navigation (RNAV) route T–269 and Alaskan Very High Frequency Omnidirectional Range (VOR) Federal Airways V–319 and V–440.

The loss of the segment of extending between the Takotna River and Fort Davis NDBs is mitigated by Alaskan VOR Federal Airway V–440.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to revoke Colored Federal airway A–1 in Alaska due to the pending decommissioning of its supporting NAVAIDs.

Colored Federal airway A–1 extends between the Abbotsford, BC, Canada and Orca Bay, AK, NDBs and between the Takotna River, AK, and Fort Davis, AK, NDBs, excluding the airspace within Canada. The FAA proposes to revoke Colored Federal airway A–1 in its entirety.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6009(c) Amber Federal Airways.

* * * * *

A–1 [Removed]

* * * * *

Issued in Washington, DC, on December 15, 2023.

Brian Konie,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023–28033 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2432; Airspace Docket No. 23–AGL–39]

RIN 2120–AA66

Amendment of Class E Airspace; Mankato, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Mankato, MN. The FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the Mankato very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operating Network (MON) Program. The name of an airport would also be updated to coincide with the FAA's aeronautical database. This action will bring the airspace into compliance with FAA orders to support instrument flight rule (IFR) operations.

DATES: Comments must be received on or before February 5, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2432 and Airspace Docket No. 23–AGL–39 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instruction for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it received on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or dely. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice (DOT/ALL–14FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraphs 6002 and 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing to amend 14 CFR part 71 by:

Modifying the Class E surface airspace at Mankato Regional Airport, Mankato, MN, by removing the Mankato VOR/DME and associated extensions from the airspace legal description; and replacing the outdated terms ''Notice to Airmen'' and ''Airport Facility/Directory'' with ''Notice to Air Missions'' and ''Chart Supplement'';

And modifying the Class E airspace extending upward from 700 feet above the surface to within a 6.7-mile (decreased from a 7-mile) radius of Mankato Regional Airport; removing the extensions to the northeast and north of the airport from the airspace legal description as they are no longer needed; adding an extension 1.9 miles each side of the 155° bearing from the Mankato RGNL: RWY 33–LOC extending from the 6.7-mile radius to 11.1 miles southeast of the airport; adding an extension 2 miles each side of the 227° bearing from the Mankato Regional Airport extending from the 6.7-mile radius to 11 miles southwest of the airport; and updating the name of Mayo Clinic Health System-Mankato (previously Immanuel-St. Joseph's Hospital) to coincide with the FAA's aeronautical database.

The FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the Mankato VOR as part of the VOR

MON Program and to support IFR operations.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area.

* * * * *

AGL MN E2 Mankato, MN [Amended]

Mankato Regional Airport, MN
(Lat. 44°13′22″ N, long. 93°55′10″ W)

Within a 4.2-mile radius of Mankato Regional Airport. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective dates and times will thereafter be continuously published in the Chart Supplement.

* * * * *

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

* * * * *

AGL MN E5 Mankato, MN [Amended]

Mankato Regional Airport, MN
(Lat. 44°13′22″ N, long. 93°55′10″ W)
Mankato RGNL: RWY 33–LOC
(Lat. 44°14′22″ N, long. 93°55′35″ W)
Mayo Clinic Health Systems-Mankato, MN, Point In Space Coordinates
(Lat. 44°09′48″ N, long. 93°57′40″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Mankato Regional Airport; and within 1.9 miles each side of the 155° bearing from the Mankato RGNL: RWY 33–LOC extending from the 6.77-mile radius to 11.1 miles southeast of Mankato Regional Airport; and within 2 miles each side of the 227° bearing from the Mankato Regional Airport extending from the 6.7-mile radius to 11 miles southwest of the Mankato Regional Airport; and within a 6-mile radius of the point in space serving Mayo Clinic Health Systems-Mankato.

* * * * *

Issued in Fort Worth, Texas, on December 18, 2023.

Martin A. Skinner,

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

[FR Doc. 2023–28089 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2466; Airspace Docket No. 23–ACE–6]

RIN 2120–AA66

Amendment of VOR Federal Airway V–220 and Revocation of VOR Federal Airways V–79 and V–380 in the Vicinity of Hastings, NE

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Very High Frequency Omnidirectional Range (VOR) Federal Airway V–220 and revoke VOR Federal Airways V–79 and V–380. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Hastings, NE (HSI), VOR/Distance Measuring Equipment (VOR/DME) navigational aid (NAVAID). The Hastings VOR is being decommissioned in support of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before February 5, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2466 and Airspace Docket No. 23–ACE–6 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs,

describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the National Airspace System as necessary to preserve the safe and efficient flow of air traffic.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

VOR Federal Airways are published in paragraph 6010(a) of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning to decommission the VOR portion of the Hastings, NE, VOR/DME in September 2024. The Hastings VOR is one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the Final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** on July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082.

Although the VOR portion of the Hastings VOR/DME is planned for decommissioning, the co-located DME portion of the NAVAID is being retained to support current and future NextGen PBN flight procedure requirements.

The VOR Federal Airways affected by the planned decommissioning of the Hastings VOR are V–79, V–220, and V–380. With the planned decommissioning of the Hastings VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected airways. As such, proposed modifications to V–220 would result in the airway segments supported by the Hastings VOR being removed and to V–79 and V–380 would result in the airways being revoked.

To address the proposed amendment and revocation actions to the affected airways, instrument flight rules (IFR) traffic could use adjacent VOR Federal Airways V–6, V–8, or V–38, or request radar vectors from air traffic control (ATC) to fly around or through the affected area. Additionally, pilots with Area Navigation (RNAV) equipped aircraft could also navigate using RNAV routes T–286, T–413, and T–468, or navigate point-to-point using the existing fixes that would remain in place to support continued operations though the affected area. Visual flight rules pilots who elect to navigate via the affected VOR Federal Airways could also take advantage of the adjacent airways or routes, or the ATC services listed previously.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend VOR Federal Airway V–220 and revoke VOR Federal Airways V–79 and V–380 due to the planned decommissioning of the VOR portion of the Hastings, NE, VOR/DME. The proposed airway actions are described below.

V–79: V–79 currently extends between the Hastings, NE, VOR/DME and the Lincoln, NE, VOR/Tactical Air Navigation (VORTAC). The FAA proposes to remove the airway in its entirety.

V–220: V–220 currently extends between the Grand Junction, CO, VOR/DME and the Columbus, NE, VOR/DME. The FAA proposes to remove the airway segment between the Kearney, NE, VOR and the Columbus VOR/DME. As amended, the airway would be changed to extend between the Grand Junction VOR/DME and the Kearney VOR.

V–380: V–380 currently extends between the Grand Island, NE, VOR/DME and the Mankato, KS, VORTAC. The FAA proposes to remove the airway in its entirety.

The NAVAID radials listed in the V–220 description in the proposed regulatory text of this NPRM are unchanged and stated in degrees True north.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant

preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–79 [Removed]

* * * * *

V–220 [Amended]

From Grand Junction, CO; INT Grand Junction 075° and Rifle, CO, 163° radials; Rifle; Meeker, CO; Hayden, CO; Kremmling, CO; INT Kremmling 081° and Gill, CO, 234° radials; Gill; Akron, CO; INT Akron 094° and McCook, NE, 264° radials; McCook; INT McCook 072° and Kearney, NE, 237° radials; to Kearney.

* * * * *

V–380 [Removed]

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Issued in Washington, DC, on December 15, 2023.

Brian Konie,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023–28031 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2023–2371; Airspace Docket No. 22–ANM–42]

RIN 2120–AA66

Establishment of Restricted Area R–4601 in the Vicinity of Townsend, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish restricted area R–4601 in the vicinity of Townsend, MT. The new restricted area would provide the Montana Army National Guard (MTARNG) and the 40th Helicopter Squadron with the ability to conduct aerial gunnery training.

DATES: Comments must be received on or before February 5, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2371 and Airspace Docket No. 22–ANM–42 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish restricted area airspace over the MTARNG Limestone Hills Training Area near Townsend, MT.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal

information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Western Service Center, Operations Support Group, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Background

The MTARNG submitted a proposal to the FAA to establish a new restricted area, R–4601, over the Limestone Hills Training Area (LHTA) near Townsend, MT, to support aerial gunnery training requirements. Currently, the LHTA consists of multiple surface-to-surface live-fire weapons ranges that are contained within a Controlled Firing Area (CFA); however aerial gunnery live-fire is not authorized within a CFA. Hazardous activities, such as aerial gunnery, are required to be contained within a restricted area. Restricted areas are designated pursuant to 14 CFR part 73 rulemaking procedures to contain activities that may present a hazard to nonparticipating aircraft.

The proposed restricted area would provide a training capability to the MTARNG in preparation for combat deployments and also the 40th Helicopter Squadron located at Malmstrom Air Force Base (AFB) in support of security operations.

The United States Air Force's Global Strike Command (AFGSC) is tasked to provide armed helicopters in support of Malmstrom AFB missile field security operations. These helicopter units require an aerial gunnery range within one flight duty period (FDP) of their permanent bases to effectively and efficiently qualify and remain proficient in aerial gunnery operations. The LHTA is the only existing facility within one FDP with the possibility to support this training requirement. LHTA is located approximately 75 nautical miles from Malmstrom AFB.

The MTARNG aviation rotary wing assets would utilize the proposed restricted area to conduct day and night aerial gunnery training on an annual basis at a minimum, to increase and maintain their operational readiness. The MTARNG aviation units would schedule the proposed restricted area for approximately 40 training events (20 days, 20 nights) per year with each training event lasting over a six-hour period of time.

The 40th Helicopter Squadron is tasked with ensuring strategic security for Malmstrom AFB by providing flexible, rapid-response helicopter airlift and security support to the 341st Missile Wing. The 40th Helicopter Squadron would schedule the proposed restricted area for approximately 60 aerial training events (30 days, 30 nights) per year with each training event lasting over a four-to-six-hour period of time.

The use of the proposed restricted area could vary due to weather, unit requirements, or scheduling conflicts.

The Proposal

The FAA is proposing an amendment to 14 CFR part 73 to establish R–4601 over the Limestone Hills Training Area in the vicinity of Townsend, MT. This action would be used to contain hazardous aerial gunnery activities. The proposed restricted area is described below.

R–4601: The proposed restricted area would extend upward from the surface of the ground to 9,000 Mean Sea Level (MSL). The restricted area would be located approximately four miles west of the Townsend Airport, MT (8U8) and extend approximately eight miles to the southwest. The restricted area would be activated by a Notice to Air Missions (NOTAM) to inform nonparticipants when the proposed restricted area is active. During periods when the restricted area airspace is not needed by the using agency for its designated purpose, the airspace will be returned to the controlling agency for access by other National Airspace System users. The controlling agency for this proposed restricted area would be the Salt Lake City Air Route Traffic Control Center.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for 14 CFR part 73 continues to read as follows:

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

§ 73.46 Montana (MT) [New]

■ 2. Section 73.46 is amended as follows:

R–4601 Townsend, MT [New]

Boundaries. Beginning at lat. 46°19′12″ N, long. 111°38′00″ W; to lat. 46°20′10″ N, long. 111°34′00″ W; to lat. 46°17′30″ N, long. 111°32′10″ W; to lat. 46°13′30″ N, long. 111°32′10″ W; to lat. 46°13′30″ N, long. 111°38′00″ W; to the point of beginning.

Designated altitudes. Surface to 9,000 feet MSL.

Time of designation. By NOTAM.

Controlling agency. FAA, Salt Lake City ARTCC.

Using agency. U.S. Army, Montana Army National Guard, Joint Forces Headquarters, Fort Harrison, MT.

* * * * *

Issued in Washington, DC, on December 15, 2023.

Brian Konie,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023–28030 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 656

RIN 1205–AC16

Labor Certification for Permanent Employment of Foreign Workers in the United States; Modernizing Schedule A To Include Consideration of Additional Occupations in Science, Technology, Engineering, and Mathematics (STEM) and Non-STEM Occupations

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Request for information.

SUMMARY: The Department of Labor's (Department or DOL) Employment and Training Administration (ETA) is considering revisions to Schedule A of the permanent labor certification process to include occupations in Science, Technology, Engineering and Mathematics (STEM) and other non-STEM occupations and invites employers and other interested parties to comment on this Request for Information (RFI). ETA's Office of Foreign Labor Certification developed this RFI and is publishing it for comment so that the public may provide input, including data, statistical metrics or models, studies, and other relevant information, on how the Department may establish a reliable, objective, and transparent methodology for revising Schedule A to include STEM and other non-STEM occupations that are experiencing labor shortages, consistent with requirements of the Immigration and Nationality Act (INA). The Department wants to ensure that it is striking an appropriate balance between the need to provide U.S. workers notice of available permanent job opportunities and the opportunity to apply for those job opportunities, and, where insufficient U.S. workers are available to satisfy an employer's need for permanent labor, the need to provide employers access to foreign labor through effective administration of the permanent labor certification program. Information received from the public will help inform decisions regarding whether or how to improve Schedule A and ensure that its purpose in responding to national labor shortages is more effectively met.

DATES: Submit written comments on or before February 20, 2024.

ADDRESSES: You may submit written comments electronically by the following method:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions on the website for submitting comments.
- *Instructions:* Include the docket number ETA–2023–0006 in your comments. All comments received will be posted without change to *https://www.regulations.gov.* Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

FOR FURTHER INFORMATION CONTACT: For further information, contact Brian Pasternak, Administrator, Office of Foreign Labor Certification, Employment and Training Administration, Department of Labor, 200 Constitution Avenue NW, N–5311, Washington, DC 20210; Telephone (202) 513–7350 (this is not a toll-free number). For persons with a hearing or speech disability who need assistance to use the telephone system, please dial 711 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION:

I. Legal Framework

Section 212(a)(5)(A) of the INA, 8 U.S.C. 1182(a)(5)(A), deems inadmissible certain foreign nationals who seek to enter the United States for purposes of employment, unless the Secretary of Labor first certifies that: (1) there are insufficient U.S. workers at the place where the foreign worker would be employed who are able, willing, qualified and available for the job the foreign worker seeks; and (2) employment of the foreign worker would not adversely affect the wages and working conditions of U.S. workers in similar jobs.[1]

In an effort to address the workforce needs of employers at a time when the U.S. economy was rapidly expanding, the Department first established a mechanism in the mid-1960s by regulation for pre-certifying job vacancies of occupations for which U.S. workers were in short supply nationwide, which became known as Schedule A of the permanent labor certification program.[2] Schedule A is set forth in the Department's permanent labor certification regulations at 20 CFR 656.5 and enumerates a list of occupations for which the Department has predetermined that the statutory requirements have been met. The occupations currently listed in Schedule A are divided into two groups. Group I consists of physical therapists and professional nurses; Group II consists of occupations that require foreign workers to possess exceptional ability in the sciences, arts, or performing arts.[3] An employer seeking to hire foreign nationals in shortage occupations on Schedule A is able to forego the need to test the labor market normally required under the Department's process for permanent labor certification, is able to bypass filing an application for permanent employment certification with the Department, and instead files an uncertified application for permanent employment certification directly with U.S. Citizenship and Immigration Services (USCIS) at the time the employer files its immigrant visa petition, or *Immigrant Petition for Alien Workers,* Form I–140.[4]

II. Background

Schedule A was proposed in 1965 by the Secretary of Labor via rulemaking modifying then 29 CFR 60.2: ''Certification and noncertification schedules. (a) Determination. To reduce the delay in processing an alien's request for visa, the determination has been made by the Secretary of Labor pursuant to section 212(a)(14) that: (1) For the categories of employment described in Schedule A and in the geographic areas therein set forth, there are not sufficient workers who are able, willing, qualified, and available for employment in such categories, and the employment of aliens in such categories and in such areas will not adversely affect the wages and working conditions of workers in the United States similarly employed.'' [5] Historically, the post-1965 permanent labor certification program, by design, relied on labor market statistics compiled by state employment service offices. The Department used that information as the basis for Schedule A. In the 1960s and 1970s, Schedule A was the product of an extensive process of economic and labor market analysis of employment demand and supply by the Department. Schedule A occupations were later identified through the application of multiple factors, including unemployment rates; occupational

[1] *See also* 20 CFR 656.1 and 656.2.

[2] *See* 30 FR 14979 (Dec. 3, 1965) (publishing initial Schedule A).

[3] *See* 20 CFR 656.5(b) and 656.15(d); *see also See* Final Rule, *Labor Certification Process for the Permanent Employment of Aliens in the United States,* 42 FR 3440 (Jan. 18, 1977), *available at https://www.dol.gov/sites/dolgov/files/OALJ/PUBLIC/INA/REFERENCES/FEDERAL_REGISTER/42_FED._REG._3440_(JAN._18,_1977).PDF* (establishing the initial framework for Group II).

[4] *See* 8 CFR 204.5(k)(4)(i); 8 CFR 204.5(l)(3)(i); *see also* 20 CFR 656.15.

[5] Notice of Proposed Rulemaking, *Availability of and Adverse Effect Upon American Workers,* 30 FR 14494, 14494 (Nov. 19, 1965), *available at https://www.govinfo.gov/content/pkg/FR-1965-11-19/pdf/FR-1965-11-19.pdf.*

projections; evidence submitted by trade associations, employers and organized labor; and technical reviews by Federal and State staff with expertise in these areas.[6] The occupational listings in the Schedule were reviewed and modified at regular intervals to reflect changing economic and labor market conditions and to prevent adverse effects on the wages or working conditions of U.S. workers. Schedule A has been revised eight times, the last time in 2004.[7] The most recent revisions to Schedule A listings in 2004 only added foreign workers of exceptional ability in the performing arts to Group II; the other revision in 2004 was procedural and clarified the professional qualifications for eligible nurses under Schedule A.[8] Some comments requesting the expansion of Schedule A listings in 2004 were rejected because the suggestions exceeded the scope of the proposal.

In part because Schedule A has not been comprehensively examined or modified in approximately three decades, and in part because Schedule A by definition allows employers to bypass filing an application for a labor certification, the Department does not have comprehensive data on how employers utilize Schedule A and the types of work performed thereunder.

In order to help gather evidence about how to determine whether to expand or alter Schedule A, the Department is seeking information from the public that will help inform this decision. In this RFI, the Department provides an overview of key research, data, and trends related to STEM occupations. We also welcome comments from the public on non-STEM occupations, including those that may be related to but not traditionally considered STEM occupations as well as those that are outside of the STEM arena but nonetheless may also face labor shortages.

Anecdotal evidence and industry research suggest that economic and labor market conditions have changed for certain industries and occupations that rely on foreign workers and various visa programs, especially in the area of STEM occupations, including occupations in the field of artificial intelligence (AI).[9] In particular, jobs in the STEM fields often require a bachelor's degree or higher, leaving few opportunities for workers younger than 25 who do not have a bachelor's degree.[10] As a result, in 2021, workers between the ages of 16 and 24 made up 12.7 percent of total employment across all occupations but only 6.8 percent of all STEM workers in the United States.[11] STEM opportunities for young workers without a college degree do exist, but they mostly fall in technician occupations. Technician jobs are an important part of meeting future demand, but they do not address the demand for jobs which require a Bachelor's degree or higher. For instance, workers in that age group accounted for 21.8 percent of all life, physical and social science technicians in the United States. A smaller percentage of younger workers held STEM jobs as life scientists (4 percent) or social scientists (2.1 percent).[12] Within the various technician-related occupations approximately 15 percent of workers in this age group were employed as agricultural and food science technicians, biological technicians or chemical technicians with another 8 percent serving as environmental science and geoscience technicians.[13] Under several Administrations, efforts have been and are presently being made at various levels, as a result of federal government, state government, and industry and non-profit initiatives, to attract and train young workers as technicians in STEM fields, such as through Registered Apprenticeship programs provided by the Department's Apprenticeship USA program and nonprofit organizations and by community colleges.[14]

While ETA is familiar with the BLS's Occupational Employment Wage Statistics (OEWS) data and Employment Projections data,[15] as well as the U.S. Census Bureau's (Census Bureau) American Community Survey (ACS) data and Current Population Survey (CPS) data, these data sources alone do not appear to be sufficient for determining appropriate revisions to Schedule A. None of the datasets of OEWS, CPS, and ACS or projections is designed to identify potential labor shortages, as identifying such shortages requires knowing about labor demand, labor supply, and how they interact. However, employment surveys or projections cannot indicate unmet demand because they only record the demand that has been met.[16]

Over the last decade, the federal government has taken steps toward diversifying the pipeline of STEM talent in the United States, primarily supporting STEM education opportunities for historically underrepresented groups in these fields.[17] According to the U.S. Government Accountability Office,[18] the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act (COMPETES Act) was passed with the overall goal of increasing federal investment in scientific research to improve U.S. economic competitiveness and increased support for education in STEM fields.[19] The COMPETES Act was signed into law on August 9, 2007. The COMPETES Act authorized various

[6] *See* Proposed Rule, *Labor Certification Process for the Permanent Employment of Aliens in the United States; Labor Market Information Pilot Program,* 58 FR 15242, 15242 (Mar. 19, 1993), *available at https://www.govinfo.gov/content/pkg/FR-1993-03-19/pdf/FR-1993-03-19.pdf.*

[7] *See, e.g.,* 31 FR 16412 (Dec. 23, 1966), 33 FR 12808 (Sept. 10, 1968), 36 FR 2462 (Feb. 4, 1971), 42 FR 3440 (Jan. 18, 1977), 45 FR 83933 (Dec. 19, 1980), 52 FR 20593 (June 2, 1987), 56 FR 54920 (Oct. 23, 1991), and 69 FR 77326 (Dec. 27, 2004).

[8] 69 FR 77326, 77333.

[9] On October 30, 2023, President Joseph R. Biden Jr. issued the *Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence* (AI E.O.), which defines AI at section 3(b). E.O. 14110, 88 FR 75191, 75193 (Nov. 1, 2023), *available at https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence.*

[10] *See* Laughlin, L. *et al.,* Who Are the STEM Workers Under Age 25?: Technician Is A Common Job Among Young STEM Workers, U.S. Census Bureau (Nov. 22, 2022), *available at https://www.census.gov/library/stories/2022/11/stem-workers-under-age-25.html.*

[11] *See id.*

[12] *See id.*

[13] *See id.*

[14] *See, e.g.,* Daniel Kuh, Ian Heckler and Alphonse Simeon, Registered Apprenticeship in Science and Engineering (May 2019), *available* at *https://www.urban.org/sites/default/files/publication/100390/registered_apprenticeship_in_science_and_engineering.pdf, and* U.S. Department of Labor, Apprenticeship USA, *available* at *https://www.apprenticeship.gov/events/diversity-stem-session-iv-innovation-today-and-tomorrow.*

[15] A complete list of OEWS occupations included in the STEM definition by the Bureau of Labor Statistics (BLS) is available at *https://www.bls.gov/oes/stem_list.xlsx;* however, different studies, research, and sources referenced herein might construe the definition of a STEM occupation more narrowly or more broadly than BLS. *See, e.g.,* Bureau of Labor Statistics, Standard Occupational Classification, About 2018 SOC System, Options for Defining STEM Occupations Under the 2018 SOC, Attachments B and C, *available at https://www.bls.gov/soc/Attachment_B_STEM_2018.pdf* and *https://www.bls.gov/soc/Attachment_C_STEM_2018.pdf.*

[16] *See* Ass'n of Science and Technology Centers, U.S. Federal Agencies and STEM Engagement, *available at https://www.astc.org/impact-initiatives/advocacy/federal-agencies/.*

[17] *See* U.S. Gov't Accountability Office, Diversifying the Pipeline of STEM Talent (Jun. 18, 2018), available at *https://www.gao.gov/blog/2018/06/19/diversifying-the-pipeline-of-stem-talent#:~:text=Over%20the%20last%20decade%2C%20the%20federal%20government%20has,opportunities%20for%20historically%20underrepresented%20groups%20in%20these%20fields.*

[18] *See* U.S. Gov't Accountability Office, America COMPETES Act: It Is Too Early to Evaluate Programs Long-Term Effectiveness, but Agencies Could Improve Reporting of High-Risk, High-Reward Research Priorities (Oct. 7, 2010), *available at https://www.gao.gov/products/gao-11-127r.*

[19] *See* 42 U.S.C. 6621.

programs at the National Science Foundation (NSF) and the Departments of Energy, Commerce, and Education intended to strengthen STEM education and research in the United States. Since its inception, the COMPETES Act has been reauthorized numerous times as various organizations have discovered that the United States's competitiveness in STEM education has deteriorated relative to advances by other countries. The most recent reauthorization, which took place in 2022, added several provisions to strengthen and expand the U.S. STEM workforce and ensure that it more accurately reflects the diversity of the nation.[20]

The Department notes that various articles and studies have been written and conducted outlining reasons why there has been a STEM shortage in the United States including: a lack of interest in STEM occupations, a STEM branding problem with younger generations, and employers' lack of access to foreign talent.[21]

Executive Order 13806, published in 2017, directs the Secretary of Defense to conduct a government-wide risk analysis of manufacturing and the defense industrial base and propose recommendations to improve economic and national security.[22] In 2021, the U.S. Department of Defense (DOD) assessed the macroeconomic forces affecting the U.S. industrial base in response to Executive Order 13806 and outlined several problems, included diminishing STEM education.[23] DOD found that the United States is graduating fewer students with STEM degrees as a percentage of population compared to China and that the United States no longer has the most STEM graduates worldwide, as it is being rapidly outpaced by China.[24] The report also noted that, as of 2017, American students made up approximately 21 percent of the computer science student body and 19 percent of electrical engineering majors among the nation's universities. In support of the DOD's conclusion that STEM-focused sectors are struggling to attract and retain top-tier technical talent from the United States,[25] data from the National Science Board (NSB) reveals that more than one-half of all graduates of engineering, computer science, and mathematics doctoral programs at U.S. universities are foreign-born, as universities are turning to foreign students to address a shortfall of U.S. candidates for those programs.[26] Many of these foreign-born, U.S.-educated and trained students entering the U.S. workforce have become U.S. permanent residents or U.S. citizens, leading the NSB to conclude that ''immigration represents a key component to building the capacity of the U.S. STEM workforce.'' [27]

Subsequently, a non-profit organization, produced an analysis of data from the Census Bureau stating that foreign-born STEM workers have made important contributions to the U.S. economy in terms of productivity and innovation.[28] Its research found that, as the demand for STEM workers continues to increase, foreign-born STEM workers will likely continue to complement the U.S. workers and play a key role in U.S. productivity and innovation.[29]

At the same time that the U.S. has shown greater reliance on foreign workers and foreign-born U.S.-educated workers, the U.S. is undergoing significant demographic changes indicating that the U.S. faces many challenges in supplying its own domestic STEM workforce. In 2017, a scientific journal determined that the U.S. had seen significant demographic trends with an aging STEM workforce that saw a decline in scientists ages 35 to 53 and a rise in scientists older than 53 between 1993 and 2010.[30] The report points out that during the same time period the average age of the scientific workforce increased from 45.1 to 48.6, whereas the average age of the general workforce only increased from 42.2 to 45.4, indicating that the STEM workforce is both older and is aging more rapidly.[31] Private sector studies have found that, as the ''baby boomer'' generation moves into retirement, millennials [32] will compose the largest share of the labor market. Millennials, however, are not showing an increased tendency to major in high-demand areas of STEM fields despite a higher proportion of this population choosing to attend college.[33] These studies suggest that younger generations trail older generations in choosing STEM majors, except for computer and information services, instead disproportionately choosing to major in business, health professions, and visual and performing arts compared to older generations.[34]

According to BLS data of job openings, hires, separations, and total employment in the United States, employment growth is projected to slow

[20] *See id.; see also* Public Law 111–358, title I, sec. 101, 124 Stat. 3984 (Jan. 4, 2011), Public Law 114–329, title III, sec. 304 (Jan. 6, 2017); and Public Law 117–167, div. B, title V, sec. 10522(e) (Aug. 9, 2022).

[21] *See, e.g.,* Weiner, B., Why the U.S. Has a STEM Shortage and How We Fix it (Part 1), Recruiting Daily (Nov. 6, 2018), *available at https://recruitingdaily.com/why-the-u-s-has-a-stem-shortage-and-how-we-fix-it-part-1/* and Pagllieri, G., STEM Hiring Trends in 2022: What Employers Need to Know, Randstad (Feb. 8, 2022), *available at https://www.randstadusa.com/business/business-insights/future-workplace-trends/stem-hiring-trends-2022-what-employers-need-to/.*

[22] Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States, 82 FR 34597 (Jul. 21, 2017), *available at https://www.federalregister.gov/documents/2017/07/26/2017-15860/assessing-and-strengthening-the-manufacturing-and-defense-industrial-base-and-supply-chain.*

[23] *See* Fiscal Year 2020 Industrial Capabilities Report, Dept. of Defense (January 14, 2021), p. 13, *available at https://www.defense.gov/News/Releases/Release/Article/2472854/dod-releases-industrial-capabilities-report/.*

[24] *Id.* at p. 102. *See also id.* at p. 15 (''Ultimately, the most important asset [the U.S.] defense industrial base possesses isn't machines or facilities, but people. America needs an ambitious effort, like the Eisenhower National Defense Education Act, to support education and training for manufacturing skills required to meet DoD and wider U.S. requirements. As the Industrial Capabilities Report notes, while China has four times the U.S. population, it has eight times as many STEM grads, while Russia has almost four times more engineers than the United States. [The United States has] lost ground also in many equally important touch labor industrial skills sets.'')

[25] *Id.* at pp. 86 (''Promising STEM and trade-skill oriented personnel are leaving the sector industry for other occupations. Individuals with these skills are becoming harder to recruit and retain due to barriers of pay, location, and cyclical sector demand.'') and 113 (''In keeping with priorities articulated by executives, workforce-related efforts undertaken by the U.S. Services due to the coronavirus pandemic focused on *retaining* rather than growing or enhancing the industrial workforce.'')

[26] *See* The STEM Workforce of Today: Scientists, Engineers, and Skilled Technical Workers, National Science Board (Aug. 31, 2021), at p. 72, *available at https://ncses.nsf.gov/pubs/nsb20212/assets/nsb20212.pdf.*

[27] *Id.* at p. 9.

[28] *See* Fact Sheet, Foreign-Born Workers in the United States, American Immigration Council (Jun. 14, 2022), *available at https://www.americanimmigrationcouncil.org/research/foreign-born-stem-workers-united-states.*

[29] *Id.* (citing microdata from the U.S. Census Bureau's 2000, 2010, and 2019 American Community Surveys).

[30] *See* Blau, David M. and Weinberg, Bruce A., Why the U.S. Science and Engineering Workforce Is Again Rapidly, Proceedings of the Nat'l Academy of Sciences of the United States of America (Apr. 11, 2017), pp. 3379–84, *available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5393244/pdf/pnas.201611748.pdf* (citing data from the 1993–2010 Surveys of Doctorate Recipients of the National Science Foundation, *available at https://nsf.gov/statistics/srvydoctoratework/*).

[31] *Id.* at p. 3380.

[32] *See* Dimock, M., Defining Where Millennials End and Generation Z Begins, Pew Research Center (Jan. 17, 2019), *available at https://www.pewresearch.org/fact-tank/2019/01/17/where-millennials-end-and-generation-z-begins/.*

[33] *See* Deloitte Insights, Issues By the Numbers, A New Understanding of Millennials: Generational Differences Reexamined, Deloitte Univ. Press (Oct. 2015), p. 2, *available at https://www2.deloitte.com/content/dam/insights/us/articles/understanding-millennials-generational-differences/DUP1276_Millennials_report_MASTER_101615.pdf.*

[34] *Id.* at p. 4.

over the next decade because of slowing population growth and changing demographics. The data outlined that the labor force participation rate for those ages 65 years and older is expected to increase to 23.3 percent in 2028, up from 19.6 percent in 2018 due to lack of sufficient retirement savings and employer-provided health insurance and employers' increased willingness to hire and retain older workers who may have institutional knowledge that is not easily replaceable, while the labor force participation of those ages 16–24 is expected to decline during that same period.[35]

These trends are also more pronounced for certain demographics. For example, additional analysis finds women are underrepresented in STEM careers and are being hindered in STEM by social barriers, like gender stereotypes and lack of representation, and discouragement.[36] According to a management consulting firm, the next wave of efficiency gains in global manufacturing will be driven by digitalization and big data on the shop floor, which will require more skilled workers with STEM knowledge, problem solving skills, and programming familiarity.[37] Additionally, the Census Bureau states that women make up approximately 47 percent of the American workforce but only 30 percent work in manufacturing. Among ways the manufacturing industry has been attracting more women are attempts to reduce the gender gap is by encouraging girls to study STEM subjects at a young age.[38]

Furthermore, there remain significant racial disparities in the technical workforce among women.[39] Recent surveys have shown that Black and Hispanic U.S. workers are vastly underrepresented in the STEM workforce.[40] According to an August 31, 2021, NSB report females with their highest degree in science and engineering (S&E) tend to work proportionately less in S&E occupations compared to men. Among women in S&E there are also tremendous disparities, with 45 percent of Asian women with such degrees working in STEM, compared to 24 percent, 22 percent, and 15 percent respectively for white, Hispanic or Latino, and Black women.[41] The U.S. Chamber of Commerce noted that the NSF implemented a strategy to address these issues through a newly funded Community College Presidents' Initiative in STEM Education by introducing STEM programs at the earliest stages of post-secondary STEM education as community colleges serve the most diverse student body in higher education and serve as a gateway to further higher education.[42]

Not only is the United States facing headwinds in developing enough U.S.-born students pursuing STEM careers to replace those entering retirement, but broader market trends also suggest that the need for STEM workers will increase in future years. The growth rate of employment in STEM fields is projected to expand significantly—specifically, by 10.8 percent through 2032, compared to 2.8 percent for all occupations.[43] Although growth in STEM occupations is led by substantial increases in mathematical science occupations (29.2 percent) and computer occupations (14.2 percent), the expected growth for every major STEM occupational classification is expected to exceed the growth for all occupations.[44]

However, the NSB, in its analysis of the U.S. STEM labor force, argued that new scientific and technological advancements and discoveries, such as quantum technologies, space exploration, and medical vaccines, are ''rapidly changing the world of work and, as a result, continue to challenge the traditional framework used to define the STEM labor force in the United States.'' [45] The basis of this report introduced a limited analysis of the skilled technical workforce (STW)

[35] *See* Dubina, Kevin S. *et al.,* Projections Overview and Highlights, 2018–2028, Bureau of Labor Statistics Monthly Labor Review (Oct. 2019), *available at https://www.bls.gov/opub/mlr/2019/article/projections-overview-and-highlights-2018-28.htm#top.*

[36] *See* Meyer B. and Daugherty, J., Paving the Way to Gender Equity Through STEM Education, U.S. Chamber of Commerce Foundation (Mar. 3, 2021), *available at https://www.uschamberfoundation.org/blog/post/paving-way-gender-equity-through-stem-education.*

[37] *See* Kautzsch, T. and Chien A., Bringing Manufacturing Jobs Back to the US?, Oliver Wyman, *available at https://www.oliverwyman.com/our-expertise/insights/2017/nov/perspectives-on-manufacturing-industries-vol-12/manufacturing-in-a-changing-world/bringing-manufacturing-jobs-back-to-the-US.html.*

[38] *See* Dowell, Earlene K.P., Manufacturing Opens More Doors to Women, U.S. Census Bureau (Oct. 3, 2022), *available at https://www.census.gov/library/stories/2022/10/more-women-in-manufacturing-jobs.html.*

[39] *See* Boggs G., *et al.,* Addressing the STEM Workforce Shortage, U.S. Chamber of Commerce Foundation (Oct. 17, 2022), *available at https://www.uschamberfoundation.org/blog/post/addressing-stem-workforce-shortage* (''Women are underrepresented in several STEM occupations, particularly in computer jobs and engineering. The racial and gender inequalities have significant income implications. Even among workers with similar education, STEM workers earn significantly more. At a time when we need to address STEM labor shortages, we cannot afford to leave segments of our population behind.'' (citing data from The Skilled Technical Workforce: Creating America's Science and Engineering Enterprise, National Science Board (Sept. 3, 2019), *available at https://www.nsf.gov/nsb/publications/2019/nsb201923.pdf*).

[40] *See* Funk C. and Parker, K., Women and Men in STEM Often at Odds Over Workplace Equity, Pew Research Center (Jan. 18, 2019), p. 24, *available at https://www.pewresearch.org/social-trends/wp-content/uploads/sites/3/2018/01/PS_2018.01.09_STEM_FINAL.pdf.* (''Blacks make up 11% of the U.S. workforce overall but represent 9% of STEM workers, while Hispanics comprise 16% of the U.S. workforce but only 7% of all STEM workers. And among employed adults with a bachelor's degree or higher, Blacks are just 7% and Hispanics are 6% of the STEM workforce.'')

[41] *See* The STEM Workforce of Today: Scientists, Engineers, and Skilled Technical Workers, National Science Board (Aug. 31, 2021), p. 69, Intersectionality In Stem, *available at https://ncses.nsf.gov/pubs/nsb20212/participation-of-demographic-groups-in-stem* (''Female S&E highest degree holders tend to work proportionately less in S&E occupations (26%) compared to men (45%) (Figure LBR–30; Table SLBR–32). However, the extent to which women with their highest degree in an S&E field worked in S&E occupations varied by race or ethnicity. Among women with their highest degree in an S&E field, Asian women worked proportionately more in S&E occupations (45%) compared to White (24%), Hispanic or Latino (22%), other races or ethnicities (21%), and Black or African American women (15%) (Figure LBR–30).'')

[42] *See* Community College Presidents' Initiative in STEM Education, Resources, *available at https://www.ccpi-stem.org/resources/* and Sdavkovich V. *et al.,* Have You Heard About the Community College Presidents' Initiative in STEM?, HigherEdJobs (May 31, 2022), *available at https://www.higheredjobs.com/articles/articleDisplay.cfm?ID=3065* (citing Fast Facts 2022, American Association of Community Colleges (May 11, 2022), *available at https://www.aacc.nche.edu/research-trends/fast-facts/* (''51 percent of community college students taking college credit classes are students of color.''))

[43] *See* Bureau of Labor Statistics, Employment Projections: Employment in STEM Occupations, Table 1.7, Occupational Projections, 2022–32, and Worker Characteristics, 2022 (Numbers in Thousands), *available at https://www.bls.gov/emp/tables/occupational-projections-and-characteristics.htm,* and Table 1.11, Employment in STEM Occupations, 2022 and Projected 2032 (Sept. 6, 2023), *available at https://www.bls.gov/emp/tables/stem-employment.htm.*

[44] *Id.* at Table 1.7. (In addition to those two occupations, BLS projects increases as well for physical scientists (5.3%), STEM post-secondary teachers (6.8%), life scientists (7.1%), and engineers (6.9%), all of which exceed the 2.8% average growth across all occupations.)

[45] *See supra* note 26, at pp. 7 (''As such, the STEM workforce described in this report includes occupations that have historically been known to require STEM skills and expertise (*e.g.,* life sciences, physical sciences, engineering, mathematics and computer sciences, social sciences, and health care) as well as occupations that are not typically considered STEM fields but that do, in fact, require STEM skills (*e.g.,* installation, maintenance and repair, construction trades, and production occupations))'' and 11; *see also supra* note 10. Non-STEM occupations primarily include occupations in management (excluding S&E and S&E-related managers, industrial production managers, and farmers, ranchers, and agricultural managers), sales (excluding sales engineers), transportation and material moving (excluding transportation inspectors and pumping station operators), office and administrative support, and education and training. *See* Table SLBR–1 for a full list of non-STEM occupations.

which included occupations that require a high level of knowledge in a technical domain but did not require a bachelor's degree.[46] As a result, the NSB suggested to broaden the definition of STEM to include workers without a bachelor's degree who are employed in S&E, S&E-related, and non-STEM middle-skill occupations.[47] The NSB also argued that building a STEM workforce demanded expanding the definition of STEM to include middle-skill occupations, such as construction, extraction, and production, pointing out that the 2019 ACS survey that finds nearly 20 million STEM workers without a bachelor's degree worked in middle-skill occupations.[48] Furthermore, others have argued that the COVID–19 outbreak has resulted in shortfalls of STEM workers and suggested that immigration can alleviate those shortages.[49] Upon review of BLS' Job Openings and Labor Turnover Survey (JOLTS), reflecting the number of yearly job openings measured as an annual mean to monthly job openings, one organization argued that the shortfalls of STEM workers has been building continuously since 2020 and cannot be solved through the domestic workforce.[50]

In evaluating the utility of expanding Schedule A to include STEM occupations, the Department invites the public to provide input on the appropriate data sources and methods for determining whether labor shortages exist, whether Schedule A should be used to alleviate any labor shortages in STEM occupations should it be determined from these data sources and methods that such shortages exist, and if so, how the Department could establish a reliable, objective, and transparent methodology for identifying STEM occupations that are experiencing labor shortages. Additionally, the Department invites the public to provide input on whether to limit examination of STEM only to those OEWS occupations used in most of the recent BLS publications,[51] or whether the STEM occupations should be expanded to include additional occupations that cover STW occupations, and whether it is justifiable to find for each such occupation that there are not and will not be sufficient U.S. workers ready, willing, able and qualified to perform positions in those occupations nationwide, considering significant government and private sector investment in STEM education and research to enhance STEM labor market participation among U.S. workers generally and among underrepresented groups specifically. Similarly, the Department encourages the public to provide input as to whether there are non-STEM occupations which should be added to Schedule A and, if such occupations exist, to provide the data sources and methods of determining such shortages exist. This input will assist the Department in fulfilling its obligation under the INA to ensure the employment of foreign workers will not adversely affect the wages and working conditions of U.S. workers. Information received from the public will help inform decisions regarding whether or how to improve Schedule A and ensure that its purpose in responding to national labor shortages is more effectively met.

The Department invites general comments and suggestions concerning:

(A) whether any STEM occupations should be added to Schedule A, and why; and

(B) defining and determining which occupations should be considered as falling under the umbrella of STEM, and why.

The Department is also specifically seeking input on the questions listed below.[52] To the extent possible and wherever appropriate, responses to this RFI should indicate the question number(s) and include specific information, data, statistical models and metrics, and any resources relied on in reaching conclusions for its claims, rather than relying on general observations.

Accordingly, the Department invites the public to answer one or more of the following questions in their submissions:

1. Besides the OEWS, ACS, and CPS, what other appropriate sources of data are available that can be used to determine or forecast potential labor shortages for STEM occupations by occupation and geographic area?

2. What methods are available that can be used alone, or in conjunction with other methods, to measure presence and severity of labor shortages for STEM occupations by occupation and geographic area?

3. How could the Department establish a reliable, objective, and transparent methodology for identifying STEM occupations with significant shortages of workers that should be added to Schedule A?

4. Should the STEM occupations potentially added to Schedule A be limited to those OEWS occupations used in most of the recent BLS publications, or should the STEM occupations be expanded to include additional occupations that cover STW occupations?

5. Beyond the parameters discussed for STW occupations, should the Department expand Schedule A to include other non-STEM occupations? If so, what should the Department consider to establish a reliable, objective, and transparent methodology for identifying non-STEM occupations with a significant shortage of workers that should be added to or removed from Schedule A?

Brent Parton,

Principal Deputy Assistant Secretary for Employment and Training, Labor.

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[46] *Id.*

[47] *Id.; see also* Employed Adults in STEM and Non-STEM Occupations, by Broad and Detailed Occupation: 2019, *available at https://ncses.nsf.gov/pubs/nsb20212/data/table/SLBR-1#.*

[48] *Compare supra* note 26, at p. 11, *with supra* note 43 (noting BLS employment projections rank construction as the industry sector with the third highest projected growth over the next 10 years behind health care and education services). *See also* U.S. Census Bureau, American Community Survey (ACS), *available at https://www.census.gov/programs-surveys/acs.*

[49] *See* Esterline, C., The Case for Updating Schedule A, Niskanen Center (Oct. 2022), *available at https://www.niskanencenter.org/wp-content/uploads/2022/10/PolicyBriefTHE-CASE-FOR-UPDATING-SCHEDULE-A.pdf* (highlighting specific benefits of using Schedule A during COVID pandemic); *see, e.g.,* Peri G. and Zaiour, R., Labor Shortages and the Immigration Shortfall, Econofact (Jan. 11, 2022), *available at https://econofact.org/labor-shortages-and-the-immigration-shortfall* and Kenan Institute of Private Enterprise, Why America Needs High Skill Immigrants, Kenan Insight (Jul. 22, 2020), *available at https://kenaninstitute.unc.edu/kenan-insight/why-america-needs-high-skilled-immigrants/* (discussing need for expanding immigration during the COVID pandemic).

[50] *See* Esterline, *supra note* 49, at pp. 3 (''According to BLS's JOLTS, from 2011 to 2021 the number of job openings increased on average 12 percent per year accounting for the downturn seen in early 2020. Further data from BLS's JOLTS points that in August 2022 approximately 6 million Americans were unemployed, yet job openings in the same month exceeded 10 million.'') and 8 (''While much can and should be done to improve STEM education in the United States or to increase the matching potential between American skills and interests and current job openings, the statistics still show that this alone will likely not be enough.'').

[51] Bureau of Labor Statistics, Occupational Employment and Wage Statistics (Feb. 4, 2022), *available at https://www.bls.gov/oes/topics.htm#stem.*

[52] The Department's issuance of this RFI and the input sought in this request are consistent with the AI E.O., which directed the Secretary of Labor, within 45 days of issuance the AI E.O., to publish a RFI soliciting public input to identify AI and other STEM-related occupations, as well as additional occupations across the economy, for which there is an insufficient number of ready, willing, able, and qualified U.S. workers for purposes of updating Schedule A. *See AI E.O., supra* note 9, at Sec. 5(e).

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 14

RIN 2900–AR93

Fee Reasonableness Reviews; Effect of Loss of Accreditation on Direct Payment

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is issuing this proposed rule to address its process for reviewing, determining, and allocating reasonable fees for claim representation, and to address the effect on direct payment of the termination of an agent's or attorney's VA accreditation.

DATES: Comments must be received on or before February 20, 2024.

ADDRESSES: Comments must be submitted through *www.regulations.gov.* Except as provided below, comments received before the close of the comment period will be available at *www.regulations.gov* for public viewing, inspection, or copying, including any personally identifiable or confidential business information that is included in a comment. We post the comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* VA will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm the individual. VA encourages 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. Any public comment received after the comment period's closing date is considered late and will not be considered in the final rulemaking.

FOR FURTHER INFORMATION CONTACT: Jonathan Taylor, Office of General Counsel (022D), 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–7699. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: Congress has authorized VA to prescribe reasonable restrictions on the amount of fees that agents or attorneys may charge claimants for services on VA benefits claims. 38 U.S.C. 5904(a)(5). In addition, VA has the authority to review a fee agreement between an agent or attorney and a claimant and order a reduction in the fee if VA finds that fee is excessive or unreasonable. 38 U.S.C. 5904(c)(3)(A). VA also has the discretion to directly pay the fee of an agent or attorney from a claimant's past-due benefits if the claimant and the agent or attorney have entered into a fee agreement that requests direct payment and meets statutory and regulatory criteria, including the requirement that the fee not exceed 20 percent of the past-due benefits awarded to the claimant. 38 U.S.C. 5904(d). VA may issue all necessary or appropriate rules and regulations to carry out these authorities. 38 U.S.C. 501(a).

Based on these authorities, VA's Office of the General Counsel (OGC), which acts as the agency of original jurisdiction for reviewing fee agreements, currently performs a ''fee reasonableness'' review in two circumstances: (1) when the claimant or VA has questioned the reasonableness of the fee set forth in the agreement, and (2) when multiple agents or attorneys provided representation. OGC provides review in the latter circumstance in order to decide the amount to be directed to each agent or attorney for purposes of direct payment, since the ''total fee payable'' in direct payment cases is limited to 20 percent of the past-due benefits awarded. *Lippman* v. *Shinseki,* 23 Vet. App. 243, 250 (2009) (citing *Scates* v. *Principi,* 282 F.3d 1362, 1365–66 (Fed. Cir. 2002)). This review ensures that claimants are not forced to part with, for example, 60 percent of their past-due benefits just because they were represented by three different attorneys with 20-percent fee agreements over the course of a case. Congress intended to protect a claimant's benefits from improper diminution by excessive legal fees, and Congress authorized VA to implement fair processes and reasonable restrictions in these circumstances. 38 U.S.C. 5904(a)(5), (c)(3)(A); *Scates,* 282 F.3d at 1366.

Over the past decade, however, there has been a steady increase in cases involving multiple agents or attorneys, as well as requests for OGC review. For example, in fiscal year 2020, OGC received approximately 150 fee reasonableness requests or referrals; in fiscal year 2023, OGC received almost 700. OGC has limited resources to issue determinations on reasonable fees in all those cases. This has led to increased inventory for all fee matters, which has delayed attorneys, agents, and claimants from promptly receiving their earned fees or benefits. To best ensure timely resolution of fee matters for all parties, VA believes it is appropriate to establish reasonable default allocation rules for fee matters and to focus OGC's resources on those cases where a party has expressed an affirmative desire for an OGC determination based on the unique circumstances of the particular case. Moreover, there are many fee matters that can be worked out between the parties, without OGC involvement, and VA wishes to encourage such resolutions. Overall, these default rules will allow attorneys, agents, and claimants (as further explained below) to receive their fees and benefits faster.

Under current practice, after issuing a decision awarding past-due benefits, if a direct-pay fee agreement has been filed, the agency of original jurisdiction (typically the Veterans Benefits Administration) issues a fee notice containing a determination on agent or attorney fee eligibility. 38 CFR 14.636(c)(4). Under this proposed rule, the fee notice would provide one of two default fee allocations depending on the posture of the case. In cases where there is a ''continuous agent or attorney''—an agent or attorney who provided representation that continued through the date of the decision awarding benefits—who meets the requirements for fee eligibility and direct payment enumerated in other paragraphs of § 14.636, the default would be allocation of the fee to that continuous agent or attorney. Otherwise, the default would be an equal split of the fee based on the number of agents or attorneys who meet the requirements for fee eligibility and direct payment plus the claimant.

The fee notice would note that any party (*i.e.,* the claimant or an agent or attorney who represented the claimant in the case) has the opportunity to request, within 60 days of the notice, OGC review of a reasonable fee allocation for the case. In other words, if any party is dissatisfied with the default fee allocation in a case, they would be free to request OGC review of reasonable fees in the case. Upon receipt of a timely request, OGC would initiate a review, provide an opportunity to respond, and issue a decision on the matter. Absent a timely request for OGC review (or a timely appeal to the Board of Veterans' Appeals regarding an agent's or attorney's fee eligibility), however, the fee would be released in accord with the default allocation in the fee notice.

As to the reason for proposing these specific default fee allocations, where a continuous agent or attorney meets the requirements for fee eligibility and direct payment, the default of allocating the fee to that agent or attorney is logical because that agent or attorney's fee is presumed reasonable under 38 CFR 14.636(f)(1). That agent or attorney—who was the representative of record

when the benefits were actually secured—is in a different position than any agents or attorneys who were discharged or withdrew prior to the award of benefits (hereinafter referred to as ''discharged agents or attorneys''), whose entitlement to a fee is not governed by a presumption but instead premised on their contribution to and responsibility for the benefits awarded. 38 CFR 14.636(f)(2); *see Scates,* 282 F.3d at 1366. Of course, if any discharged agent or attorney believes that he or she contributed meaningfully to the case, he or she can work out the matter with the continuous agent or attorney or (if that effort proves unsuccessful) request that OGC initiate a review of reasonable fees. *See generally* ABA Comm. On Ethics & Prof'l Responsibility, Formal Op. 487 (2019) (addressing fee division with client's prior counsel). Similarly, if the claimant believes the total fee to be unreasonable, he or she can work out the matter with the other parties or (if that effort proves unsuccessful) request an OGC determination on reasonable fees.

Furthermore, where all agents or attorneys were discharged prior to the date of the decision awarding benefits, the default of a split of the fee is logical because the presumption of 38 CFR 14.636(f)(1) does not apply to such agents and attorneys, and all agents or attorneys are generally in the same position vis-à-vis the fee: they are only entitled to a fee based on quantum meruit, 38 CFR 14.636(f)(2); *see Scates,* 282 F.3d at 1366. That default split should include the claimant because, historically, when OGC has reviewed fee reasonableness in cases where all agents or attorneys have been discharged, OGC has—more often than not—found it reasonable to bestow the agent(s) and/or attorney(s) less than the full potential fee (and to return the remainder to the claimant). For example, in fiscal year 2022, of the 126 fee reasonableness decisions issued addressing the situation where all agents and attorneys had been discharged, OGC returned some of the potential fee to the claimant in 107 of those decisions (84%). Overall, $2.19 million was at stake in these 126 cases, and OGC returned $1.31 million to claimants (60% of the amount at stake). Similar data has emerged through the first three quarters of fiscal year 2023. Of the 82 fee reasonableness decisions issued addressing the situation where all agents and attorneys had been discharged, OGC returned some of the potential fee to the claimant in 72 of those decisions (88%). Overall, $1.77 million was at stake in these 82 cases, and OGC returned $1.22 million to claimants (68% of the amount at stake).

This data reflects the practical reality that, when a claimant secures a favorable decision (sometimes months, often years) after agent or attorney discharge, it may be the claimant (or a Veterans Service Organization) that bears more responsibility for the benefits awarded, and the former agents or attorneys that bear less. It is reasonable for a default—which is merely a baseline that has no effect once a party requests OGC review—to reflect that reality, particularly given the general law on quantum meruit, which suggests that a default should be structured in a way that places the burden on discharged agents or attorneys to file with OGC if they believe their contributions warrant the full potential fee, not on the claimant to file with OGC if they believe otherwise. *Young* v. *Alden Gardens of Waterford, LLC,* 30 NE3d 631, 656 (Ill. App. Ct. 1st Dist. 2015); *Gold, Weems, Buser, Sues & Rundell* v. *Granger,* 947 So.2d 835, 842 (La. App. 1 Cir. 2006); *Bass* v. *Rose,* 609 SE2d 848, 853 (W. Va. 2004) (attorney bears burden of showing that fees sought are reasonable). Including the claimant in this default split also accounts for the possibility that the claimant may have entered into a non-direct pay agreement with other agents or attorneys and may be personally responsible for paying those other agents or attorneys. In any event, this type of split is just a default, aimed to provide a generally reasonable baseline in these cases; if any party believes the default split is not reasonable in a given case, they can work out another arrangement with the other parties on their own or (if that effort proves unsuccessful) request an OGC determination on reasonable fees.

These changes would be incorporated into § 14.636(i), the current paragraph addressing OGC's review of fee agreements. Proposed paragraph (i)(1) would address fee allocation notices and the default fee allocations therein. Proposed paragraph (i)(2) would address the release of allocated fees and finality at the expiration of the 60-day period for requesting OGC review. Proposed paragraph (i)(3) would address the process for requesting that OGC initiate a reasonableness review. Proposed paragraph (i)(4) would address the opportunity to submit argument and evidence during OGC's review. Proposed paragraph (i)(5) would provide the standards for OGC's decision. Proposed paragraph (i)(6) would note the right to appeal OGC's decision to the Board of Veterans' Appeals.

To be clear, the default fee allocations of this proposed rule do not relieve attorneys or agents of their ethical obligation not to accept an unreasonable fee. *See* 84 FR 138, 151 (2019) (''[P]ursuant to VA's standards of conduct in 38 CFR 14.632, attorneys and agents are prohibited from charging, soliciting, or receiving fees that are clearly unreasonable, and, if an attorney or agent [ ] is found to have violated this standard of conduct, the attorney or agent would risk losing his or her accreditation to represent claimants before VA.''); Model Rules of Prof'l Conduct r. 1.5(a) (Am. Bar Ass'n 2022). In other words, notwithstanding the default fee allocations of this proposed rule, it is a violation of VA's standards of conduct for an attorney or agent to blindly pocket fees that were unearned. 38 CFR 14.632(c)(5); *cf. Scates,* 282 F.3d at 1366 (reasonable fee for discharged agent or attorney is limited to a ''fee that fairly and accurately reflects [the attorney or agent's] contribution to and responsibility for the benefits awarded''); 38 CFR 14.636(f)(2). Thus, upon receipt of a fee allocation notice, the agent or attorney has a professional responsibility to review the default fee and ensure that it is not clearly unreasonable; if it is, that agent or attorney has an ethical obligation to return that fee to the claimant. The failure to return the fee to the claimant in such circumstances could constitute a violation of VA's standards of conduct warranting suspension or cancellation of the agent's or attorney's accreditation to represent claimants before VA. *See* 38 CFR 14.633(c)(6).

Related to that ethical issue, VA is proposing to update § 14.636(h) to address the effect on direct payment of the termination of an agent or attorney's VA accreditation. Post-termination, VA has no internal enforcement mechanism against these individuals for violating VA's standards of conduct, including the aforementioned standard that prohibits receipt of a fee that is clearly unreasonable; it would therefore complicate the ethical safeguards underpinning this proposed rule if agents or attorneys who have lost accreditation are included. Moreover, as a practical matter, it has been difficult to contact and directly pay agents or attorneys who have had their VA accreditation terminated, because they are no longer responsible for maintaining updated contact information with VA.

VA has the discretion to decline direct payment in certain circumstances notwithstanding the submission of a direct-pay fee agreement. *Ravin* v. *Wilkie,* 956 F.3d 1346, 1350 (Fed. Cir.

2020); *see* 38 U.S.C. 5904(d)(3) (Secretary ''may'' directly pay a fee to an agent or attorney upon submission of a direct-pay fee agreement). For the above reasons, VA proposes to exercise its discretion and not directly pay agents and attorneys whose accreditation has been terminated. Instead, any potential fee for these former agents or attorneys would be released to the claimant, and the agent or attorney would be responsible for collecting that fee without assistance from VA. *See* 38 CFR 14.636(g)(2). This limitation on direct payment would be placed in paragraph (h)(1)(iii). The language of current paragraph (h)(1)(iii) would be relocated to paragraph (h)(1)(iv).

Lastly, VA is proposing additional, minor revisions to § 14.636. First, VA would remove § 14.636(c)(4), since the agency of original jurisdiction's fee eligibility notice under that paragraph would now be termed a fee allocation notice under proposed § 14.636(i)(1). Second, VA would revise § 14.636(e) to use the term ''agent or attorney'' in lieu of ''representative,'' because only agents and attorneys (not all representatives) can charge a fee. Also in that paragraph, VA would reiterate that fees set forth in a fee agreement, charged, or received for services must be reasonable, consistent with VA's standards of conduct discussed above, and note that fee reasonableness for one agent or attorney can be affected by the fee entitlement of another agent or attorney. Third, while filing fee agreements within 30 days of their execution would remain a regulatory requirement, § 14.636(g)(3) would explicitly note VA's discretion to accept fee agreements filed thereafter upon a showing of sufficient cause. Fourth, VA would simplify § 14.636(k), since the ''modernized review system'' of the Veterans' Appeals Improvement and Modernization Act, Public Law 115–55 (2017), governs all decisions on new fee matters. Fifth, VA is proposing new or revised captions for paragraphs (e), (j), and (k) that more accurately convey the subject-matter of each paragraph.

Executive Orders 12866, 13563, and 14094

Executive Orders (E.O.) 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). E.O. 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 (Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Orders 12866 and 13563. The Office of Information and Regulatory Affairs has determined that this rulemaking is a significant regulatory action under E.O. 12866, as amended by Executive Order 14094. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

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). The basis for this certification is the fact that the proposed rule would merely institute reasonable default rules for fee allocation and provide that agents and attorneys who have lost their VA accreditation collect any earned fees without VA assistance. These changes would not result in any loss of fees to which an agent or attorney is reasonably entitled, because, as noted above, any party dissatisfied with the default allocation in a given case can request OGC's determination on reasonable fees in the case. 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.

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.

Paperwork Reduction Act

This proposed rule includes provisions associated with a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521) that require approval by the Office of Management and Budget (OMB). The collection of information was previously approved by OMB and assigned the control number of 2900–0605 but expired in March 2022. Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking action to OMB for review and reinstatement with change.

OMB assigns control numbers to collection of information it approves. VA 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. If OMB does not approve the collection of information as requested, VA will immediately remove the provisions containing the collection of information or take such other action as is directed by OMB.

Comments on the collection of information associated with this rulemaking should be submitted through *www.regulations.gov.* Comments should indicate that they are submitted in response to ''RIN 2900–AR93, Fee Reasonableness Reviews; Effect of Loss of Accreditation on Direct Payment'' and should be sent within 60 days of publication of this rulemaking. The collection of information associated with this rulemaking can be viewed at: *www.reginfo.gov/public/do/PRAMain.*

OMB is required to make a decision concerning the collection of information contained in this rulemaking between 30 and 60 days after publication of this rulemaking in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment on the provisions of this rulemaking.

The Department considers comments by the public on a collection of information in—

- Evaluating whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;
- Evaluating the accuracy of the Department's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

The collection of information associated with this rulemaking is

described immediately following this paragraph, under its respective title.

Title: Application for Accreditation as a Claims Agent or Attorney, Filing of Representatives' Fee Agreements and Motions for Review of Such Fee Agreements.

OMB Control No: 2900–0605.

CFR Provisions: 38 CFR 14.629, 14.636.

• *Summary of collection of information:*

(1) Applicants seeking accreditation as claims agents or attorneys to represent benefits claimants before VA must file VA Form 21a with OGC. The information requested in VA Form 21a includes basic identifying information, as well as certain information concerning training and experience, military service, and employment. *See* 38 U.S.C. 5901; 38 CFR 14.629(b).

(2) If accredited agents and attorneys wish to maintain accreditation, they must file recertifications with OGC that they have completed Continuing Legal Education (CLE) requirements and are in good standing with other courts, bars, and Federal and State agencies. *See* 38 U.S.C. 5904(a)(2)–(3); 38 CFR 14.629(b).

(3) Accredited agents and attorneys must file with VA any agreement for the payment of fees charged for representing claimants before VA. 38 U.S.C. 5904(c)(2); 38 CFR 14.636(g).

(4) Claimants, accredited agents, or accredited attorneys may request an OGC determination on a reasonable fee allocation in a given case. If they do, OGC will solicit (optional) responses from the other parties in the case. 38 U.S.C. 5904(c)(3); 38 CFR 14.636(i).

• *Description of need for information and proposed use of information:*

(1) The information in the VA Form 21a is used by OGC to determine the applicant's eligibility for accreditation as a claims agent or attorney. More specifically, it is used to evaluate qualifications, ensure against conflicts of interest, and to establish that statutory and regulatory eligibility requirements, *e.g.,* good character and reputation, are met.

(2) The information in recertifications is used by OGC to monitor whether accredited attorneys and agents continue to have appropriate character and reputation and whether they remain fit to prepare, present, and prosecute VA benefit claims.

(3) The information in a fee agreement is used by the Veterans Benefits Administration (VBA) to associate the fee agreement with the claimant's claims file, to potentially determine the attorney or agent's fee eligibility, and to potentially process direct payment of a fee from the claimant's past-due benefits. It is used by OGC to monitor whether the agreement is in compliance with laws governing paid representation, and to potentially review fee reasonableness.

(4) The information in a request for OGC fee review, or a response to such request, is used by OGC to determine the agents' or attorneys' contribution to and responsibility for the ultimate outcome of the claimant's claim, so that a determination on reasonable fees can be rendered.

• *Description of likely respondents:* Claimants, Attorneys, Agents.

• *Estimated number of respondents:*

(1) For VA Form 21a applications, 2,280.

(2) For recertifications, 4,860.

(3) For fee agreements, 27,250 (750 first time filers and 26,500 repeat filers).

(4) For requests for OGC fee review, 305 (203 initial requests and 102 party responses).

• *Estimated frequency of responses:* One time.

• *Estimated average burden per response:*

(1) For VA Form 21a applications, 45 minutes.

(2) For recertifications, 10 minutes.

(3) For fee agreements, 11 minutes (1 hour for first time filers and 10 minutes for repeat filers).

(4) For requests for OGC fee review, 2 hours (for both initial requests and party responses).

• *Estimated total annual reporting and recordkeeping burden:*

(1) For VA Form 21a applications, 1,710 hours.

(2) For recertifications, 810 hours.

(3) For fee agreements, 5,167 hours (750 hours for first time filers and 4,417 hours for repeat filers).

(4) For requests for OGC fee review, 610 hours (406 hours for initial requests and 204 hours for responses).

• *Estimated cost to respondents per year:*

(1) For VA Form 21a applications, $74,767.

(2) For recertifications, $63,779.

(3) For fee agreements, $406,850.

(4) For requests for OGC fee review, $43,133.

* To estimate the total information collection burden cost, VA used the Bureau of Labor Statistics (BLS) average hourly wage information available at *https://www.bls.gov/oes/current/oes_nat.htm.*

List of Subjects in 38 CFR Part 14

Administrative practice and procedure, Claims, Courts, Foreign relations, Government employees, Lawyers, Legal services, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Surety bonds, Trusts and trustees, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, signed and approved this document on December 12, 2023, 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.

Luvenia Potts,

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 14 as set forth below:

PART 14—LEGAL SERVICES, GENERAL COUNSEL, AND MISCELLANEOUS CLAIMS

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

Authority: 5 U.S.C. 301; 28 U.S.C. 2671–2680; 38 U.S.C. 501(a), 512, 515, 5502, 5901–5905; 28 CFR part 14, appendix to part 14, unless otherwise noted.

■ 2. Amend § 14.636 by:

■ a. Removing paragraph (c)(4);

■ b. Revising paragraphs (e), (g)(3), and (h)(1)(ii);

■ c. Redesignating paragraph (h)(1)(iii) as paragraph (h)(1)(iv);

■ d. Adding new paragraph (h)(1)(iii); and

■ d. Revising paragraphs (i) through (k).

The revisions read as follows:

§ 14.636 Payment of fees for representation by agents and attorneys in proceedings before Agencies of Original Jurisdiction and before the Board of Veterans' Appeals.

* * * * *

(e) *Fee reasonableness factors.* Fees set forth in a fee agreement, charged, or received for the services of an agent or attorney admitted to practice before VA must be reasonable. They may be based on a fixed fee, hourly rate, a percentage of benefits recovered, or a combination of such bases. Factors considered in determining whether fees are reasonable include:

(1) The extent and type of services the agent or attorney performed;

(2) The complexity of the case;

(3) The level of skill and competence required of the agent or attorney in giving the services;

(4) The amount of time the agent or attorney spent on the case;

(5) The results the agent or attorney achieved, including the amount of any benefits recovered;

(6) The level of review to which the claim was taken and the level of the review at which the agent or attorney was retained;

(7) Rates charged by other agents or attorneys for similar services;

(8) Whether, and to what extent, the payment of fees is contingent upon the results achieved;

(9) If applicable, the reasons why an agent or attorney was discharged or withdrew from representation before the date of the decision awarding benefits; and

(10) If applicable, the fee entitlement of another agent or attorney in the case.

* * * * *

(g) * * *

(3) A copy of a direct-pay fee agreement, as defined in paragraph (g)(2) of this section, must be filed with the agency of original jurisdiction within 30 days of its execution. A copy of any fee agreement that is not a direct-pay fee agreement must be filed with the Office of the General Counsel within 30 days of its execution by mailing the copy to the following address: Office of the General Counsel (022D), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Only fee agreements that do not provide for the direct payment of fees, documents related to review of fees under paragraph (i) of this section, and documents related to review of expenses under § 14.637, may be filed with the Office of the General Counsel. All documents relating to the adjudication of a claim for VA benefits, including any correspondence, evidence, or argument, must be filed with the agency of original jurisdiction, Board of Veterans' Appeals, or other VA office as appropriate. VA may accept fee agreements that were not filed within 30 days of execution upon a showing of sufficient cause.

(h) * * *

(1) * * *

(ii) The amount of the fee is contingent on whether or not the claim is resolved in a manner favorable to the claimant or appellant,

(iii) The agent or attorney is accredited (*see* §§ 14.627(a) and 14.629(b)) on the date of VA's fee allocation notice (*see* paragraph (i) of this section), and

(iv) The award of past-due benefits results in a cash payment to a claimant or an appellant from which the fee may be deducted. (An award of past-due benefits will not always result in a cash payment to a claimant or an appellant. For example, no cash payment will be made to military retirees unless there is a corresponding waiver of retirement pay. (See 38 U.S.C. 5304(a) and 38 CFR 3.750))

* * * * *

(i) *Fee review.* For purposes of this paragraph (i), ''party'' means the claimant or appellant or any agent or attorney who represented the claimant or appellant in the case; ''eligible for direct payment'' means eligible for direct payment of a fee under the requirements of paragraphs (c), (g), and (h) of this section; ''continuous agent or attorney'' means the agent or attorney who provided representation that continued through the date of the decision awarding benefits; and ''timely filed'' means within 60 days of the fee allocation notice.

(1) When one or more direct-pay fee agreements has been filed in accordance with paragraph (g) of this section and a decision awards past-due benefits in a case, the agency of original jurisdiction that issued the decision shall issue to the parties a fee allocation notice. The fee allocation notice shall decide whether the agents or attorneys who filed direct-pay fee agreements in the case are eligible for direct payment, and shall provide one of two default fee allocations:

(i) In cases where a continuous agent or attorney is eligible for direct payment, the default shall be allocation of the fee to the continuous agent or attorney.

(ii) In cases where paragraph (i)(1)(i) of this section does not apply, the default shall be an equal split of the fee based on the number of agents or attorneys who are eligible for direct payment plus the claimant or appellant.

(2) A party that disagrees with the default fee allocation in a given case may file a request for Office of the General Counsel fee review, as provided in paragraph (i)(3) of this section. A party that disagrees with a direct payment eligibility determination may only appeal to the Board of Veterans' Appeals. Absent a timely filed request for Office of the General Counsel fee review or a timely filed appeal to the Board of Veterans' Appeals, the default fee allocation described in paragraphs (i)(1)(i) and (ii) of this section is final and VA may release the fee.

(3) A request for Office of the General Counsel fee review under this paragraph (i) must be filed electronically in accordance with the instructions on the Office of the General Counsel's website, or at the following address: Office of the General Counsel (022D), 810 Vermont Avenue NW, Washington, DC 20420. The request must include the names of the veteran and all parties, the applicable VA file number, and the date of the decision awarding benefits. The request must set forth the requestor's proposal as to reasonable fee allocation, and the reasons therefor, and must be accompanied by all argument and evidence the requestor desires to submit.

(4) Upon the receipt of a timely filed request under paragraph (i)(3) of this section, or upon his or her own initiative, the Deputy Chief Counsel with subject-matter jurisdiction will initiate the Office of the General Counsel's motion for a fee review by sending notice to the parties. Not later than 30 days from the date of the motion, any party may file a response, with all argument and evidence the party desires to submit, electronically in accordance with the instructions on the Office of the General Counsel's website, or at the following address: Office of the General Counsel (022D), 810 Vermont Avenue NW, Washington, DC 20420. Such responses must be served on all other parties. The Deputy Chief Counsel with subject-matter jurisdiction may, for a reasonable period upon a showing of sufficient cause, extend the time for any party's response.

(5) The General Counsel or his or her designee shall render the Office of the General Counsel's decision on the matter. The decision will be premised on the reasonableness factors of paragraph (e) of this section, the standards of paragraph (f) of this section, the limitation on direct payment of paragraph (h)(1)(i) of this section, the claims file, the parties' submissions, and all relevant factors. The decision may address the issue of fee eligibility if no other agency of original jurisdiction has made a determination on that issue.

(6) The Office of the General Counsel's decision is a final adjudicative action that may only be appealed to the Board of Veterans' Appeals. Unless a party files a Notice of Disagreement with the Office of the General Counsel's decision, the parties must allocate any excess payment in accordance with the decision not later than the expiration of the time within which the Office of the General Counsel's decision may be appealed to the Board of Veterans' Appeals.

(j) *Failure to comply.* In addition to whatever other penalties may be prescribed by law or regulation, failure to comply with the requirements of this section may result in proceedings under § 14.633 to terminate the agent's or attorney's accreditation to practice before VA.

(k) *Appeals.* Except as otherwise provided in this section, appeals shall be initiated and processed using the procedures in 38 CFR part 20 applicable to appeals under the modernized system.

[FR Doc. 2023–28100 Filed 12–20–23; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0955; FRL–10549–01–R9]

Approval of Implementation Plans for Air Quality Planning Purposes; State of Nevada; Clark County Second 10-Year Maintenance Plan for the 1997 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve, as a revision of the Nevada state implementation plan (SIP), the State's second 10-year plan for maintaining the 1997 8-hour ozone standard in Clark County (''Clark County Second Maintenance Plan'' or ''Plan''). The Clark County Second Maintenance Plan includes, among other elements, a base year emissions inventory, a maintenance demonstration, contingency provisions, and motor vehicle emissions budgets for use in transportation conformity determinations to ensure the continued maintenance of the 1997 National Ambient Air Quality Standards for ozone (''1997 ozone NAAQS'' or ''1997 8-hour ozone standard''). With this proposed rulemaking, the EPA is initiating the adequacy process for the 2017, 2023, and 2033 motor vehicle emissions budgets. The EPA is proposing these actions because the SIP revision meets the applicable statutory and regulatory requirements for such plans and motor vehicle emissions budgets.

DATES: Comments must be received on or before January 22, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2022–0955, at *https://www.regulations.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Andrew Ledezma, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3985 or by email at *Ledezma.Andrew@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Summary of Proposed Action

Under Clean Air Act (CAA or ''the Act'') section 110(k)(3), the EPA is proposing to approve two submittals from the Nevada Division of Environmental Protection (NDEP) as a revision to the Nevada SIP: the Clark County Second Maintenance Plan dated December 21, 2021, and a supplement to the Clark County Second Maintenance Plan (''Contingency Measure Revision'') dated August 16, 2023. In this action, we refer to the Clark County Second Maintenance Plan and the Contingency Measure Revision collectively as the ''Clark County Second Maintenance Plan submittal.''

The EPA is proposing to find that the maintenance demonstration, showing how the area will continue to attain the 1997 8-hour ozone NAAQS for 10 additional years beyond the approval the State's first 10-year plan for maintaining the 1997 8-hour ozone standard in Clark County (''Clark County First Maintenance Plan'' or ''first maintenance plan'') (*i.e.,* through 2033), and the contingency provisions, describing the actions that Clark County will take in the event of a future monitored violation, meet all applicable requirements for maintenance plans and related contingency provisions in CAA section 175A. The EPA is also proposing to approve the motor vehicle emissions budgets (MVEBs or ''budgets'') in the Clark County Second Maintenance Plan because we find they meet the applicable transportation conformity requirements under 40 CFR 93.118(e).

II. Background

Sections 108 and 109 of the CAA govern the establishment, review, and revision, as appropriate, of the NAAQS to protect public health and welfare. The CAA requires the EPA to periodically review the air quality criteria, the science upon which the standards are based, and the standards themselves. Ground-level ozone is one of the criteria pollutants regulated under the NAAQS.

Ground-level ozone is generally not emitted directly by sources. Rather, directly emitted oxides of nitrogen (NO_X) and volatile organic compounds (VOC) react in the presence of sunlight to form ground-level ozone, as a secondary pollutant, along with other secondary compounds. NO_X and VOC are ''ozone precursors.'' Reduction of peak ground-level ozone concentrations is typically achieved through controlling VOC and NO_X emissions.

Scientific evidence indicates that adverse public health effects occur following exposure to ozone, particularly in children and adults with lung disease. Breathing air containing ozone can reduce lung function and inflame airways, which can increase respiratory symptoms and aggravate asthma or other lung diseases.[1]

[1] ''Fact Sheet—2008 Final Revisions to the National Ambient Air Quality Standards for Ozone,'' dated March 2008.

In 1997, the EPA revised the NAAQS for ozone, setting it at 0.08 parts per million (ppm) averaged over an 8-hour time frame.[2] The EPA set the 1997 8-hour ozone standard based on scientific evidence demonstrating that ozone causes adverse health effects at lower ozone concentrations and over longer periods of time, than was understood when the pre-existing 1-hour ozone standard was set. The EPA determined that the 1997 8-hour ozone NAAQS would be more protective of human health, especially for children and adults who are active outdoors, and individuals with a pre-existing respiratory disease, such as asthma.[3]

In 2004, the EPA designated areas of the country with respect to the 1997 8-hour ozone NAAQS.[4] Under the EPA's ''Phase 1'' implementation rule for the 1997 8-hour ozone standard [5] an area was classified under subpart 2 based on its 8-hour ozone design value (*i.e.,* the 3-year average annual fourth-highest daily maximum 8-hour average ozone concentration at the worst-case monitoring site in the area or in its immediate downwind environs), if it had a 1-hour ozone design value [6] at the time of designation at or above 0.121 ppm. All other areas were covered under subpart 1 based on their 8-hour ozone design values.[7] Clark County was designated as a subpart 1 ozone nonattainment area by the EPA on April 30, 2004, based on air quality monitoring data from 2001–2003. The designation became effective on June 15, 2004. On September 17, 2004, the EPA reduced the geographic extent of the ozone nonattainment area to encompass a portion, but not all, of Clark County.[8]

In *South Coast Air Quality Management Dist.* v. *EPA* [9] the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit, or ''Court'') vacated the EPA's Phase 1 implementation rule for the 1997 8-hour ozone standard.[10] In response to several petitions for rehearing, the D.C. Circuit clarified that the Phase 1 rule was vacated only for those parts of the rule that had been successfully challenged.[11] The decision left intact the Court's rejection of the EPA's reasons for implementing the 8-hour ozone standard in certain nonattainment areas under subpart 1 in lieu of subpart 2 of the CAA.

On May 14, 2012, in response to the Court's vacatur of the provision of the Phase 1 rule for the 1997 8-hour ozone standard that placed certain nonattainment areas, including Clark County solely under subpart 1, the EPA classified Clark County as a marginal ozone nonattainment area under subpart 2 of the CAA.[12]

On March 29, 2011, the EPA determined that the Clark County 8-hour ozone nonattainment area had attained the 1997 8-hour ozone NAAQS, based on complete, quality-assured, and certified ambient air monitoring data that showed the area monitored attainment of the 1997 8-hour ozone NAAQS for the 2007–2009 monitoring period.[13]

On April 11, 2011, NDEP submitted the Clark County First Maintenance Plan and requested that the EPA redesignate the Clark County 8-hour ozone nonattainment area to attainment for the 1997 8-hour ozone standard. On January 8, 2013, the EPA approved the Clark County First Maintenance Plan, and redesignated the area from nonattainment to attainment of the 1997 8-hour ozone NAAQS.[14]

On October 31, 2018, NDEP submitted a *Revision to Motor Vehicle Emissions Budgets in Ozone Redesignation Request and Maintenance Plan* (''2018 Ozone Maintenance Plan Revision''). The 2018 Ozone Maintenance Plan Revision updated elements of the Clark County First Maintenance Plan, including the attainment inventory, the maintenance demonstration, and the budgets. The 2018 Ozone Maintenance Plan Revision established ozone season budgets of 52.96 and 86.74 tons per day (tpd) for VOC and NO_X, respectively, for 2022 so that the area would have updated budgets available to use for transportation conformity determinations with respect to the 2015 National Ambient Air Quality Standards for ozone (''2015 ozone NAAQS'').[15] On August 27, 2019, the EPA conditionally approved the 2018 Ozone Maintenance Plan revisions, based on commitments to submit an additional SIP revision to reduce the safety margin allocations for the budgets within one year of the final conditional approval.[16]

On September 30, 2020, NDEP submitted an additional *Revision to Motor Vehicle Emissions Budgets for the 1997 ozone NAAQS, Clark County, Nevada* (''2020 Ozone Maintenance Plan Revision''). The 2020 Ozone Maintenance Plan Revision was prepared in response to the EPA's conditional approval of the 2018 Ozone Maintenance Plan Revision. The 2020 Ozone Maintenance Plan Revision revised certain budgets from the 2018 Ozone Maintenance Plan Revision to prevent interference with Reasonable Further Progress (RFP) or attainment of the 2008 and 2015 ozone NAAQS. The 2020 Ozone Maintenance Plan Revision established budgets of 23.92 and 32.16 tons per average summer day [17] for VOC and NO_X, respectively, for 2022. On October 28, 2021, with the submittal of the 2020 Ozone Maintenance Plan Revision, the EPA approved the updates to the attainment inventory, the maintenance demonstration, and the budgets to the Clark County First Maintenance Plan.[18]

On January 24, 2022, NDEP submitted the Clark County Second Maintenance Plan showing how the area will continue to attain the 1997 8-hour ozone national ambient air quality standard (NAAQS) for 10 additional years beyond the approval the State's first 10-year plan.

Lastly, on August 16, 2023, NDEP submitted the Contingency Measure Revision, which revised the contingency measure section of the Clark County Second Maintenance Plan. In this action, we are proposing action on the

[2] 62 FR 38856 (July 18, 1997).

[3] On March 27, 2008 (73 FR 16436), the EPA promulgated a revised 8-hour ozone standard of 0.075 ppm (the 2008 8-hour ozone standard), and on May 21, 2012, the EPA designated the entire state of Nevada unclassifiable/attainment for the 2008 8-hour ozone standard (77 FR 30088). This rulemaking relates only to the 1997 8-hour ozone standard and does not relate to the 2008 8-hour ozone standard.

[4] 69 FR 23858 (April 30, 2004).

[5] 69 FR 23951, (April 30, 2004).

[6] The design value for the 1-hour ozone standard is the fourth-highest daily maximum 1-hour ozone concentration over a three-year period at the worst-case monitoring site in the area.

[7] 69 FR 23951. The design value for the 8-hour standard is the three-year average of the annual fourth-highest daily maximum 8-hour ozone concentration at the worst-case monitoring site in the area.

[8] 69 FR 55956 (September 17, 2004), 70 FR 71612 (November 29, 2005), and 40 CFR 81.329. The boundaries of the Clark County ozone nonattainment area are defined in 40 CFR 81.329. Specifically, the area is defined as: ''That portion of Clark County that lies in hydrographic areas 164A, 164B, 165, 166, 167, 212, 213, 214, 216, 217, and 218 but excluding the Moapa River Indian Reservation and the Fort Mojave Indian Reservation.'' The area includes a significant portion of the unincorporated portions of central and southern Clark County, as well as the cities of Las Vegas, Henderson, North Las Vegas, and Boulder City.

[9] 472 F.3d 882 (D.C. Cir. 2007).

[10] 69 FR 23951.

[11] 472 F.3d 882 (D.C. Cir. 2007).

[12] 77 FR 28424.

[13] 76 FR 17343.

[14] 78 FR 1149.

[15] 84 FR 33038 (July 11, 2019).

[16] 84 FR 44699.

[17] According to ''Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards (NAAQS) and Regional Haze Regulations,'' dated May 2017, terminology used has changed from ''summer day'' emissions to ''ozone season'' emissions. However, ''average summer day'' emissions are used in this instance to stay consistent between motor vehicle emissions budgets of different ozone standards.

[18] 86 FR 59643.

NDEP's Clark County Second Maintenance Plan submittal.

III. Second 10-Year Maintenance Plan Submittal and Procedural Requirements

CAA section 110(a)(1) and (2) and section 110(1) require states to provide reasonable notice and public hearing prior to adoption of SIP revisions. In this action, we are proposing action on NDEP's January 24, 2022, submittal of the Clark County Ozone Second Maintenance Plan, and NDEP's August 16, 2023, submittal of the Contingency Measure Revision as a revision to the Nevada SIP, collectively referred to as the Clark County Second Maintenance Plan submittal.

Following a 30-day public comment period, the Clark County Second Maintenance Plan was adopted by the Clark County Board of Commissioners, submitted to NDEP, and submitted to the EPA. Appendix B of the Clark County Second Maintenance Plan documents the public review process followed by Clark County in adopting the plan prior to transmittal to NDEP for subsequent submittal to the EPA as a revision to the Nevada SIP. The documentation in appendix B provides evidence that reasonable notice of a public hearing was provided to the public and that a public hearing was conducted prior to adoption. Specifically, notice of the availability of, and opening of a 30-day comment period on, the draft Clark County Second Maintenance Plan was published on October 14, 2021, on the Clark County Department of Environment and Sustainability (DES) website, the DES official Facebook page, and the DES official Twitter. No comments were submitted.

On December 7, 2021, the Clark County Board of Commissioners set a public hearing for December 21, 2021, to consider and approve the Clark County Second Maintenance Plan. The announcement of the public hearing was subsequently published on the County's web page. On December 21, 2021, the Clark County Board of Commissioners adopted the Clark County Second Maintenance Plan at the close of the public hearing. Following adoption, Clark County DES forwarded the plan to NDEP, the Governor of Nevada's designee for SIP matters, and NDEP then submitted the plan as a revision to the Nevada SIP to the EPA for approval on January 24, 2022.

Appendix A of the Contingency Measure Revision documents the board approval process followed by Clark County in adopting the plan prior to transmittal to NDEP for subsequent submittal to the EPA as a revision to the Nevada SIP. On July 18, 2023, the Clark County Board of Commissioners put the Contingency Measure Revision up for public notice and adopted the Contingency Measure Revision at the close of the public hearing. Following adoption, Clark County DES forwarded the plan to NDEP and NDEP then submitted the plan, as a revision to the Nevada SIP, to the EPA for approval on August 16, 2023.

Based on the documentation contained in appendix B of the Plan and appendix A of the Contingency Measure Revision, we find that the Clark County Second Maintenance Plan submittal satisfies the procedural requirements of section 110(l) of the Act.

IV. Requirements for Second 10-Year Maintenance Plans

Section 175A of the CAA provides the general framework for a maintenance plan. The initial 10-year maintenance plan must provide for maintenance of the NAAQS for at least 10 years after redesignation, including any additional control measures necessary to ensure such maintenance. In addition, maintenance plans are to contain contingency provisions necessary to ensure the prompt correction of a violation of the NAAQS that occurs after redesignation. The contingency measures must include, at a minimum, a requirement that the state will implement all control measures contained in the nonattainment SIP prior to redesignation. Beyond these provisions, section 175A of the CAA does not define the content of a second 10-year maintenance plan.

The primary guidance on maintenance plans and redesignation requests is a September 4, 1992, memorandum from John Calcagni, titled ''Procedures for Processing Requests to Redesignate Areas to Attainment'' (Calcagni Memo).[19] The Calcagni Memo outlines the key elements of a maintenance plan, which include verification of continued attainment, monitoring network requirements, attainment emissions inventory, maintenance demonstration, and a contingency plan. We evaluate the Second 10-Year Maintenance Plan based on the satisfactory fulfillment of these and all relevant procedural requirements of the CAA.

CAA section 175A(b) requires states to submit an additional SIP revision (Second 10-Year Maintenance Plan) to maintain the NAAQS for an additional 10 years after the expiration of the 10-year period covered by the initial maintenance plan approved in connection with the redesignation of the area from nonattainment to attainment. The revision is submitted eight years after the original redesignation request and maintenance plan have been approved. The deadline to submit Clark County's Second Maintenance Plan was January 8, 2021. On January 24, 2022, NDEP submitted the Clark County Second Maintenance Plan, to meet the requirement for the subsequent maintenance plan under CAA section 175A(b). The Clark County Second Maintenance Plan is intended to provide for continued maintenance of the 1997 ozone NAAQS for the 10-year period following the end of the first 10-year period, *i.e.,* from 2024 through 2033.

V. Evaluation of the Clark County Second Maintenance Plan

Section 175A of the CAA sets forth the elements of a maintenance plan. We interpret this section of the Act to require, in general, the following core elements: attainment inventory, maintenance demonstration, monitoring network, verification of continued attainment, and contingency plan.[20] Under CAA section 175A, a maintenance plan must demonstrate continued attainment of the applicable NAAQS for at least ten years after the EPA approves a redesignation to attainment. Eight years after redesignation, the State must submit a revised maintenance plan that demonstrates continued attainment for the subsequent ten-year period following the initial ten-year maintenance period. To address the possibility of future NAAQS violations, the maintenance plan must contain such contingency provisions that the EPA deems necessary to promptly correct any violation of the NAAQS that occurs after redesignation of the area. Based on our review and evaluation of the plan, as detailed below, we are proposing to approve the Clark County Second Maintenance Plan submittal because we believe that it meets the requirements of CAA section 175A.

A. Monitoring Network Requirements

Continued ambient monitoring of an area is generally required over the maintenance period. Clark County DES currently operates ozone monitors at thirteen sites within the Clark County 8-hour ozone maintenance area.

[19] Memorandum dated September 4, 1992, from John Calcagni, Director, EPA Air Quality Management Division, to Regional Office Air Division Directors, Subject: Procedures for Processing Requests to Redesignate Areas to Attainment.

[20] Calcagni Memo, 8–13.

In the Clark County Second Maintenance Plan,[21] Clark County DES indicates its intention to continue operation of an air quality monitoring network to verify continued attainment of the 1997 8-hour ozone NAAQS.[22] The Clark County Second Maintenance Plan also notes that Clark County DES's State and Local Air Monitoring Stations (SLAMS) air quality monitoring network (which includes ambient ozone monitoring) will be reviewed annually pursuant to 40 CFR 58.20(d) to determine whether the system continues to meet the applicable monitoring objectives.[23] We approved Clark County's SLAMS air quality network in their Annual Monitoring Network Plan for year 2020 on October 28, 2020, prior to Clark County's submittal of the Clark County Second Maintenance Plan. We find the County's commitment for continued ambient ozone monitoring as set forth in the Clark County Second Maintenance Plan to be acceptable.

B. Attainment Inventory

For maintenance plans, a state should develop a comprehensive and accurate inventory of actual emissions for an attainment year which identifies the level of emissions in the area which is sufficient to maintain the NAAQS. The inventory should be developed consistent with the EPA's most recent guidance. For ozone, the inventory should be based on typical ozone season day emissions of NO_X and VOC.

In the Clark County First Maintenance Plan, Clark County DES used 2008 for the attainment year inventory, because 2008 was one of the years in the 2007–2009 three-year period when the area first attained the 1997 ozone NAAQS.[24] Clark County DES continued to monitor attainment of the 1997 ozone NAAQS in 2017. Therefore, the emissions inventory from 2017 represents emissions levels consistent with continued attainment (*i.e.,* maintenance) of the NAAQS. Thus, Clark County DES selected 2017 as the year for the attainment inventory in the Clark County Second Maintenance Plan. We consider the selection of the 2017 base year inventory to be appropriate given that it was the most recent emissions inventory associated with the reporting schedule required under the Air Emissions Reporting Requirements rule at the time of Plan drafting.

Table 1 presents the VOC and NO_X emissions estimates contained in the Clark County Second Maintenance Plan for 2017 and presents the Plan's projected emissions inventories of ozone precursors in an interim year (2023) and the maintenance plan's horizon year (2033).[25]

TABLE 1—CLARK COUNTY 2017 AND PROJECTED 2023 AND 2033 VOC AND NO_X EMISSIONS TOTAL DAILY EMISSIONS

[Tpd, average summer ozone season weekday]

Emissions source	2017		2023		2033	
	VOC	NO_X	VOC	NO_X	VOC	NO_X
Point Source	2.95	12.34	2.62	11.41	2.63	11.33
Nonpoint Source	64.69	4.69	67.83	5.03	71.31	4.78
Mobile—On-road	26.27	42.20	17.85	22.22	11.50	11.13
Mobile—Nonroad	28.86	37.45	27.24	23.27	27.82	15.37
Airports	1.96	11.90	2.64	15.53	3.05	19.77
Locomotives	0.07	1.42	0.05	1.21	0.04	0.96
Emission Reduction Bank	0.00	0.00	0.43	22.23	0.43	22.23
Biogenic	362.61	2.43	362.61	2.43	362.61	2.43
Total	487.41	112.43	481.27	103.33	479.39	88.00

Source: Clark County Second Maintenance Plan, 17, Tables 2–4 and 2–5.

[a] Emissions associated with the proposed Department of Air Force (DAF) Training Project is included in Airport emissions projections for the 2023 and 2033 emissions projections for general conformity purposes. Emissions associated with the proposed Southern Nevada Supplemental Airport and proposed Sloan Regional Heliport are included for the 2033 emissions projection for general conformity purposes.

The data shown in Table 1 in this document is based on the 2017 National Emissions Inventory (NEI).[26] The inventory addresses point sources,[27] nonpoint sources,[28] on-road mobile, non-road mobile, airports, locomotives, Emission Reduction Credits (ERCs),[29] and biogenic [30] sources. Appendix A to the Clark County Second Maintenance Plan contains source-specific descriptions of emissions calculation procedures and sources of input data.

Point sources are stationary sources that have a potential to emit (PTE) greater than 100 tons per year of NO_X or VOC. Clark County DES adopted a lower threshold by including all title V stationary sources and minor sources with a PTE greater than 10 tons of VOC or 25 tons of NO_X per year. Clark County DES based the inventory estimates on source reported actual 2017 emissions data but adjusted the reported values to reflect a typical ozone

[21] Clark County Second Maintenance Plan, 20–23.

[22] Although the Clark County Second Maintenance Plan is not explicit in this regard, we presume that Clark County DES's intention to continue operation of a monitoring network means that the agency intends to do so consistent with the EPA's monitoring requirements in 40 CFR part 58 (''Ambient Air Quality Surveillance'').

[23] The EPA's requirements for annual review of monitoring networks are no longer codified at 40 CFR 58.20(d) but are now found at 40 CFR 58.10.

[24] 76 FR 17343 (Apr. 29, 2011).

[25] The emissions inventories reflect county-wide emissions which include both the nonattainment area portion of the county and the portion of the county designated as ''unclassifiable/attainment'' for the 1997 8-hour ozone NAAQS. County-wide emissions are acceptable to characterize emissions within the Clark County ozone nonattainment area because over 95% of the population of the county resides in the nonattainment area.

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

[27] The Clark County Second Maintenance Plan uses the term, ''point sources,'' to refer to those stationary source facilities that are required to report their emissions to Clark County DES or NDEP.

[28] The Clark County Second Maintenance Plan uses the term, ''nonpoint sources,'' to refer to those stationary and area sources that fall below point source reporting levels and that are too numerous or small to identify individually.

[29] The Clark County Second Maintenance Plan uses the term, ''ERCs'' to refer to allowances earned through voluntary pollutant emission reductions such as equipment shutdowns or voluntarily installed controls.

[30] For the Clark County Second Maintenance Plan, ''biogenic sources'' include agricultural crops; lawn grass; forests that produce isoprene, monoterpene, and other VOC emissions; and soils that generate trace amounts of NO_X.

season day at each emissions unit within the source facilities based on information provided by the facilities.

Nonpoint sources include emissions from equipment, operations and activities that are numerous and in total have significant emissions. Clark County DES included emissions from minor sources, residential combustion, agricultural burning, industrial solvents and graphic arts, and degreasing operations. Clark County DES used several methods to estimate area source activity levels and emissions, including applying local activity levels, apportioning national or statewide activity levels to the local level, applying per capita emission factors considering county-specific populations and using specific method abstracts detailed within the submittal.

Non-road emissions sources include equipment that either move under their own power or can be moved from site to site.

The on-road emissions sector includes emissions from engines used primarily to propel equipment on highways and other roads, including passenger vehicles, motorcycles, and heavy-duty diesel trucks. Clark County DES used MOVES3, EPA's MOVES3 emissions factors, fleet data from Department of Motor Vehicles (DMV) registration data, Coordinated Research council (CRC) vehicle speed data, the Regional Transportation Commission (RTC) of Southern Nevada's transportation demand modeling results, vehicle classification data from the June 2018 Clark County Vehicle Classification Study,[31] and 2017 Highway Performance Monitoring System (HPMS) data from the Nevada Department of Transportation (NDOT).

Biogenic emissions are from vegetation and soil, and include crops, lawn grass, and forests. Clark County DES used the Biogenic Emissions Inventory System version 3.61 (BEIS3.61) embedded in the SMOKE 4.7 model for the month of July to generate average ozone season day emissions for Clark County.

The airport sector includes emissions from aircraft from commercial and federal aviation sources. Clark County DES relied on airport-specific emissions inventory information provided by the Clark County Department of Aviation (CCDOA) for the five commercial airports located within the nonattainment area.

Locomotives include emissions from railroad and high-speed passenger train emissions. Locomotive emissions were estimated by Clark County DES based on local activity data collected for the Clark County First Maintenance Plan and predicted emissions from high-speed passenger train service.

ERCs refer to allowances earned through voluntary pollutant emissions reductions such as equipment shutdowns or voluntarily installed controls. Clark County adopted New Source Review (NSR) rule, Section 12.7.5—Emission Reduction credits into the SIP,[32] allowing Clark County to adopt ERCs. In the Clark County First Maintenance Plan, Clark County banked NO_X and VOC credits from the Clark County Department of Air Quality and Environmental Management (DAQEM) ERC Bank,[33] Reid Gardner ERCs,[34] and Mohave ERCs.[35] In the Clark County Second Maintenance Plan, Clark County noted that ERCs have not changed from the Clark County First Maintenance Plan.

The EPA has reviewed the emissions inventory submitted by Clark County and proposes to conclude that the plan's inventory is based on reasonable assumptions and methodologies, and that the inventory is comprehensive, current, accurate, and consistent with applicable CAA provisions and the Calcagni Memo. Therefore, we are proposing that the inventory is acceptable for use in demonstrating maintenance of the 1997 ozone NAAQS.

C. Maintenance Demonstration

CAA section 175A(a) requires that the maintenance plan ''provide for the maintenance of the national primary ambient air quality standard for such air pollutant in the area concerned for at least 10 years after the redesignation.'' Generally, a state may demonstrate maintenance of the ozone NAAQS by either showing that future emissions of a pollutant or its precursors will not exceed the level of the attainment inventory or by modeling to show that the future mix of sources and emissions rates will not cause a violation of the NAAQS.[36] For areas that are required under the Act to submit modeled attainment demonstrations, the maintenance demonstration should use the same level of modeling.[37] The Clark County 8-hour ozone nonattainment area was not required to submit a modeled attainment demonstration, and thus, the Clark County Second Maintenance Plan may demonstrate maintenance based on a comparison of existing and future emissions of ozone precursors.[38]

Clark County used the 2017 national emissions inventory (NEI) data as the baseline to develop growth factors for point, nonpoint, and locomotive sources. Clark County DES used the EPA 2016 v.1 modeling platform emissions data to develop per-year growth adjustment factors for point, nonpoint, federal aviation, and locomotives. Clark County DES used local activity data to develop commercial airport growth factors and conducted MOVES3 modeling to project on-road and non-road emissions. The derived growth adjustment factors were used to extrapolate emissions to account for a 16-year (2017 through 2033) spread. The 2033 growth factors were multiplied by the 2017 actual emissions to produce the 2033 projected point source and various other stationary source emissions; including Residential Wood Combustion,[39] non-point VOC,[40] airport,[41] and locomotive emissions.[42] An interim year (2023) projected emissions inventory is also included. On-road emissions were estimated for the 2017 base year and for projection years 2023 and 2033 and reflect a 32 percent decrease in VMT from 2017 to 2023 and a 56 percent decrease in VMT from 2017 to 2033 based on Regional Transit Commission (RTC) projections.[43]

In addition to accounting for areawide growth trends, Clark County DES added emissions from specific projects that are expected to become operational during the second maintenance period,

[31] Clark County DES completed a vehicle classification study in June 2018. The study used 2014–2016 traffic count data collected by the Nevada Department of Transportation (NDOT). Clark County DES incorporated VMT mix profiles and temporal profiles, which DES incorporated into the 2017 MOVES3 input database.

[32] 79 FR 62350 (October 17, 2014).

[33] See ''DAQEM ERC Bank'' for a list of sources contributing to the DAQEM ERC Bank in Clark County.

[34] NDEP banked Reid Gardner ERCs after the NV Energy—Reid Gardner Station Power Plant, Unit #4 Steam Boiler was controlled with a low-NO_X burner in January 2010.

[35] NDEP banked Mohave ERCs after the permanent shut down and dismantling of the Southern California Edison Mohave Generating Station in November 2009.

[36] Calcagni Memo, 9–11.

[37] Id.

[38] A maintenance demonstration need not be based on ozone modeling. See *Wall* v. *EPA,* 265 F.3d. 426 (6th Cir. 2001); *Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004). See also 66 FR 53094 (October 19, 2001), and 68 FR 25418 (May 12, 2003).

[39] Clark County Second Maintenance Plan, Appendix A, 23.

[40] Clark County Second Maintenance Plan, Appendix A, 24.

[41] Clark County Second Maintenance Plan, Appendix A, 29.

[42] Clark County Second Maintenance Plan, Appendix A, 31.

[43] Clark County Second Maintenance Plan, 27, Table 6–1.

including the proposed Southern Nevada Supplemental Airport, the proposed Sloan Regional Heliport, and DAF training program in the future-year emissions inventories, and also added in ERCs from certain stationary sources in the event that the ERCs are used for the purposes of issuing permits for new or modified stationary sources in the air quality planning area. We have reviewed the methods and assumptions, as described in connection with the attainment inventory, that Clark County DES used to project emissions to 2023 and 2033 for the various source categories and find them to be reasonable.

Table 1 compares the VOC and NO_X emissions estimated for the Clark County 8-hour ozone maintenance area for 2017 with those for 2023 and 2033 by source category. The projected VOC and NO_X emissions show that VOC and NO_X emissions would remain well below the attainment levels throughout the second 10-year maintenance period and thereby adequately demonstrate maintenance through that period.

In addition, historical monitoring data presented in the plan shows a gradual downward trend in ozone design values during 2008–2020. The 1997 NAAQS level of 80 ppb was achieved in 2009, and the 2020 value of 74 ppb is well below the NAAQS.[44] This supports the maintenance demonstration, and the EPA expects this downward trend will continue given the projected emissions decreases.

D. Verification of Continued Attainment

NDEP and the Clark County Board of County Commissioners have the legal authority to implement and enforce the requirements of the Clark County Second Maintenance Plan. This includes the authority to adopt, implement and enforce any emissions control contingency measures determined to be necessary to correct ozone NAAQS violations. To verify continued attainment, Clark County DES commits in the Clark County Second Maintenance Plan to the continued operation of an ozone monitoring network that meets the EPA ambient air quality surveillance requirements.

Secondly, the transportation conformity process represents another means by which to verify continued attainment of the 1997 8-hour ozone NAAQS in the Clark County 8-hour ozone area given the relative importance of motor vehicle emissions to the overall emissions inventories of ozone precursors.[45]

Lastly, while not cited in the plan, NDEP and Clark County DES must inventory emissions sources and report to the EPA on a periodic basis under 40 CFR part 51, subpart A (''Air Emissions Reporting Requirements''). These emissions inventory updates will provide a third means with which to track emissions in the area relative to those projected in the maintenance plan and thereby verify continued attainment of the NAAQS. These methods are sufficient for the purpose of verifying continued attainment.

E. Contingency Provisions

Section 175A(d) of the Act requires that maintenance plans include contingency provisions, as the EPA deems necessary, to promptly correct any violations of the NAAQS that occur after redesignation of the area. Such provisions must include a requirement that the State will implement all measures with respect to the control of the air pollutant concerned which were contained in the SIP for the area before redesignation of the area as an attainment area.

Under section 175A(d), contingency measures identified in the contingency plan do not have to be fully adopted at the time of redesignation. However, the contingency plan is an enforceable part of the SIP and should ensure that the contingency measures are adopted expeditiously once they are triggered by a specified event. The maintenance plan should clearly identify the measures to be adopted, a schedule and procedure for adoption and implementation, and a specific timeline for action by the State. As a necessary part of the plan, the State should also identify specific indicators or triggers, which will be used to determine when the contingency measures need to be implemented.

As required by section 175A of the CAA, Clark County DES has adopted a contingency plan to address possible future ozone air quality problems.[46] Clark County DES identifies the trigger date as 60 days after a determination of a confirmed violation of the 1997 8-hour ozone NAAQS. Within 45 days of the trigger date, Clark County will notify the EPA that it is evaluating potential contingency measures. Within 90 days of the trigger date, Clark County will send a report to the EPA and then will initiate a public process to consider the recommended contingency measures, including soliciting stakeholder involvement and holding public hearings. The necessary emissions control measures will be adopted and implemented no later than 18 months after the trigger date.

Potential contingency measures listed in the maintenance plan are those emissions controls or other measures that Clark County, the Nevada State Board of Agriculture, and/or the Nevada State Environmental Commission may choose to adopt and implement in response to the contingency trigger. The contingency measures plan in the Contingency Measure Revision lists the following potential contingency measures that will be considered for adoption and implementation by the applicable State or County agency, but the Plan indicates that the list is not to be considered exclusive:

- Reid vapor pressure reduction (*i.e.,* in gasoline sold during the summer ozone season; would need to be adopted and implemented by the Nevada State Board of Agriculture);
- Inspection/maintenance program changes and additions (*e.g.,* lowering the cut points for VOCs and NO_X applicable to pre-1996 vehicles; would need to be adopted and implemented by the State Environmental Commission and/or the State Department of Motor Vehicles);
- Consumer and commercial products (Clark County would be responsible for adoption and implementation);
- Architectural surface coatings (Clark County would be responsible for adoption and implementation);
- Lawn and garden equipment use (Clark County would be responsible for adoption and implementation); and
- Establish/enhance trip reduction programs (Clark County and the RTC would be responsible for adoption and implementation).

Upon our review of the plan, we find that the contingency provisions of the Contingency Measure Revision clearly identify specific contingency measures, contain tracking and triggering mechanisms to determine when contingency measures are needed, contain a description of the process of recommending and implementing contingency measures, and contain specific timelines for action. Thus, we conclude that the contingency provisions of the Contingency Measure Revision are adequate to ensure prompt correction of a violation and therefore comply with section 175A(d) of the Act.

F. Motor Vehicle Emissions Budgets for Transportation Conformity

Section 176(c) of the CAA requires federal actions in nonattainment and

[44] Clark County Second Maintenance Plan, 12, Figure 2–1.

[45] Clark County Second Maintenance Plan, Page 15.

[46] Contingency Measure Revision, Section 2, ''Contingency Measures Plan.''

maintenance areas to conform to the SIP's goals of eliminating or reducing the severity and number of violations of the NAAQS and achieving expeditious attainment of the standards. Conformity to the SIP's goals means that such actions will not: (1) cause or contribute to violations of a NAAQS, (2) worsen the severity of an existing violation, or (3) delay timely attainment of any NAAQS or any interim milestone.

Actions involving Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) funding or approval are subject to the EPA's transportation conformity rule, codified at 40 CFR part 93, subpart A. Under this rule, RTCs in nonattainment and maintenance areas coordinate with state and local air quality and transportation agencies, the EPA, FHWA, and FTA to demonstrate that an area's regional transportation plans and transportation improvement programs conform to the applicable SIP. This demonstration is typically done by showing that estimated emissions from existing and planned highway and transit systems are less than or equal to the motor vehicle emissions budgets (''budgets'') contained in submitted or approved control strategy SIPs and maintenance plans.[47]

These control strategy SIPs and maintenance plans typically set budgets for criteria pollutants and/or their precursors to address pollution from cars and trucks. Budgets are generally established for specific years and specific pollutants or precursors. Maintenance plan submittals should identify budgets for transportation-related VOC and NO_X emissions in the last year of the maintenance period.

For budgets in a maintenance plan to be approvable, they must meet, at a minimum, the EPA's adequacy criteria.[48] To meet these requirements, the budgets must be consistent, when considered with emissions from all other sources, with maintenance of the NAAQS and reflect all the motor vehicle control measures relied upon for the maintenance demonstration. The EPA's process for determining adequacy of a budget consists of three basic steps: (1) providing public notification of a SIP submission; (2) providing the public the opportunity to comment on the MVEB during a public comment period; and (3) making a finding of adequacy. The process for determining the adequacy of a submitted budget is codified at 40 CFR 93.118(f). The EPA can notify the public by either posting an announcement that the EPA has received SIP budgets on the EPA's adequacy website, or via a **Federal Register** notice of proposed rulemaking when the EPA reviews the adequacy of a maintenance plan budget simultaneously with its review and action on the SIP submittal itself.[49]

Clark County's Second Maintenance Plan contains VOC and NO_X budgets for 2017, 2023 and 2033. Any and all comments on the approvability of the budgets should be submitted during the comment period stated in the **DATES** section of this document.

The EPA proposes to approve 2017, 2023, and 2033 budgets in the Clark County Second Maintenance Plan for transportation conformity purposes in the final rulemaking on Clark County's ozone redesignation request. If the EPA approves the budgets in the final rulemaking action, the new budgets must be used in future transportation conformity determinations for Clark County for the 2015 ozone standard. The new budgets, if approved in the final rulemaking, will be effective on the date of the EPA's final rulemaking in the **Federal Register**. The applicable VOC and NO_X MVEBs for the Clark County ozone nonattainment area are defined in table 2.

TABLE 2—PROPOSED MOTOR VEHICLE EMISSIONS BUDGETS (MVEBS) FOR CLARK COUNTY

Budget year	VOC (tpd, average summer weekday)	NO_X (tpd, average summer weekday)
2017	26.27	42.2
2023	20.92	26.77
2033	15.51	23.35

From Table 6–3 and 6–4 of the Clark County Second Maintenance Plan.

The MVEBs are the on-road mobile source VOC and NO_X emissions for Clark County for 2017, 2023 and 2033. The budgets are compatible with the 2017, 2023, and 2033 on-road mobile source VOC and NO_X emissions included in Clark County's 2017, 2023, and 2033 VOC and NO_X emission inventories, as summarized in Table 2. The derivation of the budgets is thoroughly discussed in Appendix A, Chapter 2 of Clark County's Second Maintenance Plan. While the Plan includes budgets for 2017, we are not evaluating the 2017 budgets because that year would not be used in any future conformity determination because the plan contains budgets for 2023 and because 2017 budgets are not required for the submitted second maintenance plan.

We evaluated the budgets against our adequacy criteria in 40 CFR 93.118(e)(4) and (5) as part of our review of the budget's approvability and expect to complete the adequacy review of the budgets concurrent with our final action on the Clark County's Second Maintenance Plan. The EPA is not required under its transportation conformity rule to find budgets adequate prior to proposing approval of them. In this notice, the EPA is announcing that the adequacy process for these budgets begins, and the public has 30 days to comment on their adequacy, per the transportation conformity rule at 40 CFR 93.118(f)(2)(i) and (ii).

Clark County DES developed the budgets for 2023 and 2033 using on-road motor vehicle emission estimates made using the EPA's MOVES3 model, fleet data from DMV registration data, CRC vehicle speed data, NDOT HPMS data, travel demand modeling from the Regional Transportation Commission and vehicle classification data from the June 2018 Clark County On-road Vehicle Classification Study.

As documented in the separate memorandum [50] included in the docket for this rulemaking, we preliminarily conclude that the budgets in the Second Maintenance Plan meet each adequacy criterion. While adequacy and approval

[47] Control strategy SIPs refer to RFP and attainment demonstration SIPs. 40 CFR 93.101.

[48] 40 CFR 93.118(e)(4) and (5). For more information on the transportation conformity requirement and applicable policies on MVEBs, please visit our transportation conformity website at: *http://www.epa.gov/otaq/stateresources/transconf/index.htm.*

[49] 40 CFR 93.118(f)(2).

[50] See the EPA Memorandum dated August 22, 2023 titled: Adequacy Documentation for Motor Vehicle Emissions Budgets in Clark County Second Maintenance Plan.''

are two separate actions, reviewing the budgets in terms of the adequacy criteria informs the EPA's decision to propose to approve the budgets. We have completed our detailed review and are proposing to approve the demonstration of maintenance for the 1997 ozone maintenance area through the year 2033. We have also reviewed the budgets in Clark County's Second Maintenance Plan and found that they are consistent with the maintenance demonstration for which we are proposing approval, are clearly identified and precisely quantified, are based on control measures that have already been adopted and implemented, and meet all other applicable statutory and regulatory requirements including the adequacy criteria in 40 CFR 93.118(e)(4) and (5). The EPA is proposing to approve the budgets for 2023 and 2033 as part of our approval of Clark County's Second Maintenance Plan. At the point when we either finalize the adequacy process or approve the budgets as proposed (whichever occurs first; note that they could also occur concurrently per 40 CFR 93.118(f)(2)(iii)), the budgets must be used by the Regional Transportation Commission (*i.e.,* the Metropolitan Planning Organization (MPO) for this area) for transportation conformity determinations for the Clark County 2015 ozone nonattainment area.

VI. Environmental Justice Considerations

The EPA performed a screening-level analysis using the EPA's environmental justice (EJ) screening and mapping tool (''EJSCREEN''). Our screening-level analysis included multiple environmental and demographic indicators, including the EJSCREEN ''Demographic Index,'' which is the average of an area's percentage of minority and low-income populations. The Demographic Index of Clark County is at the 68th percentile, compared to the United States as a whole.[51] The results of this analysis are being provided for informational and transparency purposes.

This action addresses a plan for continued maintenance of the 1997 ozone NAAQS for Clark County. Approval of this plan does not impose any additional regulatory requirements on sources beyond those imposed by state law. As discussed in this document, Nevada has demonstrated that the Clark County is attaining the 1997 ozone NAAQS and the Clark County Second Maintenance Plan provides for the maintenance of the NAAQS for the reminder of the maintenance period. We expect that this action will generally be neutral or contribute to reduced environmental and health impacts on all populations in Clark County, including people of color and low-income populations. At a minimum, this action would not worsen any existing air quality and is expected to ensure the area is meeting requirements to maintain air quality standards. Further, there is no information in the record indicating that this action is expected to have disproportionately high or adverse human health or environmental effects on a particular group of people.

VII. Proposed Action and Request for Public Comment

Under CAA section 110(k)(3), and for the reasons set forth in this document, the EPA is proposing to approve the Clark County Second Maintenance Plan submitted by NDEP on January 24, 2022, as a revision to the Nevada SIP.[52] We are proposing to approve the maintenance demonstration and contingency provisions as meeting all applicable requirements for maintenance plans and related contingency provisions in CAA section 175A, and the budgets for 2023 and 2033 (shown in Table 2) for transportation conformity purposes as we find they meet all applicable criteria for such budgets including the adequacy criteria under 40 CFR 93.118(e).

We are soliciting comments on these proposed actions. We will accept comments from the public for 30 days following publication of this proposal in the **Federal Register** and will consider any relevant comments before taking final action.

VIII. Statutory and Executive Order Reviews

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

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

In addition, there are no areas of Indian country within the planning area, and the state plan for which the EPA is proposing approval does not apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the Clark County Second Maintenance Plan does not apply, and therefore, this proposed action does not have tribal implications and would not, if approved, impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Particulate matter, Sulfur dioxide, Reporting and recordkeeping requirements, Volatile organic compounds.

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

[51] Clark County Ozone NAA EJSCREEN Report dated February 10, 2023.

[52] Clark County Second Maintenance Plan (submitted electronically January 24, 2022).

Dated: December 14, 2023.

Martha Guzman Aceves,

Regional Administrator, Region IX.

[FR Doc. 2023–27874 Filed 12–20–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2023–0232; FRL–11600–01–R4]

Air Plan Approval; GA; Miscellaneous Rule Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Georgia, through the Georgia Environmental Protection Division (EPD) via a letter dated October 20, 2022. The revision seeks to change Georgia's Rules for Air Quality Control in the SIP by removing the 1971 annual and 24-hour ambient air quality primary standard for sulfur dioxide (SO_2), which no longer applied in Georgia as of April 30, 2022. EPA is proposing to approve this SIP revision because the State has demonstrated that this change is consistent with the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before January 22, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. at EPA–R04–OAR–2023–0232 at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*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.*

FOR FURTHER INFORMATION CONTACT: Josue Ortiz Borrero, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8085. Mr. Ortiz Borrero can also be reached via electronic mail at *ortizborrero.josue@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On June 2, 2010, EPA revised the primary SO_2 national ambient air quality standards (NAAQS or standards) to provide requisite protection of public health with an adequate margin of safety. *See* 75 FR 35520 (June 22, 2010). Specifically, EPA established a new 1-hour SO_2 standard at a level of 75 parts per billion (ppb), codified at 40 CFR 50.17.[1] [2] The 1-hour standard is met at an ambient air quality monitoring site when the 3-year average of the annual 99th percentile of daily maximum 1-hour average concentrations is less than or equal to 75 ppb, as determined in accordance with Appendix T of 40 CFR part 50 and 40 CFR 50.17(a) and (b).[3] EPA set this new 1-hour short-term standard to replace the 1971 primary 24-hour standard of 0.14 parts per million (ppm) and the annual SO_2 standard set of 0.03 ppm.[4] [5] In the 2010 SO_2 NAAQS final rulemaking, the Administrator concluded it was appropriate to revoke the 24-hour and annual primary standards,[6] stating ''a 1-hour standard at [a] level of 75 ppb would have the effect of maintaining 24-hour and annual SO_2 concentrations generally well below the levels of the current 24-hour and annual NAAQS.'' *See* 75 FR at 35550. The final rule also states, based on health evidence and risk-based information, that the 1971 SO_2 standards '' 'are not adequate to protect public health, especially in relation to short-term exposures to SO_2 (5–10 minutes) by exercising asthmatics' '' and that the new 1-hour standard would provide requisite protection of public health with an adequate margin of safety. *See* 75 FR at 35530, 35550.

Anti-Backsliding

When EPA revised the SO_2 NAAQS in 2010, replacing the annual and 24-hour standards with a short term 1-hour standard, EPA also addressed the section 172(e) anti-backsliding provision of the CAA and determined what provisions are appropriate to provide for transition to the new standard. Section 172(e) of the CAA specifies that if EPA relaxes a NAAQS, control obligations no less stringent than those that apply in nonattainment area SIPs may not be relaxed, and adopting those controls that have not yet been adopted as needed may not be avoided. Even though the 2010 1-hour standard is more protective than the previous SO_2 NAAQS, anti-backsliding provisions were necessary to insure that the health protection provided by the prior NAAQS continues to be achieved as well as maintained as states transition to the new standard.[7] Specifically, EPA established at 40 CFR 50.4(e) when the 1971 SO_2 NAAQS would be revoked in areas, and when it was necessary to retain the older SO_2 standards, setting conditions needed for the eventual transition to the new 1-hour SO_2 NAAQS. Specifically, 40 CFR 50.4(e) provides that the 1971 SO_2 NAAQS will no longer apply to an area one year after the effective date of the designation of that area for the 2010 SO_2 NAAQS set forth in § 50.17; except that the 1971 SO_2 NAAQS remains in effect for areas that are nonattainment for that NAAQS as of the effective date of the 2010 SO_2 NAAQS, and areas not meeting the requirements of a SIP call with respect to requirements for the 1971 SO_2 NAAQS until that area submits, and EPA approves, an

[1] *See* 75 FR 35520 and *https://www.gpo.gov/fdsys/pkg/FR-2010-06-22/pdf/2010-13947.pdf.*

[2] *See also* NAAQS Table at *https://www.epa.gov/criteria-air-pollutants/naaqs-table.*

[3] On February 25, 2019, EPA finalized a second review of the SO_2 standard, retaining the existing primary 1-hour SO_2 NAAQS based on a review of the full body of currently available scientific evidence and exposure/risk information at the time. *See* 84 FR 9866 and *https://www.epa.gov/so2-pollution/primary-national-ambient-air-quality-standard-naaqs-sulfur-dioxide.*

[4] EPA promulgated the 1971 primary and secondary NAAQS for SO_2 on April 30, 1971. *See* 36 FR 8186. The 1971 primary SO_2 standards of 365 $\mu g/m^3$ (0.14 ppm), averaged over a period of 24 hours and not to be exceeded more than once per year, and 80 $\mu g/m^3$ (0.03 ppm), as an annual arithmetic mean.

[5] EPA did not revise the secondary 3-hour SO_2 NAAQS set at 0.5 ppm in the 2010 or 2019 NAAQS review.

[6] EPA arrived at the same conclusion in the 2019 review of the SO_2 standard when the agency retained the 1-hour SO_2 standard of 75 ppb stating (respecting the rationale to revoke the previous SO_2 standard) ''the evidence in this review [2019] is not substantively changed from that in the last review [2010].'' *See* 84 FR 9866 (March 18, 2019).

[7] The owner or operator of a new or modified source will still be required to demonstrate compliance with the annual and 24-hour SO_2 increments, even when their counterpart NAAQS are revoked. The annual and 24-hour increments are established in the CAA and will need to remain in the prevention of significant deterioration regulations because EPA does not interpret the CAA to authorize EPA to remove them. *See* 75 FR at 35578.

implementation plan providing for attainment of the 2010 SO_2 NAAQS.

SO_2 NAAQS Designations

After EPA promulgates a new or revised NAAQS, the agency is required to designate all areas of the country as either ''nonattainment,'' ''attainment,'' or ''unclassifiable'' for that NAAQS pursuant to section 107(d) of the CAA. The CAA requires EPA to complete the initial designations process within two years of promulgating a new or revised standard or June 2012 for the 1-hour SO_2 NAAQS. If the Administrator has insufficient information to make these designations by that deadline, the CAA provides EPA authority to extend the deadline for completing designations by up to one year. However, due to a lack of available and sufficient air quality data to inform designations, EPA was not prepared to issue designations for the 2010 primary SO_2 standard for the entire country within the CAA's two-year deadline.[8] On July 27, 2012, EPA extended the deadline for area designations for the 2010 primary SO_2 standard from June 2012 by one year to June 2013 due to having insufficient information to make initial area designations in two years. *See* 77 FR 46295 (August 3, 2012). With this extension, EPA completed initial designations on June 3, 2013, based on air quality monitoring data available at the time.

Subsequently, lawsuits were filed against EPA alleging that the Agency had failed to perform a nondiscretionary duty under the CAA by not designating all portions of the country by June 3, 2013.[9] EPA eventually entered into a consent decree on March 2, 2015, which required the agency to complete the remaining area designations in three specific deadlines or ''rounds'' of designations: July 2, 2016 (''Round 2''), December 31, 2017 (''Round 3''), and December 31, 2020 (''Round 4''). Round 1 designations were finalized as part of the 1-year extension in August 2013. Subsequently, EPA published **Federal Register** notices completing the remaining three rounds of SO_2 designations by the court-ordered deadlines. For Georgia, EPA designated areas in the state as attainment/unclassifiable in Rounds 2, 3, and 4 from 2016 through 2021, resulting in the entire state being designated as attainment/unclassifiable.[10] Thus, on April 30, 2022, one year after the effective date of the Round 4 designations, the primary 24-hour and annual SO_2 NAAQS no longer applied in Georgia.

II. EPA's Analysis of Georgia's Submittal

Georgia's October 22, 2022, submittal proposes to revise Rule 391–3–1–.02(4), ''Ambient Air Standards'', at subparagraphs (b)1 and (b)2 of paragraph (b), ''Sulfur Dioxide'' to remove the 1971 annual and 24-hour ambient air quality primary SO_2 standards which, as discussed in section I, no longer applied in Georgia after April 30, 2022. The subsequent subparagraphs at Rule 391–3–.02(4)(b), are renumbered respectively.

As described above, EPA designated all counties in Georgia as attainment/unclassifiable through the three rounds of designations for the 2010 1-hour primary NAAQS, with the final Round 4 designations effective on April 30, 2021. Thus, these 1971 standards no longer applied anywhere in Georgia effective on April 30, 2022. Moreover, with no SO_2 nonattainment areas in Georgia for the 1971 or 2010 SO_2 NAAQS, the revocation of the 1971 SO_2 standards would not be deferred until nonattainment and maintenance planning requirements are met as described above. For these reasons, EPA is proposing to approve Georgia's October 22, 2022, revision to Rule 391–3–1–.02(4), ''Ambient Air Standards'', at paragraph (b), ''Sulfur Dioxide.''

III. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, and as explained in sections I and II of this preamble, EPA is proposing to incorporate by reference Georgia Rule 391–3–1–.02(4), ''Ambient Air Standards,'' paragraph (b), ''Sulfur Dioxide,'' State effective September 19, 2022, to remove subparagraphs (b)1 and (b)2 and renumber the remaining provisions accordingly. EPA has made and will continue to make these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Proposed Action

EPA is proposing to approve Georgia's October 20, 2022, SIP submittal, which would remove the 1971 annual and 24-hour primary SO_2 NAAQS from the Georgia SIP at Rule 391–3–1–.02(4) and renumber the remaining provisions of Rule 391–3–1–.02(4)(b) accordingly for the reasons discussed herein.

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;

[8] This led EPA to convene a stakeholder process with state, tribes, industry, and non-governmental organizations in 2012 to refine the agency's analytical approach to inform designations, with credible air quality data. With input from a diverse group of stakeholders, EPA developed a comprehensive implementation strategy for the future SO_2 designations actions that focused resources on identifying and addressing unhealthy levels of SO_2 in areas where people are most likely to be exposed to violations of the standard. This resulted in the promulgation of the Data Requirements Rule (DRR) on August 21, 2015 (80 FR 51052), to inform the remaining designations.

[9] Following the initial August 5, 2013, designations, three lawsuits were filed against EPA in different U.S. District Courts, alleging the agency had failed to perform a nondiscretionary duty under the CAA by not designating all portions of the country by the June 2, 2013, deadline. In an effort intended to resolve the litigation in one of those cases, EPA and the plaintiffs, Sierra Club, and the Natural Resources Defense Council, filed a proposed consent decree with the U.S. District Court for the Northern District of California. On March 2, 2015, the court entered the consent decree and issued an enforceable order for EPA to complete the area designations by three specific deadlines according to the court-ordered schedule.

[10] *See* 40 CFR 81.311.

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and

• Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

Georgia EPD did not evaluate EJ considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this proposed action. Consideration of EJ is not required as part of this proposed action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

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

Dated: December 14, 2023.

Jeaneanne Gettle,

Acting Regional Administrator, Region 4.

[FR Doc. 2023–28085 Filed 12–20–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2022–0630; FRL–11582–01–R4]

Air Plan Approval; Georgia; Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Georgia through the Georgia Department of Natural Resources (GA DNR), Environmental Protection Division (EPD), on June 8, 2022, and on June 6, 2023. Georgia's June 8, 2022, SIP revision (hereinafter referred to as Georgia's 2022 I/M SIP revision) removes obsolete references and provisions; updates the State's inspection and maintenance (I/M) requirements; updates terminology, in part to reflect advances in test and vehicle technology; and makes other minor changes. The June 6, 2023, SIP revision (hereinafter referred to as Georgia's 2023 I/M SIP revision) removes outdated terminology; updates with new terminology; removes one requirement; and makes other minor changes to Georgia's enhanced I/M program. EPA is proposing to approve these changes pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before January 22, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2022–0630 at *www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*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 *www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Weston Freund, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8773. Mr. Freund can also be reached via electronic mail at *freund.weston@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Below provides the background for EPA's proposed actions on Georgia's 2022 and 2023 I/M SIP revisions that were submitted to EPA by GA DNR on June 8, 2022, and on June 6, 2023, respectively.

The CAA requires areas that are designated as moderate, serious, severe, or extreme ozone nonattainment areas to establish motor vehicle I/M programs to ensure regular monitoring of gasoline fueled motor vehicle emissions. *See* CAA sections 182(b)(4), (c)(3). The required monitoring is performed by periodic emissions testing of vehicles. *See* CAA sections 182(a)(2)(B), (c)(3). This emissions testing ensures that vehicles are well-maintained and operating as designed and that they do not exceed established vehicle pollutant limits. A basic I/M program is required for moderate ozone nonattainment areas, and an enhanced I/M program is required for serious, severe, or extreme ozone nonattainment areas.

In 1991, EPA classified a 13-county area in and around the Atlanta, Georgia, metropolitan area as a serious ozone nonattainment area for the 1979 1-hour ozone national ambient air quality standards (NAAQS or standard), triggering the requirement for the State to establish an enhanced I/M program for the area.[1] In 1996, Georgia submitted

[1] On November 6, 1991, EPA designated and classified the following counties in and around the Atlanta, Georgia, metropolitan area as a serious ozone nonattainment area for the 1-hour ozone NAAQS: Cherokee, Clayton, Cobb, Coweta, DeKalb,

its enhanced I/M program to EPA for incorporation into the SIP. EPA granted interim approval of the State's program in 1997 and full approval in 2000. *See* 62 FR 42916 (August 11, 1997) and 65 FR 4133 (January 26, 2000), respectively. Despite that approval, the 13-county area failed to attain the 1-hour ozone NAAQS by the November 15, 1999, the CAA deadline for serious ozone nonattainment areas. EPA issued a final rulemaking action on September 26, 2003 (68 FR 55469), to reclassify the area to severe ozone nonattainment. Subsequently, this area attained the 1-hour ozone NAAQS and EPA redesignated the area to attainment. *See* 70 FR 34660 (June 15, 2005). In addition, on April 30, 2004, EPA issued a final rulemaking action (69 FR 23951) to revoke the 1979 1-hour ozone NAAQS, effective June 15, 2005.

On July 18, 1997 (62 FR 38856), EPA established an 8-hour ozone NAAQS and subsequently designated areas. On April 30, 2004 (69 FR 23858), EPA designated a 20-county area in and around metropolitan Atlanta as a marginal ozone nonattainment area for the 1997 8-hour ozone NAAQS.[2] EPA reclassified this area as a moderate ozone nonattainment area on March 6, 2008 (73 FR 12013), because the area failed to attain the 1997 8-hour ozone NAAQS by the required attainment date of June 15, 2007. Subsequently, the area attained the 1997 8-hour ozone standard, and on December 2, 2013 (78 FR 72040), EPA redesignated the area to attainment.

On March 12, 2008, EPA revised the 8-hour ozone NAAQS. *See* 73 FR 16436 (March 27, 2008). EPA designated a 15-county area in and around metropolitan Atlanta as a marginal ozone nonattainment area for the 2008 8-hour ozone NAAQS on April 30, 2012 (effective July 20, 2012).[3] *See* 77 FR 30088 (May 21, 2012). EPA reclassified these counties as a moderate ozone nonattainment area on May 4, 2016 (effective June 3, 2016), because the area failed to attain the 2008 8-hour ozone NAAQS by the required attainment date of July 20, 2015. *See* 81 FR 26697 (May 4, 2016). Subsequently, the area attained the 2008 8-hour ozone standard and EPA redesignated the area to attainment. *See* 82 FR 25523 (June 2, 2017).

On October 1, 2015, EPA again revised the 8-hour ozone NAAQS. *See* 80 FR 65292 (October 26, 2015). EPA designated a 7-county area in and around metropolitan Atlanta as a marginal ozone nonattainment area for the 2015 8-hour ozone NAAQS on April 30, 2018 (effective August 3, 2018).[4] *See* 83 FR 25776 (June 4, 2018). Subsequently, the area attained the 2015 8-hour ozone standard and EPA redesignated the area to attainment. *See* 87 FR 62733 (October 17, 2022).

EPA is proposing to approve changes to the I/M regulations in Chapter 391–3–20—*Enhanced Inspection and Maintenance* of Georgia's SIP that were provided to EPA through a cover letter dated June 8, 2022. Specifically, Georgia's 2022 I/M SIP revision seeks to update Rule 391–3–20–.01—*Definitions;* Rule 391–3–20–.04—*Emission Inspection Procedures;* Rule 391–3–20–05—*Emission Standards;* Rule 391–3–20–.09—*Inspection Station Requirements;* Rule 391–3–20–.10—*Certificates of Authorization;* Rule 391–3–20–.11—*Inspector Qualifications and Certification;* Rule 391–3–20–.13—*Certificate of Emission Inspection;* Rule 391–3–20–.15—*Repairs and Retests;* Rule 391–3–20–.17—*Waivers;* and Rule 391–3–20–.22—*Enforcement.*

Further, EPA is proposing to approve additional changes to Georgia's I/M regulations that were provided to EPA through a cover letter dated June 6, 2023. Specifically, Georgia's 2023 I/M SIP revision seeks to update Rule 391–3–20–.01, *Definitions;* Rule 391–3–20–.03, *Covered Vehicles; Exemptions;* Rule 391–3–20–.04, *Emission Inspection Procedures;* Rule 391–3–20–.05, *Emission Standards;* and Rule 391–3–20–.11, *Inspector Qualifications and Certification.*

Collectively, the proposed changes remove obsolete references and provisions, update Georgia's I/M requirements, update terminology, correct punctuation, and make other minor changes to Georgia's SIP-approved I/M requirements. EPA is proposing to find that the changes submitted by Georgia will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable CAA requirement.[5] Thus, EPA is proposing to approve the changes to Georgia's SIP as submitted in Georgia's 2022 and 2023 I/M SIP revisions. Section III, below, provides a summary of these changes and EPA's analysis.

II. EPA's Analysis of Georgia's Submittals

A. Rule 391–3–20–.01, ''Definitions''

Both Georgia's 2022 and 2023 I/M SIP revisions update Rule 391–3–20–.01, *Definitions.* Georgia's 2022 I/M SIP revision makes a minor change to one definition. Georgia's 2023 I/M SIP revision makes further changes to Rule 391–3–20–.01 by adding a definition, removing two definitions, revising one definition, making minor grammatical changes in three definitions, and then renumbering the section to reflect these changes.

Georgia's 2022 I/M SIP revision updates the definition for ''Emission Inspection'' in Rule 391–3–20–.01. The revision changes the order of tests and inspections listed in the definition. Specifically, the ''on-board diagnostic system check'' test is moved to the beginning of listed tests and inspections, and the ''exhaust emissions test'' is moved to the end of the list. The purpose of this change is to highlight the more current widespread use of OBD as the primary method used for emission tests. Since this minor update does not change any applicable limits or requirements, it will have no impact on emissions and is consistent with CAA requirements.

Georgia's 2023 I/M SIP revision further updates Rule 391–3–20–.01 by adding a definition, removing two definitions, revising one definition, making minor grammatical changes in three definitions, and then renumbering the section to reflect these changes. First, the revision adds a definition for ''Biometrics.'' The revision adds this definition to reflect another method of identification that can be used by an inspector to initiate an inspection. Specifically, inspectors will now be able to use their own biometric login in lieu of using their personal access code to perform and record any inspections. Second, the revision removes the definitions ''Grandfathered Vehicle'' and ''Gray Market Vehicle'' since both are encompassed in the newly revised definition of ''Non-conforming Vehicle.'' The new definition for ''Non-conforming Vehicle'' applies to those vehicles that have not obtained an EPA certification or ones that have an emissions control component that is obsolete according to the manufacturer. Further, the revision to this definition adds that vehicles that qualify as non-conforming ''would be subject to an alternative tail pipe emissions standard

Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Paulding, and Rockdale. *See* 56 FR 56694.

[2] The nonattainment area for the 1997 8-hour ozone standard consisted of the following counties: Barrow, Bartow, Carroll, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Hall, Henry, Newton, Paulding, Rockdale, Spalding, and Walton.

[3] The nonattainment area for the 2008 8-hour ozone standard consisted of the following counties: Bartow, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Newton, Paulding, and Rockdale.

[4] The nonattainment area for the 2015 8-hour ozone standard consists of the following counties: Bartow, Clayton, Cobb, DeKalb, Fulton, Gwinnett, and Henry.

[5] See CAA section 110(l).

based upon its model year to obtain a vehicle registration in the Georgia covered counties.'' Since neither grandfathered vehicles nor gray market vehicles have EPA certification, both types of vehicles fall under the new definition for ''Non-conforming Vehicle,'' so removal of ''Grandfathered Vehicle'' and ''Gray Market Vehicle'' from the SIP does not result in any changes. Subsequent subparagraphs are being renumbered to reflect these changes. Third, the revision makes stylistic changes to the definitions of ''Light Duty Truck,'' and ''Light Duty Vehicle,'' by adding commas to numbers to aid with their readability. Finally, the revision corrects a grammatical mistake in the definition for ''Time Extension'' by removing an unnecessary period. Given the nature of these changes, they have no impact on emissions and are consistent with CAA requirements.

B. Rule 391–3–20–.03, ''Covered Vehicles; Exemptions''

Georgia's 2023 I/M SIP revision updates Rule 391–3–20–.03, *Covered Vehicles; Exemptions,* by removing outdated terminology, removing one requirement, making one stylistic change, and one minor grammatical change. First, the revision updates paragraph 391–3–20–.03(8) by removing the first sentence which states that ''Provisions for grandfathered vehicles, *i.e.,* gray market vehicles, kit cars, hot rods, and non-conforming vehicles are described in this subparagraph'' and by removing the term ''gray market'' from the second sentence. Neither kit cars nor hot rod vehicles have EPA certification, so both vehicles fall under the new definition for ''Non-conforming Vehicle'' in addition to those vehicles that were previously considered grandfathered or gray market. Second, the revision removes the last sentence of the paragraph which states that kit cars and hot rods which are newly registered in the counties subject to I/M after December 31, 1998, are not eligible for special inspection standards. According to GA EPD, it has granted non-conforming status to 91 kit cars and hot rods since 2007.[6] As a result of the proposed change to the last sentence of 391–3–20–.03(8), these 91 vehicles would now be eligible for a special inspection standard. Further, GA EPD stated that 3.3 million emission inspection tests were performed in 2022 alone. Given this proportionality, to the extent that kit cars and hot rods are now eligible for a special inspection standard, EPA does not believe that this change would interfere with any applicable requirement concerning attainment or any other applicable CAA requirement. Third, the revision makes a stylistic change to subparagraph 391–3–20–.03(1)(b), adding a comma to ease with the readability of a number. Finally, the revision updates paragraph 391–3–20–.03(3) with a grammatical correction by removing a comma. Given the nature of these changes, EPA is proposing to find that they are consistent with CAA requirements, including 110(l).

C. Rule 391–3–20–.04, ''Emission Inspection Procedures''

Both Georgia's 2022 and 2023 I/M SIP revisions update Rule 391–3–20–.04, *Emission Inspection Procedures.* Georgia's 2022 I/M SIP revision removes obsolete language related to an outdated testing requirement. Georgia's 2023 I/M SIP revision further changes Rule 391–3–20–.04 by updating terminology.

Georgia's 2022 I/M SIP revision updates Rule 391–3–20–.04, *Emission Inspection Procedures,* by removing obsolete language related to an outdated testing requirement. Specifically, the revision updates paragraph 391–3–20–.04(1) by removing a requirement that an emission inspector check whether a vehicle has ''tires with cords exposed'' prior to inspecting it. The outdated Acceleration Simulation Mode (ASM) inspection test was performed on a dynamometer, so the inspector was required to look for any tires with cords exposed because they could pose a safety risk during the test. The ASM test was removed as an inspection test from the Georgia SIP in 2022 because all vehicles covered under the Georgia I/M program could be inspected using the OBD inspection or TSI test instead. *See* 87 FR 41080 (July 11, 2022). Since the ASM test is no longer part of Georgia's I/M program, this change has no impact on emissions and is consistent with CAA requirements.

Georgia's 2023 I/M SIP revision further updates Rule 391–3–20–.04, *Emission Inspection Procedures,* by updating terminology in a subparagraph. Specifically, the term ''non-conforming'' replaces the term ''grandfathered'' to describe vehicles subject to the emission inspection procedures in subparagraph 391–3–20–.04(2)(c) and its corresponding subsections. This subparagraph and its corresponding subsections outline emission inspection procedures for non-conforming vehicles. As mentioned in subsection III.A of this document, the definition for ''Grandfathered Vehicle'' has been removed from the enhanced I/M rules, and instead, the newly revised definition for ''Non-conforming Vehicle'' covers these vehicles as well as others. Given the nature of these changes, they have no impact on emissions and are consistent with CAA requirements.

D. Rule 391–3–20–.05, ''Emission Standards''

Both Georgia's 2022 and 2023 I/M SIP revisions update Rule 391–3–20–.05, *Emission Standards.* Georgia's 2022 I/M SIP revision makes one language change and reorders subparagraphs to reflect technological advances in testing. Georgia's 2023 I/M SIP revision further changes Rule 391–3–20–.05 by updating terminology to be consistent with new definitions the EPA is acting on in this notice.

Georgia's 2022 I/M SIP revision updates Rule 391–3–20–.04, *Emission Inspection Procedures,* by making one language change and reordering subparagraphs to reflect the more widespread use of OBD testing. First, the revision updates paragraph 391–3–20–.05(2) to change the order of a list of inspection tests a vehicle subject to the I/M program must pass. Specifically, the OBD test is moved to the beginning of listed inspection tests, and the exhaust emissions test is moved to the end of the list. This change reflects the current, wider-spread use of the OBD test for inspection of motor vehicles as compared to exhaust emissions tests. Second, the revision changes the order of the exhaust emission testing requirements and OBD testing requirements, which were previously outlined in subparagraphs 391–3–20–.05(2)(b) and 391–3–20.05(2)(d), respectively. The revision switches the order of these testing requirements so now the OBD testing requirements are housed in subparagraph 391–3–20–.05(2)(b) and the requirements for exhaust emissions tests are in subparagraph 391–3–20–.05(2)(d). This change has also been made to reflect the wider-spread use of OBD tests as compared to exhaust emissions tests for motor vehicles subject to the Georgia I/M program. Given the nature of these changes, they have no impact on emissions and are consistent with CAA requirements.

Georgia's 2023 I/M SIP revision updates Rule 391–3–20–.05, *Emission Standards,* by removing references to hot rods in one subparagraph, and references to gray market vehicles and grandfathered vehicles in another subparagraph, replacing them all with references to ''non-conforming'' vehicles. First, in subparagraph 391–3–

[6] *See* email from Anna Aponte, GA EPD, to Josue Ortiz Borrero, EPA Region 4 (November 16, 2023), available in the docket for this proposed rulemaking.

20–.05(2)(a)4., the revision replaces the term ''hot rod'' with ''non-conforming'' in describing vehicles that shall pass the tampering inspection if either the original vehicle or the replacement engine was equipped with a catalytic converter and a catalytic converter has been installed. Since the new definition for non-conforming vehicle covers hot rods as well as certain other vehicle types, the applicability of this subparagraph expands, thus making it more stringent. Second, in subparagraph 391–3–20–.05(2)(d)2., references to ''gray market'' vehicles and ''grandfathered'' vehicles are removed. The result of this change is that the new rule describes when a vehicle defined as non-conforming is considered to have passed an exhaust emissions test. Since the new definition for non-conforming covers all gray market vehicles and grandfathered vehicles, the applicability of the subparagraph has not changed. Given the nature of these changes, they have no impact on emissions and are consistent with CAA requirements.

E. Rule 391–3–20–.09, ''Inspection Station Requirements''

Georgia's 2022 I/M SIP revision updates Rule 391–3–20–.09, *Inspection Station Requirements,* by removing outdated language, making one stylistic change, removing unnecessary language, and adding clarifying language. First, the revision removes outdated language from subparagraph 391–3–20–.09(2)(g) that requires the air intakes on both the Georgia Analyzer System (GAS) and the vehicle being inspected to be exposed to the same ambient temperature, pressure, and humidity conditions throughout an inspection. The outdated ASM test was sensitive to changes in temperature, pressure, and humidity during inspection, whereas the OBD and TSI tests are not. Since the ASM test is no longer part of the Georgia I/M program, the removal of this language will not impact emissions. In subparagraph 391–3–20–.09(2)(i), the revision makes some minor changes to several of its corresponding subsections. First, in subsection 391–3–20–.09(2)(i)(3) of the rule, the revision makes a stylistic, word choice change by replacing the phrase ''tie into'' with ''connect to'' in describing a secure internet connection that should connect GAS to each Vehicle Information Database (VID). Next, in subsection 391–3–20–.09(2)(i)(7) of the rule, the phrase ''capable of performing OBD system checks'' is deleted because all inspection stations are now required to be capable of performing OBD system checks, making the language redundant. Previously, Georgia had stations that that only tested older cars which did not have OBD systems, so this language was necessary. Finally, in subsection 391–3–20–.09(2)(i)(8), language is added indicating that a station owner will receive the currently applicable version of the Emissions Inspector Certification Training Program Manual during the inspector certification. Given the nature of these changes, they have no impact on emissions and are consistent with CAA requirements.

F. Rule 391–3–20–.10, ''Certificates of Authorization''

Georgia's 2022 I/M SIP revision updates Rule 391–3–20–.10, *Certificates of Authorization,* by adding a new requirement. Specifically, the added language now requires station owners who intend to renew their Certificate of Authorization to operate an inspection station to apply for renewal at least 30 days prior to the expiration date of the existing certification. Previously, the language said that station owners ''may apply'' but this is now updated to say that they ''must apply'' at least 30 days prior to the expiration of the existing certificate. Additionally, the revision clarifies that this subparagraph requiring a renewal application refers to ''station owners intending to renew their certificate.'' This is simply clarifying language as the subparagraph already applied to owners who were seeking renewal of their Certificate of Authorization. Given the nature of these changes, they have no impact on emissions and are consistent with CAA requirements.

G. Rule 391–3–20–.11, ''Inspector Qualifications and Certification''

Both Georgia's 2022 and 2023 I/M SIP revisions update Rule 391–3–20–.11, *Inspector Qualifications and Certification.* Georgia's 2022 I/M SIP revision adds clarifying language and makes some minor word choice changes. Georgia's 2023 I/M SIP revision further changes Rule 391–3–20–.11 by updating language to reflect advances in technology, to include some new requirements, and to make one minor grammatical change.

Georgia's 2022 I/M SIP revision updates Rule 391–3–20–.11, *Inspector Qualifications and Certification,* to add clarifying language in several places and to make some word choice changes. First, in subparagraph 391–3–20–.11(5)(a), the revision adds language to clarify that the requirement for a complete application for renewal to be submitted at least 30 calendar days prior to the expiration of the existing certificate applies to inspectors ''intending to renew their certificate.'' This new language does not add any new requirements, but better describes who the requirement applies to. Another clarifying change is made in paragraph 391–3–20–.11(6) to specify that inspectors must have the picture on their GA EPD-issued ID clearly visible on the inspector's upper body area when performing an emissions inspection. Previously, the language indicated only that the ID itself must be visible on the inspector's upper body area, so this change simply clarifies that the inspector's picture must be visible in this location. Finally, one last clarifying change is made to paragraph 391–3–20–.11(9), where the revision adds the word ''unauthorized'' to clarify who may not use a certified emission inspector's personal access code to perform any part of an emissions inspection. Previously, the paragraph read that no person should use the access code; however, this was not the purpose of the rule as the certified emission inspector should always be able to use their personal access code to perform any part of an emission inspection. This clarifying change eliminates the confusion previously caused by this paragraph. Finally, the revision makes several word choice changes. First, in several parts of the rule, the revision replaces the word ''card'' with ''badge,'' in describing the picture ID. Second, the revision removes the word ''location'' from the phrase ''visible location'' in paragraph 391–3–20–.11(6). The phrase required that an emission inspector have their ID badge clearly visible on the inspector's upper body area, so the removal of the word ''location'' does not change the meaning of the requirement. This removal is a minor change that constitutes a change in word choice. Given the nature of these changes, they have no impact on emissions and are consistent with CAA requirements.

Georgia's 2023 I/M SIP revision further updates Rule 391–3–20–.11 by adding language to reflect the use of biometric identification to initiate an inspection, to include some new requirements, and to make one minor grammatical change. First, paragraph 391–3–20–.11(8) is revised to require inspectors to notify the Management Contractor of a change to telephone or email address contact information after applying for and receiving a Certificate of Authorization. Previously, inspectors only needed to notify the Management Contractor of a change of address. Second, the revision revises paragraphs 391–3–20–.11(9) and .11(10) to reflect that, in addition to using a personal access code, inspectors may also use a

biometric login to perform parts of the inspection. Further, the revision forbids inspectors from divulging or authorizing the use of their own biometric login to any other person. This change reflects the new use of biometric logins during inspections described in section III.A of this notice. Finally, the revision makes one grammatical change to paragraph 391–3–20–.11(7) by removing a comma. Given the nature of these changes, they have no impact on emissions and are consistent with CAA requirements.

H. Rule 391–3–20–.13, ''*Certificate of Emission Inspection*''

Georgia's 2022 I/M SIP revision updates Rule 391–3–20–.13, *Certificate of Emission Inspection,* with two minor changes. First, the revision revises subparagraph 391–3–20–.13(1)(i), which specifies that inspection results for applicable inspection tests must be included in a Certificate of Emission Inspection. The change rearranges the order of applicable inspection tests to place OBD testing first. This change is made to reflect the wider-spread use of the OBD test as compared to exhaust emission tests. The second minor change updates subparagraph 391–3–20–.13(2)(c), which requires that inspectors provide vehicle owners who have failed an emission inspection with the current, quarterly RepairWatch Public Report. This report identifies repair facilities. The change adds the phrase ''access to'' at the beginning of the subparagraph to specify that the inspector must provide owners of vehicles that have failed inspection emission tests with access to the current, quarterly reports. This change is simply clarifying in nature. Given the nature of these changes, they have no impact on emissions and are consistent with CAA requirements.

I. Rule 391–3–20–.15, ''*Repairs and Retests*''

Georgia's 2022 I/M SIP revision amends Rule 391–3–20–.15, *Repairs and Retests,* by removing one outdated requirement. Specifically, in paragraph 391–3–20–.15(4), ''NO_X'' is deleted from the list of pollutants for which a vehicle must pass an exhaust test upon reinspection. Usable NO_X emission information only came with an ASM test since NO_X was released from the motor vehicle when it was under load (*i.e.,* while using the dynamometer). Although a motor vehicle still may still release NO_X emissions during a TSI test, the emissions are much lower since it is performed at idle. This NO_X information is unusable to make any determination as to whether a vehicle is adequately preventing the release of NO_X. Since the ASM test was removed in a previous SIP revision, and because none of the applicable exhaust emissions tests would provide useable NO_X emission information, this requirement is obsolete. Since the ASM test is not part of Georgia's I/M program, the changes to Rule 391–3–20–.15 have no impact on emissions and are consistent with CAA requirements.

J. Rule 391–3–20–.17, ''*Waivers*''

Georgia's 2022 I/M SIP revision updates Rule 391–3–20–.17, *Waivers,* by deleting obsolete language in one subparagraph and updating language in another. First, the revision updates subparagraph 391–3–20–.17(2)(c), by deleting the phrase ''on preprinted repair forms'' to describe how receipts for parts and labor must be submitted for repair waivers. Receipts must still be submitted, but they no longer have to be submitted on preprinted repair forms. This change does not remove any substantive requirement because receipts must still be submitted, and the minimum repair form entries have not changed. Second, the revision updates subparagraph 391–3–20–.17(2)(f) by adding clarifying language specifying that repairs for a waiver shall ''address the OBD failure'' or produce a reduction in ''tailpipe'' emissions for the pollutant that failed the previous test. Since the applicable tests required under the Georgia I/M program are either the OBD inspection test or a tailpipe emissions test (*i.e.,* TSI tailpipe emissions test), the added language clarifies what repairs should address in the event of a failure of an applicable emissions test. Given the nature of these changes, they have no impact on emissions and are consistent with CAA requirements.

K. Rule 391–3–20–.22, ''*Enforcement*''

Georgia's 2022 I/M SIP revision updates Rule 391–3–20–.22, *Enforcement,* with one minor word choice change. Specifically, in subparagraph 391–3–20–.22(2)(b), the revision replaces the word ''card'' with ''badge'' to describe the picture ID that certified emissions inspectors use. This better describes the form of ID and adds no new requirements. Given the nature of this update, it will have no impact on emissions and is consistent with CAA requirements.

III. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with the requirements of 40 CFR 51.5, and as explained in sections I and II of this preamble, EPA is proposing to incorporate by reference Georgia Rules 391–3–20–.09—*Inspection Station Requirements;* 391–3–20–.10—*Certificates of Authorization;* 391–3–20–.13—*Certificate of Emission Inspection;* 391–3–20–.15—*Repairs and Retests;* 391–3–20–.17—*Waivers;* and 391–3–20–.22— *Enforcement,* all of which have a state-effective date of April 19, 2022, into the Georgia SIP. Further, EPA is proposing to incorporate by reference Georgia Rules 391–3–20–.01, *Definitions;* Rule 391–3–20–.03, *Covered Vehicles; Exemptions;* Rule 391–3–20–.04, *Emission Inspection Procedures;* Rule 391–3–20–.05, *Emission Standards;* and Rule 391–3–20–.11, *Inspector Qualifications and Certification,* all of which have a state-effective date of March 21, 2023, into the Georgia SIP. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Proposed Actions

EPA is proposing to approve changes to Georgia's SIP-approved I/M rules as provided in Georgia's June 8, 2022, and June 6, 2023, SIP revisions. These SIP revisions include changes to 391–3–20–.01—*Definitions;* 391–3–20–.03, *Covered Vehicles; Exemptions;* 391–3–20–.04—*Emission Inspection Procedures;* 391–3–20–.05—*Emission Standards;* 391–3–20–.09—*Inspection Station Requirements;* 391–3–20–.10—*Certificates of Authorization;* 391–3–20–.11—*Inspector Qualifications and Certification;* 391–3–20–.13—*Certificate of Emission Inspection;* 391–3–20–.15—*Repairs and Retests;* 391–3–20–.17—*Waivers;* and 391–3–20–.22—*Enforcement.* EPA has made the preliminary determination that these changes are consistent with CAA requirements. Thus, EPA is proposing to these changes to Georgia's SIP.

V. Statutory and Executive Order Reviews

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

• Are not significant regulatory actions subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (88 FR 21879, April 11, 2023);
• Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
• Are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
• Do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
• Do not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
• Are not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because they approve a state program;
• Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
• Are not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

EPD did not evaluate EJ considerations as part of its SIP submittals; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in these proposed actions. Due to the nature of the actions being proposed here, these proposed actions are expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of these proposed actions, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving EJ for people of color, low-income populations, and Indigenous peoples.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: December 14, 2023.

Jeaneanne Gettle,

Acting Regional Administrator, Region 4.

[FR Doc. 2023–28105 Filed 12–20–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA–HQ–OW–2023–0222; FRL 10760–01–OW]

RIN 2040–AG30

Water Quality Standards To Protect Aquatic Life in the Delaware River

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On December 1, 2022, the U.S. Environmental Protection Agency (EPA) determined that revised water quality standards are necessary to protect aquatic life in certain water quality management zones of the Delaware River. Specifically, the EPA issued an Administrator's Determination, pursuant to the Clean Water Act (CWA), finding that a revised designated use to protect aquatic life propagation and corresponding dissolved oxygen criteria to protect that use are necessary in Zone 3, Zone 4, and the upper portion of Zone 5 (in total, river miles 108.4 to 70.0) of the Delaware River. The CWA requires the EPA to publish proposed water quality standards following an Administrator's Determination. Thus, the EPA is proposing to promulgate an aquatic life designated use that includes propagation and protective water quality criteria for dissolved oxygen for Zone 3, Zone 4, and upper Zone 5 of the Delaware River.

DATES: Comments must be received on or before February 20, 2024. Public hearing: the EPA will hold two public hearings during the public comment period. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on the public hearings.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OW–2023–0222, by any of the following methods:

• *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
• *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Office of Water Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
• *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–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 ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Hannah Lesch, Office of Water, Standards and Health Protection Division (4305T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566–1224; email address: *Lesch.Hannah@epa.gov.*

SUPPLEMENTARY INFORMATION: This proposed rule preamble is organized as follows:

I. Public Participation
A. Written Comments
B. Participation in Public Hearings
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A. Does this action apply to me?
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B. Relevant Ecological History of the Delaware River
C. Administration of Water Quality Standards in the Delaware River
D. Currently Applicable Aquatic Life Designated Uses and Dissolved Oxygen Criteria
E. Summary of the EPA's Administrator's Determination
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C. Dissolved Oxygen Criteria To Protect Aquatic Life Propagation
V. Endangered Species Act Consultation
VI. Applicability
VII. Conditions Where Federal Water Quality Standards Would Not Be Promulgated or Would Be Withdrawn
A. Conditions Where Federal Standards Would Not Be Promulgated
B. Conditions Where Federal Standards Would Be Withdrawn
VIII. Alternative Regulatory Approaches and Implementation Mechanisms
A. Water Quality Standards Variances
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C. Clean Water Act Section 303(d)/305(b) Water Quality Assessments
IX. Economic Analysis
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B. Paperwork Reduction Act (PRA)
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D. Unfunded Mandates Reform Act (UMRA)
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA)
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OW–2023–0222, at *https://www.regulations.gov* (the EPA's preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to the EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. 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). Please visit *https://www.epa.gov/dockets/commenting-epa-dockets* for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

B. Participation in Public Hearings

The EPA is offering two public hearings so that interested parties may also provide oral comments on this proposed rulemaking. For more details on the public hearings and to register to attend the hearings, please visit *https://www.epa.gov/wqs-tech/water-quality-standards-delaware-river.*

II. General Information

A. Does this action apply to me?

A range of individuals and entities could be affected by this rulemaking, if finalized. For example, entities that discharge pollutants to certain waters under the jurisdiction of the states of Delaware, New Jersey, and Pennsylvania—such as industrial facilities and municipalities that manage stormwater, separate sanitary, or combined sewer systems—could be indirectly affected by this rulemaking because Federal water quality standards (WQS) promulgated by the EPA would be the applicable WQS for these waters for CWA purposes (Table 1 of this preamble). Specifically, these WQS would be the applicable standards that must be used in CWA regulatory programs, such as permitting under the National Pollutant Discharge Elimination System (NPDES) under CWA section 402 [1] and identifying impaired waters under CWA section 303(d). In addition, individuals and entities who rely on or benefit from aquatic life in those waters may be indirectly affected.

TABLE 1—ENTITIES POTENTIALLY AFFECTED BY THIS PROPOSED RULE

Category	Examples of potentially affected entities
Industry	Industrial point sources discharging to certain waters in Delaware, New Jersey, and Pennsylvania. Commercial fishing operations that harvest fish.
Municipalities, including those with stormwater or combined sewer system outfalls.	Publicly owned treatment works or similar facilities responsible for managing stormwater, separate sanitary, or combined sewer systems that discharge to certain waters in Delaware, New Jersey, and Pennsylvania.
Recreation and Tourism	Anglers and tourists seeking recreational opportunities related to aquatic life in certain waters in Delaware, New Jersey, and Pennsylvania.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be indirectly affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

III. Background

A. Statutory and Regulatory Authority

CWA section 101(a)(2) establishes a national goal of ''water quality which provides for the protection and propagation of fish, shellfish, and wildlife, and provides for recreation in and on the water'' (hereafter, collectively referred to as ''101(a)(2) uses'' or ''101(a)(2) goals''), wherever attainable. The EPA's regulation at 40 CFR 131.10(g) implements this statutory

[1] Before any water quality-based effluent limit would be included in an NPDES permit, the permitting authority (here, the states of Delaware, New Jersey, and Pennsylvania), must first determine whether a discharge ''will cause or has the reasonable potential to cause, or contribute to an excursion above any WQS.'' 40 CFR 122.44(d)(1)(i) and (ii).

provision by requiring that WQS protect 101(a)(2) uses unless those uses are shown to be unattainable.

Under the CWA, states have the primary responsibility for reviewing, establishing, and revising WQS applicable to their waters (CWA section 303(c)). WQS define the desired condition of a water body, in part, by designating the use or uses to be made of the water and by setting the numeric or narrative water quality criteria to protect those uses (40 CFR 131.2, 131.10, and 131.11). There are two primary categories of water quality criteria: human health criteria and aquatic life criteria. Human health criteria protect designated uses such as public water supply, recreation, and fish and shellfish consumption. Aquatic life criteria protect designated uses such as protection and propagation of fish, invertebrates, and other aquatic species. Regardless of their category, water quality criteria ''must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use. For waters with multiple use designations, the criteria shall support the most sensitive use'' (40 CFR 131.11(a)(1)).

States are required to hold a public hearing to review applicable WQS at least once every three years and, if appropriate, revise or adopt new standards (CWA section 303(c)(1); 40 CFR 131.20(a)). Every three years, states must also reexamine water body segments that do not include the 101(a)(2) uses to determine if new information has become available that indicates the 101(a)(2) uses are attainable, and if so, revise the WQS accordingly (40 CFR 131.20(a)). Any new or revised WQS must be submitted to the EPA for review and approval or disapproval (CWA section 303(c)(2)(A) and (c)(3)).

CWA section 303(c)(4)(B) independently authorizes the Administrator to determine that a new or revised standard is necessary to meet CWA requirements; this action is frequently referred to as an ''Administrator's Determination.'' Pursuant to CWA section 303(c)(4)(B), after making an Administrator's Determination, the EPA must propose and promulgate WQS specified in the Administrator's Determination. If a state adopts and the EPA approves WQS that address the Administrator's Determination prior to the EPA's promulgation, then the EPA would no longer be required to promulgate WQS.

B. Relevant Ecological History of the Delaware River

The Delaware River has historically been home to numerous species of ecological, recreational, and economic importance; however, centuries of anthropogenic water quality impacts and habitat degradation, peaking in the mid-twentieth century, made portions of the river unsuitable for many aquatic species. In the 1700s and 1800s, many native fish species in the Delaware River faced declining populations due to overharvesting and the installation of physical barriers that prevented fish passage.[2] Further population declines of native oxygen-sensitive species—such as the Atlantic Sturgeon (*Acipenser oxyrinchus oxyrinchus*), American Shad (*Alosa sapidissima*), Shortnose Sturgeon (*Acipenser brevirostrum*), and Striped Bass (*Morone saxatilis*), among others [3]—were linked to accelerating degradation of water quality through the first half of the 1900s, including seasonal anoxia (*i.e.,* absence of oxygen) by the mid-twentieth century in Zone 3, Zone 4, and the upper portion of Zone 5 of the Delaware River.[4]

Dissolved oxygen is an important water quality parameter that can significantly influence the distribution and abundance of aquatic organisms and ecological relationships in aquatic ecosystems. Aquatic organisms need to obtain adequate levels of dissolved oxygen to maintain and support normal functioning, including during sensitive life stages, such as spawning, larval development, and juvenile growth.[5] As dissolved oxygen levels decrease in a waterbody, the rate at which aquatic organisms can obtain oxygen from the water decreases, resulting in impaired growth and reduced survival. Maintaining a healthy ecosystem requires dissolved oxygen levels above thresholds that impair growth and survival of aquatic species.

1. Causes of Low Dissolved Oxygen in the Specified Zones of the Delaware River

Discharges of untreated or poorly treated municipal and industrial wastewater into the specified zones of the Delaware River have historically been a major cause of water quality degradation, including oxygen depletion.[6] While conditions have significantly improved, inputs of oxygen-consuming wastes from wastewater dischargers, especially ammonia (NH_3) and ammonium (NH_4^+) (which in combination are hereafter referred to as ''ammonia nitrogen''), as well as sediment-water ammonium flux and sediment oxygen demand continue to be significant sources of oxygen demand in the specified zones of the Delaware River.[7]

Along the Delaware River, untreated wastewater discharges typically occur during and after rainfall due to combined sewer overflows (CSOs), which are a source of nutrients (*i.e.,* nitrogen and phosphorus), sediments, and toxic contaminants, and can lead to increased chemical and biological oxygen demand in the river.[8] Although the cumulative impact of historical

[2] Hardy, C.A. (1999). Fish or Foul: A History of the Delaware River Basin Through the Perspective of the American Shad, 1682 to the Present. Pennsylvania History, 66(4), 506–534. *https://digitalcommons.wcupa.edu/hist_facpub/13;* Secor, D.H. and Waldman, J. (1999). Historical abundance of Delaware Bay Atlantic sturgeon and potential rate of recovery. American Fisheries Society Symposium. 23. 203–216. *https://www.researchgate.net/publication/291783957_Historical_abundance_of_Delaware_Bay_Atlantic_sturgeon_and_potential_rate_of_recovery;* Smith, T.I.J., & Clugston, J.P. (1997) Status and management of Atlantic sturgeon, Acipenser oxyrinchus, in North America. Environmental Biology of Fishes 48, 335–346. *https://doi.org/10.1023/A:1007307507468;* National Marine Fisheries Service. (1998). Recovery Plan for the Shortnose Sturgeon (Acipenser brevirostrum). Prepared by the Shortnose Sturgeon Recovery Team for the National Marine Fisheries Service, Silver Spring, Maryland. 104 pages. *https://repository.library.noaa.gov/view/noaa/15971.*

[3] Stoklosa, A.M., Keller, D.H., Marano, R., and Horwitz, R.J. (2018). ''A Review of Dissolved Oxygen Requirements for Key Sensitive Species in the Delaware Estuary.'' Academy of Natural Sciences of Drexel University. November 2018. *https://www.nj.gov/drbc/library/documents/Review_DOreq_KeySensSpecies_DelEstuary_ANStoDRBCnov2018.pdf.*

[4] See citations in footnote 2 of this preamble; Atlantic States Marine Fisheries Commission. (1981). Interstate Fisheries Management Plan for the Striped Bass. *http://www.asmfc.org/uploads/file/1981FMP.pdf.*

[5] United States Environmental Protection Agency. (2021). Factsheet on Water Quality Parameters: Dissolved Oxygen. July 2021. Document ID: EPA 841F21007B. *https://www.epa.gov/system/files/documents/2021-07/parameter-factsheet_do.pdf;* United States Environmental Protection Agency. (2023a). Indicators: Dissolved Oxygen. June 9, 2023. *https://www.epa.gov/national-aquatic-resource-surveys/indicators-dissolved-oxygen.*

[6] Hardy (1999); Delaware River Basin Commission. (2022a). Analysis of Attainability: Improving Dissolved Oxygen and Aquatic Life Uses in the Delaware River Estuary. September 2022 Draft. See section 3—''Factors that can Improve Dissolved Oxygen in the Fish Maintenance Area.'' *https://www.nj.gov/drbc/library/documents/AnalysisAttainability/AnalysisAttainability_DRAFTsept2022.pdf.*

[7] Delaware River Basin Commission. (2022b). Modeling Eutrophication Processes in the Delaware River Estuary—Three-Dimensional Water Quality Model. *https://www.nj.gov/drbc/library/documents/AnalysisAttainability/WQModelCalibrationRpt_DRAFTsept2022.pdf.*

[8] Miskewitz, R. and Uchrin, C. (2013). In-Stream Dissolved Oxygen Impacts and Sediment Oxygen Demand Resulting from Combined Sewer Overflow Discharges. Journal of Environmental Engineering, 139(10). *https://doi.org/10.1061/(ASCE)EE.1943-7870.0000739.*

CSOs on sediment oxygen demand in the Delaware River has not been estimated, CSOs can over time increase or maintain sediment oxygen demand as untreated organic material settles on the riverbed and is broken down by oxygen consuming bacteria (thus, removing oxygen from the water column), a process that continues long after the end of an overflow event.[9] CSOs have been a persistent source of pollutants in the specified zones of the Delaware River for over a century. For example, sewer overflows from Philadelphia in the early 1900s deposited over 200,000 tons of solids per year, which, in combination with other solid wastes, created deposits 12 feet deep in the river.[10] From July 1, 2021, to June 30, 2022, Philadelphia's wastewater system alone discharged over 1.7 billion cubic feet of CSOs into the Delaware River.[11]

Although most point source discharges today are treated, treated effluent can still contain high levels of ammonia nitrogen, which depletes oxygen in the water as bacteria oxidize ammonia into nitrite, nitrate and dinitrogen gas.[12] During the reporting periods from July through October 2022, major wastewater treatment facilities along the Delaware River discharged ammonia nitrogen at monthly average concentrations ranging from a low of 0.07 milligrams nitrogen per liter (mg-N/L) at the Florence Township Sewage Treatment Plant in New Jersey (discharging into Zone 2 of the Delaware River) to a high of 35 mg-N/L at the Camden County Municipal Utilities Authority in New Jersey (discharging into Zone 3 of the Delaware River).[13]

2. Endangered Species in the Specified Zones of the Delaware River

The Delaware River is home to two oxygen-sensitive fish species—Shortnose Sturgeon and Atlantic Sturgeon—that are protected under the Federal Endangered Species Act (ESA). All populations of Shortnose Sturgeon were listed as endangered in 1967.[14] Across the U.S., Shortnose Sturgeon face ongoing threats due to water pollution, habitat degradation, and fisheries bycatch, among other factors.[15] While the historic population size of Shortnose Sturgeon in the Delaware River remains unknown, in 2006 the population was estimated to be approximately 12,000 adults.[16] The New York Bight distinct population segment (DPS) of Atlantic Sturgeon—which includes the population found in the Delaware River—was listed as endangered under the ESA in 2012.[17] In 2017, the National Oceanic and Atmospheric Administration (NOAA Fisheries) designated the Delaware River, among others, as critical habitat for the New York Bight DPS of Atlantic Sturgeon,[18] and reaffirmed its endangered listing in 2022 following a five-year review of its status.[19] The remnant population of the New York Bight DPS of Atlantic Sturgeon faces ongoing threats due to water quality in natal rivers, such as the Delaware River, as well as climate change, ship strikes, fisheries bycatch, habitat loss, and entanglement in fishing gear.[20] [21] Like the Shortnose Sturgeon, the historic population size of Atlantic Sturgeon is not well documented. However, in 1890, when the population was already declining, there were approximately 180,000 female Atlantic Sturgeon in the Delaware River.[22] Despite improvements in dissolved oxygen levels since the 1970s, it is estimated that only 125–250 adult Atlantic Sturgeon currently return to spawn in the Delaware River.[23]

In addition to being listed as endangered under the ESA, available evidence suggests that Shortnose Sturgeon and Atlantic Sturgeon are the most oxygen-sensitive species in the specified zones of the Delaware River. In general, all sturgeon species share common life history traits,[24] among which they are recognized to be relatively more sensitive to low dissolved oxygen levels compared to other co-occurring fish.[25] [26] Sturgeons are considered unusually sensitive to hypoxia given their documented metabolic and behavioral responses and limited ability to oxyregulate.[27] Juvenile Atlantic Sturgeon are particularly sensitive to low dissolved oxygen levels, especially at high water temperatures,[28] such as those typically present at the peak of summer in the Delaware River.[29] A literature review across oxygen-

[9] Miskewitz and Uchrin (2013).

[10] Hardy (1999).

[11] Philadelphia Water Department. (2022). Combined Sewer Management Program Annual Report. Stormwater Management Program Annual Report. See Appendix D—''NPDES Annual CSO Status Report FY 2022,'' Table 2—''Overflow Summary for 7/1/2021–6/30/2022.'' *https://water.phila.gov/pool/files/fy22-npdes-annual-report.pdf.*

[12] United States Environmental Protection Agency. (2023b). Ammonia. *https://www.epa.gov/caddis-vol2/ammonia.*

[13] Each individual reporting period is one month long. For the reporting period ending on September 30, 2022, Florence Township Municipal Building discharged an average of .07 mg/L of ammonia. For the reporting period ending on July 31, 2022, Camden County Municipal Utilities Authority discharged an average of 35 mg/L of ammonia. Source: U.S. Environmental Protection Agency. Integrated Compliance Information System (ICIS). Database. Retrieved June 29, 2023.

[14] **Federal Register**, Vol. 32, No. 48 (32 FR 4000). March 11, 1967. *https://www.fisheries.noaa.gov/s3//2022-12/4000-4002.pdf.*

[15] NOAA Fisheries. (2023a). Shortnose Sturgeon—Overview. *https://www.fisheries.noaa.gov/species/shortnose-sturgeon.*

[16] *Id.;* NOAA Fisheries. (2023b). Shortnose Sturgeon—Populations. *https://www.fisheries.noaa.gov/species/shortnose-sturgeon#populations.*

[17] **Federal Register**, Vol. 77, No. 24. February 6, 2012. 77 FR 5879. *https://www.federalregister.gov/documents/2012/02/06/2012-1946/endangered-and-threatened-wildlife-and-plants-threatened-and-endangered-status-for-distinct.*

[18] **Federal Register**, Vol. 82, No. 158 (82 FR 39160). August 17, 2017. 50 CFR part 226. *https://www.federalregister.gov/documents/2017/08/17/2017-17207/endangered-and-threatened-species-designation-of-critical-habitat-for-the-endangered-new-york-bight.*

[19] National Marine Fisheries Service. (2022). New York Bight Distinct Population Segment of Atlantic Sturgeon (*Acipenser oxyrinchus oxyrinchus*), 5-Year Review: Summary and Evaluation. February 17, 2022. *https://www.fisheries.noaa.gov/resource/document/new-york-bight-distinct-population-segment-atlantic-sturgeon-5-year-review.*

[20] *Ibid.* See Section 2.3.2, ''Five-Factor Analysis (threats, conservation measures, and regulatory mechanisms)'', A. through E., pp. 14–25.

[21] Dunton, K.J., Jordaan, A., Conover, D.O., McKown, K.A., Bonacci, L.A., and Frisk, M.G. (2015). Marine Distribution and Habitat Use of Atlantic Sturgeon in New York Lead to Fisheries Interactions and Bycatch. Marine and Coastal Fisheries 7:18–32. *https://doi.org/10.1080/19425120.2014.986348;* Atlantic Sturgeon Bycatch Working Group. (2022). Action Plan to Reduce Atlantic Sturgeon Bycatch in Federal Large Mesh Gillnet Fisheries. NOAA National Marine Fisheries Service. *https://media.fisheries.noaa.gov/2022-09/Final-Action-Plan-to-Reduce-Atlantic-Sturgeon-Bycatch.pdf.*

[22] Secor and Waldman (1999).

[23] White, S.L., Sard, N.M., Brundage, H.M., Johnson, R.L., Lubinski, B.A., Eackles, M.S., Park, I.A., Fox, D.A., and Kazyak, D.C. (2022). Evaluating Sources of Bias in Pedigree-Based Estimates of Breeding Population Size. Ecological Applications 32(5): e2602. *https://doi.org/10.1002/eap.2602.*

[24] **Federal Register**, Vol. 82, No. 158 (82 FR 39161). August 17, 2017. 50 CFR part 226. pp. 39161–39163. *https://www.federalregister.gov/documents/2017/08/17/2017-17207/endangered-and-threatened-species-designation-of-critical-habitat-for-the-endangered-new-york-bight.*

[25] *Ibid.* p. 39162, see Dees (1961), Sulak and Clugston (1999), Billard and Lecointre (2001), Secor and Niklitschek (2002), and Pikitch et al. (2005), cited therein.

[26] Stoklosa et al. (2018) ; Secor, D.H. and Niklitschek, E.J. (2001). Hypoxia and Sturgeons: Report to the Chesapeake Bay Program Dissolved Oxygen Criteria Team. March 29, 2001.Reference Number: [UMCES] CBL 01–0080. *https://www.researchgate.net/publication/277065759_Hypoxia_and_Sturgeons_report_to_the_Chesapeake_Bay_Program_Dissolved_Oxygen_Criteria_Team.*

[27] Secor and Niklitschek (2001). Oxyregulation refers to an organism's ability to maintain metabolic rates as the oxygen level in the water declines.

[28] Secor, D., and T. Gunderson. (1998). Effects of hypoxia and temperature on survival, growth, and respiration of juvenile Atlantic sturgeon, Acipenser oxyrinchus. Fishery Bulletin 96:603–613.; Niklitschek, E. (2001). Bioenergetics modeling and assessment of suitable habitat for juvenile Atlantic and shortnose sturgeons (Acipenser oxyrinchus and A. brevirostrum) in the Chesapeake Bay. University of Maryland at College Park.

[29] More information is available in the associated document, *Technical Support Document for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.*

sensitive species in the Delaware River indicates that Atlantic Sturgeon, particularly the juvenile life stage, have the highest documented dissolved oxygen requirements for growth and survival when compared to other oxygen-sensitive species in the specified zones of the Delaware River.[30] In its five-year review of the listing of the New York Bight DPS of Atlantic Sturgeon, NOAA Fisheries observed a continuation of low dissolved oxygen conditions in the Delaware River around the expected location of age 0–1 Atlantic Sturgeon.[31] Low oxygen levels can lead to habitat displacement effects whereby juvenile Atlantic Sturgeon seeking relief are constrained to waters that remain suboptimal for growth due to other limiting factors (*e.g.,* higher salinity waters).[32] NOAA Fisheries also noted studies linking age 0–1 Atlantic Sturgeon capture rates in the fall to the preceding summer dissolved oxygen conditions in the Delaware River, providing further evidence that low dissolved oxygen levels are a contributor to the mortality of juvenile Atlantic Sturgeon.[33]

3. Dissolved Oxygen Trends in the Specified Zones of the Delaware River

Dissolved oxygen levels in Zone 3, Zone 4, and the upper portion of Zone 5 of the Delaware River mirror trends in historic pollutant loading and recent pollution control efforts in the river. Average summer dissolved oxygen levels in the Delaware River near Chester, Pennsylvania (Zone 4) declined from near saturation in the late 1880s to near zero (*i.e.,* anoxia) in the 1950s and 1960s.[34] Starting in 1970, dissolved oxygen levels began to increase steadily in association with declining ammonia nitrogen concentrations in the river.[35] Reductions in nutrient concentrations, including ammonia nitrogen, have been documented across the Delaware River watershed through at least 2018.[36] However, dissolved oxygen levels in the summer remain low enough to limit the growth and survival of oxygen-sensitive species and life stages, such as juvenile Atlantic Sturgeon.[37] Recent modeling studies have shown that further reductions in pollutant loading, including a reduction in the volume and frequency of CSOs as well as enhanced treatment of ammonia nitrogen discharges, could significantly improve the dissolved oxygen conditions in the relevant zones of the Delaware River.[38]

C. Administration of Water Quality Standards in the Delaware River

In 1961, the Delaware River Basin Compact established the Delaware River Basin Commission (DRBC), comprised of the states of Delaware, New Jersey, New York,[39] and Pennsylvania and the Federal Government, to jointly manage the Delaware River Basin's water resources.[40] Through DRBC, each state participates in the shared governance of this regional resource and maintains sovereign rights over the portion of the river within its jurisdiction.[41]

Pursuant to the Delaware River Basin Compact, DRBC adopts WQS for interstate waters, including the Delaware River Estuary.[42] However as noted above, under the CWA, states have the primary responsibility for reviewing, establishing, and revising WQS applicable to their waters, and must submit new or revised WQS to the EPA for review and approval or disapproval.

Given the unique interjurisdictional management of the Delaware River Estuary, WQS are submitted to the EPA for review through a process coordinated across the state, regional, and Federal levels. This process begins when DRBC adopts WQS for the Delaware River Estuary. To comply with CWA section 303(c), the Estuary states of Delaware, New Jersey, and Pennsylvania have provisions in their state WQS regulations that explicitly reference or implicitly incorporate DRBC's WQS as the applicable WQS for the portions of the river under their jurisdictions. When DRBC adopts new or revised WQS, each relevant member state submits a certification to the EPA from that state's attorney general or other appropriate legal authority, in accordance with 40 CFR 131.6(e). Those certifications provide that DRBC's new or revised WQS were duly adopted pursuant to state law. The EPA then reviews whether those WQS are consistent with the CWA and the EPA's implementing regulation and approves or disapproves them.

D. Currently Applicable Aquatic Life Designated Uses and Dissolved Oxygen Criteria

In 1967, DRBC adopted WQS for the zones of the Delaware River included in this proposed rule.[43] Based on the conditions of the Delaware River at the time, DRBC concluded that ''propagation of fish'' was not attainable for Zone 3, Zone 4, and the upper portion of Zone 5 (in total, river miles 108.4 to 70.0) of the Delaware River (hereafter, referred to as ''specified zones'' or ''relevant zones''),[44] due to the presence of industrial and municipal discharges and associated low dissolved oxygen levels. DRBC, therefore, adopted WQS to include ''maintenance of resident fish and other aquatic life,'' ''passage of anadromous fish,'' and a dissolved oxygen criterion of 3.5 mg/L, as a daily average, for these

[30] Stoklosa et al. (2018).

[31] National Marine Fisheries Service (2022). See Section 2.3.2.1, ''Present or threatened destruction, modification, or curtailment of its habitat or range.''

[32] *Ibid.* See Allen et al. (2014), cited therein.

[33] *Ibid.* See Moberg and DeLucia (2016), Stetzar et al. (2015), and Park (2020), cited therein.

[34] Sharp, J. (2010). Estuarine oxygen dynamics: What can we learn about hypoxia from long-time records in the Delaware estuary? Limnology and Oceanography, 55(2), 535–548.

[35] Sharp (2010).

[36] Shoda, M.E., and Murphy, J.C. (2022). Water-quality trends in the Delaware River Basin calculated using multisource data and two methods for trend periods ending in 2018. U.S. Geological Survey Scientific Investigations Report 2022–5097. *https://doi.org/10.3133/sir20225097.*

[37] More information is available in the associated document, *Technical Support Document for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River;* Delaware River Basin Commission (2022a); Niklitschek, E., and D. Secor. (2009a). Dissolved oxygen, temperature and salinity effects on the ecophysiology and survival of juvenile Atlantic sturgeon in estuarine waters: I. Laboratory results. Journal of Experimental Marine Biology and Ecology 381:S150–S160. *https://doi.org/10.1016/j.jembe.2009.07.018;* Stoklosa et al. (2018).

[38] Delaware River Basin Commission (2022a, 2022b).

[39] Although portions of the Delaware River Estuary are within New York's jurisdiction, the EPA's proposed rulemaking is not applicable to waters under New York's jurisdiction (see section IV.A. of this preamble: Scope of EPA's Proposed Rule). Therefore, the EPA does not discuss New York's WQS further in this proposed rulemaking.

[40] DRBC was established pursuant to Federal law (75 Stat. 688 (1961)).

[41] Delaware River Basin Compact, art. 1, ''Short Title, Definitions, Purpose and Limitations,'' § 1.3(a), (b), & (c) ''Purpose and Findings,'' pp. 3 & 4, and art. 5, ''Pollution Control,'' § 5.5(b), ''Further Jurisdiction,'' p. 11, (1961), available at *https://www.nj.gov/drbc/library/documents/compact.pdf.*

[42] Delaware River Basin Compact, art. 5, ''Pollution Control,'' § 5.2, ''Policy and Standards,'' p. 11 (1961), available at *https://www.nj.gov/drbc/library/documents/compact.pdf* (DRBC ''may adopt and from time to time amend and repeal rules, regulations and standards to control . . . future pollution and abate existing pollution''). DRBC, the states, and the EPA refer to these rules, regulations, and standards as equivalent to WQS under the CWA. As such, the term WQS is used herein to refer to these rules, regulations, and standards.

[43] Delaware River Basin Commission. (2013). Delaware River Basin Water Code. *https://www.nj.gov/drbc/library/documents/watercode.pdf.*

[44] A map showing the Delaware River watershed and the specified zones is available in the docket (Docket ID No. EPA–HQ–OW–2023–0222) as well as in each of the support documents associated with this rule: *Technical Support Document for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River; Economic Analysis for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River;* and *Environmental Justice Analysis for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.*

zones of the Delaware River.[45] [46] Because these WQS provide for the ''maintenance'' and ''passage'' of aquatic life (*i.e.,* ''protection'') but not the ''propagation of fish, shellfish and wildlife,'' these WQS are not consistent with the goals specified in CWA section 101(a)(2). However, these WQS adopted in 1967 remain applicable for Zone 3, Zone 4, and the upper portion of Zone 5 of the Delaware River as directly referred to or implicitly incorporated in Delaware's, New Jersey's, and Pennsylvania's WQS.

1. Delaware's, New Jersey's, and Pennsylvania's Current Aquatic Life Designated Uses

As described in section III.C. of this preamble, Delaware, New Jersey, and Pennsylvania each has its own WQS for the specified zones of the Delaware River under its jurisdiction. Delaware's current aquatic life designated use for the specified zones of the Delaware River includes all life stages, thus including the propagation component of the CWA section 101(a)(2) use. New Jersey's aquatic life designated use for the specified zones of the Delaware River incorporate by reference the designated uses in DRBC's Water Quality Regulations. Pennsylvania's aquatic life designated uses for the specified zones of the Delaware River align with DRBC's ''maintenance'' and ''passage'' designated use (Table 2 of this preamble). Therefore, neither New Jersey's nor Pennsylvania's aquatic life designated use for the specified zones of the Delaware River include the propagation component of the CWA section 101(a)(2) use.

TABLE 2—CURRENT AQUATIC LIFE DESIGNATED USES IN ZONE 3, ZONE 4, AND UPPER-ZONE 5 OF THE DELAWARE RIVER

Entity	Designated use
DRBC [1]	Maintenance of resident fish and other aquatic life, passage of anadromous fish, wildlife.
Delaware [2]	Fish, Aquatic Life & Wildlife.[3]
New Jersey [4]	The designated uses for the mainstem Delaware River and Delaware Bay are those contained in the DRBC Water Quality Regulations.
Pennsylvania [5]	Warm Water Fishes (Maintenance Only); Migratory fishes (Passage Only).[6]

[1] Delaware River Basin Commission. ''Administrative Manual—Part III Water Quality Regulations with Amendments Through December 7, 2022.'' Accessed May 3, 2023. *https://www.nj.gov/drbc/library/documents/WQregs.pdf.*

[2] Delaware Administrative Code. ''7401 Surface Water Quality Standards.'' Title 7 Natural Resources & Environmental Control. Delaware Department of Natural Resource and Environmental Control. Accessed May 3, 2023. *https://regulations.delaware.gov/AdminCode/title7/7000/7400/7401.pdf.*

[3] Delaware defines Fish, Aquatic Life & Wildlife as, ''all animal and plant life found in Delaware, either indigenous or migratory, regardless of life stage or economic importance.'' A footnote specifies that this use includes shellfish propagation.

[4] New Jersey Administrative Code. ''N. J. A. C. 7:9B Surface Water Quality Standards.'' Accessed May 3, 2023. *https://dep.nj.gov/wp-content/uploads/rules/rules/njac7_9b.pdf.*

[5] Pennsylvania Code. ''Chapter 93. Water Quality Standards.'' Commonwealth of Pennsylvania. Accessed May 3, 2023. *https://www.pacodeandbulletin.gov/secure/pacode/data/025/chapter93/025_0093.pdf.*

[6] Pennsylvania defines its ''Warm Water Fishes'' designated use as, ''Maintenance and propagation of fish species and additional flora and fauna which are indigenous to a warm water habitat'' and defines its ''Migratory Fishes'' designated use as, ''Passage, maintenance and propagation of anadromous and catadromous fishes and other fishes which move to or from flowing waters to complete their life cycle in other waters.'' For the specified zones of the Delaware River, Pennsylvania excluded propagation from the designated uses by specifying ''Maintenance Only'' and ''Passage Only'' in parentheses.

2. Delaware's, New Jersey's, and Pennsylvania's Current Dissolved Oxygen Criteria

For dissolved oxygen in the relevant zones, all three states incorporate DRBC's water quality criteria by reference; therefore, DRBC's dissolved oxygen criteria are the applicable criteria for the relevant zones in each state (Table 3 of this preamble). As explained above with respect to the aquatic life designated use, DRBC's dissolved oxygen criteria for the specified zones of the Delaware River do not protect for aquatic life propagation and are therefore not consistent with CWA section 101(a)(2) goals.

TABLE 3—CURRENT DISSOLVED OXYGEN CRITERIA IN ZONE 3, ZONE 4, AND UPPER-ZONE 5 OF THE DELAWARE RIVER

Entity	Dissolved oxygen aquatic life criteria
DRBC [1]	24-hour average concentration shall not be less than 3.5 mg/l. During the periods from April 1 to June 15, and September 16 to December 31, the dissolved oxygen shall not have a seasonal average less than 6.5 mg/l in the entire zone.
Delaware [2]	For waters of the Delaware River and Delaware Bay, duly adopted Delaware River Basin Commission (DRBC) Water Quality Regulations shall be the applicable criteria.
New Jersey [3]	For parameters with criteria in the DRBC Water Quality Regulations, the criteria contained therein are the applicable criteria.
Pennsylvania [4]	See DRBC Water Quality Regulations.

[1] Delaware River Basin Commission. ''Administrative Manual—Part III Water Quality Regulations with Amendments Through December 7, 2022.'' Accessed May 3, 2023. *https://www.nj.gov/drbc/library/documents/WQregs.pdf.*

[2] Delaware Administrative Code. ''7401 Surface Water Quality Standards.'' Title 7 Natural Resources & Environmental Control. Delaware Department of Natural Resource and Environmental Control. Accessed May 3, 2023. *https://regulations.delaware.gov/AdminCode/title7/7000/7400/7401.pdf.*

[3] New Jersey Administrative Code. ''N. J. A. C. 7:9B Surface Water Quality Standards.'' Accessed May 3, 2023. *https://dep.nj.gov/wp-content/uploads/rules/rules/njac7_9b.pdf.*

[4] Pennsylvania Code. ''Chapter 93. Water Quality Standards.'' Commonwealth of Pennsylvania. Accessed May 3, 2023. *https://www.pacodeandbulletin.gov/secure/pacode/data/025/chapter93/025_0093.pdf.*

[45] Delaware River Basin Commission. (2015). ''Existing Use Evaluation for Zones 3, 4, & 5 of the Delaware Estuary Based on Spawning and Rearing of Resident and Anadromous Fishes.'' September 30, 2015. *https://www.state.nj.us/drbc/library/documents/ExistingUseRpt_zones3-5_sept2015.pdf.*

[46] Anadromous fish are species that are born and reared as juveniles in freshwater, migrate to marine waters where they spend most of their adult lives, and return to their natal, freshwater rivers to spawn.

3. Intersection of Delaware's, New Jersey's, and Pennsylvania's Current Aquatic Life Designated Uses and Dissolved Oxygen Criteria With CWA 101(a)(2) Goals

Table 4 of this preamble provides a summary outlining whether Delaware's, New Jersey's, and Pennsylvania's current aquatic life designated uses align with CWA section 101(a)(2) goals and whether each state's current dissolved oxygen criteria are protective of an aquatic life designated use that includes propagation. As explained above, Delaware is the only state that includes aquatic life propagation in its designated uses for the specified zones of the Delaware River. However, none of the three states' dissolved oxygen water quality criteria for the specified zones are protective of fish and shellfish propagation. Therefore, none of the states, and by extension none of the specified zones of the Delaware River, currently has a set of WQS for aquatic life that are fully consistent with the CWA section 101(a)(2) goals (*i.e.,* ''water quality which provides for the protection and propagation of fish, shellfish, and wildlife [. . .]'').

TABLE 4—INTERSECTION OF DELAWARE'S, NEW JERSEY'S, AND PENNSYLVANIA'S CURRENT AQUATIC LIFE DESIGNATED USES AND DISSOLVED OXYGEN CRITERIA WITH CWA 101(a)(2) GOALS

State	Applicable zone(s)	Designated use includes CWA section 101(a)(2) propagation component	Dissolved oxygen criteria protective of aquatic life propagation
Delaware	Upper-5	Yes	No.
New Jersey	3, 4, Upper-5	No	No.
Pennsylvania	3, 4	No	No.

E. Summary of the EPA's Administrator's Determination

On December 1, 2022, the EPA determined that the CWA section 101(a)(2) use of propagation is now attainable and therefore revised WQS are necessary to protect aquatic life in certain water quality management zones of the Delaware River.[47] Specifically, the EPA issued an Administrator's Determination, pursuant to CWA section 303(c)(4)(B), finding that a revised designated use to protect aquatic life propagation and corresponding dissolved oxygen criteria to protect that use are necessary in Zone 3, Zone 4, and the upper portion of Zone 5 (in total, river miles 108.4 to 70.0) of the Delaware River. The Administrator's Determination can be accessed at *https://www.epa.gov/wqs-tech/federally-promulgated-water-quality-standards-specific-states-territories-and-tribes.*

IV. Proposed Water Quality Standards

A. Scope of EPA's Proposed Rule

In accordance with the Administrator's Determination, the EPA's proposed rule, if finalized, would apply to Zone 3, Zone 4, and the upper portion of Zone 5 of the Delaware River (in total, river miles 108.4 to 70.0), for the states of Delaware, New Jersey, and Pennsylvania (Table 5 of this preamble).

TABLE 5—ZONES OF THE DELAWARE RIVER COVERED BY THE EPA'S PROPOSED RULE

Segment of the Delaware River	River miles	States affected
Zone 3	108.4 to 95.0	New Jersey, Pennsylvania.
Zone 4	95.0 to 78.8	New Jersey, Pennsylvania.
Zone 5—Upper Portion	78.8 to 70.0	Delaware, New Jersey.

B. Proposed Aquatic Life Designated Use

The EPA is proposing to promulgate a revised aquatic life designated use for the specified zones of the Delaware River to meet the CWA section 101(a)(2) goals (*i.e.,* ''water quality which provides for the protection and propagation of fish, shellfish, and wildlife''), as specified in the EPA's Administrator's Determination.[48] Although the relevant zones of the Delaware River are each under the jurisdiction of two or more states (Table 5 of this preamble), CWA section 303(c) assigns the individual states the role of adopting WQS. Therefore, the EPA is evaluating the aquatic life uses on a state-by-state basis.

As explained in section III.D. of this preamble, Delaware's ''Fish, Aquatic Life & Wildlife'' designated use includes all life stages of indigenous and migratory organisms; therefore, Delaware's aquatic life designated use in the specified zones under its jurisdiction is already consistent with the CWA section 101(a)(2) goals and no revisions to Delaware's aquatic life designated use are necessary to meet CWA requirements. In contrast, New Jersey's and Pennsylvania's aquatic life designated uses for the relevant zones of the Delaware River under their jurisdiction do not include ''propagation'' and are therefore not consistent with CWA section 101(a)(2) goals. As explained in section III.E. of this preamble, the EPA determined that propagation is now an attainable use in the specified zones of the Delaware River.[49] Therefore, for the portions of the specified zones under New Jersey's and Pennsylvania's jurisdiction, a

[47] December 1, 2022. Letter from Radhika Fox, Assistant Administrator, EPA Office of Water, to Steven J. Tambini, Executive Director, Delaware River Basin Commission; Shawn M. Garvin, Secretary, Delaware Department of Natural Resources and Environmental Control; Shawn M. LaTourette, Commissioner, New Jersey Department of Environmental Protection; and Ramez Ziadeh, Acting Secretary, Pennsylvania Department of Environmental Protection.

[48] The EPA's Administrator's Determination stated, ''EPA is determining [. . . that] revised aquatic life designated uses that provide for propagation of fish, consistent with CWA section 101(a)(2) and 40 CFR 131.20(a) [. . .] are necessary for zone 3, zone 4, and the upper portion of zone 5 (in total, river miles 108.4 to 70.0) of the Delaware River Estuary, to meet the requirements of the CWA.''

[49] December 1, 2022. Letter from Radhika Fox, Assistant Administrator, EPA Office of Water, to Steven J. Tambini, Executive Director, Delaware River Basin Commission; Shawn M. Garvin, Secretary, Delaware Department of Natural Resources and Environmental Control; Shawn M. LaTourette, Commissioner, New Jersey Department of Environmental Protection; and Ramez Ziadeh, Acting Secretary, Pennsylvania Department of Environmental Protection.

revised aquatic life designated use that includes propagation is necessary to meet CWA requirements and ensure that the specified zones of the Delaware River are consistent with CWA section 101(a)(2) goals.

Thus, the EPA is proposing to promulgate an aquatic life designated use for Zone 3, Zone 4, and the upper portion of Zone 5 of the Delaware River (in total, river miles 108.4 to 70.0) for the states of New Jersey and Pennsylvania, as follows: *Protection and propagation of resident and migratory aquatic life.*

C. Dissolved Oxygen Criteria To Protect Aquatic Life Propagation

The EPA is proposing to establish dissolved oxygen criteria—derived from the latest sound scientific information—for Delaware, New Jersey, and Pennsylvania, for the specified zones of the Delaware River. The proposed dissolved oxygen criteria would protect the EPA's proposed designated use for New Jersey and Pennsylvania, as well as Delaware's current aquatic life designated use for the specified zones.

1. Derivation of Dissolved Oxygen Criteria

To derive protective dissolved oxygen criteria for the specified zones of the Delaware River, the EPA used methods adapted from peer-reviewed literature and data from laboratory studies relevant to oxygen-sensitive sturgeon species in the Delaware River. Although the methods and data are from peer-reviewed scientific literature, the EPA is nonetheless in the process of completing an external peer review on the application of these methods and data in this context where the EPA is proposing criteria to protect proposed and applicable aquatic life designated uses that include propagation. This section presents a summary of the data and methods that the EPA used to derive protective dissolved oxygen criteria for this proposed rulemaking. First, the EPA describes the Agency's existing dissolved oxygen national recommendations and guidance documents. Then, the EPA explains how the Agency selected three seasons to derive criteria protective of oxygen-sensitive species in the relevant zones of the Delaware River. Next, the EPA details an Atlantic Sturgeon cohort model used to derive criteria protective of juvenile Atlantic Sturgeon during the season associated with their growth and development. After that, the EPA explains how criteria were developed to protect oxygen-sensitive species during the other two seasons. Lastly, the EPA concludes with an explanation for proposing criteria expressed as percent oxygen saturation, rather than as concentration. This section is intended to be a high-level summary of the EPA's criteria derivation methods and results for this proposed rulemaking. More details and information are available in the associated technical support document, *Technical Support Document for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.* The EPA will consider information received during the public comment period (detailed above), in addition to the external peer review of the technical support document, and accordingly may make changes to the proposed criteria for a final rule.

Existing the EPA Methodology and Guidance Documents

Under CWA section 304(a), the EPA publishes, from time to time, national recommended aquatic life criteria for a variety of pollutants and parameters. The EPA's national recommended criteria for dissolved oxygen in freshwater and saltwater environments are from the 1986 *Quality Criteria for Water* (''Gold Book'') [50] and the 2000 *Ambient Aquatic Life Water Quality Criteria for Dissolved Oxygen (Saltwater): Cape Cod to Cape Hatteras* (''Virginian Province Document''),[51] respectively. The EPA's recommendations in the Virginian Province Document state that, ''in cases where a threatened or endangered species occurs at a site, and sufficient data exist to suggest that it is more sensitive at concentrations above the criteria, it is appropriate to consider development of site-specific criteria based on this species.'' [52] As explained previously in section III.B. of this preamble, Atlantic Sturgeon and Shortnose Sturgeon are federally listed as endangered under the ESA and are uniquely sensitive to hypoxia. Given the availability of laboratory data specific to the oxygen requirements of Atlantic Sturgeon and Shortnose Sturgeon, the EPA chose to derive site-specific criteria to protect the oxygen-sensitive endangered species in the specified zones of the Delaware River and not rely on the national recommendations in the Gold Book or Virginian Province Document in this instance.

Delineating Seasons for Criteria Derivation

In consideration of available information, including information developed by DRBC, the EPA is proposing to delineate three distinct seasons for dissolved oxygen criteria development that are intended to protect Atlantic Sturgeon early life stages, while also protecting a range of other aquatic species' sensitive life stages in the specified zones. The EPA is proposing to define the *Spawning and Larval Development* season as occurring from March 1 to June 30, which generally covers spawning and egg and larval development periods for many oxygen-sensitive species, including Atlantic Sturgeon, Shortnose Sturgeon, American Shad, Atlantic Rock Crab, Channel Catfish, Striped Bass, Largemouth Bass, White Perch, and Yellow Perch.[53] The EPA is proposing to define the *Juvenile Development* season as occurring from July 1 to October 31 and the *Overwintering* season as occurring from November 1 to February 28/29, based on young-of-the-year juvenile Atlantic Sturgeon growth rates.[54] By November, growth rates are reduced by low water temperatures despite relatively high levels of dissolved oxygen.[55] While the EPA is proposing to define seasons largely based on the early life stages of Atlantic Sturgeon, the proposed seasons also generally correspond with early life stages of other oxygen-sensitive species in the specified zones of the Delaware River. By developing criteria that are protective of Atlantic Sturgeon, which, as described in section III.B. of this preamble, is the most oxygen-sensitive species in the relevant zones of the Delaware River, the EPA concluded that the criteria would also be protective of other less oxygen-sensitive resident and

[50] United States Environmental Protection Agency. (1986). Quality Criteria for Water 1986. Document ID: EPA 440/5–86–001. May 1, 1986. *https://www.epa.gov/sites/default/files/2018-10/documents/quality-criteria-water-1986.pdf.*

[51] United States Environmental Protection Agency. (2000). Ambient Aquatic Life Water Quality Criteria for Dissolved Oxygen (Saltwater): Cape Cod to Cape Hatteras. Document ID: EPA–822–R–00–012. November 2000. *https://www.epa.gov/sites/default/files/2018-10/documents/ambient-al-wqc-dissolved-oxygen-cape-code.pdf.*

[52] *Id.* Page 41.

[53] Stoklosa et al. (2018); Delaware River Basin Commission (2015); Moberg, T. and M. DeLucia. (2016). Potential Impacts of Dissolved Oxygen, Salinity and Flow on the Successful Recruitment of Atlantic Sturgeon in the Delaware River. The Nature Conservancy. Harrisburg, PA. *https://www.conservationgateway.org/ConservationPractices/Freshwater/HabitatProtectionandRestoration/Documents/DelawareAtlanticSturgeonReport_TNC5172016.pdf.*

[54] Moberg and DeLucia. (2016).

[55] This conclusion was based on results of the growth model, described in sections 3.3.3 and 4.1.2 of the associated document, *Technical Support Document for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.*

migratory aquatic species in the specified zones of the Delaware River.

Ecological Modeling To Derive Criteria for the Juvenile Development Season

The EPA obtained recent and high-quality data from a variety of sources, described below and detailed in the associated technical support document, to evaluate oxygen requirements of Atlantic Sturgeon in each season. The EPA quantified water quality conditions in the specified zones of the Delaware River using recent and high-quality monitoring data from two locations in the Delaware River. Since the Atlantic Sturgeon was listed as an endangered species in 2012, there have been few recent studies documenting their oxygen requirements. However, available data on sturgeon growth and mortality from Campbell and Goodman (2004), Niklitschek and Secor (2009a), and EPA (2003), along with methods from Niklitschek and Secor (2005) and Niklitschek and Secor (2009b), water quality monitoring data, and juvenile Atlantic Sturgeon abundance data from the Delaware Department of Natural Resources and Environmental Control (DNREC) provided the EPA with sufficient data to establish quantitative relationships between age-0 juvenile sturgeon growth, mortality, and habitat suitability.[56]

The EPA followed the peer-reviewed cohort modeling approach of Niklitschek and Secor (2005) to evaluate the effects of temperature, salinity, and dissolved oxygen on the potential growth and mortality of a hypothetical cohort or group of juvenile Atlantic Sturgeon spawned during a single year.[57] The cohort model uses growth and mortality rates to calculate the instantaneous daily production potential, or the instantaneous amount of biomass produced per unit of cohort biomass per day. The EPA used the cohort model to estimate the fraction of the cohort that survives from July 1 through October 31 (*i.e.,* the *Juvenile Development* season) and the relative change in biomass for the same period.

As part of the cohort model, the EPA developed a new mortality model and implemented a peer-reviewed bioenergetics-based growth model described by Niklitschek and Secor (2009b) to predict the daily instantaneous mortality rate and growth rate, respectively, for members of the cohort. To develop a mortality model, the EPA fit a regression to experimental data to predict mortality resulting from low dissolved oxygen at any given temperature and percent oxygen saturation.[58] Mortality rates of juvenile sturgeons increased with declining dissolved oxygen levels and increased at higher rates with both declining dissolved oxygen and increasing water temperature. The EPA validated the results of the mortality model by using observed water quality data to predict relative abundance of the Atlantic Sturgeon young-of-year cohort on October 31 and comparing those results to catch data from DNREC's juvenile abundance surveys.[59] The growth model takes a bioenergetic approach that accounts for temperature-controlled maximum metabolic rates that may be further limited by oxygen levels. Low oxygen levels limit overall metabolic rates and cause a shift in the allocation of available energy away from growth. Predicted growth rates reflect the balance between energy inputs and losses and are therefore reduced by low oxygen. Water quality monitoring data in the relevant zones of the Delaware River show that the lowest oxygen levels coincided with the highest water temperatures, resulting in lower growth rates than either condition would cause alone.

Habitat Suitability Indices have been used in the context of fish-habitat relationships, conservation management, and habitat evaluation to quantify the capacity of a given habitat to support essential life functions (*e.g.,* growth, survival, reproduction) of a selected species.[60] For this proposed rulemaking, the EPA defined a Habitat Suitability Index (HSI) for Atlantic Sturgeon as the instantaneous daily production potential, which was calculated using the cohort model. HSI evaluates the combined effect of percent oxygen saturation, water temperature, and salinity on the potential growth and survival of juvenile Atlantic Sturgeon during the *Juvenile Development* season. The EPA used quantile generalized additive models (QGAMs) to quantify relationships between computed values of HSI in each year and corresponding seasonal percentiles of daily dissolved oxygen for that year.[61] QGAMs can model the non-linear relationship between dissolved oxygen and HSI as well as predict the expected median HSI, rather than the expected mean.

The EPA followed the approach of Niklitschek and Secor (2005) to define suitable habitat for juvenile Atlantic Sturgeon growth and survival as habitats with water quality resulting in HSI greater than zero. When HSI is less than or equal to zero, seasonal average mortality rates are greater than or equal to seasonal average growth rates and the overall biomass of the cohort is likely to decrease. Conversely, a cohort of

[56] Campbell, J., and L. Goodman. (2004). Acute sensitivity of juvenile shortnose sturgeon to low dissolved oxygen concentrations. Transactions of the American Fisheries Society 133:722–776; Niklitschek, E., and D. Secor. (2009a). Dissolved oxygen, temperature and salinity effects on the ecophysiology and survival of juvenile Atlantic sturgeon in estuarine waters: I. Laboratory results. Journal of Experimental Marine Biology and Ecology 381:S150–S160. *https://doi.org/10.1016/j.jembe.2009.07.018;* United States Environmental Protection Agency. (2003). Ambient Water Quality Criteria for Dissolved Oxygen, Water Clarity and Chlorophyll a for the Chesapeake Bay and its Tidal Tributaries. Document ID: EPA 903–R–03–002. April 2003. *https://nepis.epa.gov/Exe/ZyPDF.cgi/P100YKPQ.PDF?Dockey=P100YKPQ.PDF;* Niklitschek, E.J., and D.H. Secor. (2005). Modeling spatial and temporal variation of suitable nursery habitats for Atlantic sturgeon in the Chesapeake Bay. Estuarine, Coastal and Shelf Science 64:135–148. *https://doi.org/10.1016/j.ecss.2005.02.012;* Niklitschek, E.J., and D.H. Secor. (2009b). Dissolved oxygen, temperature and salinity effects on the ecophysiology and survival of juvenile Atlantic sturgeon in estuarine waters: II. Model development and testing. Journal of Experimental Marine Biology and Ecology 381:S161–S172. *https://doi.org/10.1016/j.jembe.2009.07.019;* USGS 01467200 Delaware River at Penn's Landing, Philadelphia, PA. Retrieved March 9, 2023. *https://waterdata.usgs.gov/nwis/inventory/?site_no=01467200&agency_cd=USGS;* USGS 01477050 Delaware River at Chester PA. Retrieved January 31, 2023. *https://waterdata.usgs.gov/nwis/inventory?agency_code=USGS&site_no=01477050;* Park, I. (2023). State of Delaware Annual Compliance Report for Atlantic Sturgeon. Delaware Division of Fish and Wildlife, Department of Natural Resources and Environmental Control. September 2023.

[57] Water temperature and salinity can affect the oxygen requirements of aquatic species and are needed to compute percent oxygen saturation, a measure of dissolved oxygen availability to aquatic organisms, from dissolved oxygen concentrations.

[58] Experimental data are from Campbell and Goodman 2004, Niklitschek and Secor 2009a.

[59] USGS 01467200 Delaware River at Penn's Landing, Philadelphia, PA. Retrieved March 9, 2023. *https://waterdata.usgs.gov/nwis/inventory/?site_no=01467200&agency_cd=USGS;* USGS 01477050 Delaware River at Chester, PA. Retrieved January 31, 2023. *https://waterdata.usgs.gov/nwis/inventory?agency_code=USGS&site_no=01477050;* Park (2023).

[60] E.g., Woodland, R.J., Secor, D.H., and Niklitschek, E.J. (2009). Past and Future Habitat Suitability for the Hudson River Population of Shortnose Sturgeon: A Bioenergetic Approach to Modeling Habitat Suitability for an Endangered Species. American Fisheries Society Symposium 69: 589–604; Collier, J.J., Chiotti, J.A., Boase, J., Mayer, C.M., Vandergoot, C.S., and Bossenbroek, J.M. (2022). Assessing habitat for lake sturgeon (Acipenser fulvescens) reintroduction to the Maumee River, Ohio using habitat suitability index models. Journal of Great Lakes Research. 48(1): 219–228. *https://doi.org/10.1016/j.jglr.2021.11.006;* Brown, S.K., Buja, K.R., Jury, S.H., Monaco, M.E., and Banner, A. (2000). Habitat Suitability Index Models for Eight Fish and Invertebrate Species in Casco and Sheepscot Bays, Maine. North American Journal of Fisheries Management, 20(2): 408–435, *https://doi.org/10.1577/1548-8675(2000)020%3C0408:HSIMFE%3E2.3.CO;2.*

[61] A percentile (*e.g.,* 10th percentile) is the dissolved oxygen level below which the corresponding fraction (*e.g.,* 10%) of the daily dissolved oxygen values during the season falls below. In this case, the season is the *Juvenile Development* season (July 1–October 31).

juveniles utilizing habitat with HSI greater than zero has the potential to increase its biomass during the *Juvenile Development* season, thus contributing to successful propagation. Therefore, to derive protective dissolved oxygen criteria, the EPA evaluated seasonal percentiles of percent oxygen saturation to find the lowest value at which the QGAMs predict expected median HSI>0 as the minimum thresholds for percent oxygen saturation that, if attained, would provide suitable habitat during that seasonal period. The EPA requests comment on the conclusion that HSI greater than zero defines suitable habitat for juvenile Atlantic Sturgeon growth and survival, or alternatively, if evidence could support that a value of HSI less than zero could also be protective or if a higher HSI threshold may be needed to protect propagation in the specified zones. Similarly, the EPA requests comment on its use of QGAM to relate percentiles of dissolved oxygen levels to the conditional median HSI. These models can be understood to find the minimum dissolved oxygen level that if achieved would result in an expectation that HSI would be equal to or greater than zero as often or more often than if it is less than zero. As an alternative, the QGAM could predict a lower conditional percentile, providing a high degree of certainty that HSI would be greater than zero if the dissolved oxygen level was attained. For example, at the dissolved oxygen level where the expected 25th percentile HSI=0, HSI would be expected to equal or exceed zero 75% of the time.

The predicted HSI value relies on an expected distribution of percent oxygen saturation values during the season; therefore, the EPA selected two percent oxygen saturation percentiles as thresholds at or above which median HSI is expected to be greater than zero to maintain the expected distribution of percent oxygen saturation values. These two percentiles—the 10th percentile and the 50th percentile—describe the protective seasonal distribution of dissolved oxygen values. When both the 10th percentile and 50th percentile are attained, they function together to ensure that a detrimental shift in the oxygen distribution (*i.e.,* a shift causing more low oxygen levels) at either the low end (10th percentile) or the center (50th percentile) of the dissolved oxygen distribution has not occurred. Median HSI is expected to be zero or higher, allowing the annual cohort of juvenile Atlantic Sturgeon to maintain or increase its biomass, when the 10th percentile of oxygen saturation is at least 66% and the 50th percentile, or median, of oxygen saturation is at least 74%. Therefore, the EPA expects oxygen levels will not impair juvenile Atlantic Sturgeon during the *Juvenile Development* season if the 10th percentile of oxygen saturation is at least 66% and the 50th percentile of oxygen saturation is at least 74%.

Criteria Development for Spawning and Larval Development and Overwintering Seasons

The Atlantic Sturgeon cohort model described above relies on experimental studies that were conducted using juvenile Atlantic Sturgeon and therefore provide information that is most relevant to juvenile growth and survival.[62] Additionally, the underlying studies allocated most experimental treatments to water temperatures between 12 °C and 28 °C, with only a single experimental treatment at 6 °C and none at lower water temperatures.[63] The EPA's cohort modeling approach therefore does not apply to spawning and larval development lifestages and has minimal relevance to the overwintering period. Accordingly, the EPA did not use the cohort model to derive criteria for the *Spawning and Larval Development* or the *Overwintering* seasons.

Instead, the EPA concluded that Atlantic Sturgeon larvae were likely to be as sensitive to low dissolved oxygen as juvenile Atlantic Sturgeon[64] and that overwintering juveniles have temperature-limited metabolism and therefore have similar or slightly lower oxygen requirements than juveniles in warmer waters (*e.g.,* summer water temperatures).[65] Thus, the EPA determined that the percent oxygen saturation threshold that would be protective of juveniles experiencing stressful (high) water temperatures during the *Juvenile Development* season would also be protective of larvae and overwintering juveniles not experiencing high water temperatures. Therefore, the EPA expects oxygen levels will not impair Atlantic Sturgeon when the 10th percentile of oxygen saturation is at least 66% during the *Spawning and Larval Development* and *Overwintering* seasons. The EPA notes that from 2002–2022, the median oxygen level during the *Spawning and Larval Development* and *Overwintering* seasons was well above levels expected to negatively impact either Atlantic Sturgeon or other oxygen-sensitive species. Therefore, the EPA concluded that a second criterion for a 50th percentile was not needed during these seasons.

Criteria Expressed as Percent Oxygen Saturation

Finally, the EPA derived the proposed criteria in terms of percent oxygen saturation, rather than in units of concentration (such as milligrams per liter or mg/L) for two main reasons.[66] First, physiological effects of oxygen on aquatic organisms are *directly* related to percent oxygen saturation and *indirectly* related to dissolved oxygen concentration. As noted by Niklitschek and Secor (2009a), percent oxygen saturation or partial pressure are the most biologically relevant measures of oxygen because they determine the maximum rate at which aquatic organisms may obtain oxygen from the water. Second, percent oxygen saturation varies with water temperature less than dissolved oxygen concentration. Because oxygen solubility is higher in cold water than warm water, dissolved oxygen concentrations are often much higher in cold water. The strong negative relationship between dissolved oxygen concentration and temperature can complicate the interpretation of seasonal dissolved oxygen patterns. For example, in the Delaware River, dissolved oxygen concentrations increase quickly during fall as temperatures decrease, even though percent saturation increases more slowly. In this example, the increasing oxygen concentration gives the appearance that oxygen availability to aquatic organisms is increasing more rapidly than it is actually increasing. For Atlantic Sturgeon, this means that low levels of percent oxygen saturation may continue to impact growth and survival even though dissolved oxygen concentrations increase. Given this relationship between temperature and dissolved oxygen concentration, criteria expressed as concentration will be above or below the protective threshold at various times of the year as

[62] Experimental data are from Campbell and Goodman 2004 and Niklitschek and Secor 2009a.

[63] Niklitschek and Secor 2009a.

[64] Stoklosa et al. (2018); United States Environmental Protection Agency. (2000). Ambient Aquatic Life Water Quality Criteria for Dissolved Oxygen (Saltwater): Cape Cod to Cape Hatteras. Document ID: EPA–822–R–00–012. November 2000. *https://www.epa.gov/sites/default/files/2018-10/documents/ambient-al-wqc-dissolved-oxygen-cape-code.pdf.*

[65] Niklitschek and Secor (2009a, 2009b).

[66] Percent oxygen saturation and dissolved oxygen concentration are two different ways to measure oxygen levels in water. Dissolved oxygen concentration is the amount of oxygen dissolved in the water, typically represented as milligrams of oxygen per liter of water. Percent oxygen saturation is the ratio, expressed as a percentage, of the dissolved oxygen concentration in the water to the dissolved oxygen concentration when at equilibrium with the atmosphere.

temperature changes, whereas criteria expressed as percent oxygen saturation can be protective throughout the year.

2. Proposed Dissolved Oxygen Criteria

The EPA's proposed dissolved oxygen criteria cover three distinct seasons based largely on Atlantic Sturgeon early life stages and are intended to protect all oxygen-sensitive species in the Delaware River, as explained above. The *Spawning and Larval Development* season occurs between March 1st and June 30th and captures a comprehensive range of resident aquatic species' spawning periods.[67] The *Juvenile Development* season occurs between July 1st and October 31st and captures critical early life stage growth and development for young-of-the-year Atlantic Sturgeon. The *Overwintering* season occurs between November 1st and February 28th (or 29th, in a leap year), when juvenile Atlantic Sturgeon growth is limited by low water temperatures.

Each season has water quality criteria that each consist of three components: magnitude, duration, and exceedance frequency. The magnitude component indicates the required level of dissolved oxygen in the water, which in this proposal is presented in units of percent oxygen saturation. The duration component specifies the time period over which water quality is averaged before comparison with the criteria magnitude; in this proposal, the duration is a daily average.[68] The exceedance frequency component specifies how often (*e.g.,* percentage of the time) each criterion can be exceeded in each season while still ensuring that the use is protected. For this proposed rulemaking, the exceedance frequency is determined based on the dissolved oxygen percentile from which the magnitude is derived (*i.e.,* the 10th percentile can be exceeded 10% of the time, which for a season consisting of 123 days is 12 cumulative days of exceedance). For dissolved oxygen, an exceedance occurs when the oxygen level in the water is below the criterion value.

In this proposed rulemaking, the *Spawning and Larval Development* and *Overwintering* seasons each have a single, identical dissolved oxygen criterion with a magnitude of 66% oxygen saturation, a daily average duration, and a 10% exceedance frequency (which allows for up to 12 days of cumulative exceedance during each of these two seasons) (Table 6 of this preamble). The *Juvenile Development* season has two individually applicable dissolved oxygen criteria that together define a protective seasonal distribution of percent oxygen saturation. The criteria differ in both magnitude and exceedance frequency and both levels must be attained. The first *Juvenile Development* criterion defines the lower end of the distribution of oxygen levels and consists of a magnitude of 66% oxygen saturation, a daily average duration, and a 10% exceedance frequency (which allows for up to 12 days cumulative exceedance during the season). The second *Juvenile Development* criterion defines the center of the distribution and consists of a magnitude of 74% oxygen saturation, a daily average duration, and a 50% exceedance frequency (which allows for up to 61 days cumulative exceedance during the season) (Table 6 of this preamble).

TABLE 6—THE EPA'S PROPOSED DISSOLVED OXYGEN CRITERIA

Season	Magnitude (percent oxygen saturation)	Duration	Exceedance frequency
Spawning and Larval Development *(March 1–June 30)*.	66	Daily verage	10% *(12 Days Cumulative).*
Juvenile Development *(July 1–October 31)*	66	Daily Average	10% *(12 Days Cumulative).*
	74	Daily Average	50% *(61 Days Cumulative).*
Overwintering *(November 1–February 28/29)*	66	Daily Average	10% *(12 Days Cumulative).*

3. Alternative Options Considered

During the criteria derivation process, the EPA made several decisions based on the best available sound scientific information to ensure the dissolved oxygen criteria would be protective of the applicable and proposed aquatic life designated uses. In this section, the EPA presents three alternative options the Agency considered. For each alternative, the EPA examined information currently available at the time of this proposal. The EPA has concerns about whether each alternative would be protective of the aquatic life designated uses that include propagation; therefore, the EPA did not include any of these alternatives as part of its lead proposed criteria. However, the EPA requests comment and additional information on whether and how one or more of these alternatives could protect the applicable and proposed aquatic life designated uses in the specified zones of the Delaware River and if so, what anticipated benefits would be associated with the alternative compared to the EPA's proposed criteria.[69]

Alternative 1: Dissolved Oxygen Criteria Expressed as Concentration (mg/L).

The EPA's proposed dissolved oxygen criteria are expressed as percent oxygen saturation, as described in section IV.C.1 of this preamble. However, the EPA recognizes that some stakeholders might be more familiar with dissolved oxygen criteria expressed as concentration or might have other reasons for preferring criteria expressed as concentration. The EPA is seeking comment on whether dissolved oxygen criteria expressed as concentration (mg/L) would be protective of oxygen-sensitive species during each season.

To calculate *Juvenile Development* season criteria expressed as concentration (mg/L), the EPA followed an analogous approach to the method used for determining criteria as percent oxygen saturation, as explained in section IV.C.1 of this preamble. The EPA used quantile generalized additive models relating seasonal percentiles of dissolved oxygen concentration to the expected median habitat suitability index (HSI). The EPA selected as the alternative criteria values the dissolved

[67] Stoklosa et al. (2018); Delaware River Basin Commission (2015).

[68] The EPA selected a daily average duration because it is a readily measurable indicator of the oxygen levels at a daily timescale. The daily average is protective because variability of dissolved oxygen levels on a single day is small in the Delaware River.

[69] More information is available in the associated document, *Technical Support Document for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.*

oxygen concentration for which the expected median HSI is zero (Table 7 of this preamble).

To calculate dissolved oxygen criteria expressed as concentration for the *Spawning and Larval Development* and *Overwintering* seasons, the EPA started with the criteria computed as percent oxygen saturation (Table 6 of this preamble) and converted each of these to a concentration using each of the following two approaches, which differed based on water temperature assumptions.[70] The EPA's first approach uses the 90th percentile of water temperatures in each season, whereas the second approach uses the average water temperature in each season.[71] The 90th percentile approximates the highest water temperature in each season, which corresponds to when dissolved oxygen levels are generally at their lowest and therefore impacts to aquatic life are most likely to occur. In the Delaware River, the highest temperatures in the *Spawning and Larval Development* season occur in late June and the highest temperatures in the *Overwintering* season occur in early November. On the other hand, the EPA's second approach using an average water temperature results in the concentration that minimizes the magnitude of deviations in either direction from the protective level across the season. Because the average water temperature is lower than the 90th percentile water temperature, the EPA's second approach resulted in higher dissolved oxygen concentrations than the first approach (Table 7 of this preamble).

In table 7 below, the EPA leads with alternative criteria based on the 90th percentile water temperatures because existing dissolved oxygen criteria guidance and criteria derivation efforts in other states have commonly focused on the warmest conditions that occur, which are the most critical for mitigating impacts to aquatic life due to low oxygen.[72] For consideration, the EPA presents alternative criteria based on average water temperatures in parentheses.

TABLE 7—ALTERNATIVE 1: DISSOLVED OXYGEN CRITERIA EXPRESSED AS CONCENTRATION

[mg/L]

Season	Water temperature (°C)	Magnitude (mg/L)	Duration	Exceedance frequency
Spawning and Larval Development *(March 1–June 30)*.	*23.3 (14.7)	*5.6 (6.7)	Daily Average	10% *(12 Days Cumulative)*.
Juvenile Development *(July 1–October 31)*	+N/A	5.4	Daily Average	10% *(12 Days Cumulative)*.
N/A+	6.1	Daily Average	50% *(61 Days Cumulative)*.	
Overwintering *(November 1–February 28/29)*	*12.4 (5.6)	*7.0 (8.3)	Daily Average	10% *(12 Days Cumulative)*.

*The 90th percentile of seasonal water temperature and corresponding criterion is used for the main estimate, while the average water temperature and corresponding criterion is shown in parentheses.

+Water temperature is not applicable during the *Juvenile Development* season because the criteria magnitudes are derived from the EPA's Atlantic Sturgeon cohort model, described in section IV.C.1 of this preamble.

Concentration-based criteria derived using the EPA's first approach (based on the 90th percentile water temperatures) would be equivalent to the EPA's proposed 66% oxygen saturation when water temperature is near the 90th percentile temperature and oxygen is near the lowest point in each season. However, during periods in each season when water temperature is lower than the 90th percentile temperature, the concentration-based criteria would be below the level that is equivalent to the EPA's proposed 66% oxygen saturation level. For example, when water temperature is 2 °C in mid-winter, oxygen saturation is 66% when the dissolved oxygen concentration is 9.1 mg/L. The EPA therefore has concerns about whether dissolved oxygen criteria expressed as concentration for this alternative would be protective for the *Spawning and Larval Development* and *Overwintering* seasons. Similar to the first approach, the concentration derived using the EPA's second approach (average water temperature) is also below the level that is equivalent to 66% oxygen saturation when water temperature is below the seasonal average. During periods in each season when the water temperature is warmer than the average, concentrations calculated using the EPA's second approach would result in an oxygen saturation higher than 66%.[73]

The EPA provided the concentrations in table 7 of this preamble that result from the methods described above to help facilitate public comment. The EPA also requests public input and supporting information about other ways the Agency could develop dissolved oxygen criteria expressed as concentration—particularly for the *Spawning and Larval Development* and *Overwintering* seasons—to protect the relevant aquatic life uses in accordance with the CWA.

Alternative 2: Single Dissolved Oxygen Criterion During the Juvenile Development Season with a 10% Exceedance Frequency.

The EPA's proposed dissolved oxygen criteria for the critical *Juvenile Development* season consist of two values—one that may be exceeded 10% of the time and one that may be exceeded 50% of the time—that must both be met during the season, as explained in section IV.C.1 of this preamble. However, the EPA recognizes that some stakeholders might prefer the simpler criteria framework a single criterion would afford or may have other reasons for preferring a single value.

[70] The EPA assumed salinity = 0 for each conversion from percent oxygen saturation to concentration in the *Spawning and Larval Development* and *Overwintering* seasons.

[71] Seasonal 90th percentile and mean water temperature were calculated using the daily climatology computed for Chester for March 1, 2012–June 30th, 2022, for the *Spawning and Larval Development* season and November 1, 2011–February 28, 2022, for the *Overwintering* season.

[72] United States Environmental Protection Agency. (2000). Ambient Aquatic Life Water Quality Criteria for Dissolved Oxygen (Saltwater): Cape Cod to Cape Hatteras. Document ID: EPA–822–R–00–012. November 2000. *https://www.epa.gov/sites/default/files/2018-10/documents/ambient-al-wqc-dissolved-oxygen-cape-code.pdf;* Batiuk, R.A., Breitburg, D.L., Diaz, R.J., Cronin, T.M., Secor, D.H., and Thursby, G. (2009). Derivation of habitat-specific dissolved oxygen criteria for Chesapeake Bay and its tidal tributaries. Journal of Experimental Marine Biology and Ecology 381: S204–S215. *https://doi.org/10.1016/j.jembe.2009.07.023.*

[73] More information on dissolved oxygen trends in the specified zones of the Delaware River is available in the associated rule documents, *Technical Support Document for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River* and *Economic Analysis for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.*

The EPA is seeking comment and supporting information on applying a single dissolved oxygen criterion with a 10% exceedance frequency during the *Juvenile Development* season, including whether criteria expressed with a single criterion would protect the applicable and proposed aquatic life designated uses. This could mean applying a single criterion of 66% oxygen saturation (or 5.4 mg/L, if expressed as concentration) with a 10% exceedance frequency for the *Juvenile Development* season. The *Overwintering* and *Spawning and Larval Development* seasons are unaffected by this alternative.

The EPA also requests public input and supporting information about other potential options the Agency could consider for dissolved oxygen criteria in the form of a single criterion to protect the aquatic life uses in accordance with the CWA.

Alternative 3: Inclusion of a 1-in-3-Year Interannual Exceedance Frequency.

The EPA's proposed criteria do not include an interannual exceedance frequency and therefore would need to be met every year. However, the EPA recognizes that some stakeholders might prefer criteria with an interannual exceedance frequency to help accommodate the impact of environmental variability on dissolved oxygen conditions in the specified zones of the Delaware River. The EPA is seeking comment and supporting information on the addition of a 1-in-3-year interannual exceedance frequency as part of the dissolved oxygen criteria. The EPA is particularly interested in how and why this approach would protect the applicable and current aquatic life uses.

If a 1-in-3-year interannual exceedance frequency were included as part of the dissolved oxygen criteria, it would mean that in any three-year period, all criteria would need to be attained in at least two years. An exceedance would occur in any year where one or more of the criteria were not attained. The following two examples describe how a 1-in-3-year interannual exceedance frequency could function.

Example 1: If, in a given year, the dissolved oxygen during the *Juvenile Development* season fell below 66% saturation more than 10% of the time, then that year would not meet the *Juvenile Development* 10th percentile criterion. Therefore, that year would count as one year of exceedance towards the 1-in-3-year interannual exceedance frequency. If another criterion, for example the *Spawning and Larval Development* criterion, was not met in that same year, then it would still only count as one year of exceedance despite the fact that two criteria were not met that year (Table 8 of this preamble).

TABLE 8—EXAMPLE 1 SCENARIO WHERE DISSOLVED OXYGEN CRITERIA WITH THE 1-IN-3-YEAR INTERANNUAL EXCEEDANCE FREQUENCY ARE MET

Season	Was the seasonal criterion met?		
	Year 1	Year 2	Year 3
Spawning and Larval Development	No	Yes	Yes.
Juvenile Development—10th Percentile	No	Yes	Yes.
Juvenile Development—50th Percentile	Yes	Yes	Yes.
Overwintering	Yes	Yes	Yes.
Does the Full Year Meet Criteria?	No	Yes	Yes.

Example 2: If, in a given year, the dissolved oxygen during the *Juvenile Development* season fell below 66% saturation more than 10% of the time, then that year would not meet the *Juvenile Development* 10th percentile criterion. If the following year, the *Juvenile Development* season fell below 74% saturation more than 50% of the time, then that year would not meet the *Juvenile Development* 50th percentile criterion (Table 9 of this preamble). In this scenario, the first and second year in the three-year period both did not meet the criteria; therefore, the interannual exceedance frequency was not met.

TABLE 9—EXAMPLE 2 SCENARIO WHERE DISSOLVED OXYGEN CRITERIA WITH THE 1-IN-3-YEAR INTERANNUAL EXCEEDANCE FREQUENCY ARE NOT MET

Season	Was the seasonal criterion met?		
	Year 1	Year 2	Year 3
Spawning and Larval Development	Yes	Yes	Yes.
Juvenile Development—10th Percentile	No	Yes	Yes.
Juvenile Development—50th Percentile	Yes	No	Yes.
Overwintering	Yes	Yes	Yes.
Does the Full Year Meet Criteria?	No	No	Yes.

The EPA has historically considered it appropriate to apply a 1-in-3-year exceedance frequency in the context of aquatic life criteria for toxic pollutants, based on the ability of aquatic ecosystems to recover from criteria exceedances and natural variations in flow and the concentrations of the pollutant in a waterbody.[74] However, the EPA does not typically apply this construct to criteria for conventional water quality parameters like dissolved

[74] Stephen, C.E., Mount, D.I., Hansen, D.J., Gentile, J.R., Chapman, G.A., and Brungs, W.A. (1985). Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses. United States Environmental Protection Agency. Document ID: PB85–227049. *https://www.epa.gov/sites/default/files/2016-02/documents/guidelines-water-quality-criteria.pdf*; United States Environmental Protection Agency. (2023). Proceedings from the EPA Frequency and Duration Experts Workshop: September 11–12, 2019. Document ID: EPA–820–R–23–002. February 2023. *https://www.epa.gov/system/files/documents/2023-02/proceedings-frequency-duration-workshop.pdf.*

oxygen due to inherent differences between these parameters and toxic pollutants. For example, dissolved oxygen is typically not directly regulated in the same manner as toxic pollutants because low dissolved oxygen conditions (such as hypoxia) are a symptom of a related issue, such as nutrient or ammonia pollution.[75] The EPA also requests public input and supporting information regarding any scientific approaches that can be used to predict the impact of periodic low oxygen levels on populations of aquatic organisms.

V. Endangered Species Act Consultation

Section 7(a)(2) of the Endangered Species Act (ESA) requires that each Federal Agency ensure that any action authorized, funded, or carried out by such Agency is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of critical habitat. Pursuant to section 7(a)(2) of the ESA, the EPA will consult with NOAA Fisheries concerning this rulemaking action proposing a designated aquatic life use including propagation and associated dissolved oxygen criteria in the specified zones of the Delaware River. The EPA will work closely with NOAA Fisheries to ensure that any WQS the Agency finalizes are not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat in the specified zones of the Delaware River. As a result of this consultation, the EPA may modify some provisions of this proposed rule.

VI. Applicability

The EPA is proposing a Federal designated use that would apply in New Jersey and Pennsylvania, in addition to those states' designated uses that are already applicable. This means that for the specified zones of the Delaware River, the EPA is proposing to supplement, rather than replace, New Jersey's and Pennsylvania's currently applicable aquatic life designated uses. Therefore, New Jersey's and Pennsylvania's currently applicable aquatic life designated uses would remain applicable for CWA purposes. Those states' current water quality criteria associated with those uses would also remain applicable for CWA purposes, with the exception of any aquatic life criteria for dissolved oxygen, which would be replaced by the criteria that the EPA promulgates through this rulemaking, if finalized.[76] The EPA concluded that this approach was the best way to make clear which of the states' WQS would and would not be revised by this rulemaking, if finalized. The EPA requests comment on this approach.

In addition, the EPA is proposing dissolved oxygen criteria that would replace Delaware's, New Jersey's, and Pennsylvania's existing dissolved oxygen criteria for the specified zones of the Delaware River. The EPA notes that there are aquatic life criteria for pollutants and parameters other than dissolved oxygen that are in effect for CWA purposes—not only in the zones covered by this proposed rulemaking, but also for other zones of the Delaware River that already include aquatic life propagation as a designated use; those criteria are not impacted by this rulemaking.

Since the EPA is only proposing to promulgate revised dissolved oxygen criteria for the specified zones of the Delaware River, Delaware, New Jersey, and Pennsylvania should evaluate whether other aquatic life criteria should similarly be added or revised for the specified zones or other zones of the Delaware River. One way these states can review their WQS is through the triennial review process. As explained in section III of this preamble, states must review their WQS at least once every three years and, if appropriate, revise standards or adopt new standards (40 CFR 131.20(a)). The EPA recommends that Delaware, New Jersey, and Pennsylvania review their existing aquatic life criteria during their next triennial review to determine if new or revised aquatic life criteria would be appropriate to protect all applicable aquatic life designated uses, including any Federal designated use that the EPA may promulgate as part of a final rule.

VII. Conditions Where Federal Water Quality Standards Would Not Be Promulgated or Would Be Withdrawn

As noted, under the CWA, states and authorized tribes have the primary responsibility for developing and adopting WQS for their navigable waters (CWA section 303(a) through (c)). Although the EPA is proposing a revised aquatic life designated use and protective dissolved oxygen criteria for the specified zones of the Delaware River, each state retains the option to adopt and submit to the EPA for review its own revised designated use and dissolved oxygen criteria that are consistent with CWA section 303(c) and the EPA's implementing regulation to address the EPA's Administrator's Determination.

A. Conditions Where Federal Standards Would Not Be Promulgated

If Delaware, New Jersey, and Pennsylvania adopt and submit revised WQS that addresses the EPA's December 1, 2022, Administrator's Determination, and the EPA approves those WQS before finalizing this proposed rulemaking, then a Federal promulgation would no longer be required under the CWA. Similarly, if one state adopts and submits WQS consistent with this proposed rulemaking, and the EPA approves those WQS before finalizing this proposed rulemaking, then a Federal promulgation would no longer be required under the CWA for that state.

B. Conditions Where Federal Standards Would Be Withdrawn

If the EPA finalizes this proposed rulemaking and Delaware, New Jersey, and Pennsylvania subsequently adopt and submit revised WQS to the EPA, and the EPA approves those WQS, then the EPA would undertake a rulemaking to withdraw the federally promulgated use and/or dissolved oxygen criteria (40 CFR 131.21(c)). Similarly, if one state adopts and submits revised WQS to the EPA, and the EPA approves those WQS, then the EPA would undertake a rulemaking to withdraw the federally promulgated WQS for that state.

If Delaware's, New Jersey's, and/or Pennsylvania's adopted dissolved oxygen criteria are as stringent or more stringent than the federally promulgated criteria, then that state's criteria would immediately become the CWA-applicable criteria upon the EPA's approval. If Delaware's, New Jersey's, and/or Pennsylvania's adopted dissolved oxygen criteria are less stringent than the federally promulgated criteria, and the EPA approves those less stringent criteria, then those EPA-approved criteria would become the applicable criteria for CWA purposes only after the EPA withdraws its federally promulgated criteria for the relevant state(s).

[75] United States Environmental Protection Agency. (2000). Ambient Aquatic Life Water Quality Criteria for Dissolved Oxygen (Saltwater): Cape Cod to Cape Hatteras. Document ID: EPA–822–R–00–012. November 2000. *https://www.epa.gov/sites/default/files/2018-10/documents/ambient-al-wqc-dissolved-oxygen-cape-code.pdf.*

[76] In the December 1, 2022, Administrator's Determination, the EPA determined that revised dissolved oxygen criteria are necessary to protect a propagation designated use. This proposed rulemaking includes dissolved oxygen criteria that are protective of all life stages of resident and migratory aquatic life species in the Delaware River (section IV.C. of this preamble).

VIII. Alternative Regulatory Approaches and Implementation Mechanisms

The Federal WQS regulations at 40 CFR part 131 provide several approaches that Delaware, New Jersey, and Pennsylvania could use at each state's discretion when implementing or deciding how to implement the federally promulgated dissolved oxygen criteria, if finalized. The EPA has identified two approaches—WQS Variances and NPDES Permit Compliance Schedules—that might be of particular interest for the states covered by this proposed rulemaking. Additionally, the EPA included a discussion about CWA section 303(d)/305(b) water quality assessments to clarify potential options that may be available to states in the specific circumstances relevant to this rulemaking.

A. Water Quality Standards Variances

A WQS variance is a time-limited designated use and criterion, for a specific pollutant or water quality parameter, that reflects the highest attainable condition (HAC) during the term of the WQS variance (40 CFR 131.3(o)). WQS variances can be used to incrementally improve water quality where the designated use and criterion are unattainable for a period of time. The state would need to demonstrate that attaining the applicable designated use and dissolved oxygen criterion would not be feasible for a period of time (*i.e.,* during the term of the WQS variance) because of one of the factors specified in 40 CFR 131.14(b)(2)(i)(A) and specify the actions that will be taken to make incremental water quality improvements during the term of the WQS variance.

If Delaware, New Jersey, and/or Pennsylvania choose/s to adopt a WQS variance, the state/s must specify in the WQS variance the term and the interim requirements of the WQS variance. The term must be justified by describing the pollutant control activities expected to occur over that term to achieve the HAC. The interim requirements must be a quantitative expression that reflects the HAC using one of the options provided at 40 CFR 131.14(b)(1)(ii).

WQS variances adopted in accordance with 40 CFR 131.14 and approved by the EPA for CWA purposes provide a legal avenue for states to write NPDES permit limits that are based on the HAC during the term of the WQS variance, while simultaneously implementing controls to make incremental water quality improvements toward ultimately attaining the applicable designated use and dissolved oxygen criterion.

B. NPDES Permit Compliance Schedules

The EPA's regulations at 40 CFR 122.47 and 131.15 address how permitting authorities can use schedules for compliance with a water-quality-based effluent limitation (WQBEL) in an NPDES permit, if the discharger needs time to undertake an enforceable sequence of actions—such as facility upgrades or operation changes—leading to compliance with the WQBEL. The EPA's regulation at 40 CFR 122.47 allows states authorized to administer the NPDES program to include compliance schedules in NPDES permits, when appropriate and where authorized by the state's WQS, provided the compliance schedule authorizing provision was approved by the EPA. Such compliance schedules may be used to implement any CWA-effective WQS, including any WQS that the EPA promulgates as part of a final rule.

C. Clean Water Act Section 303(d)/305(b) Water Quality Assessments

If the EPA promulgates revised aquatic life WQS for the specified zones of the Delaware River and they become effective for CWA purposes, Delaware, New Jersey, and Pennsylvania will have an obligation under CWA sections 303(d) and 305(b) to assess whether the WQS are being attained. The EPA anticipates there may be a period of time immediately after promulgation of the revised WQS when the WQS will not be attained because the actions and procedures required to achieve compliance will take time to implement. In this scenario, any of the relevant zones not attaining the WQS should be classified as impaired on the relevant 303(d)/305(b) Integrated Report(s) (IR) that is submitted to the EPA for review.

Per the CWA and the EPA's implementing regulations, waters that are assessed as impaired by a pollutant typically require the development of a Total Maximum Daily Load (TMDL), which is a regulatory planning tool designed to restore water quality via allocations of pollutant reductions to relevant point and non-point sources. The EPA regulations also recognize that other pollution control requirements may obviate the need for a TMDL. Specifically, impaired waters do not require a TMDL if: (1) technology-based effluent limitations required by the CWA; (2) more stringent effluent limitations required by a state, local, or Federal authority; or (3) other pollution control requirements (*e.g.,* best management practices) required by a state, local, or Federal authority are stringent enough to implement applicable WQS (40 CFR 130.7(b)(1)). Impaired waters that do not require a TMDL because they satisfy one of these alternatives are commonly referred to as Category 4b waters, as described in the EPA's Integrated Reporting Guidance for CWA sections 303(d), 305(b), and 314.[77]

DRBC developed a model to evaluate sources of pollution that affect dissolved oxygen levels in the specified zones of the Delaware River and concluded that point sources are the primary contributor to oxygen depletion within those zones.[78] DRBC therefore concluded that further controls on point sources are needed to achieve dissolved oxygen water quality conditions that support aquatic life designated uses that include propagation in the specified zones. The EPA's economic analysis evaluates point source controls that are expected to result in dissolved oxygen levels that meet EPA's proposed criteria.[79] If, after finalization of this rulemaking, DRBC, Delaware, New Jersey, or Pennsylvania require effluent limitations and/or other pollution control requirements that the EPA agrees are stringent enough to implement the final dissolved oxygen criteria, the specified zones may be a candidate for Category 4b in future IRs. The EPA will work with Delaware, New Jersey, and Pennsylvania, in consultation with DRBC, on future IRs to determine the appropriate assessment status for the waters that are subject to this rulemaking.

IX. Economic Analysis

The EPA conducted an economic analysis to evaluate the potential costs and benefits associated with this proposed rulemaking. In the high-level summary of the EPA's economic analysis below, the EPA first describes a baseline scenario that is intended to characterize the world in the absence of the EPA's proposed rule. Next, the EPA describes development of a policy scenario based on potential pollution control actions that, if implemented, can be expected to meet the EPA's proposed dissolved oxygen criteria. Finally, the EPA evaluates the anticipated costs and benefits associated with the policy scenario and the EPA's proposed criteria. More details and information

[77] The EPA's Integrated Reporting Guidance is available at: *https://www.epa.gov/tmdl/integrated-reporting-guidance-under-cwa-sections-303d-305b-and-314.*

[78] Delaware River Basin Commission (2022a, 2022b).

[79] More details are available in the document, *Economic Analysis for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.*

are available in the associated document, *Economic Analysis for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.*

A. Baseline for the Analysis

The baseline is intended to characterize the world in the absence of the EPA's proposed rule. The EPA typically assumes full compliance with existing regulations and requirements—including CSO long-term control plans (LTCPs)—even if they are not yet fully implemented, as a basis for estimating the cost and benefits of proposed regulations. This baseline approach ensures that the cost and benefits of the existing regulations and requirements are not double counted.

In this economic analysis, the EPA assumes that without the proposed rule, the less stringent WQS (that do not support aquatic life propagation) currently in effect for CWA purposes would remain in effect (section III.D. of this preamble). Accordingly, the EPA assumes that water quality conditions in the specified zones of the Delaware River, particularly during the *Juvenile Development* season (July 1–October 31), would continue to experience low oxygen levels that do not support aquatic life propagation, even with implementation of existing and planned CSO LTCPs.[80] Along the specified zones of the Delaware River, there are three combined sewer systems with CSO LTCPs that are relevant for consideration by the EPA as part of the baseline. The Philadelphia Water Department, Camden County Municipal Utilities Authority, and Delaware County Regional Water Quality Control Authority all have LTCPs that are either approved or in progress.[81] The EPA expects implementation of these LTCPs, when finalized, to occur regardless of the EPA's proposed rule. Therefore, the EPA included estimated CSO volume reductions for these three dischargers as part of the baseline for this economic analysis.

DRBC modeled the effect of pollution reduction on dissolved oxygen levels in the Delaware River and provided the EPA with water quality simulation results under both baseline and ''restored'' conditions for the years 2012, 2018, and 2019.[82] Baseline simulations predict water quality conditions associated with the discharge of actual wastewater treatment plant (WWTP) flows at existing levels of treatment and after full implementation of LTCPs. The restored simulations predict water quality conditions associated with the discharge of actual WWTP flows at treatment levels that include additional effluent treatment and after full implementation of LTCPs.

Of the three available years (2012, 2018, and 2019), the EPA selected the 2019 year as representative of the most typical conditions in the relevant zones of the Delaware River. In comparison, 2012 had atypically poor conditions (low percent oxygen saturation, high water temperature), while 2018 had atypically good conditions (high percent oxygen saturation, low water temperature). Therefore, model runs used in this economic analysis are based on 2019 conditions.

B. Development of the Policy Scenario

There is a wide range of potential paths that Delaware, New Jersey, and Pennsylvania may choose to take when implementing the EPA's proposed WQS. For this economic analysis, the EPA relied on available data to develop a policy scenario based on modeled pollution controls developed by DRBC that the EPA expects would meet the Agency's proposed dissolved oxygen criteria. Actual benefits, costs, and impacts will depend on the choices that states would make in implementing the proposed WQS, which may differ from the policy scenario in this economic analysis.

The EPA's proposed dissolved oxygen criteria apply to three seasons (section IV.C. of this preamble). Therefore, when developing a policy scenario for this proposed rulemaking, the EPA evaluated potential pollution control actions that would be expected to meet the EPA's criteria in each of the three seasons. The EPA began by evaluating water quality monitoring data for the past decade from two continuous monitoring stations in the relevant zones of the Delaware River—Penn's Landing in Zone 3 and Chester in Zone 4. Based on the monitoring data, the EPA expects that the Agency's proposed dissolved oxygen criteria for the *Spawning and Larval Development* and *Overwintering* seasons will likely be met without the need for additional WWTP upgrades or other controls beyond the baseline conditions (*i.e.,* the LTCPs). Monitoring data for the *Juvenile Development* season indicated that additional pollution control actions are likely necessary to meet the EPA's proposed criteria in that season. To develop a policy scenario for the *Juvenile Development* season, the EPA relied on modeled data from DRBC predicting oxygen levels in 2019 in the specified zones of the Delaware River following a set of WWTP pollution control actions for certain dischargers. Modeled data for restored conditions are described in the baseline section above, while WWTP controls are described in the cost section below. The EPA expects that this policy scenario (hereafter, the ''2019 restored scenario'') will meet the proposed criteria during the *Juvenile Development* season.

C. Potential Costs

The EPA estimated compliance costs for the proposed WQS based on estimates for WWTPs to reduce effluent ammonia nitrogen concentrations and raise effluent dissolved oxygen concentrations. Although there are several causes that contribute to low dissolved oxygen conditions in the specified zones of the Delaware River, DRBC identified ammonia nitrogen loadings from WWTPs as the leading cause of oxygen-depletion in the river.[83] As a result, for the purpose of this economic analysis, the EPA assumed that additional pollution control technologies implemented at WWTPs is the most likely way that Delaware, New Jersey, and Pennsylvania will implement the proposed WQS. Therefore, the EPA evaluated WWTP controls rather than other non-point source controls for this cost analysis.

The EPA relied on cost information from several DRBC studies to estimate the costs of achieving the proposed WQS.[84] DRBC's 2022 *Analysis of Attainability* report categorized WWTPs as either class A′, A, or B facilities. DRBC determined that discharges from Class A′, A, and B facilities have a major

[80] While the EPA normally assumes full compliance with *existing* LTCPs, for this proposed rulemaking, the EPA is also assuming full compliance with *planned* LTCPs. Because planned LTCPs are not final and therefore are subject to change, this adds uncertainty to the baseline conditions.

[81] Delaware River Basin Commission (2022a); DELCORA. (2023). Combined Sewer System: DELCORA CSO LTCP. *https://www.delcora.org/combined-sewer-systems/delcora-cso-ltcp/*; Philadelphia Water Department. (2023). CSO Long Term Control Plan. *https://water.phila.gov/reporting/ltcp/*; State of New Jersey Division of Water Quality. (2023). Long Term Control Plan Submittals. *https://www.nj.gov/dep/dwq/cso-ltcpsubmittals.htm.*

[82] The EPA determined that the model runs from DRBC were sufficient for use in this economic analysis.

[83] Delaware River Basin Commission (2022a).

[84] *Id.;* Kleinfelder Inc. (2021). Nitrogen Reduction Cost Estimation Study Final Summary Report. *https://www.nj.gov/drbc/library/documents/NitrogenReductionCostEstimates_KleinfelderJan2021.pdf;* Kleinfelder Inc. (2023). Delaware River Basin Commission Nitrogen Reduction Cost Estimation Study—Supplemental Cost Addendum 2 Technical Memorandum—Final. *https://www.nj.gov/drbc/library/documents/NitrogenReductionCostEstimates_Kleinfelder_aug2023addendum.pdf.*

impact, a marginal impact, or no measurable impact on oxygen levels in the specified zones, respectively. The EPA's 2019 restored scenario follows DRBC's approach by including the seven Class A′ and two Class A facilities and excluded the three Class B facilities.[85]

The EPA used WWTP-specific (capital, operations and maintenance (O&M)) compliance costs from Kleinfelder Inc. (2021, 2023) to estimate compliance costs, based on the discharger classification. Total compliance costs include the costs associated with both of the following:

1. Class A′ Facilities: Costs associated with reductions in effluent ammonia nitrogen concentrations to 1.5 mg/L from May 1 through October 31 and increases in effluent oxygen concentrations to a monthly average of 6 mg/L year-round for the seven WWTPs categorized as Class A′ facilities.

2. Class A Facilities: Costs associated with reductions in effluent ammonia nitrogen concentrations to 5 mg/L from May 1 through October 31 for the two WWTPs categorized as Class A facilities.

To estimate annualized compliance costs, the EPA assumed capital costs occur upfront in 2024 followed by a 5-year construction period. Consistent with Kleinfelder Inc. (2021, 2023), the EPA assumed O&M costs occur over a 25-year period from 2029 through 2053. The EPA thus annualized costs over a 30-year analysis period between 2024 and 2053 and discounted all cost values to 2024, using a 3 percent discount rate.

Table 10 of this preamble presents the annualized compliance costs associated with achieving the EPA's proposed WQS, using a 3 percent discount rate. The estimated total annualized compliance cost across nine WWTPs is $137.1 million (2022$). These costs vary considerably between the nine WWTPs, ranging from $1.9 million at the Lower Bucks County Joint Municipal Authority WWTP to $37.6 million at the Philadelphia Water Department (PWD) Southwest Water Pollution Control Plant (2022$). Among the dischargers, PWD bears the highest proportion of total costs, with its three facilities' combined costs accounting for over 50 percent of total costs. Overall, 66 percent of the costs are attributable to capital and 34 percent are attributable to O&M.

TABLE 10—ANNUALIZED COMPLIANCE COSTS USING A 3 PERCENT DISCOUNT RATE

[Million 2022$]

Plant	State	Class	Annualized costs (millions 2022$)
Camden County Municipal Utilities Authority	NJ	A′	$16.2
City of Wilmington	DE	A′	23.9
Delaware County Regional Water Pollution Control Authority	DE	A′	9.1
Gloucester County Utilities Authority	NJ	A′	4.9
PWD Northeast Water Pollution Control Plant	PA	A′	26.2
PWD Southeast Water Pollution Control Plant	PA	A′	14.1
PWD Southwest Water Pollution Control Plant	PA	A′	37.6
Hamilton Township	NJ	A	3.3
Lower Bucks County Joint Municipal Authority	PA	A	1.9
Total			137.1

D. Potential Benefits

Water quality improvements can have a wide range of effects on water resources and the environmental goods and services that they provide, including services valued by people (*e.g.,* recreation, commercial fishing, public and private property ownership, existence services such as aquatic life, wildlife, and habitat designated uses). Some environmental goods and services (*e.g.,* commercially caught fish) are traded in markets, and thus their value can be directly observed. Other environmental goods and services (*e.g.,* recreation and support of aquatic life) cannot be bought or sold directly and thus do not have observable market values. This second type of environmental goods and services are classified as ''non-market.'' The estimated changes in the non-market values of the water resources affected by the EPA's proposed WQS (hereafter, ''non-market benefits'') are additive to market values (*e.g.,* avoided costs of producing various market goods and services).

To value non-market benefits, the EPA used a benefit transfer approach based on a meta-analysis of surface water valuation studies to evaluate the use and nonuse benefits of improved surface water quality resulting from achievement of the EPA's proposed WQS in the 2019 restored scenario.[86] The benefit transfer approach involves three main steps:

1. Estimating water quality improvements associated with attainment of the EPA's proposed WQS relative to the baseline;

2. Translating these improvements into a water quality index (WQI) that can be linked to ecosystem services and uses that are valued by society. The WQI used for this analysis includes six parameters: dissolved oxygen, biological oxygen demand (BOD), fecal coliform (FC), total nitrogen (TN), total phosphorus (TP), and total suspended solids (TSS); and

3. Estimating the dollar value of the estimated water quality improvements based on estimates of the public's willingness-to-pay (WTP) derived from a meta-analysis of surface water valuation studies.

To estimate changes in ecosystem services provided in the specified zones of the Delaware River following attainment of the proposed WQS, the EPA obtained water quality modeling data from DRBC, including dissolved oxygen, TN, and TP levels for various effluent treatment scenarios. The EPA used DRBC's modeled output of dissolved oxygen levels in the specified zones following implementation of effluent controls (described in the cost section) and based on 2019 conditions (as described in the policy scenario

[85] Delaware River Basin Commission (2022a).

[86] The EPA has used this benefit transfer approach on numerous occasions, most recently in the *Benefit and Cost Analysis for Proposed Revisions to the Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category,* which is available at *https://www.epa.gov/system/files/documents/2023-03/steam-electric-benefit-cost-analysis_proposed_feb-2023.pdf.*

section). The EPA used the 2019 restored scenario as the basis for representing conditions following the implementation of the proposed WQS, while making minor adjustments as needed [87] to ensure that predicted oxygen levels meet the EPA's proposed WQS. This analysis provides insight into the water quality improvements and benefits that are likely to result from implementation of the proposed WQS. For the remaining parameters included in the WQI (*i.e.,* BOD, FC, and TSS), the EPA relied on measured data at various locations within the specified zones.

The effluent treatment measures implemented in response to the proposed WQS would directly affect the amount of ammonia nitrogen discharged to the specified zones of the Delaware River and therefore also reduce BOD. However, DRBC's model does not account for the changes in BOD. The EPA approximated BOD concentrations following effluent treatment by assuming that baseline BOD concentrations are reduced by the same percentage change that dissolved oxygen improves within each zone (*i.e.,* Zone 3, 4, and Upper 5) of the model. The EPA kept levels for the remaining parameters (TN, TP, TSS, and FC) unchanged from baseline conditions.

Table 11 of this preamble summarizes the percent change in dissolved oxygen and BOD by zone between the baseline and the 2019 restored scenario.

TABLE 11—DISSOLVED OXYGEN AND BIOLOGICAL OXYGEN DEMAND CHANGES BETWEEN THE BASELINE AND 2019 RESTORED SCENARIOS

Zone	Percent change from baseline [a]
3	10.8
4	23.8
Upper-5	8.8

[a] The percent change for dissolved oxygen and biological oxygen demand are the same, but in opposite directions, i.e., the percent decrease in biological oxygen demand concentration is the same as the percent increase in dissolved oxygen concentration.

To quantify benefits of water quality improvements, as is consistent with past practice, the EPA analyzed the values held by households residing within 100 miles of the specified zones of the Delaware River for water quality improvements associated with the EPA's proposed WQS.[88] Households may consider waters unaffected by the EPA's proposed WQS to be substitute waters for those affected, and this can influence what households would be willing to pay for improvements associated with the proposed WQS. The EPA deems waters unaffected by the proposed WQS within the 100-mile buffer around each Census block group as viable substitutes.

The EPA estimated the economic value of water quality changes using results of a meta-analysis of 189 estimates of total WTP (including both use and nonuse values) for water quality improvements, provided by 59 original studies conducted between 1981 and 2017. The estimated econometric model allows calculation of total WTP for changes in a variety of environmental services affected by water quality and valued by people, including changes in recreational fishing opportunities, other water-based recreation, and existence services such as aquatic life, wildlife, and habitat designated uses. The model also allows the EPA to adjust WTP values based on the core geospatial factors predicted by theory to influence WTP, including: scale (the size of affected resources or areas), market extent (the size of the market area over which WTP is estimated), and the availability of substitute waters. The model also takes into account important sociodemographic characteristics, such as population and income, which vary spatially.

Table 12 in this preamble presents estimated household and total annualized WTP value for water quality improvements following attainment of the EPA's proposed WQS, based on a 3 percent discount rate. The total annualized value of water quality improvements from attainment of the proposed WQS is $112.8 million.

TABLE 12—ESTIMATED HOUSEHOLD AND TOTAL ANNUALIZED WILLINGNESS-TO-PAY (WTP) FOR WATER QUALITY IMPROVEMENTS UNDER THE EPA'S PROPOSED WATER QUALITY STANDARDS, USING A 3 PERCENT DISCOUNT RATE

Average number of affected households (millions)	Average annual WTP per household (2022$)	Total annualized WTP (millions 2022$, 3% discount rate)
14.96	$8.18	$112.8

E. Conclusion

The United States Office of Management and Budget requires that for ''significant regulatory actions'' (as defined in Executive Order 12866 and as amended and reaffirmed by Executive Order 14094), that the EPA conduct an economic analysis. While this proposed rulemaking was not deemed significant, the EPA nonetheless conducted an economic analysis to evaluate the potential costs and benefits associated with the WQS in the EPA's proposed rule. For this proposed rulemaking, the EPA determined that the potential benefits justify the potential costs. The EPA estimates that the implementation of additional effluent treatment controls at certain WWTPs could lead to $137.1 million in annualized costs over 30 years (2022$, 3% discount rate). The EPA quantified estimated non-market benefits through average annual household WTP for water quality improvements. Annualized non-market benefits total $112.8 million per year over 30 years (2022$, 3% discount rate). The EPA's monetary estimation of benefits does not account for benefits related to protections for a critically endangered species (Atlantic Sturgeon), increased housing values, or increased commercial fishing, among other benefits. Therefore, the EPA's estimation of non-market benefits is likely an underestimate of total benefits and thus total benefits could potentially equal or exceed estimated total costs.

X. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 14094, and was therefore not subject to a requirement for Executive Order 12866 review.

[87] Adjustments are detailed in section 4.2 of the associated document, *Economic Analysis for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.*

[88] The EPA's 100-mile radius assumption follows Viscusi et al. (2008), which states: 'The survey defined relevant water quality as residing in a region that is ''a 2-hour drive or so of your home, in other words, within 100 miles.'' About 80% of all recreational uses of bodies of water are within such a radius of users' homes. This 80% figure was based on data generated by EPA from the 1996 National Survey on Recreation and the Environment. Data indicates that 77.9% of boating visits, 78.1% of fishing visits, and 76.9% of swimming recreational visits are within a 100-mile radius of a given waterbody. (Citation: Viscusi, W. K., Huber, J., & Bell, J. (2008). The economic value of water quality. *Environmental and resource economics, 41*(2), 169–187.)

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2040–0049. While actions to implement these WQS, if finalized, could entail additional paperwork burden, this action does not directly contain any information collection, reporting, or record-keeping requirements.

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. This action will not impose any requirements on small entities. Small entities, such as small businesses or small governmental jurisdictions, are not directly regulated by this rulemaking.

EPA-promulgated WQS are implemented through various water quality control programs including the NPDES program, which limits discharges to navigable waters, except in compliance with a NPDES permit. CWA section 301(b)(1)(C) and the EPA's implementing regulations at 40 CFR 122.44(d)(1) and 122.44(d)(1)(A) provide that all NPDES permits must include any limits on discharges that are necessary to meet applicable WQS. Thus, under the CWA, the EPA's promulgation of WQS establishes standards that states implement through the NPDES permit process. While states have discretion in developing discharge limits, those limits ''must control all pollutants or pollutant parameters (either conventional, nonconventional, or toxic pollutants) which the Director determines are or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any [s]tate water quality standard, including [s]tate narrative criteria for water quality'' (40 CFR 122.44(d)(1)(i)).

As a result of this action, if finalized, the states of Delaware, New Jersey, and Pennsylvania will need to ensure that permits they issue include any limitations on discharges necessary to comply with the WQS established in the final rule. In doing so, each state will have several choices associated with permit writing. While each state's implementation of the rule may ultimately result in new or revised permit conditions for some dischargers, including small entities, the EPA's action, by itself, does not impose any of these requirements on small entities; in other words, these requirements are not self-implementing.

D. Unfunded Mandates Reform Act (UMRA)

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

E. Executive Order 13132: Federalism

The EPA has concluded that 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. This rulemaking would not alter Delaware's, New Jersey's, or Pennsylvania's considerable discretion in implementing these WQS, nor would it preclude any of those states from adopting revised WQS and submitting them to the EPA for review and approval either before or after promulgation of the final rule. If the states submit and the EPA approves revised WQS consistent with the CWA, then the EPA would no longer be required to promulgate Federal WQS.

Consistent with the EPA's policy to promote communications between the EPA and state and local governments, the EPA met with the states of Delaware, New Jersey, and Pennsylvania and DRBC in the process of developing this rulemaking to enable them to have meaningful input into its development. During these discussions, the EPA explained the scientific basis for the dissolved oxygen criteria to protect aquatic life propagation in the specified zones of the Delaware River and the overall timing of the Federal rulemaking effort. The EPA took these discussions with the states into account during the drafting of this rulemaking. The EPA specifically solicits comments on this proposed action from state and local officials.

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

This action does not have Tribal implications as specified in Executive Order 13175. This rulemaking will not affect federally recognized Indian tribes in Delaware, New Jersey, or Pennsylvania because the WQS would not apply to waters in Indian lands nor affect Tribal interests. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions considered significant under section 3(f)(1) of Executive Order 12866 and 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. Therefore, this action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since this action does not concern human health, the EPA's Policy on Children's Health also does not apply.

H. Executive Order 13211: Actions 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 proposes to establish Federal CWA aquatic life water quality criteria for specified zones of the Delaware River under the jurisdiction of the states of Delaware, New Jersey, and Pennsylvania.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The information supporting this Executive order review is summarized below and detailed in the associated document, *Environmental Justice Analysis for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River,* which is available in the docket for this proposed rule.

The EPA believes that the human health or environmental conditions that exist prior to this proposed action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice (EJ) concerns. For this EJ analysis, the EPA evaluated socioeconomic characteristics of communities living near the relevant zones of the Delaware River compared to communities living near other zones of the mainstem

Delaware River. The relevant zones of the Delaware River border highly urbanized areas, including cities such as Philadelphia and Wilmington. Accordingly, the EPA's analysis accounts for the distinction between urban and rural communities.[89]

The EPA obtained data from the United States Census Bureau's American Community Survey (ACS) 5-year estimates for the years 2017–2021 at the Census block group level to construct a set of eight metrics for use in this analysis: (1) *Black or African American,* (2) *Asian,* (3) *Two or More Races,* (4) *Hispanic or Latino,* (5) *Limited English Speaking Household,* (6) *Median Household Income,* (7) *Below 200% of the Poverty Level,* (8) *Education Less than a High School Diploma or Equivalent.*[90] Analysis of these eight socioeconomic metrics provides insight into the spatial distribution and prevalence of certain indicators of social vulnerability for communities near the Delaware River.[91]

The EPA extended a five-mile buffer from the specified zones to capture communities living in close proximity to waters affected by the EPA's proposed rule, if finalized.[92] Similarly, the EPA extended a five-mile buffer from other zones of the Delaware River to form a comparison group. Given the large number of block groups located near the mainstem Delaware River, communities are analyzed in groups, as follows:

- *Delaware Urban Areas:* Census block groups in urban areas within five miles of the specified zones in Delaware.
- *New Jersey Urban Areas:* Census block groups in urban areas within five miles of the specified zones in New Jersey.
- *Pennsylvania Urban Areas:* Census block groups in urban areas within five miles of the specified zones in Pennsylvania.
- *Urban Comparison Group:* Census block groups in urban areas within five miles of the remainder of the mainstem Delaware River (*i.e.,* excluding block groups within five miles of the specified zones).
- *Specified Zones Rural Areas:* Census block groups in rural areas within five miles of the specified zones in New Jersey.[93]
- *Rural Comparison Group:* Census block groups in rural areas within five miles of the remainder of the mainstem Delaware River (*i.e.,* excluding block groups within five miles of the specified zones).

The EPA aggregated data across multiple block groups using aerial apportionment and a population-weighted mean approach to ensure that block groups with larger or smaller populations were accounted for proportionally to their size. This calculation relies on an assumption that households are evenly distributed within each block group. For *Median Household Income,* the EPA aggregated data across multiple block groups using a linear interpolation calculation.

The results of the urban and rural proximity analyses differed significantly. Urban communities in Pennsylvania near the specified zones surpassed the comparison group average (or were less than the comparison group for *Median Household Income*) for all eight socioeconomic metrics. Notably, urban communities in Pennsylvania near the specified zones are over 1.7 times more likely to identify as *Black or African American,* 1.7 times more likely to live below twice the poverty level, and have $23,000 lower median household income when compared to urban communities near the remainder of the mainstem river. Urban communities within five miles of the specified zones in all three states had lower income and higher poverty rates than the comparison group. Urban communities in Delaware near the specified zones also had a higher percentage of the population identify as *Black or African American* than the comparison group, while urban communities in New Jersey had a higher percentage of the population that identifies as *Hispanic or Latino* and a greater percentage with education less than a high school degree than the comparison group. Therefore, urban communities near the specified zones—especially in Pennsylvania—exhibited differences in socioeconomic community characteristics compared to other urban communities near the Delaware River.

On the other hand, rural communities near the specified zones did not greatly differ from rural communities near other parts of the mainstem river. While rural communities near the specified zones did exceed the comparison group average for four metrics (*Black or African American, Asian, Two or More Races,* and *Limited English Speaking Household*), the differences were always less than three percentage points. Therefore, the EPA could not conclude that rural communities near the specified zones were any more or less socially vulnerable compared to other rural communities near the mainstem Delaware River.

While neither the urban nor the rural proximity analyses directly indicate which communities may be experiencing potential EJ concerns, they provide insight into community composition surrounding an environmental resource. In general, the Delaware River has had two contrasting areas of water quality for decades. In the relevant zones, water quality for aquatic life has been significantly worse than in the other zones of the river.[94] Urban areas near these zones, especially in Pennsylvania, contain communities that are likely more socially vulnerable than urban communities that live near other zones of the Delaware River, which have better water quality. This trend in water quality and dissolved oxygen across the watershed, coupled with the corresponding differences in socioeconomic community composition, reveals a potential inequitable

[89] For this analysis, the EPA defines ''urban'' and ''rural'' using the Census Urban Areas designation. More information about the Census classifications is available at *https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html.*

[90] The EPA also considered populations who identify as *American Indian and Alaskan Native, Native Hawaiian and Other Pacific Islander,* and *Some Other Race;* however, in the Delaware River watershed, these populations represent a very small fraction (often less than 1%) of the community composition. Therefore, these populations are not analyzed further in this EJ analysis.

[91] In the 2016 *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis,* the EPA defined vulnerability as the ''physical, chemical, biological, social, and cultural factors that result in certain communities and population groups being more susceptible or more exposed to environmental toxins, or having compromised ability to cope with and/or recover from such exposure.'' For this EJ analysis, the EPA focused on social vulnerability based on the metrics presented in table 3 of the associated environmental justice analysis, which broadly cover categories of race, ethnicity, linguistic isolation, income, poverty, and education. These metrics provide insight into factors that may affect the ability of communities near the Delaware River to respond to environmental hazards or cope with reduced ecosystem services that may result from inadequate water quality. Although these socioeconomic metrics are relevant to communities living near the Delaware River, they are not intended to be an exhaustive list of all factors affecting community vulnerability. (Source: United States Environmental Protection Agency. (2016). Technical Guidance for Assessing Environmental Justice in Regulatory Analysis. *https://www.epa.gov/sites/default/files/2016-06/documents/ejtg_5_6_16_v5.1.pdf.*)

[92] The EPA assumes that those living in Census block groups that are within the five-mile buffer, and therefore closest to the specified zones of the Delaware River, are most likely to be directly affected by the proposed rule. However, this assumption could underestimate directly affected communities and impact the results of the proximity analysis. Accordingly, the EPA conducted a sensitivity analysis using a ten-mile buffer and determined that community composition was not particularly sensitive to the buffer distance applied when comparing the results of the five-mile and ten-mile buffer.

[93] There are no rural areas within five miles of the specified zones in Delaware or Pennsylvania.

[94] Delaware River Basin Commission (2022a).

distribution of an environmental resource and access to clean surface waters within a single watershed.[95]

The EPA believes that this action would be likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. Specifically, the EPA identified an inequitable distribution of an environmental resource where communities with environmental justice concerns have inequitable access to clean surface waters that support CWA section 101(a)(2) goals for aquatic life. The EPA's proposed rule, if finalized and implemented, could help to lessen this inequitable distribution of an environmental resource by ensuring that WQS to protect aquatic life in the specified zones of the Delaware River meet the objectives of the CWA.

In addition to the proximity analysis, the EPA evaluated the potential distribution of costs associated with the proposed rule under the implementation (policy) scenario described in section IX of this preamble and further detailed in the EPA's associated document, *Economic Analysis for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.* For this analysis, the EPA selected Philadelphia as a case study based on the results of the proximity analysis and the large share of total estimated costs potentially incurred by the Philadelphia Water Department (PWD) compared to other WWTPs.

The EPA used two methods to assess the potential financial impact to Philadelphia households resulting from costs associated with the proposed rule. First, the EPA calculated household burden by quantifying the potential increase to consumer water and wastewater bills and calculating the percentage of median household income spent on water bills with and without costs from additional wastewater treatment plant controls. Second, the EPA examined existing water rate structures in Philadelphia and customer assistance programs to identify possible ways in which the affected municipalities could adjust rates to lessen the financial burden on low-income households.

To determine household burden, the EPA analyzed how annual water and wastewater bills might change if costs associated with additional wastewater treatment plant controls at PWD facilities are passed on to households through increased water bills.[96] The EPA analyzed the financial impact to households if costs were passed on to residential households in proportion to the estimated wastewater flow attributed to residential households.[97] DRBC estimates that approximately 15% of the flow to PWD is attributable to residential sources while 85% is attributable to non-residential sources.[98] Therefore, the EPA calculated household burden assuming 15% of the costs associated with additional wastewater treatment plant controls would be spread evenly among Philadelphia households. Under this assumption the additional annual cost per household is $18.07, which would equate to $1.50 per household per month.[99] For this analysis, the EPA analyzed household burden using the Residential Indicator in the EPA's 2023 *Clean Water Act Financial Capability Assessment Guidance* [100] and determined that while the costs associated with the proposed rule are not expected to substantially impact household burden under this scenario, water bills still have the potential to be placing a high burden on a third of Philadelphia's households. However, the actual financial burden faced by households depends on many factors, including customer assistance programs.

In July 2017, Philadelphia became the first to implement an income-based alternative water rate structure through creation of the Tiered Assistance Program (TAP). This program is structured based on household income relative to the Federal poverty level such that monthly bills are capped at 2%, 2.5%, 3%, and 4% of monthly income for consumers whose income is 0–50%, >50–100%, >100–150%, and >150% of the Federal poverty level, respectively.[101] TAP discounts are offset by a surcharge added to the water bill of non-TAP customers.

For illustrative purposes, the EPA analyzed how the TAP rate structure might apply to eligible low-income consumers with water bills that include 15% of the costs associated with additional PWD wastewater treatment plant controls.[102] Under the TAP rate structure, a three-person household with income at or below the poverty level would have annual savings of at least $294. These savings are particularly significant for households whose income is half the poverty level or below. For example, a household at 50% of the poverty level would see savings of $667.

However, the effectiveness of the TAP rate structure depends in large part on participation by eligible households. When Philadelphia launched TAP in 2017, it was estimated that around 60,000 consumers would be eligible for the program.[103] However, as of December 2022, only 14,712 households were actively participating in TAP.[104] Equally problematic as low participation rates are the high attrition rates of TAP participants. In 2022, 9,496 participants defaulted from TAP due to a failure to recertify for the program. Of those who defaulted, 75% percent did not respond to the city's request for recertification.[105] Thus, even though Philadelphia enrolled 10,405 participants in 2022, the high attrition rate in the program prevents meaningful increases in participation. Philadelphia continues outreach efforts to raise awareness about TAP; [106] however, this large gap in participation indicates that

[95] In this analysis, the EPA is not implying causality between poor water quality and socioeconomic factors.

[96] Residents in PWD's service area pay a single bill that covers both water and wastewater charges; for this analysis, the EPA uses the term ''water bill'' to refer to the single bill covering water and wastewater charges.

[97] The EPA also analyzed a conservative scenario in which 100% of costs are passed on to residential households. Results of this scenario are available in the associated document, *Environmental Justice Analysis for the Proposed Rule: Water Quality Standards to Protect Aquatic Life in the Delaware River.*

[98] Delaware River Basin Commission. (2022c). Social and Economic Factors Affecting the Attainment of Aquatic Life Uses in the Delaware River Estuary. September 2022 Draft. *https://www.nj.gov/drbc/library/documents/AnalysisAttainability/SocialandEconomicFactors_DRAFTsept2022.pdf.*

[99] As of September 1, 2023, the monthly water bill for a typical residential consumer in Philadelphia is $74.81, which equates to $897.72 annually. Source: Philadelphia Water Department. Rate Changes Effective September 2023. Web page, accessed September 26, 2023. *https://water.phila.gov/drops/new-rate-information-effective-september-2023/.*

[100] United States Environmental Protection Agency. (2023). Clean Water Act Financial Capability Assessment Guidance. Document ID: 800b21001. February 2023. *https://www.epa.gov/system/files/documents/2023-01/cwa-financial-capability-assessment-guidance.pdf.*

[101] City of Philadelphia. (2023). Annual Report to the Mayor on the Tiered Assistance Program (TAP). Department of Revenue. March 31, 2023. *https://www.phila.gov/media/20230526113411/Tiered-Assistance-Program-TAP-2022-annual-report.pdf.*

[102] The EPA does not have the necessary data to calculate a per household surcharge that could increase water bills for higher-income customers, nor did the EPA include other assistance programs in this calculation.

[103] City of Philadelphia. (2017). Philadelphia Launches New, Income-Based, Tiered Assistance Program. Press Release. Office of the Mayor. June 20, 2017. *https://www.phila.gov/press-releases/mayor/philadelphia-launches-new-income-based-tiered-assistance-program/.*

[104] City of Philadelphia. (2023). Annual Report to the Mayor on the Tiered Assistance Program (TAP). Department of Revenue. March 31, 2023. *https://www.phila.gov/media/20230526113411/Tiered-Assistance-Program-TAP-2022-annual-report.pdf.*

[105] *Id.*

[106] *Id.*

the full potential of the program is likely not being realized.

Based on the structure of TAP and the current low participation rates, low-income communities are not necessarily protected from high water bills and increasing water rates. The way the program is designed, non-TAP customers subsidize the discounts applied to TAP customers. When there is high participation, the majority of program costs are borne by higher income households and participating low-income households are protected from high water bills and increasing water rates (including potential rate increases to offset costs associated with additional wastewater treatment plant technologies). With low-participation rates, a higher proportion of low-income households are paying the TAP surcharge and face higher water rates, thus placing an undue burden on low-income households not participating in the program.

In theory, costs associated with the EPA's proposed rule—if partially or fully passed on to residential consumers—should not impact the lowest income households in Philadelphia, assuming high participation in TAP. However, the current low participation rates in TAP indicate that some low-income communities are likely burdened by high water bills and could potentially indirectly bear costs associated with the EPA's proposed rule. Although Philadelphia's TAP is innovative, additional work to increase participation (through increased enrollment and decreased attrition rates) can further advance water affordability and protect low-income households.

The example of Philadelphia's TAP illustrates how an income-based rate structure can potentially have a measurable impact on low-income communities. Municipalities potentially affected by the EPA's proposed rule might consider holistic ways to advance water affordability, which can include adoption of alternative water rate structures and assistance programs that lower water bills for low-income households. There are several considerations for municipalities if choosing to implement a program similar to TAP in Philadelphia.[107] An income-based rate structure, such as Philadelphia's TAP, might be most effective for utilities with larger service areas and higher income disparities for households within the service area. When a utility has a large customer base, it allows the utility to distribute any surcharges (to offset lost revenue) among many households.[108] In theory, this redistribution of costs means that the per household surcharge can be small and affect higher income households who might be less socially vulnerable. In addition, the effectiveness of an income-based rate structure hinges on the participation rate of low-income communities. Municipalities seeking to implement a similar program should consider practices to encourage high enrollment and high retention rates among qualified households. Such practices could include automatically enrolling households who are concurrently on other assistance programs (such as SNAP) or ensuring a user-friendly process for recertification of eligibility, if applicable. By thoughtfully and strategically advancing water affordability programs, municipalities can work towards ensuring that socially vulnerable communities are not overburdened by expensive water bills.

List of Subjects in 40 CFR Part 131

Environmental protection, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, the EPA proposes to amend 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

■ 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

■ 2. Add § 131.XX to read as follows:

§ 131.XX Water quality standards to protect aquatic life in the Delaware River.

(a) *Scope.* (1) The designated use in paragraph (b) of this section applies to river miles 108.4 to 70.0 of the Delaware River for the states of New Jersey and Pennsylvania.

(2) The aquatic life criteria in paragraph (c) of this section apply to river miles 108.4 to 70.0 of the Delaware River for the states of Delaware, New Jersey, and Pennsylvania.

(b) *Aquatic life designated use.* The aquatic life designated use is protection and propagation of resident and migratory aquatic life.

(c) *Dissolved oxygen criteria.* The applicable dissolved oxygen criteria are shown in table 1 to this paragraph (c).

TABLE 1 TO PARAGRAPH (c)—DISSOLVED OXYGEN CRITERIA

Season	Magnitude (percent oxygen saturation)	Duration	Exceedance frequency
Spawning and Larval Development *(March 1–June 30)*	66	Daily Average	10% *(12 Days Cumulative).*
Juvenile Development *(July 1–October 31)*	66	Daily Average	10% *(12 Days Cumulative).*
	74	Daily Average	50% *(61 Days Cumulative).*
Overwintering *(November 1–February 28/29)*	66	Daily Average	10% *(12 Days Cumulative).*

(d) *Applicability.* (1) The aquatic life designated use in paragraph (b) of this section applies concurrently with other applicable designated uses in New Jersey and Pennsylvania for river miles 108.4 to 70.0 of the Delaware River.

(2) The dissolved oxygen aquatic life water quality criteria in paragraph (c) of this section are the applicable dissolved oxygen criteria in Delaware, New Jersey, and Pennsylvania for river miles 108.4 to 70.0 of the Delaware River and apply concurrently with applicable water quality criteria for other parameters.

(3) The designated use and criteria established are subject to Delaware's, New Jersey's, and Pennsylvania's general rules of applicability in the same way and to the same extent as are other federally promulgated and state-adopted water quality standards in those states.

[FR Doc. 2023–27758 Filed 12–20–23; 8:45 am]

BILLING CODE 6560–50–P

[107] Mack, E.A., Wrase, S., Dahme, J., Crosby, S.M., Davis, M., Wright, M., & Muhammad, R. (2020). An Experiment in Making Water Affordable: Philadelphia's Tiered Assistance Program (TAP). Journal of the American Water Resources Association, 56(3), 431–449. *https://doi.org/10.1111/1752-1688.12830.*

[108] *Id.*

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 674

[FTA Docket No. FTA 2023–0008]

RIN 2132–AB42

State Safety Oversight

AGENCY: Federal Transit Administration (FTA), United States Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The Federal Transit Administration (FTA) is extending the comment period for the notice of proposed rulemaking regarding FTA's State Safety Oversight program, which was published on November 15, 2023, with the original comment period closing on January 16, 2024.

DATES: The comment period for the proposed rule published November 15, 2023, at 88 FR 78269, is extended. Comments are requested by February 15, 2024. Late-arriving comments will be considered to the extent practicable.

ADDRESSES: You may file comments identified by docket number FTA–2023–0008 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will 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 ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: To access the docket and read background documents or comments received, go to: *https://www.regulations.gov.* Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Ave. SE, Docket Operations, M–30, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. EST, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For program matters, contact Loretta Bomgardner, Office of Transit Safety and Oversight, FTA, telephone (202) 577–5896 or *loretta.bomgardner@dot.gov.* For legal matters, contact Richard Wong, Office of the Chief Counsel, telephone (202) 366–4011 or *richard.wong@dot.gov.* Office hours are from 8:30 a.m. to 6 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: In a letter submitted to the docket dated November 16, 2023, the American Public Transportation Association (APTA), on behalf of more than 1,300 member organizations, requested a 30-day extension of the comment period for the State Safety Oversight notice of proposed rulemaking (NPRM) published in the **Federal Register** on November 15, 2023 (88 FR 78269).

As justification for this extension, APTA cited two current rulemakings for which FTA is seeking comments, the Public Transportation Safety Certification Training NPRM (88 FR 73573) and the Hours of Service and Fatigue Risk Management ANPRM (88 FR 74107). APTA noted that transit agencies, State safety oversight agencies, and APTA are already reviewing and preparing comments, and replying to a third would be burdensome. In addition, APTA notes three Federal holidays between the time the NPRM was published and comments are due, and that many offices, including APTA, will be closed between Christmas and New Year's Day. APTA believes an extension of time would ensure that APTA and its members have the necessary time to produce a thoughtful response to the NPRM.

Given the importance of public transportation safety and the need for a more fulsome dialogue on FTA's safety priorities, FTA believes an extension of time is justified and is extending the comment period until February 15, 2024.

To ensure that comments are filed correctly, please follow the instructions in the **ADDRESSES** section above, including the docket number provided [FTA–2023–0008] in your comments.

Veronica Vanterpool,

Deputy Administrator.

[FR Doc. 2023–28155 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 675

[FTA Docket No. FTA 2023–0018]

RIN 2132–AB46

Transit Worker Hours of Service and Fatigue Risk Management

AGENCY: Federal Transit Administration (FTA), United States Department of Transportation (DOT).

ACTION: Advance notice of proposed rulemaking, extension of comment period.

SUMMARY: The Federal Transit Administration (FTA) is extending the comment period for the advance notice of proposed rulemaking regarding transit worker hours of service and fatigue risk management, published on October 30, 2023, with the original comment period closing on December 29, 2023. The extension is based on concerns from the American Public Transportation Association (APTA) that the comment period did not provide sufficient time to review and provide comprehensive comments to the ANPRM due to two Federal holidays and the closure of many offices between Christmas and New Year's Day. FTA recognizes that others interested in commenting may have similar concerns and agrees that the comment period should be extended.

DATES: The comment period for the proposed rule published October 30, 2023, at 88 FR 74107, is extended. Comments are requested by January 29, 2024. FTA will consider comments received after that date to the extent practicable.

ADDRESSES: You may file comments, identified by docket number FTA–2023–0018, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Instructions: All submissions received must include the agency name and docket number (FTA 2023–0018) for

this rulemaking. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Docket: To access the docket and read background documents or comments received, go to: *https://www.regulations.gov.* Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Ave. SE, Docket Operations, M–30, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. EST, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For program matters, contact Valerie Beck, Office of Transit Safety and Oversight, FTA, telephone (202) 366–9178 or email *FTAFitnessforDuty@dot.gov.* For legal matters, contact Emily Jessup, Office of the Chief Counsel, telephone (202) 366–8907 or email *emily.jessup@dot.gov.* Office hours are from 7:30 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: In a letter submitted to the docket dated November 29, 2023, the American Public Transportation Association (APTA) requested a 30-day extension of the comment period for the advance notice of proposed rulemaking (ANPRM) published in the **Federal Register** on October 30, 2023 (88 FR 74107).

As justification for this extension, APTA believed that it could synthesize consensus comments from the industry by the December 29, 2023, deadline, but it will be nearly impossible due to two Federal holidays between the time the NPRM was published and comments are due, and the fact that that many offices, including APTA's, will be closed between Christmas and New Year's Day. APTA also notes that it held a webinar for safety coordinators to collect comments and plans to hold another one in later December to synthesize comments. APTA also stated that intends to hold a meeting for transit CEOs to collect their thoughts on an initial draft response in late December or early January. APTA believes an extension of time would ensure that APTA and its members have the necessary time to survey, draft, and vet consensus comments and to produce a more complete response to the NPRM.

Given the importance of public transportation safety and the desire for a robust dialogue on the issues surrounding transit worker fatigue, and the likelihood that other commenters may have similar concerns, FTA believes an extension of time is justified and is extending the comment period until January 29, 2024.

FTA is not republishing the questions in this document. Instead, please refer to the ANPRM (88 FR 74107). To ensure that comments are filed correctly, please follow the instructions in the **ADDRESSES** section above and include the docket number provided [FTA–2023–0018] in your comments.

Veronica Vanterpool,

Deputy Administrator.

[FR Doc. 2023–28154 Filed 12–20–23; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2023–0220; FF09E21000 FXES1111090FEDR 245]

RIN 1018–BG92

Endangered and Threatened Wildlife and Plants; Threatened Species Status for Coal Darter With Section 4(d) Rule

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the coal darter (*Percina brevicauda*), a small, benthic freshwater fish native to the Mobile River Basin in Alabama, as a threatened species under the Endangered Species Act of 1973, as amended (Act). This determination also serves as our 12-month finding on a petition to list the coal darter. After a review of the best available scientific and commercial information, we find that listing the species is warranted. Accordingly, we propose to list the coal darter as a threatened species with a rule issued under section 4(d) of the Act (''4(d) rule'') to provide for the conservation of the species. If we finalize this rule as proposed, it would add this species to the List of Endangered and Threatened Wildlife and extend the Act's protections to the species.

DATES: We will accept comments received or postmarked on or before February 20, 2024. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. eastern time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by February 5, 2024.

ADDRESSES:

Written comments: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–R4–ES–2023–0220, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R4–ES–2023–0220, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

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

Availability of supporting materials: Supporting materials, such as the species status assessment report, are available on the Service's website at *https://www.fws.gov/office/alabama-ecological-services,* at *https://ecos.fws.gov/ecp/species/9959,* and at *https://www.regulations.gov* under Docket No. FWS–R4–ES–2023–0220.

FOR FURTHER INFORMATION CONTACT: William Pearson, Field Supervisor, U.S. Fish and Wildlife Service, Alabama Ecological Services Field Office, 1208 Main Street, Daphne, AL 36526; telephone 251–441–5181. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. Please see Docket No. FWS–R4–ES–2023–0220 on *https://www.regulations.gov* for a document that summarizes this proposed rule.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act (16 U.S.C. 1531 *et seq.*), 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 within 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 coal darter meets the Act's definition of a threatened species; therefore, we are proposing to list it as such. Listing a species as a threatened species can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process (5 U.S.C. 551 *et seq.*).

What this document does. We propose to list the coal darter as a threatened species with a rule issued under section 4(d) of the Act.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the coal darter meets the definition of a threatened species due to habitat loss or degradation from the following activities or conditions: hydrologic alteration by impoundments, including dams and other barriers; agriculture (poultry farming); urban development or change in land cover, including increased density of residential and commercial infrastructure; resource extraction, including mining and silviculture operations that do not follow State-approved best management practices (BMPs); diminished water quality from point and nonpoint source chemical contamination and sedimentation (Factor A); and climate change (Factor E).

Information Requested

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

(1) The species' biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns and the locations of any additional populations of this species;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Threats and conservation actions affecting the species, including:

(a) Factors that may be affecting the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors;

(b) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species; and

(c) Existing regulations or conservation actions that may be addressing threats to this species.

(3) Additional information concerning the historical and current status of this species.

(4) Information on regulations that may be necessary and advisable to provide for the conservation of the coal darter and that we can consider in developing a 4(d) rule for the species. In particular, we seek information concerning the extent to which we should include any of the Act's section 9 prohibitions in the 4(d) rule or whether we should consider any additional exceptions from the prohibitions in the 4(d) rule.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made solely on the basis of the best scientific and commercial data available.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *https://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *https://www.regulations.gov*.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *https://www.regulations.gov*.

Our final determination may differ from this proposal because we will consider all comments we receive during the comment period as well as any information that may become available after this proposal. Based on the new information we receive (and, if relevant, any comments on that new information), we may conclude that the species is endangered instead of threatened, or we may conclude that the species does not warrant listing as either an endangered species or a threatened species. In addition, we may change the parameters of the prohibitions or the exceptions to those prohibitions in the 4(d) rule if we conclude it is appropriate in light of comments and new information received. For example, we may expand the prohibitions to include prohibiting additional activities if we conclude that those additional activities are not compatible with conservation of the species. Conversely, we may establish additional exceptions to the prohibitions in the final rule if we conclude that the activities would facilitate or are compatible with the conservation and recovery of the species. In our final rule, we will clearly explain our rationale and the basis for our final decision, including why we made changes, if any, that differ from this proposal.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers

at least 15 days before the hearing. We may hold the public hearing in person or virtually via webinar. We will announce any public hearing on our website, in addition to the **Federal Register**. The use of virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On April 20, 2010, we received a petition from the Center for Biological Diversity (CBD), Alabama Rivers Alliance, Clinch Coalition, Dogwood Alliance, Gulf Restoration Network, Tennessee Forests Council, and West Virginia Highlands Conservancy to list 404 aquatic, riparian, and wetland species, including the coal darter, as endangered or threatened species under the Act. In response to the petition, we published a partial 90-day finding on September 27, 2011 (76 FR 59836), in which we announced our finding that the petition contained substantial information indicating that listing may be warranted for numerous species, including the coal darter.

Peer Review

A species status assessment (SSA) team prepared an SSA report for the coal darter. 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.

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 in listing actions under the Act, we solicited independent scientific review of the information contained in the coal darter SSA report. We sent the SSA report to five independent peer reviewers and received one response. Results of this structured peer review process can be found at *https://www.regulations.gov*. In preparing this proposed rule, we incorporated the results of these reviews, as appropriate, into the SSA report, which is the foundation for this proposed rule.

Summary of Peer Reviewer Comments

As discussed in Peer Review, above, we received comments from one peer reviewer on the draft SSA report. We reviewed the comment for substantive issues and new information regarding the information contained in the SSA report. The peer reviewer generally provided constructive suggestions and was broadly supportive. No substantive changes to our analysis and conclusions within the SSA report were deemed necessary, and peer reviewer comments are addressed in version 1.1 of the SSA report.

I. Proposed Listing Determination

Background

A thorough review of the taxonomy, life history, and ecology of the coal darter is presented in the SSA report (version 1.1; Service 2023, pp. 11–15).

The coal darter (*Percina brevicauda*) is a small, benthic freshwater fish native to the Mobile River Basin in Alabama. The species occurs in small to medium-sized rivers and the larger tributaries of those rivers with moderate to swift flowing water. It has been observed in riffle and run habitat, as well as in glide and pool habitat with stable sand, gravel, cobble, and bedrock substrates with low levels of siltation. The coal darter is a member of the genus *Percina* in the family *Percidae* (perches), and was originally described as the channel darter, first as *Etheostoma copelandi* (Gilbert 1891) and subsequently, as *Percina copelandi* (Moore 1957) when the channel darter was reclassified into the genus *Percina*. In 1994, the coal darter was described as a unique species, named *Percina brevicauda,* and placed with two other species recognized within the subgenus *Cottogaster* (the channel darter (*Percina copelandi*) and the pearl darter (*Percina aurora*)) (Suttkus and Bart 1994). Genetic analyses provided strong support of *Cottogaster* being a monophyletic clade, with these three species being sister clades.

The coal darter is a small, elongated, slightly compressed freshwater fish reaching up to 50 millimeters (mm) (1.96 inches (in)) in total length with smaller fins compared to other *Cottogaster* members. It has dark lateral blotches and a continuous lateral stripe pattern on the body. Nuptial males are heavily pigmented, including on the ventral surface of the head and body, giving them a dusky appearance, which is the reason for the common name, coal darter. They are diurnal feeders and consume aquatic invertebrates (insects, crustaceans, worms). Little is known about the specific life-history characteristics of the coal darter. Most of the life-history knowledge for the species is inferred from information known for the channel darter and pearl darter.

The coal darter is endemic to the eastern and central part of the Mobile River Basin in the State of Alabama. The species primarily occupies habitat above the Fall Line within the Piedmont, Ridge and Valley, and Southwestern Appalachians level III ecoregions. Additionally, there are several historical records below the Fall Line in the Cahaba River and Black Warrior River that are in the Southeastern Plains ecoregion.

Presently, the species has a disjunct distribution, with populations in the Cahaba River, the Locust Fork of the Black Warrior River, and two tributaries in the lower Coosa River (Weogufka Creek and Hatchet Creek). Within the Locust Fork watershed, occurrences are mostly in the Locust Fork mainstem, but there are also occurrences in Turkey Creek, the Little Warrior River, and Blackburn Fork. In the Cahaba River system, the coal darter is predominantly found in the mainstem of the Cahaba River with occurrences in Shades Creek and the Little Cahaba River.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in title 50 of the Code of Federal Regulations set forth the procedures for determining whether a species is an endangered species or a threatened species, issuing protective regulations for threatened species, and designating critical habitat for endangered and threatened species. In 2019, jointly with the National Marine Fisheries Service, the Service issued a final rule that revised the regulations in 50 CFR part 424 regarding how we add, remove, and reclassify endangered and threatened species and the criteria for designating listed species' critical habitat (84 FR 45020; August 27, 2019). On the same day, the Service also issued final regulations that, for species listed as threatened species after September 26, 2019, eliminated the Service's general protective regulations automatically applying to threatened species the prohibitions that section 9 of the Act applies to endangered species (84 FR 44753; August 27, 2019). Our analysis for this decision applied the regulations that are currently in effect, which include the 2019 revisions. However, we proposed further revisions to these regulations on June 22, 2023 (88 FR 40764). In case those revisions are finalized before we make a final status determination for this species, we have also undertaken an analysis of whether the decision would be different if we were to apply those proposed revisions. We concluded that the decision would have been the same if we had applied the proposed 2023 regulations. The

analyses under both the regulations currently in effect and the regulations after incorporating the June 22, 2023, proposed revisions are included in our decision file.

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 species' expected response and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the Act's definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as we 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 the foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent our decision on whether the species should be proposed for listing as an endangered or threatened species under the Act. However, it does 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.

To assess the coal darter's viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency is the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years); redundancy is the ability of the species to withstand catastrophic events (for example, droughts, large pollution events); and representation is the ability of the species to adapt to both near-term and long-term changes in its physical and biological environment (for example, climate conditions, pathogens). In general, species viability will increase with increases in resiliency, redundancy, and representation (Smith et al. 2018, p. 306). 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.

The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS–R4–ES–2023–0220 on *https://www.regulations.gov* and at *https://ecos.fws.gov/ecp/species/9959*.

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.

Individual, Population, and Species Needs

A thorough review of the coal darter's resource needs is presented in chapter

3 of the SSA report (version 1.1; Service 2023, pp. 17–18).

For the coal darter to survive and reproduce, individuals need suitable habitat that supports essential life functions at all life stages (see table 1, below). Four elements appear to be essential to the survival and reproduction of individuals: sufficient water quality, flowing water, stable substrates, and habitat heterogeneity.

For coal darter populations to be resilient, the needs of individuals require sufficient water quality, flowing water, stable substrates, and habitat heterogeneity to be met on a larger scale (see table 1, below). Stream reaches with suitable habitat must be large enough to support a sufficient reservoir of potential mates for coal darters to breed with and maintain sufficient genetic health while avoiding issues associated with small population sizes, such as genetic drift and inbreeding depression.

Connectivity is also an important factor for populations because it facilitates genetic health for populations and enables movement of individuals to suitable habitats that can accommodate the life-history needs for the species (*i.e.,* spawning, refuge, feeding). Natural flow regimes are an important resource need for coal darter populations, as flows may help trigger spawning and are a habitat requirement for all life stages.

At the species level, the coal darter needs a sufficient number and distribution of healthy populations to withstand environmental stochasticity (resiliency) and catastrophes (redundancy), and to adapt to biological and physical changes in its environment (representation). For the species to be viable, there must be adequate redundancy (suitable number, distribution, and connectivity of populations to allow the species to withstand catastrophic events) and representation (genetic and environmental diversity to allow the species to adapt to changing environmental conditions). Redundancy improves with increasing numbers of resilient populations distributed across the species' range, and connectivity (either natural or human-facilitated) allows connected populations to ''rescue'' each other after catastrophes. Representation improves with the persistence of populations having greater genetic and ecological diversity across the species' range, resulting in an increased ability to adapt to changing environmental conditions. Long-term viability will require resilient populations; for the coal darter, this will mean maintaining quality stream habitat (for example, sufficient water quality, natural flow regime, stable substrate, and adequate habitat heterogeneity) to support multiple populations across the species' range (see table 1, below).

TABLE 1—SUMMARY OF COAL DARTER INDIVIDUAL RESOURCE NEEDS BY LIFE STAGE

Life stage	Resources needed
Eggs	• Suitable gravel/cobble substrate for egg deposition. • Low amounts of silt and fine sediment. • Suitable water quality and quantity.
Larvae	• Connectivity to suitable habitat for dispersal. • Sufficient water flow for dispersal.
Juveniles	• Sufficient gravel/cobble/boulder substrate. • Aquatic invertebrate food source. • Sufficient water flow. • Presence of habitat heterogeneity (riffles, runs, pools). • Suitable water quality and quantity.
Adults	• Sufficient gravel/cobble substrate. • Sufficient structural habitat (rock, aquatic vegetation). • Aquatic invertebrate food source. • Sufficient water flow. • Presence of habitat heterogeneity (riffles, runs, pools). • Sufficient water quality and quantity.

At the species level, the coal darter requires sufficient connectivity between populations to facilitate gene flow and ensure adaptive potential. Genetic diversity should be high enough that the species will be able to adapt to changing environmental factors through the process of natural selection. Additionally, the species needs to have sufficient connectivity between enough individuals to promote an effective population size that is high enough to maintain evolutionary potential and genetic adaptive capacity. To evaluate the current and future viability of the coal darter, we assessed a range of conditions to allow us to consider the species' resiliency, representation, and redundancy.

Threats

A thorough review of the threats affecting the coal darter is presented in chapter 4 of the SSA report (version 1.1, Service 2023, pp. 23–31).

The coal darter is influenced by stressors affecting water quality, water flow, stream connectivity, and genetic diversity. The main threat is habitat loss or degradation from the following activities or conditions: hydrologic alteration by impoundments, including dams and other barriers; agriculture (poultry farming); diminished water quality from point and nonpoint source chemical contamination and sedimentation; urban development or change in land cover, including increased density of residential and commercial infrastructure; resource extraction, including mining and silviculture operations that do not follow State-approved BMPs; and climate change (Service 2023, p. 23).

Impoundments

Impoundment of rivers is a primary threat to aquatic species in the Southeast (Service 2023, pp. 23–24). Dams modify habitat conditions and aquatic communities both upstream and downstream of an impoundment. Upstream of dams, habitat is flooded and in-channel conditions change from flowing to still water, with increased depth, decreased levels of dissolved oxygen, and increased sedimentation. Downstream of dams, flow regimes of the released tailwater vary with resulting fluctuations in water temperature and dissolved oxygen levels, the substrate is scoured, and downstream reaches are eroded. These negative tailwater effects on habitat can extend many kilometers downstream. Dams fragment habitat for the coal darter by blocking corridors for

migration and dispersal, resulting in population isolation and increased risk of extirpation and extinction. All known populations of the coal darter are separated from each other by large dams. The virtually complete loss of the Coosa population and approximately 50 percent loss of the Black Warrior population are attributed to the construction of dams, reservoir creation, and channelization that occurred in these systems in the late 1800s to mid-1900s (see table 2, below). Impoundments in the Black Warrior River system were created to transport goods between Mobile and Tuscaloosa, and ultimately Birmingham. Construction of these impoundments included removal and clearing of overhanging trees and vegetation, blasting of rock and shoal complexes, removal of submerged woody debris and logs, and modification or removal of sand and gravel bars (Mettee 2019, pp. 10–22). Impoundments in the Coosa River Systems for hydroelectric power production were constructed by Alabama Power between the 1920s and 1960s. These impoundments are still in place today and significantly reduced the amount of available habitat for coal darters in the Coosa and Black Warrior River systems (Table 2).

TABLE 2—COMPARISON OF HISTORICALLY OCCUPIED RIVER LENGTHS AND CURRENTLY OCCUPIED RIVER LENGTHS OF COAL DARTERS IN THREE MAJOR RIVER SYSTEMS

[Service 2023, p. 14]

River systems	Historically occupied	Currently occupy
Black Warrior	At least 130 river miles (rmi)/209.2 river kilometers (rkm).	65 rmi/104.7 rkm.
Cahaba	133 rmi/214 rkm	114.9 rmi/184.9 rkm.
Coosa	At least 92.2 rmi/148.4 rkm	9 rmi/14.5 rkm in Hatchet Creek, one site in Weogufka Creek.

The Cahaba River, at 190 rmi/305.8 rkm long, is often referred to as Alabama's longest free-flowing stream. However, two barriers have impacted the flow of the river. The first is a low-head dam, located at Highway 280 near Acton, Alabama, and built in 1891. It is 15 feet tall and backs up water for withdrawal by Birmingham. This low-head dam is significantly smaller than the dams on the Black Warrior River and Coosa River, and as such, the Highway 280 dam has not converted vast areas of habitat, meaning habitat for the coal darter is still present and the species is still able to occupy habitat both upstream and downstream of the dam. Although coal darters occur upstream and downstream of the Highway 280 dam, this dam represents a significant barrier to upstream movement of coal darters. Downstream dispersal could be possible when larvae enter the water column and are carried downstream during a process known as pelagic larval drift (PLD). Because individuals upstream of the dam are isolated from those downstream, the upstream subpopulation is at a higher risk of genetic drift and inbreeding depression. The second barrier, the Marvel Slab, was removed in 2004; it is discussed in more detail under *Conservation Efforts and Regulatory Mechanisms,* below.

Water Quality

In general, darters tend to be sensitive to poor water quality (Service 2023, pp. 24–26). According to the Fishery Index Biotic Integrity (IBI) reports and related fish community survey work, coal darters are consistently labeled as a ''disturbance-sensitive'' or an ''intolerant'' (of habitat impairments) species. Based on its narrow distribution and habitat conditions (including water quality parameters) where coal darters are found, the coal darter needs clean, relatively clear, flowing water to survive and carry out its basic life-history functions; thus, water quality degradation is considered a threat to the species. Below, we discuss the causes of water quality degradation in more detail.

Point and Nonpoint Source Pollution—Inputs of point source pollution (discharge from an identifiable source) and nonpoint source pollution (diffuse land surface runoff) across the coal darter's range are numerous and widespread. Point source pollution originates from inadequately treated effluent from industrial plants, sanitary landfills, sewage treatment plants, active surface mining, drain fields from individual private homes, and others.

Nonpoint source pollution may originate from agricultural activities, poultry and cattle feedlots, abandoned mine runoff, construction, silviculture operations that do not follow State-approved BMPs, failing septic tanks, and contaminated runoff from urban areas. These sources have the potential to contribute pollution, including sediments, heavy metals, fertilizers, pesticides (*e.g.,* herbicides, insecticides, fungicides, and rodenticides), animal wastes, septic tank and gray water leakage, and oils and greases, to streams. Water quality declines resulting from this pollution cause nitrification, decreases in dissolved oxygen (DO) concentration, increases in acidity and conductivity, and introduction of toxicants. These alterations likely have direct (decreased survival and/or reproduction) and indirect (loss, degradation, and fragmentation of habitat) effects on coal darters. For the coal darter, submerged vegetation provides spawning habitat for adults, refugia from predators, and habitat for prey of all life stages. Aquatic vegetation also provides substrate stability for the species. Degraded water quality and high algal biomass that result from pollutant inputs cause loss of these critical submerged plant species (*e.g.,* water willow (*Justicia americana*), river weed (*Podostemum ceratophyllum*)), which are vital habitat for the coal darter and its prey.

Sedimentation—Sedimentation has been linked to changes in fish assemblages and community structure (Shepard et al. 1994; Onorato et al. 2000, pp. 56–58). A wide range of current activities and land uses can lead to excessive sedimentation within streams, which has occurred throughout the coal darter's range, especially in Hatchet Creek. Sources potentially include agricultural practices, construction activities, stormwater runoff, unpaved roads, silvicultural activities, utility crossings, and mining. Fine sediments are not only introduced into streams during present day activities, but historical land-use practices may have substantially altered hydrological and geomorphological processes such that sediments continued to be input into streams for several decades after those activities ceased.

Increases in sedimentation from sources such as agriculture, silviculture operations that do not follow State-approved BMPs, mining, and

urbanization are of concern for the coal darter and can negatively affect the species by reducing growth rates, disease tolerance, and gill function; reducing spawning habitat, reproductive success, and egg (embryo), larva, and juvenile development; reducing food availability through reductions in prey; reducing foraging efficiency; and reducing shelter (Service 2023, pp. 25–26).

Agriculture

Agricultural practices such as traditional farming, feedlot operations, and associated land-use practices can contribute pollutants to rivers. These practices can also degrade habitat by encouraging the erosion of stream banks, which results in alterations to stream hydrology and geomorphology. Nutrients, bacteria, pesticides, and other organic compounds are generally found in higher concentrations in areas around agriculture than in forested areas. Contaminants associated with agriculture (fertilizers, pesticides, herbicides, and animal waste) can cause degradation of water quality and habitats through instream oxygen deficiencies, excess nutrification, and excessive algal growths, with a related alteration in fish community composition. In the Alabama Department of Environmental Management's (ADEM's) 2022 list of impaired waters, which was prepared in accordance with section 303(d) of the Clean Water Act (CWA; 33 U.S.C. 1251 *et seq.*) and submitted to the Environmental Protection Agency (EPA), Hatchet Creek was designated as impaired due the presence of pathogens from animal feeding operations and pasture grazing, and Weogufka Creek was designated as impaired due to the presence of pathogens from pasture grazing (ADEM 2022, p. 300).

Poultry farming, undertaken primarily in poultry houses, occurs within the range of the coal darter, especially in and around the Locust Fork watershed. Poultry houses have an estimated ability to produce approximately 100 tons of litter a year (assuming a 20,000-square-foot poultry house stocked at one bird per square foot and six flocks produced per year, which is a probable underestimate of litter production per broiler house). Poultry litter is a mixture of chicken manure, feathers, spilled food, and bedding material that is used to fertilize pastureland or row crops that frequently occur adjacent to rivers and streams.

Runoff from heavy rains carries excess nutrients from chicken manure into nearby streams as a result of surface-spreading of litter. Litter can also contain arsenic, which is formed from a chemical routinely used as a feed additive to prevent disease and stimulate growth, and it enters streams through runoff (Stolze et al. 2007, p. 821). Other substances often found in poultry litter include fecal coliform, S*almonella,* and other pathogens; pesticide residue; and other heavy metals (Bolan et al. 2010, pp. 676–683). In general, the inputs from poultry litter into rivers and streams reduce water quality for the coal darter, causing physiological stress. This is especially evident in Locust Fork in the species' range (ADEM 1999, pp. 57–78, 147, 218; Deutsch et al. 1990, entire).

Resource Extraction: Mining and Oil/Gas

Coal mining in Alabama began in the early 1800s. Currently, there are active and reclaimed mines operating throughout the Black Warrior and Cahaba watersheds, and one proposed graphite mine permitted for future operations in the Coosa watershed. Surface and subsurface coal mines have the potential to degrade water quality from erosion and sedimentation, and the presence of mines near rivers and streams elevates the risk of water contamination. These mining processes expose metallic minerals, which can then enter the surrounding waterways, increasing conductivity, increasing acidity, and contaminating the waterways with heavy metals, creating toxic conditions for aquatic fauna (Stiefel and Busch 1983, pp. 187–212; Neves et al. 1997, pp. 69–70).

In addition to surface and subsurface mining, oil and gasoline extraction and transportation is also present within the range of the coal darter. In 2016, there was a near disaster in the range of the coal darter when 252,000 gallons of gasoline spilled from the Colonial Pipeline into an old mining pond that feeds into a tributary of the Cahaba (EPA 2016, unpaginated). The spill was contained before reaching the Cahaba River; however, this incident illustrates that the risk of threat to the species from resource extraction does exist.

Resource Extraction: Silviculture

The forestry industry, in the form of monoculture pine plantations, is prevalent throughout the range of the coal darter. Forestry can have negative implications for water quality in the form of nonpoint source pollution, especially when BMPs are not implemented. Excessive sedimentation in Hatchet Creek has been documented since the mid-1990s. The excessive sedimentation and subsequent loss of clean gravel and pool habitat has been attributed to forestry activities, including removal of riparian vegetation (Alabama Department of Conservation and Natural Resources (ADCNR) 2006, p. 3). Sedimentation of streams and waterways has the potential to increase due to accelerated erosion from logging roads and timber harvest. We recognize that modern silvicultural operations are widely implemented in accordance with State-approved BMPs, and the adherence to these BMPs broadly protects water quality, particularly related to sedimentation. However, in many cases, sedimentation in streams is a continuing legacy effect from past eras of poor logging practices (Service 2023, p. 27).

Urbanization

Urbanization is a significant source of water quality degradation that can reduce the survival of aquatic organisms, including the coal darter. Urbanization refers to a change in land cover and land use from forests or agriculture to increased density of residential and commercial infrastructure. Urban development can stress aquatic systems in a variety of ways, including increasing the frequency and magnitude of high flows in streams, increasing sedimentation (construction activities) and nutrient loads (lawn fertilization), increasing contamination and toxicity (from household pesticides and herbicides), altering flows because of an increase in impervious surfaces (*i.e.,* flashier flows), and altering stream morphology, stability, and chemistry, which can result in a decreased diversity of fishes, aquatic insects, plants, and amphibians. Sources and risks of an acute or catastrophic contamination event, such as a leak from an underground storage tank, pipeline, or wastewater system, or a hazardous materials spill on a highway, also increase as urbanization increases.

Changes to both frequency and magnitude of stream flows have direct effects on important structural habitat for coal darters. Stream channelization and higher flows reduce overall stream cover and other natural substrates like boulders, cobble, and gravel, and they remove large woody structures and other terrestrial plant materials. As a result, urban streams have lower habitat heterogeneity, stable substrates, and amounts of plant material, which negatively impacts the coal darter's sheltering, breeding, and feeding.

Birmingham is the third largest city in the State of Alabama and was ranked as the largest city until the 2020 census. It continues to be one of the fastest growing metropolitan areas in the State.

Despite the population of Birmingham decreasing between 1992 and 2011, urban cover over that time period increased from 9.4 percent to 35.7 percent due to expansion of the metropolitan area (Dosdogru et al. 2020, p. 2). The upper part of the Cahaba River watershed and the southeastern part of the Locust Fork watershed drain a significant portion of the Birmingham metropolitan area. The overall degradation of water and habitat quality because of increased urbanization has negative implications for coal darter populations currently, and into the future, as discussed below under *Current Condition* and *Future Condition.*

Climate Change

Changing climate conditions can influence coal darter viability through changes in water temperature and precipitation patterns that result in increased flooding, prolonged droughts, or reduced stream flows. Since the 1970s, moderate to severe droughts in the Southeast have increased by 12 percent during spring months and by 14 percent during summer months (Jones et al. 2015, p. 126). Reduced baseflows due to droughts can cause population declines, habitat loss, and degraded water quality (decreased dissolved oxygen and temperature alteration) leading to death, crowding of individuals leading to stress, and decreased reproduction in stream fish populations. Increased groundwater withdrawal for agriculture or other human needs during droughts may potentially exacerbate the impacts of reduced quantity or frequency of precipitation.

Climate models for the southeastern United States project that average annual temperatures will increase, cold days will become less frequent, the freeze-free season will lengthen by up to a month, days with temperatures exceeding 95 degrees Fahrenheit will increase, heat waves will become longer, and the number of category 5 hurricanes will increase (Ingram et al. 2013, p. 32; IPCC 2021, entire). While these climate models predict variability into the future, they suggest that the region will be subjected to more frequent large storms (hurricanes) with severe flooding and extremely low flows during droughts. Average and extreme precipitation is expected to increase, and subsequently, river flooding is also expected to increase. Extreme weather events, such as flash flooding associated with heavy precipitation events, are projected to increase in the future within the range of the coal darter, and these events can impact the coal darter through habitat degradation and displacement, injury, or even mortality (Service 2023, pp. 29–30).

Future changes in climate within the coal darter's range include increases in temperatures, especially for summer and fall, and increases in overall precipitation. Therefore, the watersheds occupied by coal darters could experience moderate to significant changes in climate by the 2050s, especially under scenarios run for representative concentration pathway (RCP) 8.5 (corresponding to high levels of carbon emissions). Increases in summer temperatures coupled with decreased instream flow can increase water temperatures and reduce dissolved oxygen levels, while flashier flows can increase soil erosion and stream sedimentation.

Low Genetic Diversity

Low genetic diversity makes the coal darter vulnerable to threats. Greater genetic diversity results in greater potential to adapt to a changing environment through natural selection. Reduced genetic diversity in a population can limit its adaptive potential. Small populations often have lower genetic diversity because there are fewer individuals. Small populations are also susceptible to genetic phenomena of inbreeding depression, population bottlenecks, and genetic drift, which can lead to a greater reduction in genetic diversity over time and reduced fitness of the population, leaving it more vulnerable to changing environmental conditions. The combination and interaction of these negative demographic and genetic effects on a small population can lead the population into an extinction vortex.

Effective population size (N_e) goes hand in hand with genetic diversity. There are two heuristics relating effective population size to conservation biology principles. The first is the 50/500 ''rule of thumb,'' which states that if a population's estimated effective population size is greater than 500, then it will maintain evolutionary potential and adaptive capacity over time. However, an effective population size of fewer than 50 would place the population in the extinction vortex, and as the N_e falls below 500 and moves towards 50, the population becomes increasingly at risk of loss in genetic variation. The more conservative theory is the 100/1,000 ''rule of thumb,'' which states that an estimated effective population size of more than 1,000 is needed to maintain evolutionary potential, and an effective population size of fewer than 100 would place the population in the extinction vortex.

In 2018 to 2020, range-wide genetic analyses were carried out for the coal darter, which included samples from the Cahaba River, Locust Fork, and Hatchet Creek. No samples were included in the analysis from Weogufka Creek, because individuals at that site were discovered in 2021, after this genetic work was completed. As such, the Coosa River system is represented only by Hatchet Creek in the genetics analysis.

Results show that populations were historically connected and shared gene flow, however they are currently functionally isolated, showing no gene flow between the three watersheds (Jones and Sandel 2019, entire; Jones 2021, entire). Genetic diversity was relatively low across all three watersheds as indicated by the observed and expected heterozygosity (H_o and H_e) and percent polymorphic loci. The Hatchet Creek population's genetic diversity is considered very low (Jones and Sandel 2019, entire; Jones 2021, entire). Effective population size (N_e), the number of breeding individuals in an idealized population that would maintain genetic diversity, was also reported for each of the watersheds. The effective population size for the Black Warrior population is 2,759 (range of 2,158–3,823); Cahaba River population is 3,145 (range of 2,423–4,480); and Coosa River population is 268 (range of 252–290) (Jones and Sandel 2019, pg. 5; Jones 2021, pg. 22). In the Coosa River, Hatchet Creek's effective population size is an order of magnitude lower than the other two populations (Jones 2021, entire).

Summary

A summary of the threats acting on coal darter populations in each river system is presented below in table 3. The magnitude of each of these threats varies from river system to river system. Details on the impacts of the different threats on coal darter populations are provided below under *Current Condition.*

TABLE 3—SUMMARY OF THREATS IN EACH RIVER SYSTEM

Black Warrior	Cahaba	Coosa
• Water quality degradation from: • Urbanization; • Active and reclaimed mines; and • Agriculture (including poultry operations); and • Silviculture—legacy effects • ~50% reduction in range. • Low genetic diversity. • Climate change.	• Water quality degradation from: • Urbanization; • Silviculture—legacy effects; • Active and reclaimed mines; and • Agriculture. • Low genetic diversity. • Climate change.	• Water quality degradation from: • Agriculture. • Silviculture—legacy effects; and • Future mining. • ~90% reduction in range. • Very low genetic diversity. • Low effective population size. • Climate change.

Conservation Efforts and Regulatory Mechanisms

The coal darter is not State-protected in Alabama but is included in the Alabama State Wildlife Action Plan (SWAP), where it is assigned a ''priority 2'' (''high conservation concern'') status (ADCNR 2015, pg. 19). There have been no captive propagation efforts for the species. The Geological Survey of Alabama (GSA) completed targeted surveys for the species in the Locust Fork in 2001, and rangewide in 2022 in partnership with the Service. Additionally, GSA, ADEM, ADCNR, and other partners have conducted fish Index of Biotic Integrity (IBI) assessments, a fish community-based assessment of stream health, in waterways throughout the State, including areas within the coal darter's range (Service 2023, pp. 31–32).

Priority watersheds within the range of the coal darter have been designated as ''strategic habitat units'' (SHUs) by the Alabama Rivers and Streams Network (ARSN). The SHU concept was created to prioritize efforts and leverage capacity among partners (government, nongovernmental organizations, private industry) to implement restoration and recovery of listed and rare aquatic species. Locust Fork, the Cahaba River, and Hatchet Creek have all been designated as SHUs. However, Weogufka Creek does not have an SHU designation.

Habitat restoration has been one of the most influential conservation efforts positively affecting coal darters. Projects, such as stream bank stabilization and dam removal, have been completed or planned by State and Federal partners, nonprofit organizations, and private landowners. These types of restoration projects are not specifically targeting coal darter conservation, but they aim to improve the habitat quality in general for the benefit of imperiled aquatic species.

Cahaba

The Cahaba River has a long history of water quality declines and subsequent remediation activities (Thom et al. 2013, pp. 60–62). In recognition of these water quality challenges, EPA and the State of Alabama began working on measures to improve the water quality of the river under the auspices of the CWA. The CWA regulates water quality standards for surface waters and discharges of pollutants into the waters of the United States. The CWA made point source discharge into navigable waters without a permit unlawful in 1972. The EPA has authority to enforce the CWA, and with that authority, has developed national water quality criteria recommendations for pollutants found in surface waters and has implemented various pollution control programs (*i.e.,* wastewater standards for industry) (EPA 2021, entire).

Stormwater runoff containing pollutants is often transported through municipal separate stormwater sewer systems (MS4s), which discharge without treatment into local waterways (Service 2023, p. 33). An MS4 is owned by a public entity and is designed to collect and convey stormwater that discharges to waters of the United States. It is not part of a combined sewer or a publicly owned treatment facility or works (EPA 2023, entire). Administered under the National Pollution Discharge Elimination System (NPDES) permit program, MS4 permits require development and implementation of a comprehensive storm water management program (SWMP) that addresses prevention, treatment, removal, monitoring, and other measures to control the quality of stormwater that travels through storm drains to waters of the United States (EPA 2021, introduction). At present, several urban areas in the Upper Cahaba are designated as part of the MS4 program. These permits are regulated under the NPDES system, are treated as point sources by the EPA, and receive waste load allocations (WLAs) under the total maximum daily load (TMDL) program, which is a calculation of the maximum amount of a particular pollutant that can enter a water body and allow that water body to meet water quality standards (Service 2023, p. 34). Thereby, under the CWA, point source discharges of pollutants (including stormwater) are currently being regulated.

In addition, there are processes in place to manage new discharges into the river from industrial sources (*e.g.,* industrial plants, mining, and wastewater). Water quality has substantially improved in recent decades due in part to the NPDES and the NPDES MS4 permits in the upper watershed, the TMDL program, and a general trend towards better stormwater management and soil retention measures in the watershed. TMDLs establish pollution reduction targets, allocate load reductions for pollutant sources, and include a margin of safety while also accounting for seasonal variability of water quality. Currently, the TMDL for Buck Creek, Cahaba Valley Creek, and the Cahaba River adhere to ADEM's water quality standards for the designated use classification of that stream. Overall, this has improved turbidity and improved nutrient loading near the coal darter population (Service 2023, pp. 34–35).

Significant habitat restoration efforts have also taken place in the Cahaba River. For example, in 2004, The Nature Conservancy, the U.S. Army Corps of Engineers, and other partners removed a vented ford dam named the Marvel Slab. Built in the 1960s and 1970s, the dam was originally used for transporting coal and timber across the river. It was 67 meters (219 feet) long, 1.8 meters (5.9 feet) tall, and 7.6 meters (24.9 feet) wide with 40 culverts through which water could flow. Ecologically, the barrier functioned as a dam, blocking upstream movement of aquatic fauna. Removal of the structure restored connectivity between the river reaches. When compared with historical records, fish monitoring conducted after the dam was removed indicated that several fish species, including two that are Federally listed under the Act, have extended their ranges as a result of the removal (Bennett et al. 2015, pp. 51–61).

Black Warrior

Currently, within the Black Warrior River system, the coal darter is restricted to the Locust Fork. The Locust Fork has its own history of water quality issues and remediation. In 1998, it was added to the EPA's list of impaired and threatened waters in Alabama (*i.e.,* Alabama's 303(d) list) due to siltation and nutrient loading concerns along with the presence of federally endangered and threatened species. The ADEM performed monitoring of four 303(d) segments between 2012 and 2016 by assessing the macroinvertebrate community and habitat quality, and evaluating water quality data (Service 2023, pp. 35–36).

From these assessments, the macroinvertebrate community was characterized as ''fair'' for each of the four segments; habitat quality was ''optimal'' at the most upstream segment, ''sub-optimal'' at the middle two segments, and ''marginal'' at the most downstream segment; and the numerical water quality parameters (total suspended solids and turbidity) were below the eco-reference guidelines for all four segments (ADEM 2018, pp. 14–16). Based on these monitoring results, in 2018, the Locust Fork was removed from the 303(d) list for siltation, and it was also removed from the 303(d) list for nutrients because a TMDL was established (Service 2023, p. 36).

Synergistic and Cumulative Effects

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 conditions of the species. Our assessment of the current and future conditions encompasses and incorporates the threats individually and primary threats cumulatively. Our current and future conditions assessment is iterative because it 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.

Current Condition

A thorough review of the coal darter's current condition is presented in chapter 5 of the SSA report (version 1.1, Service 2023, pp. 39–53).

Currently, the coal darter is known from three tributary systems of the Mobile River Basin: Locust Fork of the Black Warrior River, Cahaba River, and Hatchet and Weogufka Creeks of the Coosa River. Coal darter movements and dispersal patterns within these systems are not well understood. Recent population genetics work by University of West Alabama supports gene flow within each river system. However, migration rate estimates indicate no individuals migrating between river systems; thus, no contemporary gene flow exists between systems. These results indicate that each river system is demographically independent of each other. Using these data, populations were delineated based on river system, resulting in three populations that will serve as the resiliency units for assessing population resiliency: the Black Warrior, the Cahaba, and the Coosa. Currently, each population is found in a different Level III ecoregion. Since no other biologically meaningful boundaries are known to exist for the coal darter, we determined the representative units to be the same as the resiliency units (populations).

Based on the coal darter's individual and population needs, such as adequate water quality and quantity, the availability of clean gravel/cobble substrates, sufficient food sources, and appropriate population size and connectivity to support reproduction and recruitment within a population, we developed an approach using key habitat and demographic factors to assess population resiliency. We assessed two demographic condition parameters (genetic health and persistence through time) and two habitat condition parameters (Human Disturbance Gradient Index and habitat quantity) (see table 4, below). Based on the coal darter's lifespan, we used the time period from 2007 to 2022 to inform the current condition of the species.

For a population to be resilient in the context of genetic health, a population should have sufficient standing genetic variation and effective population size (N_e). The 50/500 and 100/1,000 ''rules of thumb'' threshold were used to describe the minimum effective population size needed for both short-term and long-term viability. Greater genetic diversity in a population will improve the fitness of a population, equating to higher survival and rebound potential in the face of demographic and environmental stochasticity. An N_e greater than 50 or 100 is necessary to prevent the deleterious effects of inbreeding depression and genetic drift (*i.e.,* short-term viability) (Service 2023, p. 41). The upper thresholds of the N_e ''rule of thumb'' (500 or 1,000) will be important for our current condition representation because above this upper threshold, a population is expected to be able to maintain its adaptive capacity (*i.e.,* long-term viability). However, the upper threshold of 500 or 1,000 is important to consider for resiliency as well, because when the N_e declines from 500 to 50, or from 1,000 to 100, the risks of genetic diversity loss progressively increase. Thus, an N_e below the upper thresholds of 500 or 1,000 are of concern for both population resiliency and species representation.

We consider a population with high resiliency to have high or moderate genetic diversity and an N_e that exceeds the 500/1,000 threshold. Thresholds for genetic diversity could not be quantified in table 4, below, because the genetic data we have available represent a snapshot of the current condition, and we do not have historical genetic data to which we can compare them. What is considered high, moderate, and low genetic diversity can vary from taxa to taxa. However, after consulting with conservation genetics experts on the coal darter's genetics and the scientific literature on genetic diversity results of other similar species, we determined that the Cahaba and Black Warrior populations exhibit ''low'' genetic diversity and the Hatchet Creek population exhibits ''very low'' genetic diversity. We used these expert opinions along with the N_e 500/1,000 ''rules of thumb'' to differentiate our ranking of moderate resiliency and low resiliency (Service 2023, pp. 41–42). We used research by University of West Alabama, which provided range-wide genetic diversity metrics and effective population size estimates for coal darter, in our assessment of current genetic health.

When determining the current condition of the coal darter, the extent of the current range in the context of the historical range was important to consider (see table 4, below). Impoundments constructed in the Black Warrior and Coosa Rivers in the late 1800s to the mid-1900s, converted mainstem areas once occupied by coal darters to unsuitable conditions, resulting in large-scale extirpation throughout the species' historical range. This was an important consideration for the species because coal darters are now restricted to smaller areas than they were previously, which has

implications for maximum attainable population size, access to suitable habitat, and the overall ability to move and disperse when conditions are unfavorable at certain locations, all of which are important needs of the species in order to successfully reproduce and maintain populations (Service 2023, p. 42).

To better assess coal darter resiliency, thresholds were standardized for each population by using a percentage of historical range in each river system to represent potential habitat for the species (see table 4, below). We determined that a population with high resiliency would have lost no more than one third of its historical range; a population with moderate resiliency would have lost between one third and two thirds of its historical range; and a population with low resiliency would have lost more than two thirds of its historical range.

The coal darter's sensitivity to habitat alterations from human activities were also used to assess resiliency. In order to describe the level of impairment and risk to natural aquatic habitats that arise from human activities, the Human Disturbance Gradient Index (HDGI) was used (see table 4, below). The HDGI considers a variety of landscape variables associated with disturbance to aquatic environments. Specifically, these variables include: human density (population count/kilometer of watershed), phosphorus load (kilograms/hectare/year), percent developed (percentage of the watershed that is developed), percent barren (percentage of the watershed that is barren due to human activities), percent pasture (percentage of the watershed that is pasture), percent crop (percentage of watershed that is used for row crops), road density (kilometers of roads/square kilometer of watershed), and road-stream crossings (number of road-stream crossings per kilometer of road). Each landscape variable is weighted by a factor known as the landscape development intensity (LDI) index, which ranges between 0 and 10, and relates land-use classifications with the intensity of nonrenewable energy consumption. An LDI of 0 corresponds to natural environments, and an LDI of 10 corresponds to highly developed urban environments. The sum of the weighted landscape variables calculated for each hydrologic unit code (HUC) 12 watershed in the range equates to the HDGI (Service 2023, pp. 42–43).

The final HDGI for each population of the coal darter was found by averaging the HDGI of its constituent HUC 12 watersheds. Stream reaches with HDGI values that exceed 200 were found to correspond to poor biological condition with low diversity of fish species, mostly inhabited by generalist species tolerant of habitat uneasiness (Service 2023, p. 43). Therefore, we expect the abundance and probability of coal darter presence to decline when HDGI scores approach and exceed 200. However, we acknowledge that landscape heterogeneity within the scale of a HUC 12 watershed may allow suitable environmental conditions to persist within an otherwise largely disturbed landscape. Further, based on our analysis, we are most confident that HDGI scores below 175 reflect good conditions and those above 300 reflect poor conditions. For these reasons, HDGI scores below 175 were classified as high condition or most suitable for the coal darter, with high probability of occurrence and high abundance; scores between 176 and 300 as moderate condition, with moderate probability of occurrence and moderate abundance; and scores greater than 300 as low condition, with the lowest probability of occurrence or very low abundance and posing the highest levels of risk to the species (Service 2023, pp. 42–43; see table 4, below).

Habitat quantity is another important metric to assess the current condition of the coal darter using HUC 12 watersheds as our units. The greater quantity of connected, suitable habitat available within a population, the greater the population resiliency. Resiliency was classified into one of three classes: High, Moderate, and Low. Thresholds for habitat quantity were established by enumerating extent of coal darter presence in the context of the historical range limits (see table 4, below).

TABLE 4—CONDITION CATEGORIES FOR DEMOGRAPHIC AND HABITAT PARAMETERS USED TO ASSESS COAL DARTER RESILIENCY

[Service 2023, p. 45]

Parameter	Condition category		
	High (3)	Moderate (2)	Low (1)
Genetic health	Genetic diversity considered ''moderate'' or ''high''; N_e exceeds the 500/1,000 ''rule of thumb'' threshold.	Genetic diversity considered ''low''; N_e exceeds the 500/1,000 ''rule of thumb'' threshold.	Genetic diversity considered ''very low''; N_e does not exceed the 500/1,000 ''rule of thumb'' threshold.
Percentage of historical range with current records.	Greater than 66 percent of historical range is currently occupied.	33–66 percent of historical range is currently occupied.	Less than 33 percent of historical range is currently occupied.
Human Disturbance Gradient Index (HDGI).	0–175	176–300	Greater than 300.
Habitat quantity	Greater than or equal to 8 currently occupied HUC 12 units.	4–7 currently occupied HUC 12 units	Fewer than 4 currently occupied HUC 12 units.

For each parameter, we assigned a score from 1 to 3 (1 = low, 2 = moderate, 3 = high) based on condition categories that we developed in coordination with species experts. For the overall resiliency of a population, scores were summed for all parameters. The minimum possible sum is 4 (a score of low for each of the four parameters), and the maximum possible sum is 12 (a score of high for each of the four parameters). We set thresholds for overall resiliency scores based on the minimum and maximum possible sums and the number of categories (3: high, moderate, low) (see table 5, below). The following discussion describes our reasoning for each parameter, the condition categories, and the methodology we used to derive an overall score for each factor.

TABLE 5—THRESHOLDS FOR OVERALL POPULATION RESILIENCY

[Service 2023, p. 45]

	Overall population resiliency		
	High	Moderate	Low
Parameter Score Sum	10–12	7–9	4–6

Resiliency

Black Warrior—The overall resiliency for the Black Warrior population is moderate (see table 6, below). Genetic diversity, as expressed by observed and expected heterozygosity and percent polymorphic loci, is considered low for this population by experts. Additionally, the effective population size is higher than the 500 or 1,000 ''rules of thumb'' threshold at 2,759 (range of 2,158–3,823) (Jones and Sandel 2019, pg. 5; Jones 2021, pg. 22). Due to the low genetic diversity but high effective population size (exceeding the 500/1,000 threshold), a score of moderate is assigned for genetic health of the Black Warrior population. The Black Warrior population has experienced a 50 percent reduction, at minimum, in occupied range due to the installation of impoundments in the late 1800s and early 1900s, resulting in a moderate score for the percentage of historical range with current records metric. The HDGI for the Black Warrior population is most heavily influenced by a combination of moderate amounts of development and urbanization in northern Jefferson County and more intensive livestock agriculture in the area. The averaged HDGI for currently occupied HUC 12 watersheds is 207, which results in a classification of moderate. With nine HUC 12 watersheds currently occupied, this population scores high for habitat quantity. However, despite the effects of these impacts, the Black Warrior population currently has an adequate effective population size and connectivity to support reproduction and recruitment.

Cahaba—The Cahaba River is considered the stronghold for the species, reflected by consistent catch records from the 1960s to present day. Trends in population numbers can be difficult to discern due to differences in sampling methods and purpose over the years, but there continues to be evidence of reproduction and recruitment. However, there is evidence that population numbers of the coal darter may be declining in the Cahaba River, especially in the upper portion of the watershed around the Birmingham metropolitan area. A comparison by experts of historical fish community records spanning from 1964–1983 to records obtained in 1994–1997 at 12 sites in the upper Cahaba River watershed in the Birmingham area indicated an overall decrease in fish species diversity, pointing to habitat degradation related to urbanization as the primary reason. Coal darters were found to have the greatest decline of all darter species, with 330 total specimens collected from historical samples (out of 46 samples) and only 6 collected from the same sites in the 1995–1997 samples (out of 48 samples). Along with coal darters, the study found disturbance-sensitive species, in general, to have decreased in percent relative abundance (Service 2023, p. 47).

The overall resiliency for the Cahaba population is moderate (see table 6, below). Genetic diversity of the Cahaba population is low, and the effective population size is higher than 500 or 1,000 ''rules of thumb'' threshold at 3,145 (range of 2,423–4,480) (Jones and Sandel 2019, pg. 5; Jones 2021, pg. 22). Due to the low genetic diversity but high effective population size (exceeding the 500/1,000 threshold), the Cahaba population scores moderate for genetic health (see table 6, below). The population genetic results indicate that the Cahaba population currently has a lower expected heterozygosity and percent polymorphic loci when compared to the Black Warrior population, yet a higher effective population size than the Black Warrior population (Service 2023, p. 46). One explanation for this could be a decrease in population size because of degraded water quality in the Cahaba River beginning in the early 1900s up to the enactment of the CWA (1972). A significant decrease in the number of individuals in this population would have resulted in a loss of genetic diversity. Because of their short generation time, coal darter numbers may have been able to rebound faster than it would take to increase genetic diversity since the latter would be dependent on the accumulation of novel mutations which would be expected to occur over thousands of years.

The Cahaba population has experienced the least reduction in range of the three populations. No major impoundments were constructed within the mainstem of the Cahaba River. However, a single low head dam located at Highway 280 currently prevents movement of coal darters upstream. While the species still occupies sites approximately 20 miles upstream of this dam, those individuals are isolated from downstream individuals and gene flow is likely unidirectional, creating a greater risk of further loss in genetic diversity in this portion of the river (Zarri et al. 2022, entire). To date, no range reduction of the species due to this dam has been observed. The Cahaba population scores high for the percentage of historical range with current records metric (see table 6, below).

The Cahaba River HDGI score is largely influenced by intense urbanization associated with the City of Birmingham and its suburbs. The averaged HDGI for currently occupied HUC 12 watersheds is 356 (Service 2023, p. 46), which results in a score of low for the Cahaba population (see table 6, below). Eight HUC 12 watersheds are currently occupied, which results in a score of high for habitat quantity (see table 6, below).

Coosa—The overall resiliency for the Coosa population is low (see table 6, below). Genetic diversity is considered very low for this population. Since Weogufka Creek discovered individuals in 2021 following the completion of the genetic analysis, only the Hatchet Creek population was used in the Coosa River system genetics results, The effective population size is above the ''rule of thumb'' threshold of 50 or 100 that is necessary to prevent deleterious effects of inbreeding depression and genetic drift. However, the effective population size is still considered low at 268 (range of 252–290) (Jones and Sandel 2019, pg. 5; Jones 2021, pg. 22) and is an order of magnitude lower than the other two populations. Furthermore, the effective population for Hatchet Creek falls in between the upper and lower bounds of the 50/500 and 100/1,000 rule thresholds, indicating that the population is at high risk of continual loss of genetic diversity. This low effective population size may also reflect the ongoing deleterious genetic effects of a population bottleneck or the

ongoing habitat limitations that prevent population sizes reaching those found in the other two populations or both (Franklin 1980, pp. 135–149; Frankham et al. 2014, pp. 56–63; Franklin et al. 2014, pp. 284–285). Based on the lower effective population size in Hatchet Creek coupled with the very low genetic diversity, the Coosa population results in a score of low for genetic health (see table 6, below).

The Coosa population has experienced the greatest range reduction of the three coal darter populations. With a 90 percent reduction in range compared to pre-impoundment historical condition, this population is assessed a score of low for the percentage of historical range with current records metric (see table 6, below).

The HDGI for the Lower Weogufka Creek HUC 12 had a value of 51.5, and the HDGI for the Lower Hatchet Creek HUC 12 had a value of 40.7 (Service 2023, p. 49). The averaged HDGI score for currently occupied HUC 12 watersheds is 46, which results in a score of high for the HDGI metric for this population (see table 6, below).

Regarding the habitat quantity metric for the Coosa population, only two HUC 12 watersheds are currently occupied: Lower Hatchet Creek and Lower Weogufka Creek. Within these two HUC 12 boundaries, the coal darter is only known from one site in Weogufka Creek and 14.5 rkm (9 rmi) of Hatchet Creek. Because of the low quantity of occupied habitat, this population scores low for the habitat quantity factor.

TABLE 6—CURRENT CONDITION RESILIENCY RESULTS BY POPULATION FOR THE COAL DARTER

[Service 2023, p. 50]

Factor	Population		
	Black Warrior	Cahaba	Coosa
Genetic health	Moderate (2)	Moderate (2)	Low (1).
Percentage of historical range with current records	50 percent: Moderate (2)	90 percent: High (3)	10 percent: Low (1).
Human Disturbance Gradient Index (HDGI)	207: Moderate (2)	356: Low (1)	46: High (3).
Habitat quantity	9: High (3)	8: High (3)	2: Low (1).
Overall resiliency	Moderate (9)	Moderate (9)	Low (6).

Representation

Representation is the ability of a species to adapt to both near-term and long-term changes in its physical and biological environment. The best available scientific information suggests using population genetic analyses to characterize the coal darter's current adaptive capacity. Due to the current isolation of coal darter populations, it is unlikely that gene flow exists among rivers (to increase genetic diversity), or that darter populations are able to shift to track suitable habitat conditions. Isolated coal darter populations must adapt to changing conditions in place, requiring sufficient genetic variation in order to respond to shifting selection pressures and any unexpected selection events, such as introduction of a novel disease or invasive species (Service 2023, p. 52).

The Cahaba River and Black Warrior populations meet the effective population size threshold ''rule of thumb'' of 500 or 1,000 to maintain evolutionary potential and adaptive capacity over time. By contrast, the Coosa population does not meet these effective population size thresholds for retaining adaptive potential. Coupled with its low genetic diversity, this population is at high risk of ongoing losses of standing genetic variation, lowering its capacity to respond to changing selection pressures.

We estimate that the coal darter has low adaptive capacity based on the poor genetic condition of the Coosa population; the low genetic diversity, yet sufficient effective population sizes, of the Black Warrior and Cahaba populations; and the lack of connectivity between populations. Overall representation for the coal darter is currently low.

Redundancy

Redundancy refers to the ability of a species to withstand catastrophic events and is measured by the amount and distribution of resilient populations across the species' range. Catastrophic events that could severely affect or extirpate entire coal darter populations include gas pipeline bursts and associated spills, changes in upstream land use that alter stream characteristics and water quality, and potential effects of climate change such as drought and increases in occurrence of flash-flooding events.

Redundancy is characterized by having multiple, resilient and representative populations of the coal darter distributed throughout the species' range. While there remain three populations distributed throughout the range and at a scale for which it would be unlikely for a single event to catastrophically affect all, one population (Coosa) has low resiliency to stochastic events and a higher risk of extirpation. The remaining two populations (Black Warrior and Cahaba) were found to be moderately resilient to stochastic events. Each population's reduced resiliency prevents them from fully contributing to a high level of redundancy; therefore, the coal darter currently exhibits a moderate level of redundancy.

Future Condition

A thorough review of the coal darter's future condition is presented in chapter 6 of the SSA report (version 1.1, Service 2023, pp. 54–58).

In our SSA report (version 1.1, Service 2023, entire), we define viability as the ability of the coal darter to sustain natural populations in river and stream systems over time. In our assessments of factors influencing viability and current condition, we found that disturbance on the landscape negatively affects the coal darter's ability to sustain natural populations and these disturbances can be attributed and measured by quantifying land use and cover types. To help address uncertainty associated with the degree and extent of potential future stressors and their impacts on the species' needs, the concepts of resiliency, redundancy, and representation were assessed using two scenarios and time stepped them at years 2040 and 2050. We devised these scenarios by identifying information on primary threat factors arising from increasing human populations and resulting alterations to the habitat. The four scenarios use the EPA's Integrated Climate and Land Use (ICLUS; version 2.1.1, EPA 2017) model, which uses human demography as a primary means to project local land-use changes in the future with consideration of climate change. It is consistent with updated global socioeconomic scenarios (shared

socioeconomic pathways (SSPs)) and global climate change model targets (representative concentration pathways (RCPs)). Using the ICLUS models, we projected the future resiliency of coal darter populations using two future scenarios that consider a range of impacts from future urbanization and land-use change along with climate change effects. Data from the ICLUS model was used to predict future HDGI scores, which can be compared with the HDGI scores of each population from our current condition analysis. While other stressors were identified as factors influencing viability, such as impoundments and genetic health, we were unable to model these factors into the future. However, these stressors are expected to continue to limit the species' viability into the future. Dams and impoundments are expected to constrain population extent, and genetic health is not expected to improve due to the long period of time required for mutations to occur that would improve genetic diversity (Service 2023, pp. 23–31).

We used the best available data and models to project changes in human disturbance under a high impact scenario and a moderate impact scenario at year 2040 and 2050 (20 and 30 years). This timeframe was reasonably certain to predict patterns of urbanization and agriculture, and how these land uses forecast patterns in the species' range relevant to the coal darter and its habitat given the species' short lifespan. In addition, catastrophic events (for example, invasive species, disease, and chemical spills) could have an immediate impact on the species, especially on the Coosa population due to its limited abundance and distribution.

Results of HDGI under the two future scenarios did not vary greatly between the two scenarios within each population (Black Warrior: 610 and 635; Cahaba: 636 and 661; Coosa: 77 and 141) (Service 2023, pp. 56–59). As stated above under *Current Condition,* HDGI scores below 175 are classified as high condition or most suitable for the coal darter, with high probability of occurrence and high abundance; scores of between 176 and 300 correspond to moderate condition, with moderate probability of occurrence and moderate abundance; and scores greater than 300 are classified as low condition, with the lowest probability of occurrence or very low abundance and posing the highest levels of risk to the species.

When compared to the current condition's HDGI, the Black Warrior and Cahaba populations' future HDGI scores nearly tripled and doubled, respectively. Therefore, aquatic habitats currently occupied by the coal darter will experience substantial levels of disturbance due to human urbanization activities, and the species' likelihood of presence and abundance will continue to decline. Furthermore, the habitat quantity will also decrease. Due to the significant projected increase in human disturbance within the Black Warrior and Cahaba populations, resiliency of each of these populations is projected to decrease from moderate to low under all future scenarios (Service 2023, p. 56).

While the future HDGI did not indicate poor habitat condition in the Coosa population, no habitat improvements are projected. The Coosa population of the coal darter is confined to small reaches of Hatchet and Weogufka creeks. These two tributaries of the Coosa River likely represent peripheral habitat that was sustained by now extirpated source populations in the Coosa River. As flow appears to be a predictor of species presence, population expansion in these streams is constrained by the lack of suitable flows and habitat in the upstream reaches. Further, given the natural state of these streams, it is unlikely density could increase. That is, the populations are likely at carrying capacity within these refugia. The Coosa population's poor genetic health is projected to decline without the influx of any new genetic material. Therefore, projected resiliency of the Coosa population remains low (Service 2023, p. 56).

The overall projected decline in resiliency decreases the Black Warrior and Cahaba populations' contribution to future redundancy. Therefore, catastrophic events that occur across the regional or State scale could cause extirpation in both populations. Furthermore, the current low resiliency in the Coosa population leaves it susceptible to extirpation, and with heavy land-use changes projected to occur on the landscape surrounding this population, this population is likely to be extirpated by the 2040 and 2050 time steps. For these reasons, the overall redundancy under all future scenarios is low.

We do not anticipate any improvement to the connectivity or adaptive capacity of the species. While our current condition assessment finds sufficient effective population size in the Black Warrior and Cahaba populations, the amount of habitat disturbance projected to occur, and probable range contraction, will reduce the effective population size and genetic diversity of these two populations. The overall representation for the coal darter under all future scenarios is assessed as low.

Determination of Coal Darter'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 an endangered species or a threatened species. The Act defines an ''endangered species'' as a species in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of 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.

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 coal darter. We considered whether the coal darter is presently in danger of extinction. Our review of the best available information indicates there are three populations across the known historical range in the Locust Fork of the Black Warrior River system, the Cahaba River system, and the Hatchet and Weogufka Creeks of the Coosa River system in Alabama. Genetic analysis indicates that the three populations were previously connected but are currently isolated and uniquely identifiable populations. Based on the coal darter's individual and population needs, an approach including two key habitat (Human Disturbance Gradient Index (HDGI) and habitat quantity) factors and two demographic (genetic health and persistence through time) factors was used to assess population resiliency with an assigned score of high, moderate, or low.

The current resiliency for both the Black Warrior and Cahaba populations is moderate. Impacts from habitat destruction and modification; the reduction of range as a result of impoundments (Black Warrior); and water quality degradation resulting from urbanization, mining, and agriculture (Factors A and E) appear to be affecting the coal darter at the population level

for these two resiliency units. Both also have low genetic diversity. The Black Warrior population has experienced at least a 50 percent reduction in occupied range due to the installation of impoundments in the late 1800s and early 1900s. However, despite the effects of these impacts, the Black Warrior and Cahaba populations currently have adequate effective population sizes and connectivity to support reproduction and recruitment. The Cahaba population has experienced the smallest range reduction (14 percent) of the three populations and has had no major impoundments constructed within the mainstem of the Cahaba River. It is considered the stronghold for the species.

The Coosa population has low resiliency due to habitat destruction and degradation resulting from dams and impoundments (Factors A and E). Only two HUC 12 watersheds are currently occupied in the Coosa population: Lower Hatchet Creek and Lower Weogufka Creek. Within these two HUC 12 boundaries, the coal darter is only known from one site in lower Weogufka Creek and 9 rmi (14.5 rkm) of lower Hatchet Creek. The genetic diversity is currently very low for this population (an order of magnitude lower than the other two populations), and its inadequate effective population size is vulnerable to the deleterious effects of inbreeding depression and genetic drift. This low effective population size may also reflect the ongoing harmful genetic effects of a population bottleneck or the ongoing habitat limitations that prevent population sizes reaching those found in the other two populations or both.

The species is currently extant in all three representation units, with two resiliency units (Black Warrior and Cahaba) having moderate resiliency. Both units with moderate resiliency contain effective populations sizes necessary for retaining adaptive potential. In contrast, the one unit (Coosa) with low resiliency does not meet the effective population size threshold for retaining adaptive potential. Coupled with low genetic diversity, the Coosa unit is currently at high risk of ongoing losses of standing genetic variation, lowering its capacity to respond to changing selection pressures.

The three populations are distributed across northern Alabama, and two of the three units across the range currently have moderate resiliency, which bolsters the species' ability to withstand catastrophic events. However, a catastrophic event (such as a chemical spill, change in upstream land use that alters stream characteristics and water quality, new impoundment, drought, or flash flood) could severely affect or extirpate coal darter populations such that the species is affected as a whole. This is exacerbated by one population (Coosa) having low resiliency to stochastic events and being at a higher risk of extirpation, while the remaining two populations (Black Warrior and Cahaba) have moderate resiliency to respond to stochastic events. Connectivity does not exist between any of the extant units. However, the species is not presently facing threats that place it at risk of extinction throughout all its range. Further, while multiple populations exist, each population's low or moderate resiliency contributes to a moderate level of redundancy for the species. Therefore, we find that the species does not meet the definition of an endangered species.

We forecasted the viability of the coal darter under four plausible scenarios into the future (summarized above under *Future Condition*). We assessed relevant risk factors that may be acting on the coal darter in the future and whether we could make reliable predictions about these factors and how they may impact the viability of the species. Since the main threats arise from increasing human populations and resultant alterations to the habitat, we used human demography as a means to project land-use changes in the future with consideration of climate change. We projected changes in human disturbance under two scenarios at year 2040 and 2050 (*i.e.,* 20 and 30 years). In considering the foreseeable future as it relates to the status of the coal darter, we considered the relevant risk factors (threats/stressors) acting on the species and whether we could draw reliable predictions about the species' response to these factors. Our analysis in the SSA report of future scenarios over an approximately 30-year timeframe encompasses the best available information for future projections of land-use change. We determined that this approximately 30-year timeframe enables us to consider the threats/stressors acting on the species and draw reliable predictions about the species' response to these factors. This 30-year timeframe allows multiple generations of the short-lived coal darter to respond to potential land-use changes.

Taking into account the primary factors influencing the species in the future (habitat destruction and degradation caused by land uses, and loss of connectivity between populations) and the potential impacts to the species' needs, we project a decline in resiliency for the coal darter throughout its range. The current low resiliency in the Coosa population leaves it vulnerable to extirpation, especially considering the major land-use changes expected to occur to this landscape, and this population is projected to remain in low condition. Furthermore, the Black Warrior and Cahaba populations are projected to decline in resiliency, as will their projected contribution to redundancy over the next 30 years. Therefore, potential catastrophic events occurring across the Southeast or in the State of Alabama could result in extirpation of any of the populations. Given the scenarios assessed, it is projected that aquatic habitats currently occupied by the coal darter will experience substantial levels of disturbance due to human activities, reducing the amount of habitat available to the species and corresponding to declines in the species' likelihood of presence and abundance. For these reasons, the overall projected redundancy for the coal darter under all future scenarios is low.

Future projections also indicate that the coal darter will continue to have low adaptive capacity (low representation) based on (1) the poor genetic condition of the Coosa population, if it remains extant in the future; (2) the low genetic diversity of the Black Warrior and Cahaba populations; and (3) the lack of connectivity between populations. Further, while the current condition assessment found sufficient effective population sizes in the Black Warrior and the Cahaba populations, the amount of habitat disturbance and range contractions that are projected to occur would likely reduce the effective population sizes and genetic diversity of these two populations. For these reasons, the overall projected representation for the coal darter under all future scenarios is low. From our future scenario assessment, we find that the coal darter will be at risk of extinction, and therefore is likely to become endangered, within the foreseeable future (*i.e.,* within the next 30 years) throughout all of its range.

Based on projected future threats, the coal darter will not have sufficient resiliency, redundancy, and representation to support species' viability. Overall, the future threats are projected to increase in magnitude and severity such that the coal darter is at risk of extinction throughout all of its range. Thus, after assessing the best available information, we conclude that the coal darter is likely to become in danger of extinction within the foreseeable future throughout all of its range.

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 within the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 435 F. Supp. 3d 69 (D.D.C. 2020) (*Everson*), vacated the provision 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'' (hereafter ''Final Policy''; 79 FR 37578, July 1, 2014) that provided if the Service determines that a species is threatened throughout all of its range, the Service will not analyze whether the species is endangered in a significant portion 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 *Everson,* 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 coal darter, 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 portions of the range where the species may be endangered.

We evaluated the range of the coal darter to determine if the species is in danger of extinction now in any portion of its range. The range of a species can theoretically be divided into portions in an infinite number of ways. We focused our analysis on portions of the species' range that may meet the definition of an endangered species. For the coal darter, we considered whether the threats or their effects on the species are greater in any biologically meaningful portion of the species' range than in other portions such that the species is in danger of extinction now in that portion.

The statutory difference between an endangered species and a threatened species is the timeframe in which the species becomes in danger of extinction; an endangered species is in danger of extinction now while a threatened species is not in danger of extinction now but is likely to become so within the foreseeable future. Thus, we considered the time horizon for the threats that are driving the coal darter to warrant listing as a threatened species throughout all of its range. We then considered whether these threats or their effects are occurring in any portion of the species' range such that the species is in danger of extinction now in that portion of its range. We examined the following threats: habitat degradation or loss stemming from hydrologic alteration by impoundments, including dams and other barriers; habitat degradation or loss stemming from urban development or change in land cover, including increased density of residential and commercial infrastructure; resource extraction, including mining and timber operations; agriculture, including poultry farming; and diminished water quality from point and nonpoint source chemical contamination and siltation, including cumulative effects.

We identified that the Coosa portion of the species' range is experiencing a concentration of the following threat at a biologically meaningful scale: habitat destruction and degradation from land uses and impoundments resulting in poor water quality (Factor A). Currently, the Coosa population unit has low resiliency, with only two HUC 12 watersheds currently occupied: Lower Hatchet Creek and Lower Weogufka Creek. This population unit has experienced the greatest range reduction (a loss of 90 percent of its historical range) of the three coal darter populations, and its low effective population size is an order of magnitude lower than the other two populations. Overall, the Coosa population lacks any adaptive potential, and it is likely that a single catastrophic event would result in the extirpation of the species from this portion. Based on this information, we conclude that the impacts are having a biologically meaningful effect on the Coosa population. Therefore, the best scientific and commercial information indicates that the Coosa population may have a different status than the other two populations in the species' range.

We then proceeded to consider whether this portion of the range (*i.e.,* the Coosa population) is significant. The Service's most recent definition of ''significant'' within agency policy guidance has been invalidated by court order (see *Desert Survivors* v. *U.S. Department of the Interior,* 321 F. Supp. 3d 1011, 1070–74 (N.D. Cal. 2018)). In undertaking this analysis for the coal darter, we considered whether the Coosa population portion of the species' range may be significant. Therefore, for the purposes of this analysis, when considering whether this portion is significant, we considered whether the portion may (1) occur in a unique habitat or ecoregion for the species; (2) contain high-quality or high-value habitat relative to the remaining portions of the range, for the species' continued viability in light of the existing threats; (3) contain habitat that is essential to a specific life-history function for the species and that is not found in the other portions (for example, the principal breeding ground for the species); or (4) contain a large geographic portion of the suitable habitat relative to the remaining portions of the range for the species.

Currently, the Coosa population represents a small portion (less than 5 percent based on current occurrences and occupied stream reaches) of the coal darter's range. In addition, this portion does not have any areas of habitat that are unique or that contain high-quality or high-value habitat relative to the remaining portions of the range. The Coosa population also does not contain habitat that is essential to a specific life-history function. Overall, we found no information that would indicate that the Coosa population constitutes a portion of the range that may be significant in terms of its geographic portion of suitable habitat, or that it is significant in terms of high-quality habitat or otherwise important for the species' life history.

The best scientific and commercial data available indicate that 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 does not conflict with the courts' holdings in *Desert Survivors* v. *U.S. Department of the Interior,* 321 F. Supp. 3d 1011, 1070–74 (N.D. Cal. 2018) and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d 946, 959 (D. Ariz. 2017) because, in reaching this conclusion, we did not apply the aspects of the Final Policy, including the definition of ''significant,'' that those court decisions held to be invalid.

Determination of Status

Our review of the best available scientific and commercial information

indicates that the coal darter meets the Act's definition of a threatened species. Therefore, we propose to list the coal darter 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 as a listed species, planning and implementation of 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, including the Service, 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 goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

The recovery planning process begins with development of a recovery outline made available to the public soon after a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions while a recovery plan is being developed. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) may be established to develop and implement recovery plans. The recovery planning process involves the identification of actions that are necessary to halt and reverse the species' decline by addressing the threats to its survival and recovery. The recovery plan 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. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery outline, draft recovery plan, final recovery plan, and any revisions will be available on our website as they are completed (*https://www.fws.gov/program/endangered-species*), or from our Alabama 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 ranges 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.

If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of Alabama would be eligible for Federal funds to implement management actions that promote the protection or recovery of the coal darter. Information on our grant programs that are available to aid species recovery can be found at: *https://www.fws.gov/service/financial-assistance.*

Although the coal darter is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7 of the Act is titled, ''Interagency Cooperation,'' and it mandates all Federal action agencies to use their existing authorities to further the conservation purposes of the Act and to ensure that their actions are not likely to jeopardize the continued existence of listed species or adversely modify critical habitat. Regulations implementing section 7 are codified at 50 CFR part 402.

Section 7(a)(2) states that each Federal action agency shall, in consultation with the Secretary, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Each Federal agency shall review its action at the earliest possible time to determine whether it may affect listed species or critical habitat. If a determination is made that the action may affect listed species or critical habitat, formal consultation is required (see 50 CFR 402.14(a)), unless the Service concurs in writing that the action is not likely to adversely affect listed species or critical habitat. At the end of a formal consultation, the Service issues a biological opinion, containing its determination of whether the Federal action is likely to result in jeopardy or adverse modification.

In contrast, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of critical habitat proposed to be designated for such species. Although the conference procedures are required only when an action is likely to result in jeopardy or adverse modification, action agencies may voluntarily confer with the Service on actions that may affect species proposed for listing or critical habitat proposed to be designated. In the event that the subject species is listed or the relevant critical habitat is designated, a conference opinion may be adopted as a biological opinion and serve as compliance with section 7(a)(2) of the Act.

Examples of discretionary actions for the coal darter that may be subject to conference and consultation procedures under section 7 of the Act are land management or other landscape-altering activities on Federal lands administered by the U.S. Department of Agriculture's U.S. Forest Service or Natural Resources Conservation Service, the U.S. Geological Survey, and the U.S. Army Corps of Engineers, as well as actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the CWA 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 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 funded, authorized, or carried out by a Federal agency—do not require section 7 consultation. Federal agencies should coordinate with the local Service Field Office (see **FOR FURTHER INFORMATION CONTACT**) with any specific questions on section 7 consultation and conference requirements.

It is the policy of the Service, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the extent known at the time a species is listed, specific activities that will not be considered likely to result in violation of section 9 of the Act. To the extent possible, activities that will be considered likely to result in violation will also be identified in as specific a manner as possible. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. Although most of the prohibitions in section 9 of the Act apply to endangered species, sections 9(a)(1)(G) and 9(a)(2)(E) of the Act prohibit the violation of any regulation, including a rule issued under section 4(d) of the Act pertaining to any threatened species of fish or wildlife, or threatened species of plant, respectively. Section 4(d) of the Act directs the Secretary to promulgate protective regulations that are necessary and advisable for the conservation of threatened species. As a result, we interpret our policy to mean that, when we list a species as a threatened species, to the extent possible, we identify activities that will or will not be considered likely to result in violation of the protective regulations under section 4(d) for that species.

At this time, we are unable to identify specific activities that will or will not be considered likely to result in violation of section 9 of the Act beyond what is already clear from the descriptions of prohibitions and exceptions we would establish by protective regulation under section 4(d) of the Act (see Provisions of the Proposed 4(d) Rule, below).

Questions regarding whether specific activities would constitute violation of section 9 of the Act should be directed to the Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

II. Proposed 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 species. The U.S. Supreme Court has noted that statutory language similar to the language in section 4(d) of the Act authorizing the Secretary to take action that she ''deems necessary and advisable'' affords a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592, 600 (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 one or more of 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, as a valid exercise of agency authority, rules developed under section 4(d) that included limited prohibitions against takings (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 WL 2344927 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 WL 511479 (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 [her] with regard to the permitted activities for those species. [She] may, for example, permit taking, but not importation of such species, 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).

The provisions of this proposed 4(d) rule would promote conservation of the coal darter by encouraging management of the landscape in ways that meet both watershed and riparian management purposes and facilitate the conservation of the species. The provisions of this proposed 4(d) rule are one of many tools that we would use to promote the conservation of the coal darter. This proposed 4(d) rule would apply only if and when we make final the listing of the coal darter as a threatened species.

As mentioned previously in Available Conservation Measures, section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, even before the listing of any species or the designation of its critical habitat is finalized, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of critical habitat proposed to be designated for such species.

These requirements are the same for a threatened species with a species-specific 4(d) rule. For example, as with an endangered species, if a Federal agency determines that an action is ''not likely to adversely affect'' a threatened species, it will require the Service's written concurrence (see 50 CFR 402.13(c)). Similarly, if a Federal agency determinates that an action is ''likely to adversely affect'' a threatened species, the action will require formal consultation with the Service and the formulation of a biological opinion (see 50 CFR 402.14(a)).

Provisions of the Proposed 4(d) Rule

Exercising the Secretary's authority under section 4(d) of the Act, we have developed a proposed rule that is designed to address the coal darter's conservation needs. As discussed previously under Summary of Biological Status and Threats, we have concluded that the darter is likely to become in danger of extinction within the foreseeable future primarily due to habitat loss or degradation from the following activities or conditions: hydrologic alteration by impoundments, including dams and other barriers;

agriculture (poultry farming); urban development or change in land cover, including increased density of residential and commercial infrastructure; resource extraction, including mining and silviculture operations that do not follow State-approved BMPs; diminished water quality from point and nonpoint source chemical contamination and sedimentation; and climate change. Section 4(d) requires the Secretary to issue such regulations as she deems necessary and advisable to provide for the conservation of each threatened species and authorizes the Secretary to include among those protective regulations any of the prohibitions that section 9(a)(1) of the Act prescribes for endangered species. We find that, if finalized, the protections, prohibitions, and exceptions in this proposed 4(d) rule as a whole satisfy the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the coal darter.

The protective regulations we are proposing for the coal darter incorporate prohibitions from section 9(a)(1) of the Act to address the threats to the species. Section 9(a)(1) prohibits the following activities for endangered wildlife: importing or exporting; take; possession and other acts with unlawfully taken specimens; delivering, receiving, carrying, 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. This protective regulation includes all of these prohibitions because the coal darter is at risk of extinction within the foreseeable future and putting these prohibitions in place would help to preserve the species' remaining populations and decrease synergistic, negative effects from other ongoing or future threats.

In particular, this proposed 4(d) rule would provide for the conservation of the coal darter by prohibiting the following activities, unless they fall within specific exceptions or are otherwise authorized or permitted: import or export; take; possession and other acts with unlawfully taken specimens; delivery, receipt, carriage, transport, or shipment in interstate or foreign commerce in the course of commercial activity; and sale or offer for sale in interstate or foreign commerce. We also include several exceptions to these prohibitions, which, along with the prohibitions, are set forth below.

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 regulations at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. Regulating take would help preserve the species' remaining populations and slow their rate of decline. Therefore, we propose to prohibit take of the coal darter, except for take resulting from those actions and activities specifically excepted by the 4(d) rule. Exceptions to the prohibition on take would include all of the general exceptions to the prohibition on take of endangered wildlife, as set forth in 50 CFR 17.21, and additional exceptions, as described below.

The proposed 4(d) rule would also provide for the conservation of the species by allowing exceptions that incentivize conservation actions or that, while they may have some minimal level of take of the coal darter, are not expected to rise to the level that would have a negative impact (*i.e.,* would have only de minimis impacts) on the species' conservation. The proposed exceptions to the prohibitions include: take incidental to any otherwise lawful activity caused by channel restoration; streambank restoration; habitat improvement activities; and silviculture and forestry activities that follow best management practices (described below). These are expected to have negligible impacts to the coal darter and its habitat.

Channel Restoration—Channel restoration is used as a technique to restore degraded, physically unstable streams back to natural, physically stable, ecologically functioning streams. When done correctly, these projects reduce, ameliorate, or fix unnatural erosion, head cutting, and/or sedimentation. Thus, channel restoration projects result in geomorphically stable stream channels that maintain the appropriate lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation and include stable riffle-run-pool complexes that consist of silt-free gravel, coarse sand, cobble, boulders, woody structure, and river weed (*Podostemum ceratophyllum*). This provision of the proposed 4(d) rule for channel restoration would promote conservation of the coal darter by excepting incidental take resulting from activities that would improve channel conditions and restore degraded, physically unstable streams or stream segments. We anticipate these activities will advance ecological conditions within a watershed to a more natural state that would benefit the coal darter.

Streambank Stabilization—Streambank stabilization is used as a habitat restoration technique to restore degraded and eroded streambanks back to natively vegetated, stable streambanks. When done correctly, these projects reduce bank erosion and instream sedimentation, resulting in improved habitat conditions for aquatic species. Therefore, we would allow streambanks to be stabilized using the following bioengineering methods: native live stakes (live, vegetative cuttings inserted or tamped into the ground in a manner that allows the stake to take root and grow), native live fascines (live branch cuttings, usually willows, bound together into long, cigar-shaped bundles), planting of bare-root seedlings or native brush layering (cuttings or branches of easily rooted tree species layered between successive lifts of soil fill). All methods should use plant species native to the region where the project is being conducted. These methods would not include the sole use of quarried rock (riprap) or the use of rock baskets or gabion structures, but quarried rock (riprap), rock baskets, or gabion structures could be used in conjunction with the allowed bioengineering methods described above. This provision of the proposed 4(d) rule would promote conservation of the coal darter by excepting from the prohibition on incidental take those streambank stabilization activities that would improve habitat conditions by reducing bank erosion and instream sedimentation.

Habitat Improvement Activities—Activities that improve watershed, riparian, or habitat conditions within the range of the coal darter would provide for the conservation of the species. Activities carried out under the Working Lands for Wildlife program of the Natural Resources Conservation Service, U.S. Department of Agriculture, or similar projects, which may include projects funded by the Service's Partners for Fish and Wildlife Program or the EPA's 319 grant program, would benefit the species if they do not alter habitats known to be used by the species beyond its tolerances and are implemented with a primary objective of improving environmental conditions to support the aquatic biodiversity of flowing water habitats. This provision of the proposed 4(d) rule would promote conservation of the coal darter by excepting from the prohibition on incidental take those activities described above that improve conditions for the species and that would likely increase resiliency in the

Black Warrior, Cahaba, and Coosa Rivers resiliency units.

Silviculture and Forestry Management Activities—Silviculture and forest management activities that use State-approved BMPs to protect water and sediment quality and stream and riparian habitat would provide for the conservation of the coal darter. Best management practices would have to be designed to reduce sedimentation, erosion, and bank destruction, thereby protecting instream habitat for the species. We recognize that silvicultural operations are widely implemented in accordance with State-approved BMPs (as reviewed by Cristan et al. 2018, entire), and the adherence to these BMPs broadly protects water quality, particularly related to sedimentation (as reviewed by Cristan et al. 2016, entire; Warrington et al. 2017, entire; Schilling et al. 2021, entire). This provision of the 4(d) rule would promote conservation of the coal darter by excepting from the prohibition on incidental take those silviculture and forest management activities that use State-approved BMPs because this exception would allow these activities to continue while protecting the coal darter's habitat.

Despite these prohibitions regarding threatened species, we may under certain circumstances issue permits to carry out one or more otherwise-prohibited activities, including those described above. The regulations that govern permits for threatened wildlife state that the Director may issue a permit authorizing any activity otherwise prohibited with regard to threatened species. These include permits 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 (50 CFR 17.32). The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

We recognize the 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 us in implementing all aspects of the Act. In this regard, section 6 of the Act provides that we must 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 us in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve coal darter that may result in otherwise prohibited take without additional authorization.

Nothing in this proposed 4(d) rule would 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 conservation partnerships for the management and protection of the coal darter. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service, where appropriate. We ask the public, particularly State agencies and other interested stakeholders that may be affected by the proposed 4(d) rule, to provide comments and suggestions regarding additional guidance and methods that the Service could provide or use, respectively, to streamline the implementation of this proposed 4(d) rule (see Information Requested, above).

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.

We have found critical habitat to be prudent and determinable for the coal darter and have developed a proposed critical habitat rule for this species. On October 25, 2023, we were informed that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) determined that our proposed critical habitat rule is significant under Executive Order 12866. Therefore, we will publish a proposed critical habitat rule for the coal darter following interagency review of the proposed critical habitat rule.

Required Determinations

Clarity of the Rule

We are required by E.O.s 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

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

(3) Use clear language rather than jargon;

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

(5) Use lists and tables wherever possible.

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

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

Regulations adopted pursuant to section 4(a) of the Act are exempt from the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and do not require an environmental analysis under NEPA. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This includes listing, delisting, and reclassification rules, as well as critical habitat designations and species-specific protective regulations promulgated concurrently with a decision to list or reclassify a species as threatened. The courts have upheld this position (*e.g., Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995) (critical habitat); *Center for Biological Diversity* v. *U.S. Fish and Wildlife Service,* 2005 WL 2000928 (N.D. Cal. Aug. 19, 2005) (concurrent 4(d) rule)).

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), E.O. 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 federally recognized Tribes on a government-to-government basis. In accordance with Secretary's 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 occupied range of the coal darter, so no Tribes would be affected by the listing of the species.

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 Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Alabama Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.11, amend paragraph (h) by adding an entry for ''Darter, coal'' to the List of Endangered and Threatened Wildlife in alphabetical order under FISHES to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	* * *
Fishes				
*	*	*	*	* * *
Darter, coal	*Percina brevicauda*.	Wherever found ..	T	[**Federal Register** citation when published as a final rule]; 50 CFR 17.44(ii).[4d]
*	*	*	*	* * *

■ 3. Amend § 17.44 by adding paragraph (ii) to read as follows:

§ 17.44 Special rules—fishes.

* * * * *

(ii) Coal darter (*Percina brevicauda*).

(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the coal darter. Except as provided under paragraph (ii)(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 wildlife, as set forth at § 17.21(d)(1) for endangered wildlife.

(iv) Interstate or foreign commerce in the course of 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 (c)(4) for endangered wildlife.

(iii) Take, as set forth at § 17.31(b).

(iv) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife.

(v) Take incidental to an otherwise lawful activity caused by:

(A) Channel restoration projects that create natural, physically stable, ecologically functioning streams. These projects can be accomplished using a variety of methods, but the desired outcome is a natural channel with geomorphically stable stream channels that maintain the appropriate lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation and include stable riffle-run-pool complexes that consist of silt-free gravel, coarse sand, cobble, boulders, woody structure, and river weed (*Podostemum ceratophyllum*).

(B) Streambank stabilization projects that use bioengineering methods to replace pre-existing, bare, eroding stream banks with natively vegetated, stable stream banks, thereby reducing bank erosion and instream sedimentation, and improving habitat conditions for the coal darter. Stream banks may be stabilized using native live stakes (live, vegetative cuttings inserted or tamped into the ground in a manner that allows the stake to take root and grow), native live fascines (live branch cuttings, usually willows, bound together into long, cigar-shaped bundles), planting of bare-root seedlings or native brush layering (cuttings or branches of easily rooted tree species layered between successive lifts of soil fill). Stream banks must not be stabilized solely through the use of quarried rock (riprap) or the use of rock baskets or gabion structures.

(C) Activities that improve the watershed, riparian, or habitat conditions for the coal darter within the range of the species. Activities carried out under the Working Lands for Wildlife program of the Natural Resources Conservation Service, U.S.

Department of Agriculture, or similar projects, which may include projects funded by the Service's Partners for Fish and Wildlife Program or the Environmental Protection Agency's 319 grant program, benefit the species if they do not alter habitats known to be used by the species beyond its tolerances and are implemented with a primary objective of improving environmental conditions to support the aquatic biodiversity of flowing water habitats.

(D) Silviculture and forest management activities that use State-approved best management practices to protect water and sediment quality and stream and riparian habitat. Best management practices must be designed to reduce sedimentation, erosion, and bank destruction, thereby protecting instream habitat for the coal darter.

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2023–27873 Filed 12–20–23; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 88, No. 244
Thursday, December 21, 2023

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

Agricultural Marketing Service

[Doc. No. AMS–CN–23–0072]

Notice of Request for an Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Marketing Service's (AMS) intention to request approval from the Office of Management and Budget for an extension of and revision to the currently approved information collection Cotton Classification and Market News Service.

DATES: Comments on this notice must be received by February 20, 2024 to be assured consideration.

ADDRESSES: Written comments may be submitted via mail or hand delivery to Cotton Research and Promotion, Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia, 22406. All comments received will be posted without change, including any personal information provided, at *https://www.regulations.gov* and will be included in the record and made available to the public. Please do not include personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Comments may be submitted anonymously. All comments received will be made available for public inspection at Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia, 22406. A copy of this document may be found at: *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Shethir M. Riva, Director, Research and Promotion, Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia, 22406, Telephone (540) 361–2726, Facsimile (540) 361–1199, or Email at *CottonRP@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Cotton Classification and Market News Service.

OMB Number: 0581–0009.

Expiration Date of Approval: March 31, 2024.

Type of Request: Extension and Revision of a Currently Approved Information Collection.

Abstract: The Cotton Classification and Market News Service program provides market information on cotton prices, quality, stocks, demand and supply to growers, ginners, merchandisers, textile mills and the public for their use in making sound business decisions. The Cotton Statistics and Estimates Act (7 U.S.C. 471–476), authorizes and directs the Secretary of Agriculture to: (a) Collect and publish annually, statistics or estimates concerning the grades and staple lengths of stocks of cotton, known as the carryover, on hand on the 1st of August each year in warehouses and other establishments of every character in the continental U.S., and following such publication each year, to publish at intervals, in his/her discretion, his/her estimate of the grades and staple length of cotton of the current crop (7 U.S.C. 471) and (b) Collect, authenticate, publish and distribute by radio, mail, or otherwise, timely information of the market supply, demand, location, and market prices of cotton (7 U.S.C. 473b). The Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627) authorizes and directs the Secretary of Agriculture to collect and disseminate marketing information, including adequate outlook information on a market-area basis, for the purpose of anticipating and meeting consumer requirements, aiding in the maintenance of farm income, and bringing about a balance between production and utilization of agricultural products.

The information collection requirements in this request are essential to carry out the intent of the Acts and to provide the cotton industry the type of information they need to make sound business decisions. The information collected is the minimum required. Information is requested from growers, cooperatives, merchants, manufacturers, and other government agencies. This includes information on cotton, cottonseed and cotton linters.

The information collected is used only by authorized employees of the USDA, AMS. The cotton industry is the primary user of the compiled information and AMS and other government agencies are secondary users.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.13 hours per response.

Respondents: Cotton Merchandisers, Textile Mills, Ginners.

Estimated Number of Respondents: 635.

Estimated Number of Responses per Respondent: 6.57.

Estimated Number of Responses: 4,175.

Estimated Total Annual Burden on Respondents: 540.

Comments are invited on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Shethir M. Riva, Director, Research and Promotion, Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia 22406, Telephone (540) 361–2726, Facsimile (540) 361–1199, or Email at *CottonRP@usda.gov.* 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.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2023–28074 Filed 12–20–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by January 22, 2024 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number, and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: APHIS Pest Reporting and Asian Longhorned Beetle Program.

OMB Control Number: 0579–0311.

Summary of Collection: Under the Plant Protection Act (7 U.S.C. 7701, *et seq.*), the Secretary of Agriculture is authorized to prohibit or restrict the importation, entry, or movement of plants and plant pests to prevent the introduction of plant pests into, or their dissemination within, the United States. Plant health regulations promulgated by the United States Department of Agriculture under this authority specifically address control programs for a number of pests and diseases of concern, including Asian longhorned beetle, emerald ash borer beetle, and citrus greening, to name a few. The Animal and Plant Health Inspection Service (APHIS) will collect information using a Plant Protection and Quarantine pest reporting form and Asian longhorned beetle unified survey form, and other information collection activities.

Need and Use of the Information: APHIS relies on the public to report sightings of plant pests or suspicious signs of pest or disease damage they may see in their local area. This reporting will be done through online forms for reporting pests, and additional information collection activities such as cooperative agreements for inspection; compliance training workshops; contracts for inspection; homeowner releases or refusals to inspect; homeowner chemical treatment releases; letters of warning of litigation and warrant; litigations and warrants; homeowner releases for tree removal; removals and monitoring; contracts for treatment; removals and disposals; disposal and marshalling yard activities; and certificate or permit cancellation appeals.

Failing to collect this information could result in APHIS not receiving information about where infestations may exist, causing them to linger unreported and grow. Infestations of high-consequence pests or diseases, such as Asian longhorned beetle, emerald ash borer beetle, citrus greening, and others, could lead to significant economic damage to crops, forests, and landscapes.

Description of Respondents: Individuals; Business or other for-profit; State, Local, and Tribal Governments.

Number of Respondents: 16,308.

Frequency of Responses: Recordkeeping: Reporting: On occasion.

Total Burden Hours: 85,999.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2023–28086 Filed 12–20–23; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–423–813]

Citric Acid and Certain Citrate Salts From Belgium: Final Results of the Sunset Review of the Antidumping Duty Order

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

SUMMARY: On September 22, 2023, the U.S. Department of Commerce (Commerce) issued the preliminary results of the first full five-year sunset review of the antidumping duty (AD) order on citric acid and certain citrate salts (citric acid) from Belgium. We received no comment from interested parties in opposition to our preliminary results. As a result of our analysis, Commerce finds that revocation of the AD order on citric acid from Belgium would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Deborah Cohen, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4521.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2023, Commerce published the initiation of the sunset review of the AD order on citric acid from Belgium [1] in the **Federal Register** pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] As Commerce received a substantive response from Citribel nv (Citribel),[3] which claimed interested party status under section 771(9)(A) of the Act as a foreign producer and foreign exporter of citric acid, Commerce notified the U.S. International Trade Commission (ITC) that it would conduct a full sunset review of the *Order* pursuant to 19 CFR 351.218(e)(2).[4]

On September 22, 2023, Commerce published the *Preliminary Results,* finding that dumping was likely to

[1] *See Citric Acid and Certain Citrate Salts from Belgium, Colombia and Thailand: Antidumping Duty Orders,* 83 FR 35214 (July 25, 2018) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 35832 (June 1, 2023).

[3] *See* Citribel's Letter, ''Citribel N.V.'s Substantive Response,'' dated July 3, 2023.

[4] *See* Commerce's Letter, ''Sunset Reviews Initiated on June 1, 2023,'' dated July 25, 2023.

continue or recur if the *Order* were revoked, and determined to the report to the ITC rates up to 19.30 percent as the margin of dumping likely to prevail.[5] We invited interested parties to comment on the *Preliminary Results*.[6] We received a case brief from Archer Daniels Midland Company, Cargill, Incorporated, and Primary Products Ingredients Americas LLC (collectively, the domestic interested parties), which notes their agreement with the preliminary determination that revocation of the *Order* would be likely to lead to continuation or recurrence of dumping, which they state was appropriately based on Commerce's finding that import volumes of the subject merchandise declined significantly after issuance of the *Order*.[7]

We received no further case or rebuttal briefs from interested parties; thus, the record reflects no opposition to the *Preliminary Results* nor presents substantive issues which require further consideration. Accordingly, the final results remain unchanged from the *Preliminary Results.*

Scope of the Order

The merchandise covered by this *Order* includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. For a full description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of dumping at a weighted-average dumping margin up to 19.30 percent.

As noted above, Commerce received no comments in opposition to its *Preliminary Results.* As a result, we have not modified our analysis, and no issues and decision memorandum accompanies this **Federal Register** notice. We are adopting the *Preliminary Results* as the final results.

Administrative Protective Order

This notice also serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This five-year sunset review and notice are in accordance with sections 751(c)(5)(A), 752(c), and 777(i) of the Act and 19 CFR 351.218(f)(3).

Dated: December 15, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–28138 Filed 12–20–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–823–815]

Oil Country Tubular Goods From Ukraine: Final Results of Antidumping Duty Administrative Review; 2021–2022

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that oil country tubular goods (OCTG) from Ukraine were sold at prices below normal value during the period of review (POR) July 1, 2021, through June 30, 2022.

DATES: Applicable December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Toni Page, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1398.

SUPPLEMENTARY INFORMATION:

Background

On August 3, 2023, Commerce published the *Preliminary Results* of this administrative review.[1] Interpipe,[2] the sole mandatory respondent, and the domestic interested party Vallourec Star, L.P. (Vallourec), each submitted comments on the *Preliminary Results*.[3] For a description of the events since the *Preliminary Results,* as well as a full discussion of the issues raised by parties for these final results, *see* the Issues and Decision Memorandum.[4] Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [5]

The products covered by the *Order* are OCTG from Ukraine. For a full description of the scope, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in Interpipe's case brief and Vallourec's letter in lieu of rebuttal brief are addressed in the Issues and Decision Memorandum. A list of these issues 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 Review

We have calculated the following estimated weighted-average dumping

[5] *See Citric Acid and Certain Citrate Salts from Belgium: Preliminary Results of the Sunset Review of the Antidumping Duty Order,* 88 FR 65365 (September 22, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[6] *Id.,* 88 FR at 65366.

[7] *See* Domestic Interested Parties' Letter, ''Domestic Industry's Case Brief,'' dated October 23, 2023. The domestic interested parties note that, should the final results of the 2021–2022 administrative review of the *Order* be finalized prior to the instant sunset final results, the affirmative decision that revocation would likely lead to the continuance of dumping could be additionally supported with a finding that dumping continued after issuance of the *Order.* However, because the final results of the 2021–2022 administrative review have not yet been issued at the time of signature of this notice, we continue to decline to consider the unfinalized dumping margins of the ongoing 2021–2022 administrative review for the purposes of the instant determination.

[1] *See Oil Country Tubular Goods from Ukraine: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022,* 88 FR 51289 (August 3, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] Commerce has previously determined that Interpipe Europe S.A.; Interpipe Ukraine LLC; PJSC Interpipe Niznedneprovsky Tube Rolling Plant; and LLC Interpipe Niko Tube are affiliated and treated as a single entity (*i.e.,* Interpipe). *See Preliminary Results* PDM at ''Summary.''

[3] *See* Interpipe's Letter, ''Case Brief for Interpipe,'' dated September 5, 2023; *see also* Vallourec's Letter, ''Letter in Lieu of Rebuttal Brief,'' dated September 11, 2023.

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review: Oil Country Tubular Goods from Ukraine, 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[5] *See Termination of the Suspension Agreement on Certain Oil Country Tubular Goods from Ukraine, Rescission of Administrative Review, and Issuance of Antidumping Duty Order,* 84 FR 33918 (July 16, 2019) (*Order*).

margin for Interpipe for the POR, July 1, 2021, through June 30, 2022:

Exporter or producer	Weighted-average dumping margin (percent)
Interpipe Europe S.A./Interpipe Ukraine LLC/PJSC Interpipe Niznedneprovsky Tube Rolling Plant/LLC Interpipe Niko Tube	4.89

Disclosure

Normally, Commerce will disclose the calculations performed in connection with the final results of a review to interested parties within five days of the date of publication of the notice of final results in the **Federal Register**.[6] However, because Commerce made no change to the preliminary weighted-average dumping margin calculation for Interpipe, there are no calculations to disclose.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with these final results of review.[7] For Interpipe, we will calculate importer-specific assessment rates on the basis of the ratio of the total amount of antidumping duties calculated for each importer's examined sales and the total entered value of the sales, in accordance with 19 CFR 351.212(b)(1). Where an importer-specific *ad valorem* assessment rate is not zero or *de minimis,* Commerce will instruct CBP to collect the appropriate duties at the time of liquidation.

Consistent with Commerce's assessment practice, for entries of subject merchandise during the POR produced by Interpipe for which it did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[8]

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 for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Interpipe will be equal to the weighted-average dumping margin established in these final results; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review or in a prior segment of the proceeding, but the producer was covered, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 7.47 percent established in the less-than-fair-value investigation.[9]

These cash deposit requirements, 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)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), 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 the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

Dated: December 14, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of the Issue
Comment: Whether to Grant Interpipe a Constructed Export Price Offset
V. Recommendation

[FR Doc. 2023–28036 Filed 12–20–23; 8:45 am]
BILLING CODE 3510–DS–P

[6] *See* 19 CFR 351.224(b).

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

[8] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[9] *See Order,* 84 FR at 33919.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–837]

Polyethylene Terephthalate Film, Sheet, and Strip From Taiwan: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2021–2022

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Nan Ya Plastics Corporation (Nan Ya) made no sales of subject merchandise to the United States at less than normal value during the period of review (POR) July 1, 2021, through June 30, 2022. We also continue to find that Shinkong Materials Technology Corporation (SMTC)/Shinkong Synthetic Fibers Corporation (SSFC) had no shipments of subject merchandise to the United States during the POR.

DATES: Applicable December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Charles DeFilippo, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3797.

SUPPLEMENTARY INFORMATION:

Background

On June 26, 2023, Commerce published the *Preliminary Results* and invited interested parties to comment.[1] This review covers two respondents: Nan Ya Plastics Corporation (Nan Ya); and Shinkong Materials Technology Corporation (SMTC)/Shinkong Synthetic Fibers Corporation (SSFC). On July 26, 2023, we received a case brief from DuPont Teijin Films, Mitsubishi Chemical America, Inc.—Polyester Film Division, and SK Microworks America, Inc. (collectively, the petitioners).[2] On August 2, 2023, we received a rebuttal brief from Nan Ya.[3] On October 23, 2023, we extended the deadline for these final results to December 14, 2023.[4] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[5]

Scope of the Order[6]

The products covered by this *Order* are polyethylene terephthalate film, sheet, and strip (PET film) from Taiwan. For a full description of the scope of the *Order, see* the Issues and Decision Memorandum.

Analysis of Comments Received

We address the issue raised in the case and rebuttal briefs in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is included in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *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 Determination of No Shipments

In the *Preliminary Results,* Commerce determined that SMTC and its affiliate SSFC had no shipments of PET film during the POR, based on a response of the U.S. Customs and Border Protection (CBP) to Commerce's no-shipment inquiry, as well as certifications and supporting documentation provided by SMTC/SSFC.[7] We received no comments from any interested party on our preliminary finding. As there is no information on the record that calls into question the finding in the *Preliminary Results,* we continue to find in the final results of this review that SMTC/SSFC had no shipments of subject merchandise during the POR.

Final Results of Review

As a result of this review, Commerce determines that the following weighted-average dumping margin exists for the period July 1, 2021, through June 30, 2022:

Producer/exporter	Weighted-average dumping margin (percent)
Nan Ya Plastics Corporation	0.00

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in connection with these final results of review to interested parties within five days after public announcement of the final results or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2) of the Act and 19 CFR 351.212(b)(1), Commerce has determined, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. Because we calculated a zero percent margin in the final results of this review for Nan Ya, in accordance with 19 CFR 351.212 we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. In addition, as Commerce continues to find that SMTC/SSFC did not have any shipments of subject merchandise during the POR, we will instruct CBP to liquidate any suspended entries of subject merchandise associated with SMTC/SSFC at the all-others rate.

Commerce intends to issue appropriate assessment instructions directly to CBP no earlier than 35 days after the date of publication of the final results of this administrative 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 administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Nan Ya will be zero, the rate established in the final results of this review; (2) for previously reviewed or investigated companies not covered in this review, the cash deposit rate will continue to be the company specific rate published for the most recent period; (3) if the exporter is not a firm covered in this or any previous review or in the original less-than-fair-value (LTFV) investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous review or the LTFV investigation, the cash deposit rate will continue to be the all-others rate of 2.40 percent, which is the all-others rate established by Commerce in the LTFV investigation.[8] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties

[1] *See Polyethylene Terephthalate Film, Sheet, and Strip From Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2021–2022,* 88 FR 41378 (June 26, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Petitioners' Letter, ''Petitioners' Case Brief,'' dated July 26, 2023 (Petitioners' Case Brief).

[3] *See* Nan Ya's Letter, ''Polyethylene Terephthalate (PET) Film from Taiwan,'' dated August 2, 2023 (Nan Ya's Rebuttal Brief).

[4] *See* Memorandum, ''Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated October 23, 2023.

[5] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[6] *See Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan,* 67 FR 44174 (July 1, 2002) (*Order*).

[7] For a full discussion of this determination, *see Preliminary Results* PDM.

[8] *See Order.*

occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

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(a)(3), 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 the terms of an APO is a sanctionable violation.

Notification to Interested Parties

These results are being issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h).

Dated: December 14, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of the Issue
Comment: Whether to Rely on Facts Available and Apply an Adverse Inference Regarding Nan Ya's Cost Reporting
V. Recommendation

[FR Doc. 2023–28027 Filed 12–20–23; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–148]

Gas Powered Pressure Washers From the People's Republic of China: Final Affirmative Determination of Sales at Less-Than-Fair Value, and Final Affirmative Critical Circumstances Determinations, in Part

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that gas powered pressure washers (pressure washers) from the People's Republic of China (China) are being, or are likely to be, sold in the United States at less-than-fair value (LTFV). The period of investigation is April 1, 2022, though September 30, 2022.

DATES: Applicable December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Hermes Pinilla, AD/CVD Operations, Office I, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3477.

SUPPLEMENTARY INFORMATION:

Background

On August 3, 2023, Commerce published in the **Federal Register** the *Preliminary Determination* in this LTFV investigation.[1] Commerce invited parties to comment on the *Preliminary Determination*.[2]

For a complete description of the events that occurred since the *Preliminary Determination, see* the Issues and Decision Memorandum.[3] The Issues and Decision Memorandum is a public document and is made available to the public 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 complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The products covered by this investigation are pressure washers from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

During this LTFV investigation, Commerce received scope comments from interested parties. Commerce issued a Preliminary Scope Memorandum to address the comments and set aside a period of time for parties to address scope issues in scope-specific case and rebuttal briefs.[4] We received comments from interested parties on the Preliminary Scope Memorandum, which we addressed in the Final Scope Memorandum.[5] We did not make any changes to the scope of the investigation from the scope published in the *Preliminary Determination,* as provided in Appendix I.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum and are listed in Appendix II of this notice.

Final Affirmative Determination of Critical Circumstances

For the *Preliminary Determination,* in accordance with section 733(e)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.206(c)(1), Commerce preliminarily found that critical circumstances exist with respect to imports of pressure washers exported by Jiangu Jianghuai Engine Co., Ltd. (JD Power) and the China-wide entity.[6]

No parties submitted comments regarding this finding. Thus, our determination of critical circumstances is unchanged for the final determination. Accordingly, pursuant to section 735(a)(3)(B) of the Act and 19 CFR 351.206, we continue to find that critical circumstances exist for JD Power and the China-wide entity.

Regarding the companies receiving a separate rate, we preliminarily found that critical circumstances do not exist.[7] For the final determination, we continue to find that the variance of shipments between the base and comparison period is explained by seasonal trends and, therefore, consistent with our practice,[8] we continue to find that critical circumstances do not exist regarding the separate rate companies.

Verification

Commerce was unable to conduct an on-site verification of the information relied upon in making its final determination. However, from August 20 through 22, 2023, we took additional steps, in lieu of an on-site verification to verify the information relied upon in

[1] *See Gas Powered Pressure Washers from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Critical Circumstances Determination, in Part, Postponement of Final Determination, and Extension of Provisional Measures,* 88 FR 51279 (August 3, 2023) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *Id.*

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination of Sales at Less-Than-Fair-Value and Final Affirmative Critical Circumstances Determinations, in Part: Gas Powered Pressure Washers from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See* Memorandum, ''Preliminary Scope Decision Memorandum,'' dated June 8, 2023 (Preliminary Scope Memorandum).

[5] *See* Memorandum, ''Final Scope Decision Memorandum,'' dated August 22, 2023.

[6] *See Preliminary Determination.*

[7] *Id.*

[8] *See Pentaflouroethane (R–125) from the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances, in Part,* 87 FR 1117 (January 10, 2022), and accompanying IDM at Comment 1.

making this final determination, in accordance with section 782(i) of the Act,[9] by conducting virtual verification of JP Power.

Separate Rates

For the final determination, we continue to find that JD Power, Sumec Hardware and Tools Co., Ltd., and Zhejiang Danau Machine Co., Ltd., are eligible for separate rates. Generally, Commerce looks to section 735(c)(5)(A) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate rate respondents which we did not individually examine. The statute further provides that, where all margins are zero, *de minimis,* or based entirely on facts available under section 776 of the Act, Commerce may use ''any reasonable method'' for assigning the rate to non-selected respondents.[10] As explained further below, for the final determination, we based JD Power's dumping margin on total adverse facts available (AFA). Because there is only one dumping margin, and it is based entirely on facts available, Commerce has assigned, as any reasonable method, an average of the range of dumping margins in the Petition to the separate rate companies for this final determination.[11] This approach is consistent with our practice.[12]

Combination Rates

In the *Initiation Notice,*[13] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. For the list of respondents that established eligibility for separate rates and the exporter/producer combination rates applicable to these respondents, *see* the Final Determination section.

China-Wide Entity and Use of AFA

For the purposes of this final determination, consistent with the *Preliminary Determination,*[14] we relied solely on the application of AFA for the China-wide entity, pursuant to sections 776(a) and (b) of the Act. In selecting the AFA rate for the China-wide entity, Commerce's practice is to select a rate that is sufficiently adverse to ensure that the uncooperative party does not obtain a more favorable result by failing to cooperate than if it had fully cooperated.[15] A detailed discussion of our application of AFA is provided in the *Preliminary Determination.*[16]

As discussed in the Issues and Decision Memorandum, we determined that total AFA is warranted regarding JD Power, and thus, for purposes of this final determination, we have applied a dumping margin rate of 274.37, which represents the highest individual dumping margin calculated for a mandatory respondent in this investigation and is the same rate applied to the China-wide entity. Because this constitutes primary information from the normal course of the investigation, the statutory corroboration requirement in section 776(c) of the Act does not apply.

Final Determination

Commerce determines that the following estimated weighted-average dumping margins exist for the period April 1, 2022, through September 30, 2022:

Exporter	Producer	Estimated weighted-average dumping ≤margin (percent)
Jiangsu Jianghuai Engine Co., Ltd	Jiangsu Jianghuai Engine Co., Ltd	274.37
Sumec Hardware and Tools Co., Ltd	Sumec Hardware and Tools Co., Ltd	189.52
Zhejiang Danau Machine Co., Ltd	Zhejiang Danau Machine Co., Ltd	189.52
China-Wide Entity		274.37

Disclosure

Normally, Commerce will disclose to the parties in a proceeding the calculations performed in connection with a final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). Because we applied total AFA to JD Power and the China-wide entity in accordance with 776 of the Act, which was based on our antidumping duty calculation from the *Preliminary Determination,* there are no calculations to disclose for this final determination. However, we intend to disclose to interested parties the calculations and analysis performed in this final determination for critical circumstances within five days of any public announcement or, if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**.

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination* and in accordance with section 735(c)(1)(B) of the Act, for JD Power and the China-wide entity, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption, on or after May 5, 2023, which is 90 days prior to the date of the date of publication of the

[9] *See* Memorandum, ''Verification of Jiangu Jianghuai Engine Co., Ltd,'' dated September 13, 2023.

[10] *See* section 735(c)(5)(B) of the Act.

[11] *See* Petitioner's Letter, ''Petition for the Imposition of Antidumping and Countervailing Duties,'' dated December 29, 2022 (the Petition); *see also* Initiation Checklist, ''Gas Powered Pressure Washers from the People's Republic of China,'' dated January 19, 2023, at 8.

[12] *See Polyester Textured Yarn from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures,* 84 FR 31297 (July 1, 2019), and accompanying PDM at 12, unchanged in *Polyester Textured Yarn from the People's Republic of China: Final Determination of Sales at Less Than Fair Value, and Final Affirmative Determination of Critical Circumstances,* 84 FR 63850 (November 19, 2019).

[13] *See Gas Powered Pressure Washers from the People's Republic of China and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations,* 88 FR 4807, 4811 (January 25, 2023) (*Initiation Notice*).

[14] *See Preliminary Determination* PDM at 18.

[15] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Purified Carboxymethyl Cellulose from Finland,* 69 FR 77216 (December 27, 2004), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Purified Carboxymethyl Cellulose from Finland,* 70 FR 28279 (May 17, 2005).

[16] *See Preliminary Determination* PDM at 18–19.

affirmative *Preliminary Determination* in the **Federal Register**, at the cash deposit rate indicated above.

For the separate rate companies, we will instruct CBP to continue to suspend liquidation of subject merchandise, entered, or withdrawn from warehouse, for consumption, on or after August 3, 2023, which is the date of publication of the affirmative *Preliminary Determination* in the **Federal Register**, at the cash deposit rate indicated in the above table.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), we will instruct CBP to require a cash deposit for such entries of merchandise equal to the amount by which the normal value exceeds the U.S. price as follows: (1) the cash deposit rate for the exporter/producer combination listed in the table above will be the rate identified in the table; (2) for all combinations of Chinese producers/exporters of subject merchandise that have not established eligibility for their own separate rates, the cash deposit rate will be the rate established for the China-wide entity; and (3) for all third country exporters of subject merchandise, the cash deposit rate will be the cash deposit rate applicable to the Chinese producer/exporter that supplied that third country exporter.

U.S. International Trade Commission (ITC) Notification

In accordance with section 735(d) of the Act, we will notify the ITC of our affirmative determination of sales at LTFV. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without consent of the Assistant Secretary for Enforcement and Compliance.

Because the final determination in this proceeding is affirmative, in accordance with section 735(b) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of gas pressure washers from China no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated, and all cash deposits will be refunded or canceled, as Commerce determines to be appropriate.

If the ITC determines that such injury does exist, Commerce intends to issue an antidumping duty order, in accordance with section 736(a) of the Act, directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Notification Regarding APO

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanctions.

Notification to Interested Parties

This determination is issued and published in pursuant with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 18, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is cold water gas powered pressure washers (also commonly known as power washers), which are machines that clean surfaces using water pressure that are powered by an internal combustion engine, air-cooled with a power take-off shaft, in combination with a positive displacement pump. This combination of components (*i.e.,* the internal combustion engine, the power take-off shaft, and the positive displacement pump) is defined as the ''power unit.'' The scope of the investigation covers cold water gas powered pressure washers, whether finished or unfinished, whether assembled or unassembled, and whether or not containing any additional parts or accessories to assist in the function of the ''power unit,'' including, but not limited to, spray guns, hoses, lances, and nozzles. The scope of the investigation covers cold water gas powered pressure washers, whether or not assembled or packaged with a frame, cart, or trolley, with or without wheels attached.

For purposes of this investigation, an unfinished and/or unassembled cold water gas powered pressure washer consists of, at a minimum, the power unit or components of the power unit, packaged or imported together. Importation of the power unit whether or not accompanied by, or attached to, additional components including, but not limited to a frame, spray guns, hoses, lances, and nozzles constitutes an unfinished cold water gas powered pressure washer for purposes of this scope. The inclusion in a third country of any components other than the power unit does not remove the cold water gas powered pressure washer from the scope. A cold water gas powered pressure washer is within the scope of this investigation regardless of the origin of its engine. Subject merchandise also includes finished and unfinished cold water gas powered pressure washers that are further processed in a third country or in the United States, including, but not limited to, assembly or any other processing that would not otherwise remove the merchandise from the scope of this investigation if performed in the country of manufacture of the in-scope cold water gas powered pressure washers.

The scope excludes hot water gas powered pressure washers, which are pressure washers that include a heating element used to heat the water sprayed from the machine.

Also specifically excluded from the scope of this investigation is merchandise covered by the scope of the antidumping and countervailing duty orders on certain vertical shaft engines between 99cc and up to 225cc, and parts thereof from the People's Republic of China. *See Certain Vertical Shaft Engines Between 99 cc and Up to 225cc, and Parts Thereof from the People's Republic of China: Antidumping and Countervailing Duty Orders,* 86 FR 023675 (May 4, 2021).

The cold water gas powered pressure washers subject to this investigation are classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings 8424.30.9000 and 8424.90.9040. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Affirmative Determination of Critical Circumstances
IV. Changes Since the *Preliminary Determination*
V. Application of Facts Available and Adverse Inferences
VI. Discussion of the Issues
  Comment 1: Whether Commerce Incorrectly Ended Its Verification of JD Power
  Comment 2: Arguments Regarding Calculations
VII. Recommendation

[FR Doc. 2023–28137 Filed 12–20–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket Number: 231218–0309]

RIN: 0693–XC135

Request for Information (RFI) Related to NIST's Assignments Under Sections 4.1, 4.5 and 11 of the Executive Order Concerning Artificial Intelligence (Sections 4.1, 4.5, and 11)

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice; request for Information.

SUMMARY: The National Institute of Standards and Technology (NIST) is seeking information to assist in carrying out several of its responsibilities under the Executive order on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence issued on October 30, 2023. Among other things, the E.O. directs NIST to undertake an initiative for evaluating and auditing capabilities relating to Artificial Intelligence (AI) technologies and to develop a variety of guidelines, including for conducting AI red-teaming tests to enable deployment of safe, secure, and trustworthy systems.

DATES: Comments containing information in response to this notice must be received on or before February 2, 2024. Submissions received after that date may not be considered.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic submission: Submit electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov* and enter NIST–2023–0309 in the search field,

2. Click the ''Comment Now!'' icon, complete the required fields, and

3. Enter or attach your comments.

Electronic submissions may also be sent as an attachment to *ai-inquiries@nist.gov* and may be in any of the following unlocked formats: HTML; ASCII; Word; RTF; Unicode, or .pdf.

Written comments may also be submitted by mail to Information Technology Laboratory, ATTN: AI E.O. RFI Comments, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8900, Gaithersburg, MD 20899–8900.

Response to this RFI is voluntary. Submissions must not exceed 25 pages (when printed) in 12-point or larger font, with a page number provided on each page. Please include your name, organization's name (if any), and cite ''NIST AI Executive order'' in all correspondence.

Comments containing references, studies, research, and other empirical data that are not widely published should include copies of the referenced materials. All comments and submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Relevant comments will generally be available on the Federal eRulemaking Portal at *www.regulations.gov.* After the comment period closes, relevant comments will generally be available on *https://www.nist.gov/artificial-intelligence/executive-order-safe-secure-and-trustworthy-artificial-intelligence.* NIST will not accept comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. Therefore, do not submit confidential business information or otherwise sensitive, protected, or personal information, such as account numbers, Social Security numbers, or names of other individuals.

FOR FURTHER INFORMATION CONTACT: For questions about this RFI contact: *ai-inquiries@nist.gov* or Rachel Trello, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8900, Gaithersburg, MD 20899, (202) 570–3978. Direct media inquiries to NIST's Office of Public Affairs at (301) 975–2762. Users of telecommunication devices for the deaf, or a text telephone, may call the Federal Relay Service toll free at 1–800–877–8339.

Accessible Format: NIST will make the RFI available in alternate formats, such as Braille or large print, upon request by persons with disabilities.

SUPPLEMENTARY INFORMATION: NIST is responsible for contributing to several deliverables assigned to the Secretary of Commerce. Among those is a report identifying existing standards, tools, methods, and practices, as well as the potential development of further science-backed and non-proprietary standards and techniques, related to synthetic content, including potentially harmful content, such as child sexual abuse material and non-consensual intimate imagery of actual adults. NIST will also assist the Secretary of Commerce to establish a plan for global engagement to promote and develop AI standards.

Respondents may provide information on one or more of the topics in this RFI and may elect not to address every topic.

NIST is seeking information to assist in carrying out several of its responsibilities under Sections 4.1, 4.5, and 11 of E.O. 14110. This RFI addresses the specific assignments cited below. Other assignments to NIST in E.O. 14110 related to cybersecurity and privacy, synthetic nucleic acid sequencing, and supporting agencies' implementation of minimum risk-management practices are being addressed separately. Information about NIST's assignments and plans under E.O. 14110, along with further opportunities for public input, may be found here: *https://www.nist.gov/artificial-intelligence/executive-order-safe-secure-and-trustworthy-artificial-intelligence.*

In considering information for submission to NIST, respondents are encouraged to review recent guidance documents that NIST has developed with significant public input and feedback, including the NIST AI Risk Management Framework (*https://www.nist.gov/itl/ai-risk-management-framework*). Other NIST AI resources may be found on the NIST AI Resource Center (*https://airc.nist.gov/home*). In addition, respondents are encouraged to take into consideration the activities of the NIST Generative AI Public Working Group (*https://airc.nist.gov/generative_ai_wg*).

Information that is specific and actionable is of special interest, versus general statements about the challenges and needs. Copyright protections of materials, if any, should be clearly noted. Responses which include information generated by means of AI techniques should be identified clearly.

NIST is interested in receiving information pertinent to any or all of the assignments described below.

1. Developing Guidelines, Standards, and Best Practices for AI Safety and Security

NIST is seeking information regarding topics related to generative AI risk management, AI evaluation, and red-teaming.

a. E.O. 14110 Sections 4.1(a)(i)(A) and (C) direct NIST to establish guidelines and best practices in order to promote consensus industry standards in the development and deployment of safe, secure, and trustworthy AI systems. Accordingly, NIST is seeking information regarding topics related to this assignment, including:

(1) Developing a companion resource to the AI Risk Management Framework (AI RMF), NIST AI 100–1 (*https://www.nist.gov/itl/ai-risk-management-framework*), for generative AI. Following is a non-exhaustive list of possible topics that may be addressed in any comments relevant to AI RMF companion resource for generative AI:

- Risks and harms of generative AI, including challenges in mapping, measuring, and managing trustworthiness characteristics as defined in the AI RMF, as well as harms related to repression, interference with democratic processes and institutions, gender-based violence, and human rights abuses (see *https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/11/01/remarks-by-vice-president-harris-on-the-future-of-artificial-intelligence-london-united-kingdom*);
- Current standards or industry norms or practices for implementing AI RMF core functions for generative AI (govern, map, measure, manage), or gaps in those standards, norms, or practices;
- Recommended changes for AI actors to make to their current governance practices to manage the risks of generative AI;
- The types of professions, skills, and disciplinary expertise organizations need to effectively govern generative AI, and what roles individuals bringing such knowledge could serve;
- Roles that can or should be played by different AI actors for managing risks and harms of generative AI (*e.g.,* the role of AI developers vs. deployers vs. end users);
- Current techniques and implementations, including their feasibility, validity, fitness for purpose, and scalability, for:
  - Model validation and verification, including AI red-teaming;
  - Human rights impact assessments, ethical assessments, and other tools for identifying impacts of generative AI systems and mitigations for negative impacts;
  - Content authentication, provenance tracking, and synthetic content labeling and detection, as described in Section 2a below; and
  - Measurable and repeatable mechanisms to assess or verify the effectiveness of such techniques and implementations.
- Forms of transparency and documentation (*e.g.,* model cards, data cards, system cards, benchmarking results, impact assessments, or other kinds of transparency reports) that are more or less helpful for various risk management purposes (*e.g.,* assessment, evaluation, monitoring, and provision of redress and contestation mechanisms) and for various AI actors (developers, deployers, end users, etc.) in the context of generative AI models, and best practices to ensure such information is shared as needed along the generative AI lifecycle and supply chain);
- Economic and security implications of watermarking, provenance tracking, and other content authentication tools;
- Efficacy, validity, and long-term stability of watermarking techniques and content authentication tools for provenance of materials, including in derivative work;
- Criteria for defining an error, incident, or negative impact;
- Governance policies and technical requirements for tracing and disclosing errors, incidents, or negative impacts;
- The need for greater controls when data are aggregated; and
- The possibility for checks and controls before applications are presented forward for public consumption.

(2) Creating guidance and benchmarks for evaluating and auditing AI capabilities, with a focus on capabilities and limitations through which AI could be used to cause harm. Following is a non-exhaustive list of possible topics that may be addressed in any comments relevant to AI evaluations:

- Definition, types, and design of test environments, scenarios, and tools for evaluating the capabilities, limitations, and safety of AI technologies;
- Availability of, gap analysis of, and proposals for metrics, benchmarks, protocols, and methods for measuring AI systems' functionality, capabilities, limitations, safety, security, privacy, effectiveness, suitability, equity, and trustworthiness. This includes rigorous measurement approaches for risks and impacts such as:
  - Negative effects of system interaction and tool use, including from the capacity to control physical systems or from reliability issues with such capacity or other limitations;
  - Exacerbating chemical, biological, radiological, and nuclear (CBRN) risks;
  - Enhancing or otherwise affecting malign cyber actors' capabilities, such as by aiding vulnerability discovery, exploitation, or operational use;
  - Introduction of biases into data, models, and AI lifecycle practices;
  - Risks arising from AI value chains in which one developer further refines a model developed by another, especially in safety- and rights-affecting systems;
  - Impacts to human and AI teaming performance;
  - Impacts on equity, including such issues as accessibility and human rights; and
  - Impacts to individuals and society; including both positive and negative impacts on safety and rights.
- Generalizability of standards and methods of evaluating AI over time, across sectors, and across use cases;
- Applicability of testing paradigms for AI system functionality, effectiveness, safety, and trustworthiness including security, and transparency, including paradigms for comparing AI systems against each other, baseline system performance, and existing practice, such as:
  - Model benchmarking and testing; and
  - Structured mechanisms for gathering human feedback, including randomized controlled human-subject trials; field testing, A/B testing, AI red-teaming.

b. E.O. 14110 Section 4.1(a)(ii) directs NIST to establish guidelines (except for AI used as a component of a national security system), including appropriate procedures and processes, to enable developers of AI, especially of dual-use foundation models, to conduct AI red-teaming tests to enable deployment of safe, secure, and trustworthy systems. The following is a non-exhaustive list of possible topics that may be addressed in any comments relevant to red-teaming:

- Use cases where AI red-teaming would be most beneficial for AI risk assessment and management;
- Capabilities, limitations, risks, and harms that AI red-teaming can help identify considering possible dependencies such as degree of access to AI systems and relevant data;
- Current red-teaming best practices for AI safety, including identifying threat models and associated limitations or harmful or dangerous capabilities;
- Internal and external review across the different stages of AI life cycle that are needed for effective AI red-teaming;
- Limitations of red-teaming and additional practices that can fill identified gaps;
- Sequence of actions for AI red-teaming exercises and accompanying necessary documentation practices;
- Information sharing best practices for generative AI, including for how to share with external parties for the purpose of AI red-teaming while protecting intellectual property, privacy, and security of an AI system;
- How AI red-teaming can complement other risk identification and evaluation techniques for AI models;
- How to design AI red-teaming exercises for different types of model risks, including specific security risks (*e.g.,* CBRN risks, etc.) and risks to individuals and society (*e.g.,* discriminatory output, hallucinations, etc.);
- Guidance on the optimal composition of AI red teams including different backgrounds and varying levels of skill and expertise;

• Economic feasibility of conducting AI red-teaming exercises for small and large organizations; and

• The appropriate unit of analysis for red teaming (models, systems, deployments, etc.)

2. Reducing the Risk of Synthetic Content

NIST is seeking information regarding topics related to synthetic content creation, detection, labeling, and auditing.

a. E.O. 14110 Section 4.5(a) directs the Secretary of Commerce to submit a report to the Director of the Office of Management and Budget (OMB) and the Assistant to the President for National Security Affairs identifying existing standards, tools, methods, and practices, along with a description of the potential development of further science-backed standards and techniques for reducing the risk of synthetic content from AI technologies. NIST is seeking information regarding the following topics related to reducing the risk of synthetic content in both closed and open source models that should be included in the Secretary's report, recognizing that the most promising approaches will require multistakeholder input, including scientists and researchers, civil society, and the private sector. Existing tools and the potential development of future tools, measurement methods, best practices, active standards work, exploratory approaches, challenges and gaps are of interest for the following non-exhaustive list of possible topics and use cases of particular interest.

• Authenticating content and tracking its provenance;

• Techniques for labeling synthetic content, such as using watermarking;

• Detecting synthetic content;

• Resilience of techniques for labeling synthetic content to content manipulation;

• Economic feasibility of adopting such techniques for small and large organizations;

• Preventing generative AI from producing child sexual abuse material or producing non-consensual intimate imagery of real individuals (to include intimate digital depictions of the body or body parts of an identifiable individual);

• Ability for malign actors to circumvent such techniques;

• Different risk profiles and considerations for synthetic content for models with widely available model weights;

• Approaches that are applicable across different parts of the AI development and deployment lifecycle (including training data curation and filtering, training processes, fine-tuning incorporating both automated means and human feedback, and model release), at different levels of the AI system (including the model, API, and application level), and in different modes of model deployment (online services, within applications, open-source models, etc.);

• Testing software used for the above purposes; and

• Auditing and maintaining tools for analyzing synthetic content labeling and authentication.

3. Advance Responsible Global Technical Standards for AI Development

NIST is seeking information regarding topics related to the development and implementation of AI-related consensus standards, cooperation and coordination, and information sharing that should be considered in the design of standards.

a. E.O. 14110 Section 11(b) directs the Secretary of Commerce, within 270 days and in coordination with the Secretary of State and the heads of other relevant agencies, to establish a plan for global engagement on promoting and developing AI consensus standards, cooperation, and coordination, ensuring that such efforts are guided by principles set out in the NIST AI Risk Management Framework (*https://www.nist.gov/itl/ai-risk-management-framework*) and the U.S. Government National Standards Strategy for Critical and Emerging Technology (*https://www.whitehouse.gov/wp-content/uploads/2023/05/US-Gov-National-Standards-Strategy-2023.pdf*). The following is a non-exhaustive list of possible topics that may be addressed:

• AI nomenclature and terminology;

• Best practices regarding data capture, processing, protection, quality, privacy, transparency, confidentiality, handling, and analysis, as well as inclusivity, fairness, accountability, and representativeness (including non-discrimination, representation of lower resourced languages, and the need for data to reflect freedom of expression) in the collection and use of data;

• Examples and typologies of AI systems for which standards would be particularly impactful (*e.g.,* because they are especially likely to be deployed or distributed across jurisdictional lines, or to need special governance practices);

• Best practices for AI model training;

• Guidelines and standards for trustworthiness, verification, and assurance of AI systems;

• AI risk management and governance, including managing potential risk and harms to people, organizations, and ecosystems;

• Human-computer interface design for AI systems;

• Application specific standards (*e.g.,* for computer vision, facial recognition technology);

• Ways to improve the inclusivity of stakeholder representation in the standards development process;

• Suggestions for AI-related standards development activities, including existing processes to contribute to and gaps in the current standards landscape that could be addressed, and including with reference to particular impacts of AI;

• Strategies for driving adoption and implementation of AI-related international standards;

• Potential mechanisms, venues, and partners for promoting international collaboration, coordination, and information sharing on standards development;

• Potential implications of standards for competition and international trade; and

• Ways of tracking and assessing whether international engagements under the plan are having the desired impacts.

Across all these topics, NIST is seeking information about costs and ease of implementation for tools, systems, practices, and the extent to which they will benefit the public if they can be efficiently adopted and utilized.

Authority: Executive Order 14110 of Oct. 30, 2023; 15 U.S.C. 272.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2023–28232 Filed 12–19–23; 4:15 pm]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Availability of a Draft Programmatic Environmental Assessment for Vessel Operations

AGENCY: Office of Marine and Aviation Operations (OMAO), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of availability; request for comments.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA), Office of Marine and Aviation Operations (OMAO) has prepared a draft programmatic environmental

assessment (PEA) in accordance with the National Environmental Policy Act of 1969 (NEPA), as amended by the Fiscal Responsibility Act of 2023, to analyze the potential environmental impacts associated with OMAO's ongoing vessel operations as the NOAA fleet is modernized over a 15-year timeframe from 2023 to 2038.

The Draft PEA assesses the direct, indirect, and cumulative environmental impacts from OMAO vessel operations while NOAA ships are underway, during which time OMAO conducts training, testing, calibration, and troubleshooting of vessel equipment and instruments in preparation for use by other NOAA Line Offices (LOs) or organizations outside of NOAA. OMAO's Proposed Action in the Draft PEA would ensure that NOAA's current and future fleet is maintained and operated in a safe, environmentally compliant manner, thus allowing NOAA to fulfill its at-sea mission objectives and data collection requirements in marine, coastal, and freshwater environments. The purpose of this NOA is to invite affected government agencies, non-governmental organizations, tribes and tribal organizations, and interested members of the public to participate in the Draft PEA process and provide comments on the structure, contents, and analysis in the Draft PEA. Publication of this document begins the 40-day public comment period for the Draft PEA.

DATES: Written comments on the Draft PEA will be accepted on or before January 31, 2024.

ADDRESSES: The Draft PEA can be viewed or downloaded from the OMAO website at *http://omao.noaa.gov/noaa-vessel-operations-draft-pea.* Written comments on OMAO's Draft PEA may be submitted by one of the following methods:

- *Mail:* Please direct written comments to DOC/NOAA/OMAO: Hannah Staley, Sea Grant Fellow, Office of Marine and Aviation Operations, National Oceanic and Atmospheric Administration, 1315 East-West Highway, Silver Spring, MD 20910.
- *Email: omaoenvironmental.compliance@noaa.gov*.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NOAA. All comments received are part of the public record. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NOAA will accept anonymous comments.

FOR FURTHER INFORMATION CONTACT: Hannah Staley, Sea Grant Fellow, *omaoenvironmental.compliance@noaa.gov;* 301–713–1045.

SUPPLEMENTARY INFORMATION: The Draft PEA examines the environmental effects of OMAO's operation of NOAA vessels in United States (U.S.) waters, including the oceans from the U.S. baseline, also known as the territorial sea baseline, to the limits of the U.S. Exclusive Economic Zone (EEZ), and the U.S. portions of the Great Lakes. The geographic scope extends to the international maritime boundaries with Canada and Mexico. The PEA also considers OMAO's operations in areas outside of U.S. jurisdiction. Under the Draft PEA's Proposed Action, OMAO would continue to operate, maintain, and manage the NOAA fleet as the existing fleet is updated and aging vessels are replaced with new vessels. Specifically, the Draft PEA focuses its analysis on the environmental impacts of OMAO's vessel operations while NOAA ships are underway (*i.e.,* when ships are either moving in open water or secured to a specific location in open water), but not for scientific research activities conducted by another NOAA Line Office or organization outside of NOAA. During this time, OMAO conducts training, testing, calibration, and troubleshooting of vessel equipment and instruments to maintain mission-readiness levels in support of NOAA's at-sea observational requirements. Examples of routine vessel operations include vessel movement; anchoring; waste handling and discharges; vessel repair and maintenance; uncrewed marine systems operations; uncrewed aircraft systems operations; small boat operations; and over the side handling, crane, davit, and winch operations.

OMAO has prepared the Draft PEA to analyze the physical, biological, economic, and social impacts to the human environment from OMAO vessel operations over a 15-year timeframe from 2023 to 2038. OMAO notes that almost half of NOAA's ships will exceed their design service life during the timeframe of this Draft PEA; therefore, NOAA needs to invest in modernizing its fleet to maintain fleet capabilities for its primary missions. OMAO supports NOAA's primary missions by operating, managing, and maintaining NOAA's fleet of vessels, vessel equipment, and instruments, and NOAA's Uncrewed Systems Operation Program, of which only Uncrewed Marine Systems (UMS) and Uncrewed Aerial Systems (UAS) deployed directly from NOAA vessels are considered in this Draft PEA. OMAO maintains these vessels, equipment, and systems at mission-readiness levels, facilitating all of NOAA's at-sea and data collection requirements.

OMAO's Draft PEA evaluates three alternatives:

- Alternative A—No Action—Continue Vessel Operations with Current NOAA Fleet: Under Alternative A, OMAO would continue to use the current NOAA fleet to conduct routine vessel operations, in addition to the testing, calibrating, training, and troubleshooting of vessel equipment and instruments, to support NOAA's primary missions and at-sea capabilities. OMAO would operate ships in the NOAA fleet until the end of their service life, and would continue to support projects undertaken by other NOAA Line Offices or organizations outside of NOAA at the current level of activity, for as long as the fleet capacity allows. Additionally, OMAO is constructing two oceanographic research vessels that are expected to come online in 2025, and awarded contracts in July 2023 for two new charting and mapping vessels that are expected to come online in 2027 and 2028 for a total of four new ships. This alternative also analyzes impacts from the additional ''greening'' techniques that are currently being implemented across the NOAA fleet, which include goals for fuel efficiency and emissions reductions. New ships would be integrated with greener technologies including improvements in wastewater and solid waste management, supplemental power generation, and hull protection; new technologies for data collection; and advancements in ship infrastructure. This alternative reflects the ships, technology, equipment, fleet utilization, scope, and methods currently in use by OMAO.

- Alternative B—Vessel Operations with Fleet Modernization and Optimizing At-Sea Capabilities: This alternative consists of Alternative A plus implementing measures for long-term modernization of the NOAA fleet and fleet management best practices. Fleet modernization is expected to result in a NOAA fleet of similar size to the current fleet, but with new ships coming online as older ships retire, in addition to newer and more efficient technologies and fleet utilization resulting in the capacity to provide more days-at-sea (DAS) than Alternative A. Specific examples of additional measures adopted under Alternative B over the next 15 years would include:

○ Designing and constructing up to four additional ships needed to replace vessels that would reach the end of their design service life between 2023 and 2038 (resulting in a total of 8 new ships when combined with the four new ships being constructed under Alternative A);

○ Extending service life of the existing fleet by conducting material condition assessment surveys and mid-life repairs; and

○ Increasing NOAA fleet utilization, which would provide more DAS compared to Alternative A;

Under Alternative B, all the activities described in Alternative A would continue, many at a higher level of effort. The nature of these actions would not change, but the overall level of activity would be increased.

• Alternative C—Vessel Operations with Fleet Modernization and Optimization with Greater Funding Support: Alternative C includes all the activities and measures described in Alternative B, but with an increase in overall funding of 20 percent relative to Alternative B, resulting in the capacity to provide more DAS. Specific examples of additional measures adopted under Alternative C over the next 15 years would include:

○ Designing and constructing two new ships in addition to the eight new ships that would be added to the NOAA fleet between 2023 and 2038 under Alternative B;

○ Increasing the number of uncrewed systems integrated into new ships that would be added to the NOAA fleet;

○ Shortening the timeframe of fleet improvement activities and the induction of new ships into the fleet;

○ Greening techniques proposed for the new ships would be implemented across the current fleet over a shorter timeframe;

○ Shortening of the timeframe to improve the OMAO small boat fleet; and

• Purchasing or developing technology to enable more efficient scheduling of vessels, equipment, and personnel to maximize crew productivity and enhance overall fleet performance, which would provide more DAS.

Under Alternative C, all the activities described in Alternative B would occur, many at a higher level of effort. The nature of these actions would not change, but the overall level of activity would be increased.

The official public review and comment period ends on January 31, 2024. Please visit the OMAO website for additional information and to access the Draft PEA: *http://omao.noaa.gov/noaa-vessel-operations-draft-pea.*

Classification: The Draft PEA was prepared in accordance with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) as amended by the Fiscal Responsibility Act of 2023, Public Law 118–5 (2023); Council on Environmental Quality (CEQ) Regulations for Implementing the Procedural Provisions of NEPA (40 CFR 1500–1508 (1978)); NOAA's Policy and Procedures for Compliance with the National Environmental Policy Act and Related Authorities (NOAA Administrative Order (NAO) 216–6A and Companion Manual for NAO 216–6A), and other relevant federal and state laws and regulations.

Dated: December 18, 2023.

Richard W. Spinrad,

Under Secretary of Commerce for Oceans and Atmosphere and NOAA Administrator.

[FR Doc. 2023–28120 Filed 12–20–23; 8:45 am]

BILLING CODE 3510–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD587]

Marine Mammals; File No. 27592

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Shannon Atkinson, Ph.D., University of Alaska Fairbanks, 17101 Point Lena Loop Road, Juneau, AK 99801 has applied in due form for a permit to import, export, and receive marine mammal parts for scientific research.

DATES: Written comments must be received on or before January 22, 2024.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 27592 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 27592 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Erin Markin, Ph.D., (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The applicant proposes to receive, import, and export marine mammal parts from cetaceans and pinnipeds annually for scientific research. Marine mammal parts will not exceed 1,000 animals per year within order Cetacea (dolphins, porpoises, and whales) and 500 animals per year within order Pinnipedia (seals and sea lions, excluding walrus). Secondary to research, marine mammal parts may also be used for educational purposes. Import and export activities would occur world-wide. Sources of samples include U.S. subsistence harvests and stranded animals in foreign countries. Samples may also be obtained within the United States or abroad from animals held in captivity, authorized researchers or collections, and soft or hard parts that sloughed, excreted, or naturally discharged. No live animals would be harassed or taken, lethally or otherwise, under the requested permit. The requested duration of the permit is 5 years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: December 14, 2023.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023–28151 Filed 12–20–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Dr. Nancy Foster Scholarship Program

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on September 19, 2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration, NOAA, Commerce.

Title: Dr. Nancy Foster Scholarship Program.

OMB Number(s): None.

Type of Request: Regular submission extension of a current information collection and revision.

Control Number: 0648–0432.

Form Number of Respondents: 190 (pre-application), 50 (full application).

Average Hours per Response: Pre-application: 3 hours; Application: 5 hours; Letters of recommendation: 45 minutes; Biographical sketch and photograph of awardees:1 hour; Annual progress reports: 4 hours; Two-year follow up survey: 10 minutes.

Total Annual Burden Hours: 570 burden hours for pre-application; 250 hours full application.

Needs and Uses: This is a request for extension of an existing information collection and a revision to include a pre-application component. NOAA's Office of National Marine Sanctuaries administers the Dr. Nancy Foster Scholarship Program which recognizes outstanding achievement in master's and doctoral degrees in oceanography, marine biology, or maritime archaeology—this can include but is not limited to ocean and/or coastal: engineering, social science, marine education, marine stewardship, resource management disciplines—and particularly to encourage women and members of minority groups to apply. The scholarship supports independent graduate level research through financial support of graduate degrees in such fields. Gender and minority status are not considered when selecting award recipients. However, special outreach efforts are employed to solicit applications from women and members of minority groups. Scholarships are distributed by disciplines, institutions, and geography, and by degree sought, with selections within distributions based on financial need, the potential for success in a graduate level studies program (academic achievement), and the potential for achieving research and career goals. Data collection in the form of a pre and full application, letters of recommendation, grade point average documents, research outline, a letter of financial need statement, and a declaration statement are all required to apply for the scholarship.

Affected Public: Individuals.

Frequency: Once.

Respondent's Obligation: Voluntary.

Legal Authority: 16 U.S.C. 1445c–1 and 16 U.S.C. 1445c.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering the title of the collection.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2023–28113 Filed 12–20–23; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

United States Integrated Ocean Observing System Advisory Committee

AGENCY: National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of new member solicitation for the United States Integrated Ocean Observing System (U.S. IOOS) Advisory Committee.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) is soliciting applications for membership on the United States Integrated Ocean Observing System Advisory Committee (the Committee), which is a Federal advisory committee. Members of the Committee will fulfill the requirements of the Integrated Coastal and Ocean Observation System (ICOOS) Act of 2009 (the Act). The Committee provides advice to the Under Secretary of Commerce for Oceans and Atmosphere and to the Interagency Ocean Observation Committee on the planning, integrated design, operation, maintenance, enhancement, and expansion of the United States Integrated Ocean Observing System (U.S. IOOS).

DATES: Nominations should be submitted no later than January 17, 2024. Applications received after January 17, 2024 may not be considered during this membership application cycle, but may be considered for future membership cycles. Please note the original deadline of January 2, 2024 has been extended to January 17, 2024 to allow more time for application submissions.

ADDRESSES: Submit an application for Committee membership, including cover letter, resume, and requested items below, to Laura Gewain via Email *Laura.Gewain@noaa.gov.* Please direct any questions regarding application submission to Laura Gewain via Email or Telephone: 240–533–9456.

FOR FURTHER INFORMATION CONTACT: Krisa Arzayus, 1315 East-West Highway, Station 2616, Silver Spring, MD 20910; Telephone: 240–533–9455; Email: *Krisa.Arzayus@noaa.gov*.

SUPPLEMENTARY INFORMATION: U.S. IOOS promotes research to develop, test, and deploy innovations and improvements in coastal and ocean observation technologies and modeling systems, addresses regional and national needs for ocean information, gathers data on key coastal, ocean, and Great Lakes variables and ensures timely and sustained dissemination and availability of these data for societal benefits. U.S. IOOS benefits national safety, the economy, and the environment through support for national defense, marine commerce and forecasting, navigation safety, weather, climate, energy siting and production, economic development, ecosystem-based management of marine and coastal areas, conservation of ocean and coastal resources and public safety.

The Act requires the establishment and administration of this Committee by the Under Secretary of Commerce for Oceans and Atmosphere.

NOAA will hereby accept applications for membership on the Committee to fill ten vacancies that will occur on September 14, 2024. These appointments shall serve for a three-year term, which will end September 13, 2027. An individual so appointed may subsequently be appointed for an additional three-year term. The ICOOS Act states: ''Members shall be qualified by education, training, and experience to evaluate scientific and technical information related to the design, operation, maintenance, or use of the [Integrated Ocean Observing] System, or use of data products provided through the System.'' NOAA encourages individuals with expertise in Great Lakes; philanthropy; NGO; scientific institutions (Academic); IOOS regional interests; state, local and tribal interests; renewable energy, including offshore wind; blue economy; social science; public-private partnerships; marine technologies industries; data management and architecture; ocean and coastal leadership; and other science-related fields to submit applications for Committee membership. This notice responds to the ICOOS Act of 2009 (Pub. L. 111–11, section 12304), which requires the Under Secretary of Commerce for Oceans and Atmosphere to solicit nominations for Committee membership. The Committee will advise the NOAA Administrator or Interagency Ocean Observation Committee on matters related to the responsibilities and authorities set forth in section 12302 of the ICOOS Act of 2009 and other appropriate matters as the Under Secretary refers to the Committee for review and advice.

The United States Integrated Ocean Observing System Advisory Committee will provide advice on:

(a) administration, operation, management, and maintenance of the Integrated Coastal and Ocean Observation System (the System);

(b) expansion and periodic modernization and upgrade of technology components of the System;

(c) identification of end-user communities, their needs for information provided by the System, and the System's effectiveness in disseminating information to end-user communities and to the general public; and

(d) additional priorities, including—

(1) a national surface current mapping network designed to improve fine scale sea surface mapping using high frequency radar technology and other emerging technologies to address national priorities, including Coast Guard search and rescue operation planning and harmful algal bloom forecasting and detection that—

(i) is comprised of existing high frequency radar and other sea surface current mapping infrastructure operated by national programs and regional coastal observing systems;

(ii) incorporates new high frequency radar assets or other fine scale sea surface mapping technology assets, and other assets needed to fill gaps in coverage on United States coastlines; and

(iii) follows a deployment plan that prioritizes closing gaps in high frequency radar infrastructure in the United States, starting with areas demonstrating significant sea surface current data needs, especially in areas where additional data will improve Coast Guard search and rescue models;

(2) fleet acquisition for unmanned maritime systems for deployment and data integration to fulfill the purposes of this subtitle;

(3) an integrative survey program for application of unmanned maritime systems to the real-time or near real-time collection and transmission of sea floor, water column, and sea surface data on biology, chemistry, geology, physics, and hydrography;

(4) remote sensing and data assimilation to develop new analytical methodologies to assimilate data from the System into hydrodynamic models;

(5) integrated, multi-State monitoring to assess sources, movement, and fate of sediments in coastal regions;

(6) a multi-region marine sound monitoring system to be—

(i) planned in consultation with the IOOC, NOAA, the Department of the Navy, and academic research institutions; and

(ii) developed, installed, and operated in coordination with NOAA, the Department of the Navy, and academic research institutions; and (e) any other purpose identified by the Administrator or the Council.

The Committee's voting members will be appointed by the Under Secretary of Commerce for Oceans and Atmosphere. Members shall be qualified by education, training, and experience to evaluate scientific and technical information related to the design, operation, maintenance, or use of the System, or the use of data products provided through the System. Members are selected on a standardized basis, in accordance with applicable Department of Commerce guidance. Members will be appointed for three-year terms, renewable once. One Committee member will be designated by the Under Secretary as chairperson. Full-time officers or employees of the United States may not be appointed as a voting member. Members will be appointed as special Government employees (SGEs) for purposes of section 202(a) of title 18, United States Code. Members serve at the discretion of the Under Secretary and are subject to government ethics standards. Members of the Committee will not be compensated for service on the Committee, but they may be allowed travel expenses, including per diem in lieu of subsistence, in accordance with subchapter I of chapter 57 of title 5, United States Code.

The Committee will meet at least once each year, and at other times at the call of the Under Secretary, the Interagency Ocean Observation Committee, or the Committee Chairperson. The Committee has approximately fifteen voting members. This solicitation is to obtain candidate applications for up to ten full voting member vacancies.

To apply for membership, applicants must submit the following five items, including a cover letter that responds to the five questions below. The entire package should be a maximum length of eight pages or fewer. NOAA is an equal opportunity employer.

(1) A cover letter that responds to the five questions listed below and serves as a statement of interest to serve on the panel. Please see ''Short Response Questions'' below.

(2) Highlight the nominee's specific area(s) of expertise relevant to the purpose of the Panel from the list in the **Federal Register** Notice.

(3) A short biography of 300 to 400 words.

(4) A current resume

(5) The nominee's full name, title, institutional affiliation, mailing address, email, phone, fax and contact information.

Short Response Questions:

(1) List your area(s) of expertise, as listed above.

(2) List the geographic region(s) of the country with which you primarily associate your expertise. This does not need to be the region in which the nominee currently resides.

(3) Describe your leadership or professional experience that you believe will contribute to the effectiveness of this panel.

(4) Describe your familiarity and experience with U.S. IOOS data, products, and services.

(5) Generally describe the breadth and scope of your knowledge of stakeholders, users, or other groups who interact with NOAA or other U.S. IOOS

agencies and whose views and input you believe you can share with the panel.

Individuals Selected for Committee Membership

Upon selection and agreement to serve on the United States Integrated Ocean Observing System Advisory Committee, one becomes a Special Government Employee (SGE) of the United States Government. An SGE is an officer or employee of an agency who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, for not to exceed 130 days during any period of 365 consecutive days, either on a full-time or intermittent basis. After the membership selection process is complete, applicants who are selected to serve on the Committee must complete the following actions before they can be appointed as a Committee member:

(a) Background Check (on-line Background Check process and fingerprinting conducted through NOAA Office of Human Capital Services); and

(b) Confidential Financial Disclosure Report: As an SGE, one is required to file annually a Confidential Financial Disclosure Report to avoid involvement in a real or apparent conflict of interest. One may find the Confidential Financial Disclosure Report at the following website: *http://www.usoge.gov/forms/form_450.aspx*.

Privacy Act Statement

Authority. The collection of information concerning nominations to the IOOS AC is authorized under the FACA, 5 U.S.C. App. and its implementing regulations, 41 CFR part 102–3, and in accordance with the Privacy Act of 1974, as amended, (Privacy Act) 5 U.S.C. 552a.

Purpose. The collection of names, contact information, resumes, professional information, and qualifications is required in order for the Under Secretary to appoint members to the IOOS AC.

Routine Uses. NOAA will use the nomination information for the purpose set forth above. The Privacy Act of 1974 authorizes disclosure of the information collected to NOAA staff for work-related purposes and for other purposes only as set forth in the Privacy Act and for routine uses published in the Privacy Act System of Records Notice COMMERCE/DEPT–11, Candidates for Membership, Members, and Former Members of Department of Commerce Advisory Committees, available at *https://www.osec.doc.gov/opog/PrivacyAct/SORNs/dept-11.html*, and the System of Records Notice COMMERCE/DEPT–18, Employees Personnel Files Not Covered by Notices of Other Agencies, available at *https://www.osec.doc.gov/opog/PrivacyAct/SORNs/DEPT-18.html*.

Disclosure. Furnishing the nomination information is voluntary; however, if the information is not provided, the individual would not be considered for appointment as a member of the IOOS AC.

Krisa M. Arzayus,

Deputy Director, U.S. Integrated Ocean Observing System Office, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2023–28125 Filed 12–20–23; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Implementation of Vessel Speed Restrictions To Reduce the Threat of Ship Collisions With North Atlantic Right Whales

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on September 22, 2023 (88 FR 65367) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration, Commerce.

Title: Implementation of Vessel Speed Restrictions to Reduce the Threat of Ship Collisions with North Atlantic Right Whales.

OMB Control Number: 0648–0580.

Form Number(s): None.

Type of Request: Regular submission. Extension of a current information collection.

Number of Respondents: 3,624.

Average Hours per Response: Five minutes for safety deviation logbook entry; one hour for electronic survey; two hours and 30 minutes for focus groups.

Total Annual Burden Hours: 674.

Needs and Uses: The National Marine Fisheries Service (NMFS) is requesting renewal of a currently approved collection of information. On October 10, 2008, NMFS published a final rule with regulations (0648–AS36) implementing seasonal speed restrictions along the east coast of the U.S. to reduce the incidence and severity of vessel collisions with endangered North Atlantic right whales (73 FR 60173). The final rule contained a mandatory collection-of-information requirement subject to the Paperwork Reduction Act (PRA). Specifically, 50 CFR 224.105(c) requires a logbook entry to document that a deviation from the speed limit was necessary for safe maneuverability under certain conditions. On November 18, 2021, the information collection was revised to include a voluntary survey of vessel operators to evaluate their ability and willingness to: (1) comply with North Atlantic right whale mandatory speed restrictions, and (2) cooperate with voluntary speed reduction efforts to protect North Atlantic right whales, which are promoted through NMFS outreach efforts. NOAA collects information from two types of vessels (pleasure yachts and large ocean-going vessels) in two different areas of the North Atlantic right whales' range using voluntary online surveys and small focus groups. The surveys collect information about vessel operators' time spent on the water, experience and knowledge about large whales, knowledge of North Atlantic vessel strike reduction efforts, opinions about these whales and conservation efforts, and their preferred means of receiving information. Results from this information collection will be used to develop effective outreach to these vessel communities, with the long-term goal of improving the communities' compliance with mandatory measures and cooperation with voluntary measures that support North Atlantic right whale vessel strike reduction conservation efforts.

Affected Public: Individuals or households; Business or other for-profit organizations.

Frequency: Logbook: As needed; Surveys and Focus Groups: Once

Respondent's Obligation: Logbook entries are required to lawfully deviate from the speed regulations; survey is voluntary.

Legal Authority: Endangered Species Act, 16 U.S.C. 1531 *et seq.;* and Marine Mammal Protection Act, 16 U.S.C. 1361 *et seq.*

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0580.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2023–28121 Filed 12–20–23; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Technology Advisory Committee

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of meeting.

SUMMARY: The Commodity Futures Trading Commission (CFTC) announces that on January 8, 2024, from 12:30 p.m. to 4:30 p.m. Eastern Standard Time, the Technology Advisory Committee (TAC or Committee) will hold an in-person public meeting at the CFTC's Washington, DC headquarters with options for the public to attend virtually. At this meeting, the TAC will discuss digital assets and blockchain technology, cybersecurity, and emerging and evolving technologies.

DATES: The meeting will be held on January 8, 2024, from 12:30 p.m. to 4:30 p.m. Eastern Standard Time. Please note that the meeting may end early if the TAC has completed its business. Members of the public who wish to submit written statements in connection with the meeting should submit them by January 15, 2024.

ADDRESSES: The meeting will take place in the Conference Center at the CFTC's headquarters, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. You may submit public comments, identified by ''Technology Advisory Committee,'' through the CFTC website at *https://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the website. If you are unable to submit comments online, contact Anthony Biagioli, Designated Federal Officer, via the contact information listed below to discuss alternate means of submitting your comments. Any statements submitted in connection with the committee meeting will be made available to the public, including publication on the CFTC website, *https://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Anthony Biagioli, TAC Designated Federal Officer, Commodity Futures Trading Commission, 2600 Grand Boulevard, Suite 210, Kansas City, MO 64108; (816) 960–7722; or *abiagioli@cftc.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public with seating on a first-come, first-served basis. Members of the public may also listen to the meeting by telephone by calling a domestic or international toll or toll-free number to connect to a live, listen-only audio feed. Call-in participants should be prepared to provide their first name, last name, and affiliation.

Domestic Numbers: +1 669 254 5252, +1 646 964 1167, +1 646 828 7666, +1 551 285 1373, +1 669 216 1590, +1 415 449 4000, 833 568 8864 (Toll Free), or 833 435 1820 (Toll Free).

International Numbers: Will be posted at *https://cftc-gov.zoomgov.com/u/abv5ZYUUGp.*

Call-In/Webinar ID: 161 668 0789.

Pass Code/Pin Code: 339674.

Members of the public may also view a live webcast of the meeting via the *https://www.cftc.gov* website. The meeting agenda may change to accommodate other TAC priorities. For agenda updates, please visit *https://www.cftc.gov/About/AdvisoryCommittees/TAC#:~:text=The%20Technology%20Advisory%20Committee%20(TAC,of%20technology%20in%20the%20markets.*

After the meeting, a transcript of the meeting will be published through a link on the CFTC's website, *http://www.cftc.gov.* Persons requiring special accommodations to attend the meeting because of a disability should notify the contact person above.

(Authority: 5 U.S.C. 1009(a)(2).)

Dated: December 18, 2023.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2023–28126 Filed 12–20–23; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2023–HQ–0016]

Proposed Collection; Comment Request

AGENCY: Department of the Air Force, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the United States Air Force (USAF) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 20, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any

personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to USAF Information Collections Office, 1800 USAF Pentagon, Suite 4C146, Washington, DC 20330, ATTN: Ms. Mia Day, or call 703–697–4593.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Air Force Recruiting Information Support System—Total Force (AFRISS–TF); OMB Control Number 0701–0150.

Needs and Uses: Recruiting requires the collection of specific information on prospective USAF, Air National Guard, and Air Force Reserve Command enlistees, officers, and health profession personnel entering into duty. The information is used to create the initial personnel record that is used to prescreen and qualify enlistees, line officers, and health professionals fit for service and ultimately induction into one of the three USAF commands. The information is also collected to process security clearances for those individuals requiring clearances for sensitive and classified positions. The respondents are recruiting applicants of the USAF who may seek more information or request copies of their personal information. The collection instrument is a list of questions asked by the recruiter that cannot be found on the SF–86; information taken from the SF–86 can complete the rest of the recruit's application. Collections instruments are completed by applicants and recruiters into the system of record as applicable to their recruiting and application purposes. All completed instruments of collection reside in the system of record which has safeguards in place to protect privacy information. The result of successful information collection is the successful accession of an applicant in the USAF and the safe keeping of said applicant's personal information.

Affected Public: Individuals or households.

Annual Burden Hours: 25,000.

Number of Respondents: 100,000.

Responses per Respondent: 1.

Annual Responses: 100,000.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

Dated: December 15, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–28077 Filed 12–20–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2023–HQ–0018]

Proposed Collection; Comment Request

AGENCY: Department of the Army, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Army announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 20, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to United States Army Installation Management Command Headquarters, 2405 Gun Shed Road, Bldg. 2261 JBSA-Fort Sam Houston, TX 78234, ATTN: Mrs. Kelly Frank, or call 210–466–1200.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Installation Management Command Survivor Outreach Service System (SOS IMCOM); OMB Control Number 0702–0148.

Needs and Uses: SOS is an Army-wide program that provides dedicated and comprehensive support services to all family members of soldiers who die while on active duty, including Regular Army, United States Army National Guard and Reserves patrons. SOS Support Coordinators serve as the main Survivor advocate. They facilitate support groups, provide life skills education, assist survivors in managing applicable life-long benefit transition milestones, connect survivors with counseling resources, and represent the command in contacts with community organizations. SOS Financial Counselors help survivors by assisting with budget counseling, debt management, education, and higher education needs. SOS staff members are required to make periodic communication with Survivors—at a minimum of one contact annually—to conduct well-being checks and milestone management reviews or determine the level of support Survivors desire. Information gathered in these meetings is input into the SOS application collection instrument by SOS staff members. No customers have access to the collection instrument. SOS staff members collect the information from the survivors and document the information as a direct contact within the SOS application case notes. The successful result of the information collection as a whole is an organized and up-to-date database of essential information on survivors that allows SOS to better provide the support they deserve.

Affected Public: Business or other for-profit; individuals or households.

Annual Burden Hours: 54,013.

Number of Respondents: 72,307.

Responses per Respondent: 2.49.

Annual Responses: 180,044.

Average Burden per Response: 18 minutes.

Frequency: On occasion.

Dated: December 15, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–28080 Filed 12–20–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0042]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 22, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, (571) 344–1358, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Uniformed Services Employment and Reemployment Rights Act (USERRA) Inquiry and Support Request; DD Form 3021; OMB Control Number 0704–ERRA.

Type of Request: New.

Number of Respondents: 977.

Responses per Respondent: 1.

Annual Respondents: 977.

Average Burden per Response: 5 minutes.

Annual Burden Hours: 81.

Needs and Uses: This form is intended for those who are experiencing civilian employment problems related to military obligations and is needed to record information related to the mediation of disputes and answering of inquiries related to the USERRA; by tracking case assignments and mediation results of potential conflicts between employers and the National Guard, Reserves, or National Disaster Medical Service members they employ; and by reporting statistics related to the Employer Support of the Guard and Reserve (ESGR) Ombudsman Program in aggregate and at the state committee-level. These records are also used as a management tool for statistical analysis, tracking, reporting, evaluating program effectiveness and conducting research. Service members will request ESGR assistance as related to their rights and responsibilities pursuant to USERRA. Electronic form to be submitted through the *www.ESGR.mil* website, *https://www.esgr.mil/USERRA/USERRA-Contact/USERRA-Support-Request/t/1.*

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan, 571–372–0493, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 15, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–28078 Filed 12–20–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Intent To Grant an Exclusive License; Kapalya, Inc.

AGENCY: National Security Agency, Department of Defense (DoD).

ACTION: Notice of intent.

SUMMARY: The National Security Agency hereby gives notice of its intent to grant Kapalya, Inc. a revocable, non-assignable, exclusive, license to practice the following Government-Owned invention as described and claimed United States Patent Serial Number (USPSN), 17/934,216, Security System for Hardening a Digital System Against Malware and Method of Operation.

DATES: Anyone wishing to object to the grant of this license has until January 5, 2024 to file written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

ADDRESSES: Written objections are to be filed with the National Security Agency Technology Transfer Program, 9800 Savage Road, Suite 6843, Fort George G. Meade, MD 20755–6843.

FOR FURTHER INFORMATION CONTACT: Linda L. Burger, Director, Technology Transfer Program, 9800 Savage Road, Suite 6843, Fort George G. Meade, MD 20755–6843, telephone (443) 634–3518.

SUPPLEMENTARY INFORMATION: The prospective exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The patent rights in these inventions have been assigned to the United States Government as represented by the National Security Agency.

Dated: December 15, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–28073 Filed 12–20–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0125]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of Local Defense Community Cooperation (OLDCC) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the

functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 20, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the OLDCC, 2231 Crystal Drive, Arlington, Virginia, 22202, ATTN: Ms. Michelle Volkema, or call 703–697–2176.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Revitalizing Base Closure Communities, Economic Development Conveyance Annual Financial Statement; OMB Control Number 0790–0004.

Needs and Uses: The information collection requirement is necessary to verify that Local Redevelopment Authority (LRA) recipients of Economic Development Conveyances (EDCs) are in compliance with the requirement that the LRA reinvest proceeds from the use of EDC property for seven years. Respondents are LRAs that have executed EDC agreements with a Military Department that transferred property from a closed military installation. As provided by 32 CFR 174.9, such agreements require that the LRA reinvest the proceeds from any sale, lease, or equivalent use of EDC property (or any portion thereof) during at least the first seven years after the date of the initial transfer of the property to support the economic redevelopment of, or related to, the installation. The Secretary of Defense may recoup from the LRA such portion of these proceeds not used to support the economic redevelopment of, or related to, the installation. LRAs are subject to this same seven-year reinvestment requirement if their EDC agreement is modified to reduce the debt owed to the Federal Government. Military Departments monitor LRA compliance with this provision by requiring an annual financial statement certified by an independent Certified Public Accountant. No specific form is required.

Affected Public: State and local governments.

Annual Burden Hours: 960.

Number of Respondents: 24.

Responses per Respondent: 1.

Annual Responses: 24.

Average Burden per Response: 40 hours.

Frequency: Annually.

Dated: December 15, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–28083 Filed 12–20–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0123]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the OUSD(A&S) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 20, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Armed Forces Pest Management Board (AFPMB), Contingency Liaison Office, ATTN: Captain Eric Hoffman, 2460 Linden Lane, Bldg. 172, Silver Spring, MD 20910, or call the AFPMB Contingency Liaison Office at 301–295–7476.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Pre-Embarkation Certificate of Disinsection; DD Form 3044; OMB Control Number 0704–0568.

Needs and Uses: The information collection requirement is necessary to provide proof of aircraft disinsection to foreign countries that require it before cargo and aircrew will be allowed to dis-embark in those countries. This standardized form that is used across the DoD satisfies the documentation requirements of disinsection for all 14 countries that currently require it.

Affected Public: Individuals or households.

Annual Burden Hours: 167.

Number of Respondents: 1,000.

Responses Per Respondent: 1.
Annual Responses: 1,000.
Average Burden per Response: 10 minutes.
Frequency: On occasion.

Dated: December 15, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–28082 Filed 12–20–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–HA–0126]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Health Agency (DHA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 20, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to DHA, 7700 Arlington Blvd., Falls Church, VA 22042, Amanda Grifka, 703–681–1771.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Knowledge, attitudes, and practices on Coronavirus Disease of 2019 (COVID–19) vaccination among service members and medical beneficiaries; OMB Control Number 0720–VACC.

Needs and Uses: Although a safe and effective vaccine against COVID–19 is available and approved by the United States Food and Drug Administration, there is no guarantee that people who would benefit from the vaccine will agree to take it. Vaccine hesitancy, the concern about vaccination of oneself or of one's children, has been increasing in the U.S. and could present a barrier to widespread vaccination against COVID–19. COVID–19, the disease caused by severe acute respiratory syndrome coronavirus 2, has an adverse effect on combat readiness. The proposed project aims to assist the DoD in ongoing service-wide COVID–19 vaccination program through surveying the knowledge, attitudes, and practices of a population of service members and medical beneficiaries at a large military base in the United States: Joint Base Lewis McChord (JBLM) in Washington state. The project will leverage existing partnerships between medical and public health personnel at Madigan Army Medical Center, the Military HIV Research Program at Walter Reed Army Institute of Research, and the Henry M. Jackson Foundation to rapidly implement and complete the project. The study population will be active-duty personnel and medical beneficiaries of the Military Health System aged 18 and over at JBLM.

Affected Public: Individuals or households.
Annual Burden Hours: 250.
Number of Respondents: 1,000.
Responses per Respondent: 1.
Annual Responses: 1,000
Average Burden per Response: 15 minutes.
Frequency: On occasion.

Dated: December 15, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–28084 Filed 12–20–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0124]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Threat Reduction Agency (DTRA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 20, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public

viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to DTRA, 8725 John J. Kingman Road, Stop 6210, Fort Belvoir, VA 22060–6201 Attn: LCDR James D. Franks, USN; or call (800) 462–3683.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Nuclear Test Personnel Review Forms; DTRA Form 150, DTRA Form 150A, DTRA Form 150B, DTRA Form 150D; OMB Control Number 0704–0447.

Needs and Uses: The information collection requirement is necessary to provide recognition, verify participation, and/or collect irradiation scenario information from nuclear test participants to perform radiation dose assessments. This information is used to award the Atomic Veterans Service Certificate (AVSC) to eligible veterans and to process claims submitted by veterans seeking radiogenic disease compensation from the Department of Veterans Affairs (VA) and/or the Department of Justice (DOJ). This information may also be used in approved veteran epidemiology studies that study the health impact of nuclear tests on U.S. veterans. Respondents include Veterans and civilian test participants, and their representatives, who apply for the AVSC or file radiogenic disease compensation claims with the VA or DOJ and require information from the Department of Defense.

Affected Public: Individuals or households.

Annual Burden Hours: 113.

Number of Respondents: 278.

Responses per Respondent: 1.

Annual Responses: 278.

Average Burden per Response: 24.4 minutes.

Frequency: On occasion.

Dated: December 15, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–28081 Filed 12–20–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0214]

Evaluation of Full-Service Community Schools; Correction

AGENCY: Department of Education (ED), Institute of Education Sciences (IES).

ACTION: Correction notice.

SUMMARY: On December 18, 2023, the U.S. Department of Education published a 60-day comment period notice in the **Federal Register** with FR DOC# 2023–27726 (Page 87416, Column 3, Page 87417, Column 1, Column 2) seeking public comment for an information collection entitled, ''Evaluation of Full-Service Community Schools''. The docket number is incorrect. The correct docket number is ED–2023–SCC–0214.

The PRA Coordinator, Strategic Collections and Clearance, Office of the Chief Data Officer, Office of Planning, Evaluation and Policy Development, hereby issues a correction notice as required by the Paperwork Reduction Act of 1995.

Dated: December 18, 2023.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Office of the Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023–28147 Filed 12–20–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2023–OCTAE–0193]

Proposed Waiver and Extension of the Project Period for the Tribally Controlled Postsecondary Career and Technical Institutions Program

AGENCY: Office of Career, Technical, and Adult Education, Department of Education.

ACTION: Proposed waiver and extension of the project period.

SUMMARY: The Secretary proposes to waive the requirements in the Education Department General Administrative Regulations that generally prohibit project periods exceeding five years and project period extensions involving the obligation of additional Federal funds. Under the proposed waiver and extension, for projects funded in fiscal year (FY) 2019 under the Tribally Controlled Postsecondary Career and Technical Institutions Program (TCPCTIP), Assistance Listing Number 84.245A, the project period would be extended through FY 2027, if Congress continues to appropriate funds under the existing program authority.

DATES: We must receive your comments on or before January 22, 2024.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail or commercial delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov,* including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ.''
- *Postal Mail or Commercial Delivery:* If you mail or deliver your comments, address them to Hugh Reid, U.S. Department of Education, 400 Maryland Avenue SW, Room 4A–172, Washington, DC 20202–7241.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Hugh Reid. Telephone: (202) 245–7491. Email: *hugh.reid@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding this proposed waiver and extension. We are particularly interested in receiving comments on the potential impact that the proposed waiver and extension may have on TCPCTIP and on potential applicants that may be eligible to apply for grant awards under any new TCPCTIP notice inviting applications, should there be one. Eligible applicants for TCPCTIP are Tribally controlled postsecondary career and technical institutions that do not receive Federal support under Title I of the Tribally Controlled College or University Assistance Act of 1978 (*25 U.S.C. 1801 et seq.*) or the Navajo Community College Act (*25 U.S.C. 640a et seq.*).

We invite you to assist us in complying with the specific requirements of Executive Orders 12866, 13563, and 14094 and their

overall requirement of reducing regulatory burden that might result from the proposed waiver and extension. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program. During and after the comment period, you may inspect public comments about the proposed waiver and extension by accessing *Regulations.gov*. To inspect the public comments in person, please contact the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this proposed waiver and extension. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

Section 117 of the Carl D. Perkins Career and Technical Education Act of 2006 (Pub. L. 115–224) (Perkins V or the Act), authorizes the Secretary to make grants to Tribally controlled postsecondary career and technical institutions that do not receive Federal support under Title I of the Tribally Controlled Colleges and Universities Assistance Act of 1978 (25 U.S.C. 1802, *et seq.*) or the Navajo Community College Act (Pub. L. 92–189; 85 Stat. 646) for career and technical education programs for Native American students and for the institutional support costs of the grant.

Current TCPCTIP grantees, selected based on the TCPCTIP notice inviting applications published in the **Federal Register** (84 FR 29854) on June 25, 2019 (NIA), operate career and technical education programs for Native American students as authorized by section 117 of Perkins V (20 U.S.C. 2327). The budget and project period for the two TCPCTIP grantees is scheduled to end with funds awarded in FY 2023.

For these projects, the Secretary proposes to waive the requirements of *34 CFR 75.250* and *34 CFR 75.261(c)(2),* which limit project periods to 60 months and restrict project period extensions that involve the obligation of additional Federal funds. The Secretary makes these proposals because section 117(i) of Perkins V authorizes appropriations for activities under section 117 of the Act, through FY 2024 (20 U.S.C. 2327(i)). The Secretary also proposes to extend the project period for the two current TCPCTIP grantees (20 U.S.C. 2327(a)) through FY 2027, if Congress continues to appropriate funds under the existing program authority. The proposed waiver and extension would enable the two current TCPCTIP grantees to request and continue to receive Federal funds beyond the 60-month limitation set by *34 CFR 75.250.*

Moreover, with the proposed waiver and extension, the Department would not announce a new competition or make new awards until FY 2027, if Congress continues to authorize and appropriate funds under the existing program authority. Instead, current TCPCTIP projects funded under the NIA could be continued at least through the FY 2027 budget and project period, if Congress continues to appropriate funds for TCPCTIP under the existing program authority.

We believe that the proposed waiver and extension is in the public interest, given that the Navajo Technical University and the United Tribes Technical College are the only two eligible entities for the TCPCTIP program, and those entities are the current grantees. Running another competition in which the same entities would receive awards is not an effective use of Department and grantee resources. Further, allowing these grantees to continue their projects would provide continuity in the current projects and resources for the current beneficiaries of the grantees' programs.

If we announce the proposed waiver and extension as final, we will base our decisions regarding annual continuation awards on the program narratives, budgets, budget narratives, and program performance reports, submitted by current grantees, and the requirements in *34 CFR 75.253.* Any activities to be carried out during the year or years of continuation awards would have to be consistent with, or be a logical extension of, the scope, goals, and objectives of each grantee's application, as approved following the 2019 TCPCTIP competition. If we publish the proposed waiver and extension as final, we would award continuation grants based on information provided to us by each grantee, indicating that it is making substantial progress performing its TCPCTIP grant activities.

The proposed extension of the project period and waiver of *34 CFR 75.250* and *75.261(c)(2)* would not exempt the current TCPCTIP grantees from the appropriation account-closing provisions of *31 U.S.C. 1552(a),* nor would they extend the availability of funds previously awarded to current TCPCTIP grantees. As a result of *31 U.S.C. 1552(a),* appropriations available for a limited period may be used for payment of valid obligations for only five years after the expiration of their period of availability for Federal obligation. After that time, the unexpended balance of those funds would be canceled and returned to the U.S. Treasury Department and be unavailable for restoration for any purpose (*31 U.S.C. 1552(b)*).

Tribal Consultation: On September 5, 2023, the Department solicited Tribal input [1] on the proposed waiver and extension for TCPCTIP, pursuant to Executive Order 13175, Consultation and Coordination With Indian Tribal Governments. Tribal members participated by a video conference platform. A total of 66 Tribal members and eight Tribal leaders participated. None of the participants raised objections to the proposed waiver and extension during the consultation or its written comment period that ended October 5, 2023.

Regulatory Flexibility Act Certification

The Secretary certifies that the proposed waiver and extension would not have a significant economic impact on a substantial number of small entities.

The only small entities that would be affected by the proposed waiver and extension are the two grantees selected based on the NIA currently receiving Federal funds. These are the only entities eligible to receive a grant under this program.

The Secretary certifies that the proposed waiver and extension would not have a significant economic impact on these entities because the proposed waiver and extension would impose minimal compliance costs to extend projects already in existence, and the activities required to support the additional year or years of funding would not impose additional regulatory burdens or require unnecessary Federal supervision.

Paperwork Reduction Act of 1995

The proposed waiver and extension do not contain any information collection requirements.

Intergovernmental Review

The TCPCTIP is not subject to Executive Order 12372 and the regulations in *34 CFR part 79.*

Accessible Format: On request to the program contact person listed under **FOR**

[1] Tribal Consultation on Tribally Controlled Postsecondary Career and Technical Institutions Program (TribalConsultationNotice_08172023.pdf (*ed.gov*)).

FURTHER INFORMATION CONTACT, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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

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

Program Authority: 20 U.S.C. 2327.

Amy Loyd,

Assistant Secretary for Career, Technical, and Adult Education.

[FR Doc. 2023–28127 Filed 12–20–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Proposed Extension

AGENCY: Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Notice and request for comments.

SUMMARY: EIA invites public comment on the proposed three-year extension, with change, of Form EIA–111 *Quarterly Electricity Imports and Exports Report,* as required by the Paperwork Reduction Act of 1995. Form EIA–111 collects information on U.S. imports and exports of electricity. Data are used to obtain estimates on the flows of electricity into and out of the United States.

DATES: EIA must receive all comments on this proposed information collection no later than February 20, 2024. If you anticipate difficulty in submitting comments within that period, contact the person listed in **ADDRESSES** as soon as possible.

ADDRESSES: Written comments may only be sent electronically by email to *EIA111@eia.gov.*

FOR FURTHER INFORMATION CONTACT: Glenn McGrath at (202) 586–4325 or by email at *glenn.mcgrath@eia.gov.* The form and instructions are available at *http://www.eia.gov/survey/changes/electricity/.*

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) *OMB No.:* 1905–0208;

(2) *Information Collection Request Title:* Quarterly Electricity Imports and Exports Report;

(3) *Type of Request:* Three-year extension with change;

(4) *Purpose:* Form EIA–111 collects U.S. electricity import and export data on a quarterly basis. The data are used to measure the flow of electricity into and out of the United States. The import and export data are reported by U.S. purchasers, sellers and transmitters of wholesale electricity, including persons authorized by Order to export electric energy from the United States to foreign countries, persons authorized by Presidential Permit to construct, operate, maintain, or connect electric power transmission lines that cross the U.S. international border, and U.S. Balancing Authorities that are directly interconnected with foreign Balancing Authorities. Such entities report monthly flows of electric energy received or delivered across the border, the cost associated with the transactions, and actual and implemented interchange.

(4a) *Proposed Changes to Information Collection:* There is a reduction in the number of survey respondents required to file EIA–111 reports. This reduces the annual estimated responses and associated burden hours. There is no change to the content collected on the EIA–111.

(5) *Annual Estimated Number of Respondents:* 153;

(6) *Annual Estimated Number of Total Responses:* 612;

(7) *Annual Estimated Number of Burden Hours:* 918;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $80,196.48 (918 burden hours times $87.36 per hour). EIA estimates that respondents will have no additional costs associated with the surveys other than the burden hours and maintenance of the information as part of the normal course of business.

Comments are invited on whether or not: (a) The proposed collection of information is necessary for the proper performance of agency functions, including whether the information will have a practical utility; (b) EIA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, is accurate; (c) EIA can improve the quality, utility, and clarity of the information it will collect; and (d) EIA can minimize the burden of the collection of information on respondents, such as automated collection techniques or other forms of information technology.

Statutory Authority: 15 U.S.C. 772(b) and 42 U.S.C. 7101 *et seq.*

Signed in Washington, DC, on December 18, 2023.

Samson A. Adeshiyan,

Office Director, Office of Statistical Methods & Research, U.S. Energy Information Administration.

[FR Doc. 2023–28142 Filed 12–20–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC23–14–000]

Commission Information Collection Activities (FERC–717); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of extension of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (''Commission'' or ''FERC'') is soliciting public comment on the extension to the information collection, FERC–717 (Standards for Business Practices and Communication Protocols for Public Utilities) (OMB Control No. 1902–0173), which will be submitted to the Office of Management and Budget (OMB) for review.

DATES: Comments on the collection of information are due [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: Send written comments on the information collections to OMB through *www.reginfo.gov/public/do/PRAMain.* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number (1902–0173) in the subject line of your comments. Comments should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

A copy of the comments should also be sent to the Commission, in Docket No. IC23–14–000 by any of the following methods:

- *eFiling at Commission's website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *U.S. Postal Service Mail:* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.
- Effective July 1, 2020, delivery of filings other than by eFiling or the U.S. Postal Service should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Instructions:

OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain.* Using the search function under the ''Currently Under Review'' field, select Federal Energy Regulatory Commission; click ''submit,'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Jean Sonneman may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–6362.

SUPPLEMENTARY INFORMATION:

Title: FERC–717, Standards for Business Practices and Communication Protocols for Public Utilities.

OMB Control No.: 1902–0173.

Type of Request: Three-year approval of the FERC–717 information collection requirements with no changes to the current reporting requirements.

Abstract: This notice pertains to a requirement that Transmission Providers [1] provide certain information regarding their transmission operations on an Open Access Same-Time Information System (OASIS). This requirement was established because the Commission has determined that Transmission Customers [2] must have simultaneous access to the same information available to the Transmission Provider in order to receive nondiscriminatory transmission services in accordance with section 205 of the Federal Power Act.[3]

Section 205 of the Federal Power Act (FPA) requires that all rates and charges for the transmission or sale of electric energy and all rules and regulations affecting or pertaining to such rates and charges be just and reasonable. Section 206 of the FPA (16 U.S.C. 824e) authorizes FERC to initiate a proceeding to address any ''rate, charge or classification'' related to the transmission or sale of electricity that the agency determines is ''unjust, unreasonable, unduly discriminatory or preferential.''

Commission regulations at 18 CFR 35.28 and 18 CFR part 37 are in accordance with FPA Sections 205 and 206. The regulation at 18 CFR 35.28 applies to any public utility that owns, operates, or controls interstate transmission facilities and any non-public utility seeking voluntary compliance with jurisdictional transmission tariff reciprocity conditions. These entities must offer transmission service on an open and non-discriminatory basis pursuant to a pro forma Open Access Transmission Tariff (OATT).

Part 37 applies to any public utility that owns, operates, or controls facilities used for the transmission of electric energy in interstate commerce and to transactions performed under the pro forma OATT established under 18 CFR 35.28. As stated at 18 CFR 37.2, the purpose of 18 CFR part 37 is to ensure that potential customers of open access transmission service receive access to information that will enable them to obtain transmission service on a non-discriminatory basis from any Transmission Provider.[4] The regulations in 18 CFR part 37 provide standards of conduct and require the Transmission Provider (or its agent) to create and operate an Open Access Same-Time Information System (OASIS) that gives all users of the open access transmission system access to the same information.

Regulations at 18 CFR part 37 authorize Transmission Providers to operate an OASIS either individually or jointly with other Transmission Providers. These regulations also provide that a Transmission Provider may delegate this responsibility to a Responsible Party [5] such as another Transmission Provider, an Independent System Operator, a Regional Transmission Group, or a Regional Reliability Council.

The collection of information in accordance with FERC–717 is necessary for the implementation of OASIS. The regulation at 18 CFR 37.6 lists the information that Transportation Providers or Responsible Parties must calculate and post on OASIS. Paragraph (a) of section 37.6 provides that the information posted on OASIS must be in such detail and the OASIS must have such capabilities as to allow Transmission Customers [6] to:

(1) Make requests for transmission services offered by Transmission Providers, Resellers [7] and other providers of ancillary services, request the designation of a network resource, and request the termination of the designation of a network resource;

(2) View and download in standard formats, using standard protocols,[8] information regarding the transmission system necessary to enable prudent business decision making;

(3) Post, view, upload and download information regarding available products and desired services;

(4) Clearly identify the degree to which transmission service requests or schedules were denied or interrupted;

(5) Obtain access, in electronic format, to information to support available transmission capability calculations and historical transmission service requests and schedules for various audit purposes; and

(6) Make file transfers and automated computer-to-computer file transfers and queries as defined by the Standards and Communications Protocols Document.

[1] Under 18 CFR 37.3(a), a ''Transmission Provider'' is any public utility that owns, operates, or controls facilities used for the transmission of electric energy in interstate commerce.

[2] Under 18 CFR 37.3(b), a ''Transmission Customer'' is any eligible customer (or its designated agent) that can or does execute a transmission service agreement or can or does receive transmission service.

[3] 16 U.S.C. 824d.

[4] As defined at 18 CFR 37.3(a), a ''Transmission Provider'' is any public utility that owns, operates, or controls facilities used for the transmission of electricity in interstate commerce.

[5] Under 18 CFR 37.3(c), a ''Responsible Party'' is a Transmission Provider or an agent to whom the Transmission Provider has delegated the responsibility of meeting any of the requirements of 18 CFR part 37.

[6] As defined at 18 CFR 37.3(b), a ''Transmission Customer'' is any eligible customer (or its designated agent) that can or does execute a transmission service agreement or can or does receive transmission service.

[7] As defined at 18 CFR 37.3(d), a ''Reseller'' is any Transmission Customer who offers to sell transmission capacity it has purchased.

[8] The standard protocols are included in the Standards for Business Practices and Communication Protocols for Public Utilities adopted by the Wholesale Electric Quadrant (WEQ) of the North American Energy Standards Board (NAESB). The Commission adopted the protocols by reference in 18 CFR 38.1(b)(2)(iv) in a final rule at 86 FR 29491 (June 2, 2021). The protocols remain effective at present.

Calculation Methods, Availability of Information, and Requests

The regulation at 18 CFR 37.6(b)(2) provides that information used to calculate any posting of ATC and TTC [9] must be dated and time-stamped and all calculations shall be performed according to consistently applied methodologies referenced in the Transmission Provider's transmission tariff and shall be based on Commission-approved Reliability Standards, business practice and electronic communication standards, and related implementation documents, as well as current industry practices, standards and criteria. Such calculations shall be conducted in a manner that is transparent, consistent with anticipated system conditions and outages for the relevant timeframe, and not unduly discriminatory or preferential.

On request, the Responsible Party must make all data used to calculate ATC, TTC, Capacity Benefit Margin,[10] and Transmission Reliability Margin [11] for any constrained posted paths publicly available in electronic form within one week of the posting. The information is required to be provided only in the electronic format in which it was created, along with any necessary decoding instructions, at a cost limited to the cost of reproducing the material. This information is to be retained for six months after the applicable posting period.

System planning studies, facilities studies, and specific network impact studies performed for customers or the Transmission Provider's own network resources are to be made publicly available in electronic form on request and a list of such studies must be posted on the OASIS. A study is required to be provided only in the electronic format in which it was created, along with any necessary decoding instructions, at a cost limited to the cost of reproducing the material. These studies are to be retained for five years.

Posting Requirements

Paragraph (b)(3) of 18 CFR 37.6 requires Transmission Providers to calculate and post the ATC, TTC, CBM, and TRM in megawatts for each Posted Path.[12] Paragraph (c) of 18 CFR 37.6 requires Transmission Providers to post prices and a summary of the terms and conditions associated with all transmission products offered to Transmission Customers. Paragraph (d) of 18 CFR 37.6 requires Transmission Providers to post any ancillary service required to be provided or offered under the pro forma OATT.

Standards of Conduct

The Commission established Standards of Conduct at 18 CFR 37.4 requiring that personnel engaged in transmission system operations function independently from personnel engaged in marketing functions. The Standards of Conduct were designed to prevent employees of a public utility (or any of its affiliates) engaged in marketing functions from preferential access to OASIS-related information or from engaging in unduly discriminatory business practices. Companies were required to separate their transmission operations/reliability functions from their marketing/merchant functions and prevent system operators from providing merchant employees and employees of affiliates with transmission-related information not available to all customers at the same time through public posting on the OASIS.

The information that must be posted at OASIS sites is listed at 18 CFR 37.6. The required postings include business practices, communication protocols, transfer capacity, transmission service products, and prices. Some of the required business practices and communication protocols are incorporated by reference at 18 CFR 38.1(b).

The 60-day notice was published on October 13, 2023 (88 FR 70967) and no comments were received during the comment period.

Type of Respondents: Transmission Providers and Responsible Parties.

Estimate of Annual Burden [13]: The previous information collection request (ICR Reference No. 202002–1902–006) in the year 2020 was approved by OMB with a one-time burden that was expected to be completed in Year One. As averaged over a three-year period, the annual responses were estimated as 165 annually, 10 hours per response, and total hours of 1,650 hours. These burdens are not included in this information collection request because all respondents have complied with that one-time burden. The removal of those burdens constitutes a program change.

The estimated annual number of responses for the ongoing information collection activity are adjusted in this information collection request from 162 to 216, an increase of 54 responses. Based on a review of the information collection since our last submission, we have determined this change in number of responses is due to changes in the regulated industry.

The current burden estimates are shown in the following table.

[9] As defined at 18 CFR 37.6(b)(1): (1) ATC is the transfer capability remaining in the physical transmission network for further commercial activity over and above already committed uses, or such definition as contained in Commission-approved Reliability Standards. (2) TTC is the amount of electric power that can be moved or transferred reliably from one area to another area of the interconnected transmission systems by way of all transmission lines (or paths) between those areas under specified system conditions, or such definition as contained in Commission-approved Reliability Standards.

[10] As defined at 18 CFR 37.6(b)(1)(vii), ''Capacity Benefit Margin'' means the amount of TTC preserved by the Transmission Provider for load-serving entities, whose loads are located on that Transmission Provider's system, to enable access by the load-serving entities to generation from interconnected systems to meet generation reliability requirements, or such definition as contained in Commission-approved Reliability Standards.

[11] As defined at 18 CFR 37.6(b)(1)(viii), ''Transmission Reliability Margin'' is the amount of TTC necessary to provide reasonable assurance that the interconnected transmission network will be secure, or such definition as contained in Commission-approved Reliability Standards.

[12] As defined at 18 CFR 37.6(b)(1)(i), ''Posted Path'' means any control area to control area interconnection; any path for which service is denied, curtailed, or interrupted for more than 24 hours in the past 12 months; and any path for which a customer requests to have ATC or TTC posted. For this last category, the posting must continue for 180 days and thereafter until 180 days have elapsed from the most recent request for service over the requested path. For purposes of this definition, an hour includes any part of an hour during which service was denied, curtailed, or interrupted.

[13] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

[14] The Commission staff thinks that the average respondent for this collection is similarly situated to the Commission, in terms of salary plus benefits. Based upon FERC's FY 2022 annual average of $199,867 (for salary plus benefits), the average hourly cost is $96/hour.

BURDEN ESTIMATES FOR FERC–717, STANDARDS FOR BUSINESS PRACTICES AND COMMUNICATION PROTOCOLS FOR PUBLIC UTILITIES

Information collection requirement	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hours and cost per response [14]	Total annual burden hours and total annual cost
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)
Open Access Same-Time Information (OASIS)	216	1	216	30 hrs.; $2,880	6,480 hrs.; $622,080

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: December 15, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–28130 Filed 12–20–23; 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: EC24–25–000.

Applicants: Moonshot Solar, LLC, PGR 2022 Lessee 5, LLC.

Description: Joint Application for Authorization Under section 203 of the Federal Power Act of Moonshot Solar, LLC, et al.

Filed Date: 12/15/23.

Accession Number: 20231215–5193.

Comment Date: 5 p.m. ET 1/5/24.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL23–95–000; ER14–225–009.

Applicants: New Brunswick Energy Marketing Corporation, New Brunswick Energy Marketing Corporation.

Description: New Brunswick Energy Marketing Corporation submits Response to Show Cause Order.

Filed Date: 12/8/23.

Accession Number: 20231208–5225.

Comment Date: 5 p.m. ET 12/29/23.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER23–2359–004.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Amendment to ISA/CSA SA Nos. 6967 & 6968; Queue No. AD2–100/131–Docket ER23–2359 to be effective 9/6/2023.

Filed Date: 12/15/23.

Accession Number: 20231215–5223.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–19–001.

Applicants: Cottontail Solar 1, LLC.

Description: Tariff Amendment: Response to Deficiency Letter to be effective 1/15/2024.

Filed Date: 12/15/23.

Accession Number: 20231215–5206.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–20–001.

Applicants: Cottontail Solar 2, LLC.

Description: Tariff Amendment: Response to Deficiency Filing to be effective 12/4/2023.

Filed Date: 12/15/23.

Accession Number: 20231215–5208.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–21–001.

Applicants: Cottontail Solar 8, LLC.

Description: Tariff Amendment: Response to Deficiency Letter to be effective 12/15/2023.

Filed Date: 12/15/23.

Accession Number: 20231215–5213.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–116–001.

Applicants: Rhythm Ops, LLC.

Description: Tariff Amendment: Rhythm Ops LLC Supplemental Filing to be effective 12/16/2023.

Filed Date: 12/14/23.

Accession Number: 20231214–5205.

Comment Date: 5 p.m. ET 1/4/24.

Docket Numbers: ER24–134–001.

Applicants: Three Rivers District Energy, LLC.

Description: Tariff Amendment: Amendment to 1 to be effective 12/18/2023.

Filed Date: 12/15/23.

Accession Number: 20231215–5222.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–672–000.

Applicants: Moonshot Solar, LLC.

Description: Baseline eTariff Filing: Moonshot Solar, LLC MBR Tariff to be effective 2/1/2024.

Filed Date: 12/14/23.

Accession Number: 20231214–5211.

Comment Date: 5 p.m. ET 1/4/24.

Docket Numbers: ER24–673–000.

Applicants: PGR 2022 Lessee 5, LLC.

Description: Baseline eTariff Filing: PGR 2022 Lessee 5, LLC MBR Tariff to be effective 2/1/2024.

Filed Date: 12/14/23.

Accession Number: 20231214–5213.

Comment Date: 5 p.m. ET 1/4/24.

Docket Numbers: ER24–674–000.

Applicants: GenOn Energy Management, LLC.

Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/15/2023.

Filed Date: 12/14/23.

Accession Number: 20231214–5215.

Comment Date: 5 p.m. ET 1/4/24.

Docket Numbers: ER24–675–000.

Applicants: Pennsylvania Electric Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Pennsylvania Electric Company submits tariff filing per 35.13(a)(2)(iii: Penelec submits One Construction Agreement, SA No. 6640 to be effective 2/14/2024.

Filed Date: 12/15/23.

Accession Number: 20231215–5035.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–676–000.

Applicants: Golden Fields Solar IV, LLC

Description: § 205(d) Rate Filing: SFA Amendment Filing to be effective 12/16/2023.

Filed Date: 12/15/23.

Accession Number: 20231215–5042.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–677–000.

Applicants: New York Independent System Operator, Inc., Niagara Mohawk Power Corporation.

Description: § 205(d) Rate Filing: New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: NYISO–NMPC Joint 205: Scnd Amnd

LGIA for Sithe Independence Facility SA1160 to be effective 12/1/2023.

Filed Date: 12/15/23.

Accession Number: 20231215–5047.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–678–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of WMPA, SA No. 6228; Queue No. AF2–057 Re: Withdrawal to be effective 2/14/2024.

Filed Date: 12/15/23.

Accession Number: 20231215–5065.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–679–000.

Applicants: Duke Energy Florida, LLC, Duke Energy Carolinas, LLC.

Description: Compliance filing: Duke Energy Florida, LLC submits tariff filing per 35: DEF-Compliance Filing—Attachment J to Joint OATT (LGIP/LGIA) to be effective 4/1/2024.

Filed Date: 12/15/23.

Accession Number: 20231215–5067.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–680–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to CTOA re: Removal of ITCI as TO to be effective 2/14/2024.

Filed Date: 12/15/23.

Accession Number: 20231215–5082.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–681–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to Tariff RE: Removal of ITCI as TO to be effective 2/14/2024.

Filed Date: 12/15/23.

Accession Number: 20231215–5100.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–682–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: SCE 3rd Amend LGIA, Genesis McCoy Solar TOT223/SA109 + Termination LA (SA252) to be effective 2/14/2024.

Filed Date: 12/15/23.

Accession Number: 20231215–5105.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–683–000.

Applicants: Duke Energy Carolinas, LLC, Duke Energy Florida, LLC, Duke Energy Progress, LLC.

Description: Compliance filing: Duke Energy Carolinas, LLC submits tariff filing per 35: Revisions to Attachment M to Joint OATT (SGIP/SGIA) to be effective 4/1/2024.

Filed Date: 12/15/23.

Accession Number: 20231215–5112.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–684–000.

Applicants: Fitchburg Gas and Electric Light Company, ISO New England Inc.

Description: § 205(d) Rate Filing: Fitchburg Gas and Electric Light Company submits tariff filing per 35.13(a)(2)(iii: FG&E; Request to Correct the Tariff Record to be effective 3/1/2020.

Filed Date: 12/15/23.

Accession Number: 20231215–5128.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–685–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: PowerSouth NITSA Amendment (Add Five Points 115 kV DP) to be effective 11/20/2023.

Filed Date: 12/15/23.

Accession Number: 20231215–5141.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–686–000.

Applicants: New York Independent System Operator, Inc., PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: NYISO–PJM Joint 205 re: JOA tariff revisions to be effective 2/14/2024.

Filed Date: 12/15/23.

Accession Number: 20231215–5165.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–687–000.

Applicants: Golden Fields Solar III, LLC.

Description: § 205(d) Rate Filing: Certificate of Concurrence to be effective 12/16/2023.

Filed Date: 12/15/23.

Accession Number: 20231215–5166.

Comment Date: 5 p.m. ET 1/5/24.

Docket Numbers: ER24–688–000.

Applicants: Florida Power & Light Company.

Description: § 205(d) Rate Filing: FPL Amendments to OATT NWFL System Formula Rate Template to be effective 2/15/2024.

Filed Date: 12/15/23.

Accession Number: 20231215–5171.

Comment Date: 5 p.m. ET 1/5/24.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: December 15, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–28133 Filed 12–20–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–492–000]

Florida Gas Transmission Company, LLC; Notice of Availability of the Environmental Assessment for the Proposed South Louisiana Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the South Louisiana Project, proposed by Florida Gas Transmission Company, LLC (FGT) in the above-referenced docket. FGT requests to increase its certificated capacity and throughput by 100,000 million British thermal units per day to its shipper, Florida Power & Light Company, to diversify its supply sources of natural gas for downstream customers. FGT would accomplish this by modifying certain compressor stations in St. Landry, East Baton Rouge, and Washington Parishes, Louisiana, and Perry County, Mississippi.

The EA assesses the potential environmental effects of the construction and operation of the South Louisiana Project in accordance with the requirements of the National Environmental Policy Act. The FERC

staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The proposed South Louisiana Project includes the following facilities:

- uprating two existing natural gas-fired compressor turbine units at FGT's existing Compressor Station 7.5 in St. Landry Parish, Louisiana from 6,500 horsepower (hp) to 7,700 hp, each;
- adding process cooling units to support the existing gas compressor units at FGT's existing Compressor Station 8 in East Baton Rouge Parish, Louisiana;
- installing one new 7,700 hp natural gas-fired turbine compressor unit at FGT's existing Compressor Station 9 in Washington Parish, Louisiana;
- installing one new 15,900 hp natural gas-fired compressor turbine unit at FGT's existing Compressor Station 10 in Perry County, Mississippi; and
- installing and modifying auxiliary facilities as needed at each location.

The Commission mailed a copy of the *Notice of Availability* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; and newspapers and libraries in the project area. The EA is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the natural gas environmental documents page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). In addition, the EA may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://elibrary.ferc.gov/eLibrary/search*), select ''General Search'' and enter the docket number in the ''Docket Number'' field (*i.e.,* CP23–492). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

The EA is not a decision document. It presents Commission staff's independent analysis of the environmental issues for the Commission to consider when addressing the merits of all issues in this proceeding. Any person wishing to comment on the EA may do so. Your comments should focus on the EA's disclosure and discussion of potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on this project, it is important that we receive your comments in Washington, DC on or before 5:00 p.m. Eastern Time on January 16, 2024.

For your convenience, there are three methods you can use to file your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature on the Commission's website (*www.ferc.gov*) under the link to FERC Online. This is an easy method for submitting brief, text-only comments on a project;

(2) You can also file your comments electronically using the eFiling feature on the Commission's website (*www.ferc.gov*) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP23–492–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered. Only intervenors have the right to seek rehearing or judicial review of the Commission's decision. At this point in this proceeding, the timeframe for filing timely intervention requests has expired. Any person seeking to become a party to the proceeding must file a motion to intervene out-of-time pursuant to Rule 214(b)(3) and (d) of the Commission's Rules of Practice and Procedures (18 CFR 385.214(b)(3) and (d)) and show good cause why the time limitation should be waived. Motions to intervene are more fully described at *https://www.ferc.gov/how-intervene.*

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Dated: December 15, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–28131 Filed 12–20–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM19–12–000]

Revisions to the Filing Process for Commission Forms; Notice of eForms Updates

Notice is hereby given that, on March 28, 2024, the eXtensible Business Reporting Language (XBRL) taxonomies, validation rules, and rendering files needed to file the FERC Form Nos. 1, 1–F, 2, 2–A, 3–Q electric, 3–Q natural gas,

6, 60, and 714,[1] will be updated to Version 2024–04–01.[2] Version 2024–04–01 will be effective starting with the first quarter 2024 forms.

The draft updated (Version 2024–01–01) taxonomies, validation rules, and rendering files are currently available for download in the eForms portal (*https://ecollection.ferc.gov*) and are available for testing in the eForms portal. Suggestions on the draft Version 2024–01–01 taxonomies can be provided by March 1, 2024, through *https://XBRLview.ferc.gov.*

FERC Form filings due after March 28, 2024, must be filed using the Version 2024–04–01 taxonomies, validation rules, and rendering files, including the 2023 FERC Form Nos. 60 and 714 [3] and the 2024 FERC Form Nos. 1, 1–F, 2, 2–A, 3–Q electric, 3–Q natural gas, and 6. Please see the Taxonomy History page (*https://ecollection.ferc.gov/taxonomy History*) for detailed version information organized by form.

Dated: December 15, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–28129 Filed 12–20–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR24–22–000.
Applicants: Gulf Coast Express Pipeline LLC.
Description: § 284.123(g) Rate Filing: Hub Services Term Extension to be effective 12/31/2023.
Filed Date: 12/15/23.
Accession Number: 20231215–5107.
Comment Date: 5 p.m. ET 1/5/24.
§ 284.123(g) Protest: 5 p.m. ET 2/13/24.

Docket Numbers: PR24–23–000.
Applicants: CR Permian Natural Gas Transmission, LLC.
Description: § 284.123(g) Rate Filing: CR Permian Natural Gas Transmission SOC Filing to be effective 12/15/2023.
Filed Date: 12/15/23.
Accession Number: 20231215–5121.
Comment Date: 5 p.m. ET 1/5/24.
§ 284.123(g) Protest: 5 p.m. ET 2/13/24.

Docket Numbers: RP24–246–000.
Applicants: Midcontinent Express Pipeline LLC.
Description: § 4(d) Rate Filing: Non-Conforming Agmt Update Permanent Release XTO to ExxonMobil to be effective 1/1/2024.
Filed Date: 12/14/23.
Accession Number: 20231214–5167.
Comment Date: 5 p.m. ET 12/26/23.

Docket Numbers: RP24–247–000.
Applicants: Portland Natural Gas Transmission System.
Description: Compliance filing: 2023 Fuel Mechanism Report to be effective N/A.
Filed Date: 12/15/23.
Accession Number: 20231215–5039.
Comment Date: 5 p.m. ET 12/27/23.

Docket Numbers: RP24–248–000.
Applicants: Tres Palacios Gas Storage LLC.
Description: § 4(d) Rate Filing: TPGS Second Revised Volume No. 1 Baseline eff 1–15–24 to be effective 1/15/2024.
Filed Date: 12/15/23.
Accession Number: 20231215–5062.
Comment Date: 5 p.m. ET 12/27/23.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding. The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: December 15, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–28132 Filed 12–20–23; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2019–0188; FRL–11621–01–OCSPP]

RTI International and ToxStrategies LLC; Transfer of Data (December 2023)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces that pesticide related information submitted to EPA's Office of Pesticide Programs (OPP) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), including information that may have been claimed as Confidential Business Information (CBI) by the submitter, will be transferred to RTI International and its subcontractor, ToxStrategies LLC., in accordance with the CBI regulations. RTI International and its subcontractor, ToxStrategies LLC., have been awarded a contract to perform work for OPP, and access to this information will enable RTI International and its subcontractor, ToxStrategies LLC., to fulfill the obligations of the contract.

DATES: RTI International and its subcontractor, ToxStrategies LLC., will be given access to this information on or before December 26, 2023.

FOR FURTHER INFORMATION CONTACT: William Northern, Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1493 email address: *northern.william@epa.gov.*

SUPPLEMENTARY INFORMATION:

[1] The Commission adopted the XBRL process for filing these forms in Order No. 859. *Revisions to the Filing Process for Comm'n Forms,* Order No. 859, 167 FERC ¶ 61,241 (2019).

[2] The Commission adopted the final XBRL taxonomies, protocols, implementation guide, and other supporting documents, and established the implementation schedule for filing the Commission Forms following a technical conference in this proceeding. *Revisions to the Filing Process for Comm'n Forms,* 172 FERC ¶ 61,059 (2020). The Commission also stated that technical updates, such as the updates referenced here, will not take effect until at least 60 days after issuance of a notice from the Office of the Secretary. *Id.* P 26.

[3] The changes to FERC Form Nos. 60 and 714 consist of minor updates to the version dates, rendering files, and time zone abbreviations for these forms.

I. General Information

A. Does this action apply to me?

This action applies to the public in general. As such, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0188, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (202) 566–0294. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

II. Contractor Requirements

Under Contract No. 68HERC24F0015, RTI International and its subcontractor, ToxStrategies LLC., will manage all aspects of the task order including, but not limited to, the technical, quality assurance, schedule, cost, and communication requirements.

The Contractor shall only work on tasks in the Performance Work Statement as directed by the TOCOR. The TOCOR shall identify specific due dates for deliverables for Tasks 3–4 via technical direction. Technical direction will be provided in writing by the Contracting Officer or the TOCOR as delegated by the Contracting Officer.

The Contractor shall schedule at least biweekly meetings (teleconference, in-person, Skype, Adobe Connect, or other media) with the TOCOR to discuss the status of the work including reporting any issues with respect to schedule slip or cost overruns. The TOCOR will identify, as needed, other individuals who should participate in these calls. Additional teleconference calls may be scheduled by the TOCOR as needed. Note: Telephone or in-person reports are not replacements for required written communications.

In addition to biweekly meetings, the Contractor shall update the TOCOR via telephone (and follow-up via email) and, in writing, via email, of any issues on an ongoing basis.

The Contractor shall immediately inform the TOCOR when any hours or costs for any task has exceeded or is expected to exceed the contractor estimate by >10%.

The Contractor shall immediately inform the TOCOR of any problems that may impact the production, budget, and/or delivery of deliverables.

The Contractor shall provide the combined monthly status report and financial in PDF format, with the financial report also provided in a spreadsheet format such as Excel or CSV.

OPP has determined that access by RTI International and its subcontractor, ToxStrategies LLC., to information on all pesticide chemicals is necessary for the performance of this contract.

Some of this information may be entitled to confidential treatment. The information has been submitted to EPA under FIFRA sections 3, 4, 6, and 7 and under FFDCA sections 408 and 409.

In accordance with the requirements of 40 CFR 2.307(h)(2), the contract with RTI International and its subcontractor, ToxStrategies LLC., prohibits use of the information for any purpose not specified in the contract; prohibits disclosure of the information to a third party without prior written approval from the Agency; and requires that each official and employee of the contractor sign an agreement to protect the information from unauthorized release and to handle it in accordance with the *FIFRA Information Security Manual.* In addition, RTI International and its subcontractor, ToxStrategies LLC. are required to submit for EPA approval a security plan under which any CBI will be secured and protected against unauthorized release or compromise. No information will be provided to RTI International and its subcontractor, ToxStrategies LLC., until the requirements in this document have been fully satisfied. Records of information provided to RTI International and its subcontractor, ToxStrategies LLC., will be maintained by EPA Project Officers for this contract. All information supplied to RTI International and its subcontractor, ToxStrategies LLC., by EPA for use in connection with this contract will be returned to EPA when RTI International and its subcontractor, ToxStrategies LLC., have completed their work.

Authority: 7 U.S.C. 136 *et seq.;* 21 U.S.C. 301 *et seq.*

Dated: December 15, 2023.

Kimberly Smith,

Acting Director, Information Technology and Resources Management Division, Office of Program Support.

[FR Doc. 2023–28088 Filed 12–20–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1003; FR ID 191626]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before February 20, 2024. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No

person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

OMB Control Number: 3060–1003.

Title: Communications Disaster Information Reporting System (DIRS).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government; Federal Government.

Number of Respondents and Responses: 400 respondents; 104,000 responses.

Estimated Time per Response: 1 hour—1.5 hours (average per response).

Frequency of Response: On occasion and Annual Reporting Requirements and Recordkeeping Requirements.

Obligation to Respond: Voluntary. Statutory authority for this collection is contained in sections 1, 4(i), 4(j), 4(o), 251(e)(3), 254, 301, 303(b), 303(g), 303(r), 307, 309(a), 309(j), 316, 332, and 403 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 154(i)–(j) & (o), 251(e)(3), 254, 301, 303(b), 303(g), 303(r), 332, 403, and 1302.

Total Annual Burden: 16,320 hours.

Total Annual Cost: No Cost.

Needs and Uses: The Commission launched the Disaster Information Reporting System (DIRS) in 2007 pursuant to its mandate to promote the safety of life and property through the use of wire and radio communication as required by the Communications Act of 1934, as amended. DIRS is a voluntary, efficient, and web-based system that communications companies may use to report their infrastructure status during times of crisis (*e.g.,* related to a disaster). DIRS uses a number of template forms tailored to different communications sectors (*i.e.,* wireless, wireline, broadcast, and cable) to facilitate the entry of this information. To use DIRS, a company first inputs its emergency contact information. After this, they submit information using the template form appropriate for their communications sector. In a *Second Report and Order* adopted on March 18, 2021, as FCC 21–34, the Commission adopted rules allowing certain federal, state, and Tribal Nation agencies (Participating Agencies) to access to certain geographically relevant reports filed in the Commission's Disaster Information Reporting System (DIRS). The information collections and record keeping provisions adopted will allow Participating Agencies to apply for, and receive access to, DIRS report in the areas where they have jurisdiction. The collection will further enable these Participating Agencies, at their election, to share DIRS reports with qualified local agencies whose jurisdiction is affected by a disaster, while still maintaining the confidentiality of the substantive data. The changes to the data collections fields in the DIRS filings made by service providers will further facilitate the ability of Participating Agencies to access those reports relevant to their specific geographies. Finally, the changes to the information collection and associated recordkeeping requirements, including retention by participating agencies of qualification forms submitted by local agency seeking access to DIRS data, as well as a list of which local agencies receive information from the Participating Agency, training materials setting clear parameters for the use of DIRS data, and a list of those persons granted DIRS account access, will enable auditing functions to ensure accountability in the use of DIRS information and immediate reporting of breaches of access or confidentiality protocols.

The Commission notes that the information sharing framework established in the Second Report and Order allows for access to be granted not only for DIRS, but also to the Commission's Network Outage Reporting System (NORS). We note that the process and requirements for Participating Agencies under this framework is identical, regardless of whether they seek access to NORS, DIRS, or both. Because the Commission anticipates that NORS and DIRS access will be requested together in most cases, it believes that the estimated burden hours and costs for Participating Agencies associated with DIRS access are fully included in the estimates that it has separately submitted as part of its collection on Part 4 of the Commission's Rules Concerning Disruptions to Communications, OMB Control No. 3060–0484. To avoid double-counting the estimated burden hours and costs associated with both collections, the Commission estimates the marginal cost of the Participating Agency aspect of this collection to be zero.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–28096 Filed 12–20–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX; FR ID 191715]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before February 20, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Application to Participate in a 5G Fund Auction, FCC Form 184.

Form Number: FCC Form 184.

Type of Review: New collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and state, local or tribal governments.

Number of Respondents and Responses: 300 respondents and 300 responses.

Estimated Time per Response: 7 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection 47 U.S.C. 154, 254 and 303(r).

Total Annual Burden: 2,100 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission will use the information collected under this information collection to determine whether applicants are qualified to participate in a 5G Fund auction.

In its November 2011 *USF/ICC Transformation Order,* the Commission took numerous steps to comprehensively reform and modernize the universal service program to ensure that robust, affordable fixed and mobile voice and broadband service are available to those in rural, insular, and high cost areas of the country. *Connect America Fund et al.,* Order and Further Notice of Proposed Rulemaking, FCC 11–161 (*USF/ICC Transformation Order*). Among other things, the Commission (1) established a two-phased Mobility Fund to award universal service support for mobile services in a cost-effective manner to no more than one provider per area in areas where a private-sector business case was lacking, (2) directed that universal service support under the Mobility Fund be awarded by competitive bidding, (3) adopted the rules and framework for Mobility Fund Phase I, and (4) sought comment on the rules and proposed framework for Mobility Fund Phase II. In its February 2017 *Mobility Fund Phase II Report and Order,* the Commission adopted the rules and framework for Mobility Fund Phase II to provide ongoing universal service support over a ten-year term to areas of the country unlikely to receive 4G LTE service absent subsidies, along with the framework for a challenge process to resolve disputes about areas that were found to be presumptively ineligible for support. *Connect America Fund; Universal Service Reform—Mobility Fund II,* Report and Order and Further Notice of Proposed Rulemaking, FCC 17–11. However, in its October 2020 *5G Fund Report and Order,* the Commission established the 5G Fund as a replacement for Mobility Fund Phase II, and adopted the framework and rules for the 5G Fund to award universal service support in two phases through separate reverse auctions to ensure the deployment of high-speed, 5G mobile service in areas unlikely to see such service absent subsidies. *Establishing a 5G Fund for Rural America,* Report and Order, FCC 20–150 (*5G Fund Report and Order*). In the *5G Fund Report and Order,* the Commission, among other things, adopted a two-stage application process for 5G Fund auctions consisting of pre-auction requirements for applicants seeking to participate in a 5G Fund auction and post-auction requirements for winning bidders applying for 5G Fund support. The Commission decided that applicants seeking to participate in a 5G Fund auction would be required to provide both the information required by section 1.21001(b) of the Commission's existing Part 1, Subpart AA universal service competitive bidding rules, 47 CFR 1.21001(b), and the additional application disclosures and certifications specific to the 5G Fund required by section 54.1014(a) of the Commission's rules, 47 CFR 54.1014(a).

Under this new information collection, the Commission will collect the information, disclosures, and certifications required by sections 1.21001(b) and 54.1014(a) of the Commission's rules from each applicant seeking to participate in a 5G Fund auction, and will use the information, disclosures, and certifications to determine whether an applicant is legally, technically, and financially qualified to participate in a 5G Fund auction. To aid in collecting this information, the Commission has created FCC Form 184, which will be used to provide the information, disclosures, and certifications required by sections 1.21001(b) and 54.1014(a). Commission staff will review the information, disclosures, and certifications collected on FCC Form 184 as part of the pre-auction process, prior to the start of the auction, and determine whether each applicant satisfies the Commission's requirements to participate in an auction for 5G Fund support. Without the information collected on FCC Form 184, the Commission will not be able to determine if an applicant is legally qualified to participate in a 5G Fund auction and has complied with the various applicable regulatory and statutory auction requirements for such participation. This approach provides an appropriate screen to ensure serious participation without being unduly burdensome.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–28097 Filed 12–20–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than January 5, 2024.

A. Federal Reserve Bank of Kansas City Jeffrey Imgarten, Assistant Vice President, One Memorial Drive, Kansas City, Missouri 64198–0001. Comments can also be sent electronically to *KCApplicationComments@kc.frb.org:*

1. *The Gary and Dixie Beymer Trust, Gary Beymer and Dixie Beymer, as co-trustees, all of Lakin, Kansas; the Robert Beymer Revocable Trust dtd 02/24/2022, Robert Beymer as trustee, the Diane Beymer Credit Shelter Trust, Robert Beymer as trustee, all of Garden City, Kansas; C. Easton Beymer, Kingwood, Texas; Blake Beymer, Holcomb, Kansas; Brick Beymer and Michelle Thompson (née Beymer), both of Lakin, Kansas; Caitlin Orcutt (née Beymer), Milliken, Colorado; and Taryn Remey (née Beymer), McPherson, Kansas;* to form the Beymer Family Control Group, a group acting in

concert, to retain voting shares of Lakin Bancshares, Inc., and thereby indirectly retain voting shares of the KCB Bank, both of Lakin, Kansas.

Board of Governors of the Federal Reserve System.

Erin M. Cayce,

Assistant Secretary of the Board.

[FR Doc. 2023–28035 Filed 12–20–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9889–N]

Charter Renewal for Advisory Committee on Ground Ambulance and Patient Billing (GAPB)—November 16, 2023

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, requires the Secretary of Health and Human Services (HHS), the Secretary of Labor, and the Secretary of the Treasury (the Secretaries) to establish and convene an advisory committee for the purpose of reviewing options to improve the disclosure of charges and fees for ground ambulance services, better inform consumers of insurance options for such services, and protect consumers from balance billing (the ''GAPB Advisory Committee'' or the ''Committee''). The Secretaries established the GAPB Advisory Committee on November 16, 2021 with a standard 2-year expiration period ending November 16, 2023. In accordance with the Federal Advisory Committee Act (FACA), HHS is hereby giving notice that the charter for the Advisory Committee on Ground Ambulance and Patient Billing (GAPB) was renewed effective November 16, 2023.

DATES: The charter for the Advisory Committee on GAPB was renewed is November 16, 2023.

ADDRESSES: Inquiries about the Committee can be mailed to Center for Consumer Information & Insurance Oversight, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop WB–22–75, Baltimore, MD 21244–8016.

FOR FURTHER INFORMATION CONTACT: Shaheen Halim, CMS, by phone (410) 786–0641 or via email at gapbadvisorycommittee@*cms.hhs.gov.*

Press inquiries may be submitted by phone at (202) 690–6145 or via email at *press@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 117(a) of the No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, div. BB, tit. I, Public Law 116–260 (Dec. 27, 2020), requires the Secretaries of Labor, HHS, and the Treasury to establish and convene an advisory committee for the purpose of reviewing options to improve the disclosure of charges and fees for ground ambulance services, better inform consumers of insurance options for such services, and protect consumers from balance billing. The GAPB Advisory Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463 (Oct. 6, 1972), as amended, 5 U.S.C. App. 2.

The GAPB Advisory Committee first convened in 2023. It will make recommendations with respect to the disclosure of charges and fees for ground ambulance services and insurance coverage, consumer protection and enforcement authorities of the Departments of Labor, Health and Human Services, and the Treasury (the Departments) and relevant States, and the prevention of balance billing to consumers. The recommendations shall address options, best practices, and identified standards to prevent instances of balance billing; steps that can be taken by State legislatures, State insurance regulators, State attorneys general, and other State officials as appropriate, consistent with current legal authorities regarding consumer protection; and legislative options for Congress to prevent balance billing. The purpose of renewing the GAPB Advisory Committee is to provide the Committee with more time to review relevant information, review options and best practices, and consider the recommendations that it has been charged with making. A copy of the charter and other information regarding the GAPB Advisory Committee's activity can be found at: *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb.* The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: December 18, 2023.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–28128 Filed 12–20–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3455–PN]

Medicare and Medicaid Programs; Application From The Compliance Team (TCT) for Continued Approval of its Rural Health Clinics Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from the Compliance Team (TCT) for continued recognition as a national accrediting organization (AO) for Rural Health Clinics (RHCs) that wish to participate in the Medicare or Medicaid programs. The statute requires that within 60 days of receipt of an organization's complete application, the Centers for Medicare & Medicaid Services (CMS) publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by January 22, 2024.

ADDRESSES: In commenting, refer to file code CMS–3455–PN.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3455–PN, P.O. Box 8013, Baltimore, MD 21244–8013.

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–3455–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Joy Webb (410) 786–1667.

Shonte Carter (410) 786–3532.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. We 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. We continue 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.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a Medicare-participating Rural Health Clinic (RHC), provided certain requirements are met. Sections 1861(aa)(1) and (2) and 1905(l)(1) of the Social Security Act (the Act) establish distinct criteria for an entity seeking designation as an RHC. Regulations concerning provider agreements are at 42 CFR part 489, and those pertaining to activities relating to the survey and certification of facilities and other entities are at 42 CFR part 488. The regulations at 42 CFR part 491 specify the conditions that a RHC must meet to participate in the Medicare program.

Generally, to enter into an agreement, a RHC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 491 of our regulations. Thereafter, the RHC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

However, there is an alternative to surveys by State agencies. Section 1865(a)(1) of the Act provides that if a provider entity demonstrates through accreditation by a Center for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under 42 CFR part 488, subpart A must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AO are set forth at § 488.4 and 488.5. The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of their accreditation program every 6 years or sooner as determined by CMS.

The Compliance Team's (TCT's) term of approval for their RHC accreditation program expires July 17, 2024.

II. Approval of Deeming Organization

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a national AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of TCT's request for continued approval for its RHC accreditation program. This notice also solicits public comment on whether TCT's requirements meet or exceed the Medicare conditions for certification (CfCs) for RHCs.

III. Evaluation of Deeming Authority Request

TCT submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its RHC accreditation program. This application was determined to be complete on October 25, 2023. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of TCT will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of TCT's standards for RHCs as compared with CMS' RHC CfCs.
- TCT's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of TCT's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited RHCs.

++ TCT's processes and procedures for monitoring RHCs found out of compliance with TCT's program requirements. These monitoring procedures are used only when TCT identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c).

++ TCT's capacity to report deficiencies to the surveyed RHCs and respond to the RHC's plan of correction in a timely manner.

++ TCT's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of TCT's staff and other resources, and its financial viability.

++ TCT's capacity to adequately fund required surveys.

++ TCT's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ TCT's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ TCT's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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 preamble, and when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–28111 Filed 12–20–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2565]

510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review; Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review.'' This draft guidance provides FDA's current thinking regarding the 510(k) Third Party (3P510k) Review Program and review of Emergency Use Authorizations (EUA) requests by a third party review organizations (3PEUA review). The 3P510k Review Program and 3PEUA review create an alternative process for manufacturers to seek review of 510(k) submissions and EUA requests to assist FDA in reviewing in a timely manner. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by February 20, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–2565 for ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the

SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2438, Silver Spring, MD 20993–0002, 301–796–6524.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review.'' This draft guidance updates the previously issued ''510(k) Third Party Review Program'' guidance to further clarify the 3P510k Review Program and outline how FDA may use third party review organizations to review EUA requests under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3) and consistent with section 565(i) of the FD&C Act (21 U.S.C. 360bbb–4(i)).

This draft guidance distinguishes FDA's expectations for the 3P510k Review Program and for 3PEUA review; describes the factors FDA will use in determining device type eligibility for review by 3P510k Review Organizations; describes FDA's expectations for third party organizations when conducting substantial reviews of 510(k) submissions and EUA requests; outlines FDA's process for the recognition, rerecognition, suspension, and withdrawal of recognition for 3P510k Review Organizations; and describes the expectations regarding compensation to third party review organizations. This draft guidance, when final, will also outline FDA's current thinking on leveraging the International Medical Device Regulators Forum's documents for the 3P510k Review Program. When finalized, this guidance will supersede the final guidance entitled ''510(k) Third Party Review Program; Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations'' published in the **Federal Register** of March 12, 2020 (85 FR 14489).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on 510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI01500013 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB.

21 CFR part; guidance; or FDA form	Topic	OMB control No.
''510(k) Third-Party Review Program''	510(k) Third-Party Review Program	0910–0375
807, subpart E	Premarket notification	0910–0120
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
''Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders''.	Emergency Use Authorization	0910–0595
''Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes''.	Appeals Process	0910–0738

Dated: December 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28095 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2009; FDA–2022–E–2010; FDA–2022–E–2011; FDA–2022–E–2012; and FDA–2022–E–2013]

Determination of Regulatory Review Period for Purposes of Patent Extension; LYBALVI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for LYBALVI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by February 20, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 18, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 20, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2022–E–2009; FDA–2022–E–2010; FDA–2022–E–2011; FDA–2022–E–2012; and FDA–2022–E–2013 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; LYBALVI.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory

review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, LYBALVI (olanzapine and samidorphan), which is indicated for the treatment of:

- Schizophrenia in adults
- Bipolar I disorder in adults
  - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance monotherapy treatment

Subsequent to this approval, the USPTO received patent term restoration applications for LYBALVI (U.S. Patent Nos. 7,262,298; 9,119,848; 9,126,977; 10,300,054; and 10,716,785) from Alkermes Inc. and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 28, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of LYBALVI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for LYBALVI is 4,564 days. Of this time, 4,003 days occurred during the testing phase of the regulatory review period, while 561 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* November 30, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 30, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* November 15, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for LYBALVI (NDA 213378) was initially submitted on November 15, 2019.

3. *The date the application was approved:* May 28, 2021. FDA has verified the applicant's claim that NDA 213378 was approved on May 28, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 311 days, 646 days, 1,325 days, 1,328 days, or 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28094 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4201]

Agency Information Collection Activities; Proposed Collection; Comment Request; Examination of Implied Claims in Direct-to-Consumer Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled ''Examination of Implied Claims in Direct-to-Consumer Prescription Drug Promotion.''

DATES: Either electronic or written comments on the collection of information must be submitted by February 20, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 20, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets

Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–4201 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Examination of Implied Claims in Direct-to-Consumer Prescription Drug Promotion.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.* The draft survey instrument is available upon request from *DTCresearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Examination of Implied Claims in Direct-to-Consumer Prescription Drug Promotion

OMB Control Number 0910–NEW

I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated, so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and the characteristics of the disease and product impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience. Our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area, advertising features.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research,* which includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

Direct-to-consumer (DTC) prescription drug promotion may include truthful and non-misleading claims about the product. A particular claim may be direct (explicit) or indirect (implied or implicit). Some prior

research has shown that implied claims are misremembered as explicit claims (Ref. 1). Other research has shown that claims can result in a misleading impression of the product through implication, rather than literal interpretation (Ref. 2). Understanding how consumers who self-report having been diagnosed with a target condition interpret implied claims in DTC prescription drug promotion—and how their perceptions differ from those of consumers who have not been diagnosed with the target condition—will provide valuable insight into the relevance and impact of various product attributes and promotional claims on treatment decisions.

The current project will test the impact of several implied claims in DTC prescription drug advertising on consumer perceptions. The project has two phases: experimental and conjoint analysis. In the experimental phase, participants will view one version of a DTC television ad containing both explicit and one of four implicit product claims of interest or a control ad containing only explicit claims, and be asked their impressions of the product's risks, benefits, and other attributes. In the conjoint analysis phase, we will conduct a best-worst scaling (BWS) experiment to elicit the relative importance of various characteristics of immunotherapies indicated to treat patients with advanced melanoma, including several implied claims. For this study, we will use an object case design, which does not require us to manipulate different levels of the characteristics included in the design. Participants will be shown a series of choice tasks that are each made up of different subsets of an experiment-wide list of characteristics. Each participant will complete several tasks, and will be asked to first select which one they would care about the most if they were considering an immunotherapy, followed by the characteristic they would care about the least.

We are proposing to include 13 characteristics in our BWS experiment. Each task will include only four of those characteristics, the combination of which will be drawn from a balanced incomplete block design (BIBD; see Ref. 3). A BIBD ensures that (1) each task contains the same number of characteristics; (2) each characteristic occurs the same number of times across tasks; and (3) each pair of characteristics is shown to participants the same number of times over the entire experiment. These three properties are desirable for meeting estimation assumptions (*e.g.,* balance and orthogonality). An additional (and unique) favorable property of including 13 characteristics in the experiment is that BIBDs exist that yield 13 tasks with 4 characteristics per task. Thirteen is a manageable number of tasks for a single participant to complete, and as a result, the full experimental design will be replicated by each participant.

We estimate that participation in the study will take approximately 20 minutes. Adult voluntary participants aged 18 years or older will be recruited by email through an internet panel, and participant eligibility will be determined with a screener at the beginning of the online survey. We will exclude individuals who work in healthcare settings, employees of the Department of Health and Human Services, or individuals who work in the marketing, advertising, or pharmaceutical industries. Half the sample will consist of individuals who self-identify as cancer survivors, excluding survivors of certain nonmelanoma skin cancers.

The target sample size for the experimental phase is 1,030 adults and the target sample size for the conjoint analysis phase is 800 adults. Prior to conducting the main study for both the experimental phase and conjoint analysis phase, we will conduct at least one wave of pretests for each study phase: one before the experimental phase and one before the conjoint analysis phase. If the first pretest wave reveals that changes to the measurement instruments, stimuli, or procedures are required, a second pretest wave (for either the experimental phase, conjoint phase, or both) will be conducted with revised materials. The target sample size for each wave of pretests is 120 adults, split evenly between the experimental and conjoint analysis phases.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Experimental phase Pretest 1 Screener [3]	132	1	132	0.08 (5 minutes)	11
Experimental Phase Pretest 1	66	1	66	0.33 (20 minutes)	22
Conjoint Analysis Phase Pretest 1 Screener [3]	132	1	132	0.08 (5 minutes)	11
Conjoint Analysis Phase Pretest 1	66	1	66	0.33 (20 minutes)	22
Experimental Phase Pretest 2 Screener [3 4]	132	1	132	0.08 (5 minutes)	11
Experimental Phase Pretest 2 [4]	66	1	66	0.33 (20 minutes)	22
Conjoint Analysis Phase Pretest 2 Screener [3 4]	132	1	132	0.08 (5 minutes)	11
Conjoint Analysis Phase Pretest 2 [4]	66	1	66	0.33 (20 minutes)	22
Experimental Phase Screener [3]	2,266	1	2,266	0.08 (5 minutes)	181
Experimental Phase Main Study	1,133	1	1,133	0.33 (20 minutes)	374
Conjoint Analysis Phase Screener [3]	1,760	1	1,760	0.08 (5 minutes)	141
Conjoint Analysis Phase Main Study	880	1	880	0.33 (20 minutes)	290
Total			6,831		1,118

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.
[3] Number of screener respondents assumes a 50 percent eligibility rate with targeted recruitment.
[4] Pretest 2 will be conducted only if changes to study materials for the respective study phase are made in response to the findings of Pretest 1 for that phase.

As with most online and mail surveys, it is always possible that some participants are in the process of completing the survey when the target number is reached and that those surveys will be completed and received before the survey is closed out. To account for this, we have estimated approximately 10 percent overage for

samples in the pretest and main study of the experimental phase and conjoint analysis phase.

II. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register,** but websites are subject to change over time.

1. Harris, R.J., M.L. Trusty, J.I. Bechtold, et al. ''Memory for Implied Versus Directly Stated Advertising Claims,'' *Psychology & Marketing,* vol. 6, issue 2, pp. 87–96, 1989, *https://doi.org/10.1002/mar.4220060202.*
2. Burke, R.R., W.S. DeSarbo, R.L. Oliver, et al. ''Deception By Implication: An Experimental Investigation,'' *Journal of Consumer Research,* vol. 14, issue 4, pp. 483–494, 1988, *https://doi.org/10.1086/209130.*
3. Louviere, J.J., T.N. Flynn, and A.A.J. Marley, *Best-Worst Scaling: Theory, Methods, and Applications.* Cambridge: Cambridge University Press, 2015.

Dated: December 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28093 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1136]

Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' This guidance provides recommendations to sponsors on the development of monoclonal antibody products targeting SARS–CoV–2 intended for the prevention or treatment of COVID–19, including addressing the impact of emerging variants. The recommendations focus on the data and information that may be used to support a request for emergency use authorization (EUA) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance supersedes the guidance entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2, Including Addressing the Impact of Emerging Variants, During the COVID–19 Public Health Emergency'' issued on February 22, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on December 21, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–1136 for ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building,

4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Maria Clary, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4638, Silver Spring, MD 20993–0002, 240–402–8615.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' This guidance provides recommendations to sponsors on the development of monoclonal antibody products targeting SARS–CoV–2 intended for the prevention or treatment of COVID–19. The recommendations focus on the data and information that may be used to support a request for EUA under section 564 of the FD&C Act (21 U.S.C. 360bbb–3). Specifically, the guidance discusses the manufacturing, pharmacology/toxicology, virologic, and clinical considerations to support EUA.

This guidance supersedes the guidance for industry entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2, Including Addressing the Impact of Emerging Variants, During the COVID–19 Public Health Emergency,'' which was published in February 2021. FDA issued the guidance to communicate its policy for the duration of the COVID–19 public health emergency (PHE) declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). In the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed certain guidance documents that FDA was revising to continue in effect for 180 days after the expiration of the COVID–19 PHE declaration, during which time FDA planned to further revise the guidances. The February 2021 guidance on development of monoclonal antibody products targeting SARS–CoV–2 is included in this list.

Although circumstances have improved, SARS–CoV–2 remains in broad circulation throughout the United States. The virus has and continues to evolve over time, and in certain instances, mutations in the virus have greatly reduced the activity of monoclonal antibody therapies available for the prevention or treatment of COVID–19, resulting in vulnerable populations having limited preventative and therapeutic options. FDA retains the ability to issue an EUA under section 564 of the FD&C Act for products to treat or prevent COVID–19, so the recommendations in this guidance are still pertinent (88 FR 16644). This guidance is intended to remain in effect only for the duration of the declaration by the Secretary of HHS under section 564 of the FD&C Act effective March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic (85 FR 18250). In revising this guidance, FDA considered comments received on the 2021 guidance as well as the Agency's experience issuing COVID–19-related EUAs. In addition, editorial changes were made to improve clarity.

Given the need to ensure that sponsors are aware of our current recommendations to facilitate timely development of monoclonal antibody products targeting SARS–CoV–2, FDA is issuing this guidance for immediate implementation without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C)(i) of the FD&C Act (21 U.S.C. 371(h)(1)(C)(i))). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices (see § 10.115(g)(3)).

The guidance represents the current thinking of FDA on ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 pertaining to new drug applications have been approved under 0910–0001. The collections of information pertaining to EUA of medical products have been approved under OMB control number 0910–0595.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28092 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, U.S. Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting. This meeting will be open to the public. Preregistration is required for the public to attend the meeting, provide comments, and/or distribute printed material(s) to ACMH members. Information about the meeting is available from the designated contact person and will be posted on the HHS Office of Minority Health (OMH) website: *www.minorityhealth.hhs.gov.* Information about ACMH activities can be found on the OMH website under the heading *About OMH, Committees and Working Groups.*

DATES: The ACMH meeting will be held on February 13–14, 2024 from 8:30 a.m. to 5:30 p.m. EST each day. If the Committee completes its work before 5:30 p.m., the meeting will adjourn early.

ADDRESSES: The meeting will be held at the Tower Building at 1101 Wootton Parkway, Lower Level Conference Room, Rockville, Maryland 20852 and will be accessible by webcast. Members of the public must register for the meeting by 5:00 p.m. EST on January 30, 2024. Registered webcast participants will receive webcast access information prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer,

Advisory Committee on Minority Health, OMH, HHS, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville, Maryland 20852. Phone: 240–453–6816; email: *OMH-ACMH@hhs.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105–392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on the development of goals and program activities related to OMH's duties. The topic to be discussed during the meeting is the implementation of the anticipated updates to the Office of Management and Budget (OMB) federal race and ethnicity data collection standards. The focus will be on opportunities for supporting community awareness of and engagement in future efforts to implement the revised race and ethnicity data collection standards, anticipated to be published by the OMB no later than Summer 2024. The recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform efforts related to implementation of the revised OMB standards. Information on OMB's Interagency Technical Working Group on Race and Ethnicity Standards can be found on this website: *spd15revision.gov.*

The meeting is open to the public. Any individual who wishes to attend the meeting must register by sending an email to *OMH-ACMH@hhs.gov* by 5:00 p.m. EST on January 30, 2024. Each registrant should provide their name, affiliation, phone number, email address, days attending, and if participation is in-person or via webcast. Registrants will receive webcast access information via email. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact *OMH-ACMH@hhs.gov* and reference this meeting. Requests for special accommodation should be made during registration or at least ten (10) business days prior to the meeting.

Registered members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to two minutes per speaker during the time allotted. Individuals of the public may also submit and distribute electronic or printed statements or material(s) related to this meeting's topic. Written comments should not exceed two pages in length. Individuals planning to submit material should email the material to *OMH-ACMH@hhs.gov* at least five (5) business days prior to the meeting.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2023–28101 Filed 12–20–23; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Role of Tau Oligomer Polymorphism in Alzheimer's Disease and Related Disorders.

Date: March 6, 2024.

Time: 11:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nesar Uddin Akanda, Ph.D., M.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2E405, Bethesda, MD 20892, (301) 594–8984, *nesar.akanda@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28023 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a 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 materials, 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 Library of Medicine Special Emphasis Panel; Conflicted and Other Applications (R01, R13 and K99 and Curation).

Date: March 28, 2024.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Ali Sharma, Ph.D., Scientific Review Officer, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 500, Bethesda, MD 20892–7968, *ali.sharma@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28071 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Biomarkers Validation for Alzheimer's Disease and Related Dementia.

Date: March 13, 2024.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nesar Uddin Akanda, Ph.D., M.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2E405, Bethesda, MD 20892, (301) 594–8984, *nesar.akanda@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28022 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Literature Selection Technical Review Committee.

The meeting will be open to the public as indicated below. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, must notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

The meeting is devoted to the review and evaluation of journals for potential indexing by the National Library of Medicine and will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), title 5 U.S.C., as amended. Premature disclosure of the titles of the journals as potential titles to be indexed by the National Library of Medicine, the discussions, and the presence of individuals associated with these publications could significantly frustrate the review and evaluation of individual journals.

Name of Committee: Literature Selection Technical Review Committee.

Date: February 22–23, 2024.

Closed: February 22, 2024, 8:00 a.m. to 10:00 a.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

Open: February 22, 2024, 10:00 a.m. to 10:30 a.m.

Agenda: NLM Directors' Report.

Place: National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

Closed: February 22, 2024, 10:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

Closed: February 23, 2024, 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Babski, Associate Director, Division of Library Operations, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894, 301–827–4279, *babskid@mail.nih.gov.*

In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice at least 10 days in advance of the meeting.

Information is also available on the Institute's/Center's home page: *https://www.nlm.nih.gov/medline/medline_about_lstrc.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28072 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Mechanisms Underlying Heterogeneity of Cognitive Outcomes in Synucleinopathy.

Date: January 22, 2024.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joshua Jin-Hyouk Park, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2W200, Bethesda, MD 20892, (301) 496–6208, *joshua.park4@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28026 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; GEMSSTAR.
Date: February 22–23, 2024.
Time: 9:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Rajasri Roy, Ph.D., M.D., M.P.H., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2W200, Bethesda, MD 20892, (301) 496–9666, *rajasri.roy@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28021 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Advancing Mobile Monitoring of Intraindividual Change in ADRD.
Date: February 22, 2024.
Time: 12:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Joshua Jin-Hyouk Park, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg. Suite 2W200, Bethesda, MD 20892, (301) 496–6208, *joshua.park4@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28069 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Dementia Caregiver Support Intervention.
Date: January 22, 2024.
Time: 10:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Sandhya Sanghi, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2N230, Bethesda, MD 20892, (301) 496–2879, *sandhya.sanghi@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28019 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Gene-Environment Interplay II.
Date: January 9, 2024.
Time: 1:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Nijaguna Prasad, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2W200, Bethesda, MD 20892, (301) 496–9667, *prasadnb@nia.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28018 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; Youth Violence Prevention Interventions (R01—Clinical Trial Required).

Date: January 26, 2024.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIMHD DEM II, Suite 800, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, Office of Extramural Research Administration, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 594–2704, *ismonddr@mail.nih.gov*.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; Strengthening Research Opportunities for NIH Grants (STRONG): Structured Institutional Needs Assessment and Action Plan Development for Resource Limited Institutions (RLIs) (UC2).

Date: February 5, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIMHD DEM II, Suite 800, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Xinli Nan, M.D., Ph.D., Scientific Review Officer, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, (301) 594–7784, *Xinli.Nan@nih.gov*.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Mentored Career and Research Development Awards (Ks).

Date: February 29–March 1, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIMHD DEM II, Suite 800, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, Office of Extramural Research Administration, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 594–2704, *ismonddr@mail.nih.gov*.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; Research Centers in Minority Institutions (RCMI) Program.

Date: March 6–7, 2024.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIMHD DEM II, Suite 800, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karen Nieves-Lugo, M.P.H., Ph.D., Scientific Review Officer, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 402–1366, *karen.nieveslugo@nih.gov*.

Dated: December 18, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28122 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Alzheimer's Disease and Proteolytic and Metabolic Dysfunction.

Date: March 20, 2024.

Time: 11:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nesar Uddin Akanda, Ph.D., M.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2E405, Bethesda, MD 20892, (301) 594–8984, *nesar.akanda@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28024 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Transition to Aging Research Award for Predoctoral Students.

Date: February 8, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mariel Jais, Ph.D., M.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue Gateway Bldg., Suite 2E400, Bethesda, MD 20892, (301) 594–2614, *mariel.jais@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28070 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a 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 materials, 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: Biomedical Informatics, Library and Data Sciences Review Committee (BILDS).

Date: March 7, 2024.

Time: March 7, 2024, 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 6705 Rockledge Drive, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Zoe E. Huang, MD, Chief Scientific Review Officer, Scientific Review Office, Extramural Programs, National Library of Medicine, National Institutes of Health (NIH), 6705 Rockledge Drive, Suite 500, Bethesda, MD 20892–7968, 301–594–4937, *huangz@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28068 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Sex Differences in AD.

Date: February 15, 2024.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dario Dieguez, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2W200, Bethesda, MD 20892, (301) 827–3101, *dario.dieguez@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28020 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Exercise training in older adults and the physiologic and functional responses.

Date: February 21, 2024.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nesar Uddin Akanda, Ph.D., M.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2E405, Bethesda, MD 20892, (301) 594–8984, *nesar.akanda@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28025 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Regents of the National Library of Medicine.

The meeting will be open to the public as indicated below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, 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: Board of Regents of the National Library of Medicine.

Date: February 6, 2024.

Open: February 6, 2024, 10:00 a.m. to 4:00 p.m.

Agenda: Program Discussion.

Place: National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

Closed: February 6, 2024, 4:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Contact Person: Christine Ireland, Committee Management Officer, Division of Extramural Programs, National Library of Medicine, Bethesda, MD 20892, 301–594–4929, *irelanc@mail.nih.gov.*

Any member of the public may submit written comments no later than 15 days in advance of the meeting. Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nlm.nih.gov/od/bor/bor.html* where additional information for the meeting will be posted when available. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*) on February 6, 2024.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28065 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting.

The meeting will be open to the public as indicated below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for review, discussion, and evaluation of individual intramural programs and projects conducted by the National Library of Medicine, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Board of Scientific Counselors.

Date: April 18, 2024.

Open: 11:00 a.m. to 12:35 p.m.

Agenda: Program Discussion and Investigator Report.

Place: National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

Closed: 12:35 p.m. to 2:30 p.m.

Agenda: To review and evaluate personal qualifications, performance, and competence of individual investigators.

Contact Person: David Landsman, Ph.D., Branch Chief, National Library of Medicine, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894, 301–435–5981, *landsman@mail.nih.gov.*

Any member of the public may submit written comments no later than 15 days in advance of the meeting. Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Open sessions will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*) on April 18, 2024. Please direct any questions to the Contact Person listed on this notice.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28067 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council for Biomedical Imaging and Bioengineering, January 23, 2024, 12 p.m. to January 23, 2024, 04 p.m., National Institutes of Health, Democracy II, 6707 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** on October 25, 2023, 88FR69211.

There is a time change for the National Advisory Council for Biomedical Imaging and Bioengineering meeting on January 23, 2024. The Open Session of the Council meeting will begin at 11:00 a.m. and conclude at 2:00 p.m. on January 23, 2024. The meeting is partially Closed to the public.

Dated: December 18, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28123 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2023–0019; OMB No. 1660–0058]

Agency Information Collection Activities: Submission for OMB Review, Comment Request; Fire Management Assistance Grant Program

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30-Day notice of revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, this notice seeks comments concerning the information collected as required for Fire Management Assistance Grant Program (FMAGP) eligibility determinations, grants management, and compliance with other Federal laws and regulations.

DATES: Comments must be submitted on or before January 22, 2024.

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 information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Antonio Jones, FMAG Program Manager, at (540) 326–1928 or *fema-recovery-pa-policy@fema.dhs.gov.* You may contact the Information Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The information collected is required for Fire Management Assistance Grant

Program (FMAGP) eligibility determinations, grants management, and compliance with other Federal laws and regulations. The FMAGP was established under Section 420 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5187, as amended by § 303 of the Disaster Mitigation Act of 2000 and authorizes the President to provide assistance to any state or local government for the mitigation, management, and control of any fire on public or private forest land or grassland that threatens such destruction as would constitute a major disaster. 44 CFR part 204 specifies the information collections necessary to facilitate the provision of assistance under the FMAGP. Additionally, the information collection is used by both FEMA Regional and State staff to facilitate the declaration request and grant administration processes of FMAGP, as well as end of year internal reporting of overall declaration requests and estimated grant outlays.

This proposed information collection previously published in the **Federal Register** on August 11, 2023, at 88 FR 54633 with a 60-day public comment period. The public comment period closed on October 10, 2023, with three public comments received. Two comments from individuals are not germane to this collection. One comment from a state agency asked several questions about each instrument in turn and a summary of FEMA's responses to those questions are below.

Question: Who is the intended audience for each of these instruments?

FEMA Response: The intended audience is the state, local, Tribal, or territorial governments around the country for the mitigation, management, and control of any declared fire on public or private forest land or grassland that threatens such destruction as would constitute a major disaster.

Question: Is the Project Number known at the time these instruments are filled out?

FEMA Response: In the FEMA Go system, the project number will be a system-generated data element, auto populated as part of the collection of information process. The Applicant will not need to manually enter a project number when completing the instrument in a web-based interface or in hard copy (if necessary).

Question: Is the Recipient the same as Applicant? If so, we suggest using the same terminology.

FEMA Response: No. The Recipient is the state, local, Tribal, or territorial government who is awarded an FMAG grant and is accountable for the use of the funds provided. This generally includes the state as designated in the FEMA-State Agreement for the FMAG. After an FMAG declaration, a tribal government may choose to be a Recipient, or it may act as a Subrecipient under the state. For more information regarding the definition of the terms ''Applicant'' and ''Recipient'' refer to 44 CFR 204.3—Definitions (*https://www.ecfr.gov/current/title-44/section-204.3*).

Question: Are ''Summary Record and Summary Template'' the same? If so, we suggest using the same terminology.

FEMA Response: The summary report and summary template should be the same thing. The Agency will consider whether the language can be standardized or if the summary template will be something the Applicant completes in the web-based system.

Question: For the Principal Advisor's Report's Prevailing Weather Conditions, is this at the time of the FMAG request? Verbally or in writing?

FEMA Response: The prevailing weather can be provided verbally and later confirmed with a written submission from either real time observations when completing the report or through various weather-related sources and monitoring agencies.

Question: For the Principal Advisor's Report's Prediction of Weather and Fire Conditions for the Next 24 Hours (Fire Behavior), are these for the following 24 hours after the request has been made? Verbally or in writing?

FEMA Response: These are for the following 24 hours after the request has been made. These predictions can be provided verbally and later confirmed with a written submission from various weather-related sources and monitoring agencies.

Question: We suggest using the term ''Subgrantee'' and not ''Applicant'' throughout the Request for Fire Management Assistance Subgrant.

FEMA Response: The term ''Applicant'' is correct, per 44 CFR part 204.3, and will not be revised on the FMAG instruments.

Question: Is the ''Applicant'' on the Request for Fire Management Assistance Subgrant different from the ''Applicant'' listed on forms FF–104–FY–23–100, –101, –102, and –103?

FEMA Response: No, the term ''Applicant'' refers to the same entity across the FMAG-related instruments.

The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Fire Management Assistance Grant Program.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0058.

FEMA Forms: FEMA Form FEMA Form FF–104–FY–21–165 (formerly FEMA Form 078–0–1), Principal Advisor's Report; FEMA Form FF–104–FY–21–166 (formerly FEMA Form 078–0–1), Request for Fire Management Assistance Declaration; FEMA Form FF–104–FY–21–167 (formerly FEMA Form 089–0–24), Request for Fire Management Assistance Subgrant; FEMA Form FF–104–FY–23–100, Application for Management Costs; FEMA Form FF–104–FY–23–101, Project Application for Emergency Protective Measures; FEMA Form FF–104–FY–23–102, Project Application for Firefighting Activities; FEMA Form FF–104–FY–23–103 Time Extensions; No form, FEMA-State Agreement and Amendment; No form, State Administrative Plan for Fire Management Assistance; No form, Appeal Letter; No form, Duplication of Benefits Letter; and No form, Training Sessions.

Abstract: The information collected is required for Fire Management Assistance Grant Program (FMAGP) eligibility determinations, grants management, and compliance with other Federal laws and regulations. The FMAGP was established under the Robert T. Stafford Disaster Relief and Emergency Assistance Act and authorizes the President to provide assistance to any state or local government for the mitigation, management, and control of any fire on public or private forest land or grassland that threatens such destruction as would constitute a major disaster. Federal regulations specify the information collections necessary to facilitate the provision of assistance under the FMAGP. Additionally, the information collection is used by both FEMA Regional and State staff to facilitate the declaration request and grant administration processes of FMAGP, as well as end of year internal reporting of overall declaration requests and estimated grant outlays.

Affected Public: State, Local or Tribal Government.

Estimated Number of Respondents: 278.

Estimated Number of Responses: 953.

Estimated Total Annual Burden Hours: 1,211.

Estimated Total Annual Respondent Cost: $105,406.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $682,930.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the Agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Millicent Brown Wilson,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2023–28149 Filed 12–20–23; 8:45 am]

BILLING CODE 9111–24–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_CO_FRN_MO4500170984]

Notice of Realty Action: Direct Sale of Public Land in Eagle County, CO

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action.

SUMMARY: The Bureau of Land Management (BLM) is proposing a noncompetitive (direct) sale of 7.55 acres of public land in Eagle County, Colorado, to Sweetwater Rydev LLC, to resolve an inadvertent unauthorized use of public lands. The sale will be subject to the applicable provisions of the Federal Land Policy and Management Act of 1976 (FLPMA) and BLM land sale regulations. The proponent would purchase the parcel for the appraised fair market value of the land, which is $24,000.

DATES: Interested parties may submit written comments regarding this direct sale by February 5, 2024.

ADDRESSES: Mail written comments to Larry W. Sandoval Jr., BLM Field Manager, Colorado River Valley Field Office, 2300 River Frontage Road, Silt, CO 81652, or by email to *blm_co_si_crvfo_webmail@blm.gov.*

FOR FURTHER INFORMATION CONTACT: Jill Bogdanovich, Realty Specialist, BLM, Colorado River Valley Field Office, phone (970) 876–9024, or by email at *jbogdanovich@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Jill Bogdanovich. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The BLM will consider the direct sale in accordance with Section 203 of FLPMA for the following public lands:

Sixth Principal Meridian, Colorado

T. 4 S., R. 86 W.,
Sec. 9, lots 18 and 28.

The area described contains 7.55 acres, according to the official plat of the survey of the said land, on file with the BLM.

The proposed sale is in conformance with the BLM Colorado River Valley Field Office Record of Decision and Approved Resource Management Plan decision LRT–MA–10 (page 108) approved in June 2015. A parcel-specific Environmental Assessment (EA), document number DOI–BLM–CO–N040–2018–0009–EA, was prepared in connection with this realty action. It can be viewed online at *https://eplanning.blm.gov/eplanning-ui/project/110929/510.* The land is suitable for direct sale under FLPMA, without competition, consistent with 43 CFR 2711.3–3(a)(5), because there is a need to resolve an inadvertent and unauthorized use of public lands, which are encumbered by privately owned improvements.

Pursuant to the requirements of 43 CFR 2711.1–2(d), publication of this notice in the **Federal Register** will segregate the land from all forms of appropriation under the public land laws, including the mining laws, except for the sale provisions of FLPMA. Until completion of the sale, the BLM will no longer accept land use applications affecting the public land. The segregative effect will terminate upon issuance of a patent, publication in the **Federal Register** of a termination of the segregation, or on December 21, 2025, unless extended by the BLM Colorado State Director in accordance with 43 CFR 2711.1–2(d) prior to the termination date.

The patent, if issued, will be subject to the following terms, covenants, conditions, and reservations:

1. A mineral reservation to the United States for all minerals;

2. A reservation to the United States for ditches and canals constructed by authority of the United States under the Act of August 30, 1890;

3. Valid existing rights issued prior to conveyance;

4. An appropriate indemnification clause protecting the United States from claims arising out of the patentee's use, occupancy, or operations on the patented lands;

5. Additional terms and conditions that the authorized officer deems appropriate.

The EA, appraisal, maps, and Environmental Site Assessment are available for review (see the **FOR FURTHER INFORMATION CONTACT** section earlier). Interested parties may submit, in writing, any comments concerning the sale, including notifications of any encumbrances or other claims relating to the parcel, to the address listed earlier (see **ADDRESSES**).

The BLM Colorado State Director will review any adverse comments regarding this direct sale and may sustain, vacate, or modify this realty action, in whole or in part. In the absence of timely objections, this realty action will become the final determination of the Department of the Interior. In addition to the publication in the **Federal Register**, the BLM will also publish this notice in the Post Independent newspaper and Vail Daily newspaper, once a week for 3 consecutive weeks.

Before including your address, phone number, email address, or other personal identifying information in your comments, the BLM will make your entire comment—including your personal identifying information—publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 CFR 2710)

Douglas J. Vilsack,

BLM Colorado State Director.

[FR Doc. 2023–28045 Filed 12–20–23; 8:45 am]

BILLING CODE 4331–16–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—The National Advanced Mobility Consortium, Inc.

Notice is hereby given that, on December 1, 2023, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), The National Advanced Mobility Consortium, Inc. (''NAMC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. In preparation of the GFY 2023 filing, The National Advanced Mobility Consortium, Inc. determined that an incorrect membership list was inadvertently filed in 2022. A corrected membership list for GFY 2022 and GFY 2023 is included herein. Specifically, during Government Fiscal Year (GFY) 2022, A.T. Kearney Public Sector and Defense Services, LLC, Arlington, VA; Aegis Power Systems, Inc., Murphy, NC; Allied Defense, Sarasota, FL; Analytical Graphics, Inc., dba Ansys Government Initiatives, Exton, PA; Applied Systems Engineering Inc. dba ASEI, Niceville, FL; Apptronik, Inc, Austin, TX; Armag Corporation, Bardstown, KY; Automotive International INC—ValuGard, Cincinnati, OH; Autonodyne LLC, Boston, MA; AvaWatz Company, Addison, TX; Aveox Inc., Simi Valley, CA; BC Engineered Products, Morristown, NJ; Caterpillar Inc., Peoria, IL; Cornerstone Research Group, Miamisburg, OH; Cummins Power Generation Inc, Fridley, MN; Czero Inc, Fort Collins, CO; D & R Technical Solutions, Inc, Vestal, NY; DiSTI Corporation, Orlando, FL; Empirical Systems Aerospace, Inc., San Luis Obispo, CA; EngeniusMicro, Huntsville, AL; Essex Electro Engineers, Inc, Schaumburg, IL; Fairwinds Technologies LLC, Annapolis, MD; Front End Analytics, Boston, MA; FSI Defense, Fort Worth, TX; Hendrickson USA, L.L.C., Woodridge, IL; Herley Industries Inc., dba Ultra Intelligence & Communications SFP, Lancaster, PA; HIAB USA INC., Perrysburg, OH; HIPPO POWER LLC DBA HIPPO MULTIPOWER, RIVERSIDE, MO; Hupp and Associates Inc., dba Hupp Aerospace Defense, New Haven, IN; Hyperion Technology Group, Inc., Tupelo, MS; Jaxon Engineering and Maintenance, LLC, Colorado Springs, CO; Jet Machine and Manufacturing, Cincinnati, OH; Keshik Mobile Power Systems, Northborough, MA; Leadtank Incorporated, dba RobosoftAI, Thousand Oaks, CA; Link Mfg., Ltd., Sioux Center, IA; McCormick Stevenson Corporation, Dunedin, FL; $NINO_X$ 360 LLC, Redwood City, CA; NTL Industries Inc., Sterling Heights, MI; Orbital Research Inc, Cleveland, OH; Pacific Defense, El Segundo, CA; Palantir USG, Inc., Palo Alto, CA; PD Power Systems, LLC, Springfield, VA; Peerless Technologies Corporation, Fairborn, OH; Powertrain Rockford Inc, Loves Park, IL; Rebellion Defense, Inc., Washington, DC; Reveal Technology Inc, San Carlos, CA; RMD LLC, Nipomo, CA; Rocky Mountain Scientific Laboratory, Littleton, CO; Scale AI, San Francisco, CA; Scientific Applications & Research Associates, Inc. (SARA), Cypress, CA; Special Operations Solutions dba Aevex Engineering and Technology, Harrisonburg, VA; The Spectrum Group, LLC, Alexandria, VA; Trident Systems Incorporated, Fairfax, VA; TurbineOne, San Francisco, CA; Uptake Technologies, Inc, Chicago, IL; Vadum, Inc., Raleigh, NC; XMCO INC., Warren, MI, and specifically during GFY 2023, 3M Government Markets, Washington, DC; Advanced Conversion Technology, Inc., Middletown, PA; Advanced Technology Systems Company (ATSC), McLean, VA; AEROGLOW LLC, Fredericksburg, VA; AimLock Inc., Littleton, CO; Amentum Services, Inc., Germantown, MD; Applied Intuition, Mountain View, CA; ARES Security Corporation, Vienna, VA; AZAK, Inc., Driggs, ID; BAE Systems Information and Electronic Systems Integration, Inc., Merrimack, NH; BlackBar Engineering, Sierra Vista, AZ; BlueRISC, Inc., Amherst, MA; BlueSpace.ai, Emeryville, CA; Broadband Antenna Tracking Systems, Inc, Indianapolis, IN; CDM ELECTRONICS, INC., Turnersville, NJ; Dayton T. Brown, Bohemia, NY; DRS Network & Imaging Systems, LLC, Melbourne, FL; EnerSys, Macomb, MI; EnQuanta, Minneapolis, MN; Exergi Predictive LLC, Hugo, MN; Exotic Automation & Supply, New Hudson, MI; EZ–A Consulting, LLC, Bel Air, MD; FD Software Enterprises LLC, East Stroudsburg, PA; Galois, Inc., Portland, OR; Hawk Technologies, LLC, Hancock, MI; Hazard Protection Systems, Inc., Anchorage, AK; Hiller Measurements Inc, Austin, TX; Huntsman International LLC, The Woodlands, TX; Karagozian & Case, Glendale, CA; Kevadiya Inc, Pontiac, MI; Kostas Research Institute (KRI) at Northeastern University, Burlington, MA; LiquidPiston, Inc., Bloomfield, CT; Luna Labs USA, LLC, Charlottesville, VA; MATBOCK, LLC, Virginia Beach, VA; Mission Solutions Group, North Charleston, SC; Moog Inc., East Aurora, NY; Noblis, Inc., Reston, VA; NVIDIA Corporation, Durham, NC; Paradigm Research and Engineering, Ann Arbor, MI; Parry Labs LLC, Alexandria, VA; PHUOC LUONG dba TWF ENTERPRISE, San Jose, CA; Plexus Corp.—Neenah Design Center, Neenah, WI; Pliant Energy Systems LLC, Brooklyn, NY; Quantum Imaging Inc., Colorado Springs, CO; Seiler Instrument and Manufacturing Company, Inc., Saint Louis, MO; Signal Systems Corporation, Millersville, MA; Skayl LLC, Westminster, MD; The Armored Group, LLC, Phoenix, AZ; Triton Systems Inc., Chelmsford, MA; Ultra Advanced Tactical Systems, Austin, TX; Visible Assets, Inc., Stratham, NH; and VTN Manufacturing Inc., Fremont, CA, have been added as parties to this venture.

Also during GFY 2022, Adsys Controls, Inc., Irvine, CA; AimLock, Littleton, CO; Alion Science and Technology, McLean, VA; Ametek | Spectro Scientific, Chelmsford, MA; AVL Powertrain Engineering, Inc., Plymouth, MI; BlackHorse Solutions, Inc., Herndon, VA; Brenner Tank Services LLC, Fond du Lac, WI; Brighton Cromwell, LLC, Randolph, NJ; Buffalo Armory LLC, Buffalo, NY; CertTech LLC, Saginaw, MI; Chase Defense Partners, Hampton, VA; Cherokee Nation Aerospace & Defense, Tulsa, OK; Compusult Systems Inc., Chantilly, Virginia; ContiTech USA, Inc. (Formerly Veyance Technologies, Inc.), St Marys, OH; CoorsTek Incorporated, Golden, CO; Czero, Inc., Fort Collins, CO; Embedded Systems Inc dba ESI Motion, Simi Valley, CA; EndoSec LLC, Washington, DC; Florida Institute for Human and Machine Cognition, Inc. (IHMC), Pensacola, FL; Galvion Ltd, Portsmouth, NH; Gravikor, Inc., Ann Arbor, MI; IERUS Technologies, Inc., Huntsville, AL; Island City Engineering LLC, Merrill, WI; iXblue Defense Systems, Inc., Natick, MA; John H. Northrop & Associates, Inc., Alexandria, VA; Kaman Precision Products (div of Kaman Aerospace Corp), Middletown, CT; Kevin Diaz, Niceville, FL; Kopis Mobile, Flowood, MS; L3 Technologies, Inc. (Communication Systems-East), Camden, NJ; LiquidPiston, Inc., Bloomfield, CT; Lynntech, Inc., College Station, TX; Maynard Steel Casting Company, Milwaukee, WI; Military Systems Group, Inc., Nashville, TN; Mission Secure, Inc., Charlottesville, VA; Nahsai, LLC, Ann Arbor, MI;

Numurus LLC, Seattle, WA; ODU–USA, Inc., Camarillo, CA; Photodon, LLC, Traverse City, MI; Pi Innovo LLC, Plymouth, MI; Precision Advanced Machining Co., Clinton Township, MI; Quantum Ventura Inc., Los Angeles, CA; Real-Time Analyzers, Inc., Middletown, CT; ServiceNow, Santa Clara, CA; Steelhead Composites, Golden, CO; Systematic Inc., Centreville, VA; T.E.A.M., Inc., Woonsocket, RI; The TireBall Company, Crestwood, KY; The University of Texas at Austin, Austin, TX; TORC Robotics, Blacksburg, VA; Triad Services Group Inc., Madison Heights, MI; University of Delaware Center for Composite Materials, Newark, DE; Virginia Polytechnic Institute and State University, Blacksburg, VA; VITEC, Inc., Atlanta, GA; Volans-I, San Francisco, CA; XPER (formerly Ibis-Tek), Butler, PA; YawPITCH, LLC, Holland, MI, and during GFY 2023, Abaco Systems, Huntsville, AL; Acrow Corp of America, Inc., Parsippany, NJ; Aegis Systems Inc. (Actuate), New York, NY; AMBOT, Reno, NV; AmSafe, Inc., Phoenix, AZ; AOM Engineering Solutions LLC, Dearborn Heights, MI; API Heat Transfer, Inc., Buffalo, NY; Applied Minds, LLC, Burbank, CA; APT-Research, Inc., Huntsville, AL; Armag Corporation, Bardstown, KY; ASRC Federal Mission Solutions, Moorestown, NJ; ATI Inc. (Alloy Technology Innovations Inc.), Lexington, KY; Autonodyne LLC, Boston, MA; B&H INTERNATIONAL LLC, BAKERSFIELD, CA; BlackBar Engineering, Sierra Vista, AZ; CAMX Power LLC, Lexington, MA; Clemson University—College of Engineering and Science, Clemson, SC; CP Technologies LLC (Chassis Plans LLC), Prescott, AZ; D–2 Incorporated, Bourne, MA; DataRobot, Boston, MA; DB Santasalo—USA, Greer, SC; Deep Analytics LLC, Montpelier, VT; Dell Technologies, Apex, NC; DOLL America Inc., Allenwood, NJ; DroneShield LLC, Warrenton, VA; Eck Industries, Inc., Manitowoc, WI; Essex Electro Engineers, Inc, Schaumburg, IL; Fenix Group Inc., Chantilly, VA; FPH USA, Roseville, MI; Future Tense LLC dba CalypsoAI Labs, Richmond, VA; Gen3 Defense and Aerospace LLC, Grand Rapids, MI; General Electric Aviation Systems, LLC, Grand Rapids, MI; Georgia Tech Applied Research Corporation (Georgia Tech Research Corporation), Atlanta, GA; Grand Valley Mfg, Titusville, PA; Great Lakes Systems & Technology LLC, Chesterfield Twp, MI; Gunite Corporation (Accuride Corporation), Rockford, IL; Hamilton Sundstrand Corporation (Colins Aerospace Company), Rockford, IL; Intelligent Automation, Inc., Rockville, MD; International Logistics Systems, Inc., Glen Rock, PA; Janus Communications, Irvine, CA; Jaxon Engineering and Maintenance, LLC, Colorado Springs, CO; Jenoptik Advanced Systems, LLC, Rochester Hills, MI; JWF Defense Systems, Johnstown, PA; Keshik Mobile Power Systems, Northborough, MA; L3Harris Technologies √ Link Training & Simulation, Arlington, TX; L3 TECHNOLOGIES INC. COMMUNICATIONS SYSTEMS WEST OPERATING DIVISION, Salt Lake City, UT; Macomb Community College, Warren, MI; MAK Technologies, Orlando, FL; Maxar Space Robotics LLC (formerly SSL Robotics LLC), Pasadena, CA; Mayer Alloys Corporation, Ferndale, MI; Metalbuilt LLC, Chesterfield, MI; Michigan Engineering Services, LLC, Ann Arbor, MI; Microsoft Corporation, Redmond, WA; NetCentric Technology, LLC, Neptune, NJ; $NINO_X$ 360 LLC, Redwood City, CA; Nu-Trek, Inc., San Diego, CA; O'Gara-Hess & Eisenhardt Armoring Company LLC, Fairfield, OH; Onodi Tool & Engineering, Melvindale, MI; Patriot Products Inc, Franklin, IN; PD Systems, Sterling Heights, MI; PHUOC LUONG dba TWF ENTERPRISE, San Jose, CA; Planck Aerosystems, San Diego, CA; Quantum Research International, Inc., Huntsville, AL; Rebellion Defense, Inc., Washington, DC; Red Berry Innovations, Inc., Springfield, NE; Red Hat Professional Consulting, Inc., Raleigh, NC; Regents of the University of Michigan, Dearborn, MI; Remotec Inc (formerly Northrop Grumman Remotec), Clinton, TN; Reveal Technology Inc, San Carlos, CA; Robo-Team NA, Inc., Rockville, MD; Robotire, Inc., Canton, MI; SAPA Transmission, Inc., Fort Lauderdale, FL; Sarcos LC, Salt Lake City, UT; Seco USA, Inc, Rockville, MD; Senseeker Engineering, Santa Barbara, CA; Shield AI, San Diego, CA; Silicon Forest Electronics, Vancouver, WA; Sonalysts, Inc., Waterford, CT; Spear Power Systems Inc., Grandview, MO; Spectra Technologies, LLC, East Camden, AR; Stephens Pneumatics, Inc., Haslet, TX; Syntonics LLC, Columbia, MD; Technology Service Corporation, Arlington, VA; TeleSwivel, LLC, Durham, NC; TexPower, Inc., Austin, TX; The Entwistle Company, Hudson, MA; Underground Pipeline, INC, Eagle, WI; University of Texas at Arlington (Research Institute), Arlington, TX; and VRC Metals Systems, LLC, Box Elder, SD, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and NAMC intends to file additional written notifications disclosing all changes in membership.

On October 15, 2009, NAMC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 30, 2009 (52 FR 8375).

The last notification was filed with the Department on October 17, 2022. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on November 8, 2022 (87 FR 67488).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2023–28139 Filed 12–20–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Joeseph Potter, D.D.S.; Decision and Order

On July 12, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Joeseph Potter, D.D.S. (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. FP7517456 at the registered address of 3145 Larimer Street, Denver, Colorado 80205. *Id.* at 1. The OSC alleged that Registrant's registration should be revoked because Registrant is ''currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of Colorado, the state in which [he is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of his right to file with DEA a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 1–2.[1] ''A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing

[1] Based on the Government's submissions in its RFAA dated September 7, 2023, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the Government's Notice of Service of Order to Show Cause included as an attachment a Form DEA–12 signed by Registrant indicating that Registrant was personally served with the OSC on July 19, 2023. RFAAX 1, at 6.

and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e).

Further, ''[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67.'' *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 3; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, the Colorado Dental Board issued an Order of Suspension, effective October 12, 2022, suspending Registrant from the practice of dentistry in the state of Colorado. RFAAX 2, at 2. According to Colorado online records, of which the Agency takes official notice, Registrant's Colorado dental license remains suspended.'' [2] Colorado Division of Professions and Occupations License Search, *https://apps2.colorado.gov/dora///licenselookup.aspx* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice dentistry in Colorado, the state in which he is registered with DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, D.O.,* 76 FR 71371, 71372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, D.O.,* 43 FR 27616, 27617 (1978).[3]

According to Colorado statute, ''[e]very person who manufactures, distributes, or dispenses any controlled substance within this state . . . shall obtain . . . a registration, issued by the respective licensing board . . . . For purposes of this section and this article [ ], 'registration' or 'registered' means . . . the licensing of dentists by the Colorado dental board . . . .'' Colo. Rev. Stat. 18–18–302(1) (2023).

Here, the undisputed evidence in the record is that Registrant lacks authority to practice dentistry in Colorado. As discussed above, a dentist must be a licensed practitioner to dispense a controlled substance in Colorado. Thus, because Registrant lacks authority to practice dentistry in Colorado and, therefore, is not authorized to handle controlled substances in Colorado, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FP7517456 issued to Joeseph Potter, D.D.S. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Joeseph Potter, D.D.S, to renew or modify this registration, as well as any other pending application of Joeseph Potter, D.D.S., for additional registration in Colorado. This Order is effective January 22, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 12, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–28013 Filed 12–20–23; 8:45 am]

BILLING CODE 4410–09–P

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to DEA Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.gov.*

[3] This rule derives from the text of two provisions of the Controlled Substances Act (CSA). First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . ., to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1) (this section, formerly 823(f), was redesignated as part of the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022)). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR 71371–72; *Sheran Arden Yeates, D.O.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, D.O.,* 58 FR 51104, 51105 (1993); *Bobby Watts, D.O.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR 27617.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Mark Young, M.D.; Decision and Order

On July 14, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Mark R. Young, M.D. (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. BY9053240 at the registered address of 401 23rd Street Suite 207, Glenwood Springs, Colorado 81601. *Id.* at 1. The OSC alleged that Registrant's registration should be revoked because Registrant is ''currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in Colorado, the state in which [he is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of his right to file with DEA a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* (citing 21 CFR 1301.43). Here, Registrant did not

request a hearing. RFAA, at 1–2.[1] ''A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e).

Further, ''[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67.'' *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 3; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, the Colorado Medical Board issued an Order of Suspension, effective April 20, 2023, suspending Registrant from the practice of medicine in the state of Colorado. RFAAX 2, at 2. According to Colorado online records, of which the Agency takes official notice, Registrant's Colorado physician license remains suspended.''[2] Colorado Division of Professions and Occupations License Search, *https://apps2.colorado.gov/dora///licenselookup.aspx* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice medicine in Colorado, the state in which he is registered with DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, D.O.,* 76 FR 71371, 71372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, D.O.,* 43 FR 27616, 27617 (1978).[3]

According to Colorado statute, ''[e]very person who manufactures, distributes, or dispenses any controlled substance within this state . . . shall obtain . . . a registration, issued by the respective licensing board . . . . For purposes of this section and this article [ ], 'registration' or 'registered' means . . . the licensing of physicians by the Colorado medical board . . . .'' Colo. Rev. Stat. 18–18–302(1) (2023).

Here, the undisputed evidence in the record is that Registrant lacks authority to practice medicine in Colorado. As discussed above, a physician must be a licensed practitioner to dispense a controlled substance in Colorado. Thus, because Registrant lacks authority to practice medicine in Colorado and, therefore, is not authorized to handle controlled substances in Colorado, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BY9053240 issued to Mark Young, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Mark Young, M.D., to renew or modify this registration, as well as any other pending application of Mark Young, M.D., for additional registration in Colorado. This Order is effective January 22, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 12, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–28016 Filed 12–20–23; 8:45 am]

BILLING CODE 4410–09–P

[1] Based on the Government's submissions in its RFAA dated September 12, 2023, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the Government's included Notice of Service of Order to Show Cause includes as an attachment a Form DEA–12 signed by Registrant indicating that Registrant was personally served with the OSC on July 20, 2023. RFAAX 1, Attachment B.

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to DEA Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.gov.*

[3] This rule derives from the text of two provisions of the Controlled Substances Act (CSA). First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . ., to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1) (this section, formerly 823(f), was redesignated as part of the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. 117–215, 136 Stat. 2257 (2022)). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR 71371–72; *Sheran Arden Yeates, D.O.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, D.O.,* 58 FR 51104, 51105 (1993); *Bobby Watts, D.O.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR 27617.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23–52]

Frank A. Hooper, D.V.M.; Decision and Order

On June 6, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Frank A. Hooper, D.V.M. (Respondent). OSC, at 1, 3. The OSC proposed the revocation of Respondent's DEA Certificate of Registration No. BH4810518 at the registered address of 100B Old Woodruff Road, POB 123, Greer, South Carolina 29651. *Id.* at 1. The OSC alleged that Respondent's DEA registration should be revoked because

Respondent is ''without authority to prescribe, administer, dispense, or otherwise handle controlled substances in South Carolina, the state in which [he is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

On July 19, 2023, Respondent requested a hearing. On July 27, 2023, the Government filed a Motion for Summary Disposition, to which Respondent did not respond. On August 14, 2023, the Chief Administrative Law Judge (Chief ALJ) granted the Government's Motion for Summary Disposition and recommended the revocation of Respondent's registration, finding that because Respondent lacks state authority to handle controlled substances in South Carolina, the state in which he is registered with DEA, ''there is no other fact of consequence for this tribunal to decide.'' Order Granting the Government's Motion for Summary Disposition and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (RD), at 5. Respondent did not file exceptions to the RD.

Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the Chief ALJ's rulings, findings of fact, conclusions of law, and recommended sanction as found in the RD and summarizes and expands upon portions thereof herein.

Findings of Fact

On February 21, 2023, the South Carolina State Board of Veterinary Medical Examiners issued an Order of Temporary Suspension that suspended Respondent's South Carolina veterinary license. RD, at 4.[1] Further, on March 27, 2023, the South Carolina Department of Health and Environmental Control Bureau of Drug Control (SC DHEC Bureau of Drug Control) cancelled Respondent's South Carolina controlled substances registration. RD. at 4 n.3.[2]

According to South Carolina online records, of which the Agency takes official notice, Respondent's South Carolina veterinary license remains suspended.[3] South Carolina Board of Veterinary Medical Examiners, Licensee Lookup, *https://verify.llronline.com/LicLookup/Vet/Vet.aspx?div=40* (last visited date of signature of this Order). Further, Respondent's South Carolina controlled substances registration is listed with an expiration date of March 27, 2023. SC DHEC Bureau of Drug Control, Controlled Substances Registration Verification, *https://apps.dhec.sc.gov/DrugControl/Licensing/Home/Verify* (last visited date of signature of this Order).

Accordingly, the Agency finds that Respondent is not currently licensed to engage in veterinary practice nor to handle controlled substances in South Carolina, the state in which he is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371, 71372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).[4]

According to South Carolina statute, ''[e]very person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, shall obtain a registration issued by the [Department of Health and Environmental Control] in accordance with its rules and regulations.'' S.C. Code 44–53–290(a) (2023). Further, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for the delivery.'' *Id.* 44–53–110(15).

Here, the undisputed evidence in the record is that Respondent currently lacks authority to dispense controlled substances in South Carolina because his South Carolina controlled substance registration has been cancelled. As discussed above, an individual must hold a controlled substance registration to dispense a controlled substance in South Carolina. Thus, because Respondent lacks authority to handle controlled substances in South Carolina, Respondent is not eligible to maintain a DEA registration. RD, at 5. Accordingly, the Agency will order that Respondent's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BH4810518 issued to Frank A. Hooper, D.V.M. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Frank A. Hooper, D.V.M., to renew or modify this registration, as well as any other pending application of Frank A. Hooper, D.V.M., for additional registration in South Carolina. This Order is effective January 22, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 12, 2023, by Administrator

[1] *See also* Government's Notice of Filing of Evidence of Lack of State Authority; Service of Order to Show Cause; and Motion for Summary Disposition, Exhibit (GX) 2, at 1; Declaration of S.N.R., at 3.

[2] *See also* GX 7; Declaration of Diversion Investigator, at 3.

[3] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Respondent may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.gov.*

[4] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . ., to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1) (this section, formerly 823(f), was redesignated as part of the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. 117–215, 136 Stat. 2257 (2022)). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR 27617.

Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–28015 Filed 12–20–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0003]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; ARCOS Transaction Reporting

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Drug Enforcement Administration, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until February 20, 2024.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott A Brinks, Regulatory Drafting and Policy Support Section, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261; Email: *DPW@dea.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: Section 307 of the Controlled Substances Act (21 U.S.C. 827) requires controlled substance manufacturers and distributors to make periodic reports to DEA regarding the sale, delivery, and other disposal of certain controlled substances. These reports help ensure a closed system of distribution for controlled substances, and are used to comply with international treaty obligations.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *The Title of the Form/Collection:* ARCOS Transaction Reporting.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Form 333. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public: Private Sector—business or other for-profit. The obligation to respond is mandatory per 21 CFR 1304.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates that 1,181 registrants participate in this information collection. The time per response is 0.50 minutes to complete the DEA–333 (paper) and 0.25 minutes to complete DEA–333 (online).

6. *An estimate of the total annual burden (in hours) associated with the collection:* DEA estimates that this collection takes 2,850 annual burden hours.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* $0.

TOTAL BURDEN HOURS

Activity	Number of respondents	Total annual responses	Time per response (hours)	Total annual burden (hours)
DEA Form: 333 (online)	31	110	0.50	55
DEA Form: 333 (paper)	1,150	11,180	0.25	2,795
Unduplicated Totals	1,181	11,290	.....	2,850

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: December 18, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–28107 Filed 12–20–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Extension of Comment Period on Proposed Consent Decrees Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Clean Water Act (CWA), and the Oil Pollution Act (OPA)

On November 1, 2023, the Department of Justice lodged two proposed consent decrees with the United States District Court for the District of Oregon in the lawsuit entitled *United States of America et al.* v. *ACF Industries LLC, et al.,* Civil Action No. 3:23–cv–1603 (D. Or.). Notice of this settlement was published in the **Federal Register** at 88 FR 78063 (Nov. 14, 2023), which announced a 45-day comment period. Based on the date of that **Federal Register** notice, the comment period was scheduled to end on December 29, 2023.

On December 11, 2023, Plaintiffs in the above-captioned settlement received a request to extend the comment period by an additional forty-five (45) days. After considering this request, Plaintiffs have decided to extend the original comment period by an additional thirty (30) days. This extension provides a total comment period of seventy-five (75) days, through and including January 28, 2024.

Comments on the proposed Consent Decrees should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America et al.* v. *ACF Industries LLC, et al.,* D.J. Ref. No. 90–11–2–06787/2.

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, DC 20044–7611.

During the public comment period, the Consent Decrees may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decree/us-et-al-v-acf-industries-llc-et-al.* Please note that this website contains the corrected version of the cash-out consent decree but not the version originally lodged with the court. The corrected version of the cash-out consent decree adds a legal entity for one of the settling defendants that inadvertently was omitted but does not change the scope of the operations covered by the consent decree or the amounts to be paid under the consent decree. Please refer to the corrected version of the cash-out consent decree when submitting comments. We will provide a paper copy of the Consent Decrees 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 $45.25 (without attachments) or $631.25 (with attachments) (25 cents per page reproduction cost) payable to the United States Treasury.

Kathryn C. Macdonald,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2023–28017 Filed 12–20–23; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0021]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; Dispensing Records of Individual Practitioners

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Drug Enforcement Administration, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until February 20, 2024.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott A Brinks, Regulatory Drafting and Policy Support Section, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261; Email: *DPW@dea.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: Pursuant to 21 U.S.C. 827(c), practitioners who regularly dispense or administer controlled substances to patients and charge them for the substances and those practitioners who administer controlled substances in the course of maintenance or detoxification treatment shall keep records of such activities, and accordingly must comply with the regulations on recordkeeping.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *The Title of the Form/Collection:* Dispensing Records of Individual Practitioners.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* No form number is associated with this collection. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public: Private Sector—business or other for-profit. The obligation to respond is mandatory per 21 CFR 1304.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates that 72,333 registrants participate in this information collection. The time per response is 0.5 minutes for Dispensing records of individual practitioners and Recordkeeping requirements of collectors.

6. *An estimate of the total annual burden (in hours) associated with the collection:* DEA estimates that this collection takes 36,197 annual burden hours.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* $0.

TOTAL BURDEN HOURS

Activity	Number of respondents	Total annual responses	Time per response (hours)	Total annual burden (hours)
Dispensing records of individual practitioners	62,392	62,392	0.5	31,196
Recordkeeping requirements of collectors	9,941	9,941	0.5	4,971
Unduplicated Totals	72,333	72,333	N/A	36,167

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: December 18, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–28108 Filed 12–20–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Veterans' Employment and Training Service

Agency Information Collection Activities; Comment Request: Employment Navigator Data Collection and Matching

ACTION: Request for public comments.

SUMMARY: The Department of Labor's (DOL) Veterans' Employment and Training Service (VETS) is soliciting comments concerning a proposed authority to conduct the information collection request (ICR) titled, ''Employment Navigator Data Collection and Matching.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: All comments must be received on or before February 20, 2024.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained at no cost by contacting Serge King by telephone at 202.693.2982 (this is not a toll-free number), or by email at *king.serge.a@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Veterans' Employment and Training Service, Transition Assistance Program, 200 Constitution Ave NW, Room S1212, Washington DC 20210; or by email: *king.serge.a@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Serge King by telephone at 202.693.2982 (this is not a toll-free number) or by email at *king.serge.a@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

DOL seeks approval of a new information collection request (ICR) titled ''Employment Navigator Data Collection and Matching''. This request is for a ''common forms'' clearance process. There are three forms included in this ICR. The first form is a data collection mechanism for transitioning service members to provide general characteristics and background information as services are received from Employment Navigators. The second form includes additional data that is captured from government and non-government partners who will provide the service member, veteran, or spouse addition job seeker assistance after Employment Navigator data entry is complete. This form also includes any employment-related outcomes (*e.g.* job placement, job retention, and hourly wages earned) for each participant. The last form is a registration and validation form that all necessary partner entities must complete in order to be considered for partner status.

Authority: 44 U.S.C. 3506(c)(2)(A) authorizes this information collection. This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request

for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB 1293–0016.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL–VETS.

Type of Review: EXTENSION.

Title of Collection: Employment Navigator Data Collection and Matching.

Forms: Employment Navigator Intake (VETS–NEW1); Employment Navigator Partner Intake (VETS–NEW2); Employment Navigator Partner Validation Input (VETS–NEW3).

OMB Control Number: 1293–0016.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 22,550.

Frequency: Annually.

Total Estimated Annual Responses: 22,550.

Estimated Average Time per Response: Varies.

Estimated Total Annual Burden Hours: 6,885 hours.

Total Estimated Annual Other Cost Burden: $204,425.25.

James D. Rodriguez,

Assistant Secretary for Veterans' Employment and Training Service.

[FR Doc. 2023–28087 Filed 12–20–23; 8:45 am]

BILLING CODE 4510–79–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meeting of Humanities Panel

AGENCY: National Endowment for the Humanities; National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: The National Endowment for the Humanities (NEH) will hold two meetings of the Humanities Panel, a federal advisory committee, during January 2024. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965.

DATES: See **SUPPLEMENTARY INFORMATION** for meeting dates. The meetings will open at 8:30 a.m. and will adjourn by 5:00 p.m. on the dates specified below.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, Room 4060, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. 10), notice is hereby given of the following meetings:

1. Date: January 11, 2024

This meeting will discuss applications on the topics of History, International Relations, and Law, for the Kluge Fellowships grant program, submitted to the Library of Congress.

2. Date: January 12, 2024

This meeting will discuss applications on the topics of Arts, Literature, Media, and Communication, for the Kluge Fellowships grant program, submitted to the Library of Congress.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of title 5, U.S.C., as amended. I have made this determination pursuant to the authority granted me by the Chair's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: December 15, 2023.

Jessica Graves,

Paralegal Specialist, National Endowment for the Humanities.

[FR Doc. 2023–28014 Filed 12–20–23; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities; Submission to the Office of Management and Budget for Renewal; Comment Request; NSF's Eddie Bernice Johnson INCLUDES Initiative National Network Survey

AGENCY: National Science Foundation (NSF).

ACTION: Notice and request for comments.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, NSF is providing the opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection.

DATES: Written comments on this notice must be received by February 20, 2024, to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to the address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite E7465, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: NSF's Eddie Bernice Johnson INCLUDES Initiative National Network Survey.

OMB Number: 3145–0256.

Expiration Date of Approval: February 29, 2024.

Type of Request: Intent to seek approval to renew with change an information collection.

Abstract: NSF's Eddie Bernice Johnson INCLUDES Initiative (the INCLUDES Initiative) is a comprehensive national effort to enhance U.S. leadership in science, technology, engineering, and

mathematics (STEM) discoveries and innovations by catalyzing the STEM enterprise for inclusive change, resulting in a STEM workforce that reflects the diverse population of the Nation. The INCLUDES Initiative aligns with NSF's commitment to equity, inclusion, and broadening participation in the STEM fields and NSF's strategic objectives communicated in the *NSF Strategic Plan for Fiscal Years (FY) 2022–2026* (*https://www.nsf.gov/pubs/2022/nsf22068/nsf22068.pdf*).

The INCLUDES initiative is supported by NSF's Eddie Bernice Johnson INCLUDES Coordination Hub (INCLUDES Coordination Hub; *www.includesnetwork.org*), an NSF-supported project that provides focused capacity building supports around data and information gathering; learning, community building and engagement; and storytelling, and communications to NSF's Eddie Bernice Johnson INCLUDES National Network (INCLUDES National Network).

NSF is requesting OMB approval for the INCLUDES Coordination Hub to collect information from members of the INCLUDES National Network.

Why you are collecting it: The INCLUDES Coordination Hub seeks to collect data from INCLUDES National Network members to: (1) shape INCLUDES Coordination Hub's activities (*e.g.,* to identify support needs in the coming year; to inform Shared Measures and Network communication, engagement, learning, and community building, and expansion goals); (2) assess the development and progress of the INCLUDES National Network; and (3) inform the INCLUDES Coordination Hub's assessment of progress toward its theory of change.

What information is being collected: The collected information will include information on how and why respondents engage with the Network, each respondent's perspectives on desired outcomes and ways in which the INCLUDES National Network is informing and supporting their efforts to change systems to broaden participation in STEM, in addition to full name, affiliated organizations, email addresses, and home states. Personally identifiable information (PII) is collected primarily to categorize responses based on respondents' roles in the INCLUDES National Network. PII will be accessed only by the INCLUDES Coordination Hub. Any public data reporting will be in aggregate form, and any personal identifiers will be removed.

Respondents: All members of the INCLUDES National Network will be invited to respond to the survey. The INCLUDES National Network is comprised of individuals who are interested in or working directly to broaden participation in STEM. Some of these individuals are INCLUDES grantees; others have received NSF awards outside of INCLUDES or pursue broadening participation in STEM with support from other sources, including grants from federal, state, philanthropic, or business entities. Some are representatives of these various types of funders or businesses, such as program officers at NSF, other federal agencies, and private foundations, as well as interested individuals unaffiliated with particular grant programs.

Estimated number of respondents: 840 (representing a 21% response rate).

Use of the Information: The information collected is primarily for the use of the INCLUDES Coordination Hub to track the health, development, expansion, and diversification of the Network, understand the utility of the INCLUDES Coordination Hub in supporting Network members' success, and for informing design decisions the INCLUDES Coordination Hub will make regarding future programming and support provided to National Network members.

Estimate burden on the public: Estimated at 280 hours, per year, for the duration of the Coordination Hub's cooperative agreement with NSF. It is beneficial for NSF and the Coordination Hub to have access to this information annually to track progress toward the INCLUDES Initiative's goals of supporting constituencies in identifying shared goals and objectives and understanding National Network members' impact.

Average Time per Reporting: The online survey is comprised primarily of closed-ended questions and is designed to be completed by respondents in under 20 minutes.

Frequency: Once per year for the duration of the INCLUDES Coordination Hub's cooperative agreement with NSF.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information 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 on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Please submit one copy of your comments by only one method. All submissions received must include the agency name and collection name identified above for this information collection. Commenters are strongly encouraged to transmit their comments electronically via email. Comments, including any personal information provided become a matter of public record. They will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request.

Dated: December 18, 2023.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2023–28156 Filed 12–20–23; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; National Science Foundation Research Traineeship Program Monitoring System

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing the opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by February 20, 2024 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite E7465, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: National Science Foundation Research Traineeship (NRT) Monitoring System.

OMB Number: 3145–0263.

Expiration Date of Approval: November 30, 2024.

Type of Request: Intent to seek approval to renew an information collection.

Proposed Project: The National Science Foundation's (NSF's) Division of Graduate Education (DGE) in the Directorate for STEM Education (EDU) administers the NSF Research Traineeship (NRT) program. The NRT program is designed to encourage the development and implementation of bold, new, and potentially transformative models for STEM graduate education training. The NRT program seeks to ensure that graduate students in research-based master's and doctoral degree programs develop the skills, knowledge, and competencies needed to pursue a range of STEM careers. NRT is dedicated to effective training of STEM graduate students in high-priority interdisciplinary or convergent research areas through the use of a comprehensive traineeship model that is innovative, evidence-based, and aligned with changing workforce and research needs.

Previously, NRT awardees provided NSF with information on their activities through periodic research performance progress reports. The NRT monitoring system (also referred to as the NRT reporting system) has replaced these reports with a tailored program monitoring system that uses internet-based information and communication technologies to collect, review, and validate specific data on NRT awards. EDU is committed to ensuring the efficiency and effectiveness with which respondents provide and NSF staff can access and analyze data on funded projects within the NRT programs.

The NRT monitoring system includes subsets of questions aimed at the different project participants (*i.e.,* Principal Investigators (PIs), and trainees), and allows for data analysis and data report generation by authorized NSF staff. The collection generally includes three categories of descriptive data: (1) Staff and project participants (data that are necessary to determine individual-level treatment and control groups for future third-party study or for internal evaluation); (2) project implementation characteristics (also necessary for future use to identify well-matched comparison groups); and (3) project outputs (necessary to measure baseline for pre- and post-NSF-funding-level impacts). NRT awardees will be required to report data on an annual basis for the life of their award.

Use of the Information: NSF will primarily use the data from this collection for program planning, management, and audit purposes to respond to queries from the Congress, the public, NSF's external merit reviewers, who serve as advisors, including Committees of Visitors (COVs), the NSF's Office of the Inspector General, and as a basis for either internal or third-party evaluations of individual programs. This information is required for effective administration, communication, program and project monitoring and evaluation, and for measuring attainment of NSF's program, project, and strategic goals, and as identified by the President's Accountability in Government Initiative; GPRA, and the NSF's Strategic Plan. The Foundation's FY 2022–2026 Strategic Plan may be found at: *https://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf22068.*

Since this collection will primarily be used for accountability and evaluation purposes, including responding to queries from COVs and other scientific experts, a census, rather than sampling design, typically is necessary. At the individual project level, funding can be adjusted based on individual project's responses to some of the surveys. Some data collected under this collection will serve as baseline data for separate research and evaluation studies.

NSF-funded contract or grantee researchers and internal or external evaluators in part may identify control, comparison, or treatment groups for NSF's education and training portfolio using some of the descriptive data gathered through this collection to conduct well-designed, rigorous research and portfolio evaluation studies.

Burden on the Public: Estimated at 82 hours per award for 120 awards for a total of 9,840 hours (per year).

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information 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 on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: December 15, 2023.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2023–28046 Filed 12–20–23; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2023–0149]

Information Collection: Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-Level Waste Disposal Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-Level Waste Disposal Facilities.''

DATES: Submit comments by February 20, 2024. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0149. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David C. Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0149 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0149.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The supporting statement is available in ADAMS under Accession No. ML23284A044.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0149, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* 10 CFR part 62, Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-Level Waste Disposal Facilities.
2. *OMB approval number:* 3150–0143.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* Not applicable.
5. *How often the collection is required or requested:* On occasion.
6. *Who will be required or asked to respond:* Any low-level waste generator or governor of a State on behalf of generators seeking emergency access to an operating low-level waste disposal facility or an exemption from the requirements in part 62 of title 10 of the *Code of Federal Regulations* (10 CFR).
7. *The estimated number of annual responses:* 2.
8. *The estimated number of annual respondents:* 1.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 233.
10. *Abstract:* 10 CFR part 62 sets out the information that must be provided to the NRC by any low-level waste generator or governor of a State on behalf of generators seeking emergency access to an operating low-level waste disposal facility. The information is required to allow the NRC to determine if denial of disposal constitutes a serious and immediate threat to public health and safety or common defense and security. 10 CFR part 62 also provides that the Commission may grant an exemption from the requirements in this part upon application of an interested person or upon its own initiative.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.
2. Is the estimate of the burden of the information collection accurate? Please explain your answer.
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: December 18, 2023.

For the Nuclear Regulatory Commission.

Kristen E. Benney,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2023–28144 Filed 12–20–23; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2023–0083]

Information Collection: NRC Form 833, Form To Propose a Generic Issue

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on this proposed information collection. The information collection is entitled, NRC Form 833, ''Form to Propose a Generic Issue (GI).''

DATES: Submit comments by February 20, 2024. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0083. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical

questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* David C. Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0083 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0083. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2023–0083 on this website.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML23110A007. The supporting statement is available in ADAMS under Accession No. ML23102A009.

• *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

• *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0083, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* NRC Form 833, Form to Propose a Generic Issue (GI).

2. *OMB approval number:* An OMB control number has not yet been assigned to this proposed information collection.

3. *Type of submission:* New.

4. *The form number, if applicable:* Form 833.

5. *How often the collection is required or requested:* On Occasion.

6. *Who will be required or asked to respond:* The public.

7. *The estimated number of annual responses:* 1.

8. *The estimated number of annual respondents:* 1.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 1.

10. *Abstract:* NRC Form 833 is used for submission of a proposed generic safety issue that has potential for affecting two or more nuclear facilities. The form calls for information on the nature of the postulated issue and why it represents a potential generic unresolved safety issue. The issue may affect public health, safety, common defense and security, or environment; and it is not being addressed by other regulatory processes.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.

2. Is the estimate of the burden of the information collection accurate? Please explain your answer.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: December 18, 2023.

For the Nuclear Regulatory Commission.

Kristen E. Benney,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2023–28145 Filed 12–20–23; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–124 and CP2024–130; MC2024–125 and CP2024–131; MC2024–126 and CP2024–132]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 26, 2023.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER**

INFORMATION CONTACT section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–124 and CP2024–130; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 148 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 15, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* December 26, 2023.

2. *Docket No(s).:* MC2024–125 and CP2024–131; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 142 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 15, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* December 26, 2023.

3. *Docket No(s).:* MC2024–126 and CP2024–132; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 149 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 15, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* December 26, 2023.

This Notice will be published in the **Federal Register**.

Jennie L. Jbara,

Alternate Certifying Officer.

[FR Doc. 2023–28109 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® 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:* December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. 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 12, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 36 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–114, CP2024–119.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28051 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 12, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 139 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–111, CP2024–116.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28054 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 15, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 148 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–124, CP2024–130.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28063 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® 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:* December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. 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 12, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 37 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–115, CP2024–120.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28052 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 15, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 142 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–125, CP2024–131.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28057 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 12, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 140 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–116, CP2024–121.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28055 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® 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:* December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. 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 11, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 33 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–109, CP2024–114.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28048 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® 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:* December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. 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 11, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 32 to Competitive Product List.* Documents

are available at *www.prc.gov,* Docket Nos. MC2024–110, CP2024–115.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28047 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 15, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 149 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–126, CP2024–132.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28064 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 12, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 141 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–117, CP2024–122.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28056 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 14, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 146 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–122, CP2024–128.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28061 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® 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:* December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. 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 12, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 35 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–113, CP2024–118.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28050 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 14, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 145 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–121, CP2024–127.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28060 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® 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:* December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. 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 12, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 34 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–112, CP2024–117.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28049 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 13, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 143 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–118, CP2024–124.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28058 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 14, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 147 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–123, CP2024–129.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28062 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 13, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 144 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–119, CP2024–125.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28059 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® 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:* December 21, 2023.

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 11, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 138 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–108, CP2024–112.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–28053 Filed 12–20–23; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–361, OMB Control No. 3235–0411]

Submission for OMB Review; Comment Request; Extension: Rule 489 and Form F–N

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''Paperwork Reduction Act''), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the

previously approved collection of information discussed below.

Rule 489 (17 CFR 230.489) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) requires foreign banks and foreign insurance companies and holding companies and finance subsidiaries of foreign banks and foreign insurance companies that are exempted from the definition of ''investment company'' by virtue of rules 3a–1 (17 CFR 270.3a–1), 3a–5 (17 CFR 270.3a–5), and 3a–6 (17 CFR 270.3a–6) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) to file Form F–N (17 CFR 239.43) to appoint an agent for service of process when making a public offering of securities in the United States. The information is collected so that the Commission and private plaintiffs may serve process on foreign entities in actions and administrative proceedings arising out of or based on the offer or sales of securities in the United States by such foreign entities.

The Commission received an average of 25 Form F–N filings per year over the last three years (2020–2022). The Commission has previously estimated that the total annual burden associated with information collection and Form F–N preparation and submission is one hour per filing. Based on the Commission's experience with disclosure documents generally, the Commission continues to believe that this estimate is appropriate. Thus the estimated total annual burden for rule 489 and Form F–N is 25 hours.

Estimates of the average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms. Compliance with the collection of information requirements of rule 489 and Form F–N is mandatory to obtain the benefit of the exemption. Responses to the collection of information will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by January 22, 2024 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: December 18, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28117 Filed 12–20–23; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–240, OMB Control No. 3235–0216]

Submission for OMB Review; Comment Request; Extension: Rule 19a–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Section 19(a) (15 U.S.C. 80a–19(a)) of the Investment Company Act of 1940 (the ''Act'') (15 U.S.C. 80a) makes it unlawful for any registered investment company to pay any dividend or similar distribution from any source other than the company's net income, unless the payment is accompanied by a written statement to the company's shareholders which adequately discloses the sources of the payment. Section 19(a) authorizes the Commission to prescribe the form of such statement by rule.

Rule 19a–1 (17 CFR 270. 19a–1) under the Act, entitled ''Written Statement to Accompany Dividend Payments by Management Companies,'' sets forth specific requirements for the information that must be included in statements made pursuant to section 19(a) by or on behalf of management companies.[1] The rule requires that the statement indicate what portions of distribution payments are made from net income, net profits from the sale of a security or other property (''capital gains'') and paid-in capital. When any part of the payment is made from capital gains, rule 19a–1 also requires that the statement disclose certain other information relating to the appreciation or depreciation of portfolio securities. If an estimated portion is subsequently determined to be significantly inaccurate, a correction must be made on a statement made pursuant to section 19(a) or in the first report to shareholders following the discovery of the inaccuracy.

The purpose of rule 19a–1 is to afford fund shareholders adequate disclosure of the sources from which distribution payments are made. The rule is intended to prevent shareholders from confusing income dividends with distributions made from capital sources. Absent rule 19a–1, shareholders might receive a false impression of fund gains.

Based on a review of filings made with the Commission, the staff estimates that approximately 12,900 series of registered investment companies that are management companies may be subject to rule 19a–1 each year,[2] and that each portfolio on average mails two statements per year to meet the requirements of the rule.[3] The staff further estimates that the time needed to make the determinations required by the rule and to prepare the statement required under the rule is approximately 1 hour per statement. The total annual burden for all portfolios therefore is estimated to be approximately 25,800 burden hours.[4]

The staff estimates that approximately one-third of the total annual burden (8,600 hours) would be incurred by a paralegal with an average hourly wage rate of approximately $253 per hour,[5] and approximately two-thirds of the annual burden (17,200 hours) would be incurred by a compliance clerk with an average hourly wage rate of $82 per

[1] Section 4(3) of the Act (15 U.S. C. 80a–4(3)) defines ''management company'' as ''any investment company other than a face amount certificate company or a unit investment trust.''

[2] This estimate is as of December 2022 and is based on the Commission staff's review of EDGAR filings through July 31, 2023; the number of management investment company portfolios that make distributions for which compliance with rule 19a–1 is required depends on a wide range of factors and can vary greatly across years; therefore, the calculation of estimated burden hours below is based on the total number of management investment company portfolios, each of which may be subject to rule 19a–1.

[3] A few portfolios make monthly distributions from sources other than net income, so the rule requires them to send out a statement 12 times a year; other portfolios never make such distributions.

[4] This estimate is based on the following calculation: 12,900 management investment company portfolios × 2 statements per year × 1 hour per statement = 25,800 burden hours.

[5] Hourly rates are derived from the Securities Industry and Financial Markets Association (''SIFMA''), Management and Professional Earnings in the Securities Industry 2013, modified to account for an 1800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

hour.[6] The staff therefore estimates that the aggregate annual burden, in dollars, of the hours needed to comply with the paperwork requirements of the rule is approximately $3,586,200 (($8,600 hours × $253 = $2,175,800) + (17,200 hours × $82 = $1,410,400)). It is estimated that there is no cost burden of rule 19a–1 other than these estimates.

To comply with state law, many investment companies already must distinguish the different sources from which a shareholder distribution is paid and disclose that information to shareholders. Thus, many investment companies would be required to distinguish the sources of shareholder dividends whether or not the Commission required them to do so under rule 19a–1.

These estimates are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. Compliance with the collection of information required by rule 19a–1 is mandatory for management companies that make statements to shareholders pursuant to section 19(a) of the 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 control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by January 22, 2024 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: December 18, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28118 Filed 12–20–23; 8:45 am]

BILLING CODE 8011–01–P

[6] Hourly rates are derived from SIFMA's Office Salaries in the Securities Industry 2013, modified to account for an 1800-hour work-year and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99191; File No. SR–BOX–2023–30]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend IM–7150–1 and Rule 7250 (Quote Mitigation)

December 15, 2023.

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 11, 2023, BOX Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend IM–7150–1 and Rule 7250 (Quote Mitigation). The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *https://rules.boxexchange.com/rulefilings.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to modernize and improve the operation of the rules. Specifically, the Exchange is proposing to amend: (1) IM–7150–1 to remove certain language to provide better consistency with the surveillance the Financial Industry Regulatory Authority, Inc. (''FINRA'') currently provides for the Exchange; and (2) Rule 7250 (Quote Mitigation) to update and clarify the quote mitigation process used by the Exchange. The Exchange is proposing to make such changes in response to requests from Exchange Regulation Staff in an effort to improve the efficacy of the Exchange's existing regulatory framework.

IM–7150–1

IM–7150–1 (a) currently provides that: ''it shall be considered conduct inconsistent with just and equitable principles of trade for any Initiating Participant to engage in a pattern of conduct where the Initiating Participant submits Primary Improvement Orders into the PIP process for two (2) contracts or less for the purpose of manipulating the PIP process in order to gain a higher allocation percentage than the Initiating Participant would have otherwise received in accordance with the allocation procedures set forth in Rule 7150.'' [3] The Exchange now proposes to remove the language that states, ''2 contracts or less.''

FINRA currently provides surveillance for this requirement for the Exchange and other options exchanges. FINRA's surveillance program monitors for manipulative activity by a market participant and includes surveillance designed to detect activity where an Initiating Participant submits Primary Improvement Orders into the PIP process for four (4) contracts or less for the purpose of manipulating the PIP process in order to gain a higher allocation percentage than the Initiating Participant would have otherwise received. Even though IM–7150–1 as written, notates that a pattern of orders for two (2) contracts may indicate manipulation of the PIP Process, FINRA has identified the potential for manipulation for orders greater than two (2) contracts and expanded such surveillance accordingly. For example, unbundling an order for 50 contracts into four (4) lots may have the same effect as unbundling the order for two (2) contracts.[4] Under the current rule

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* IM–7150–1.

[4] For example, for one instance of 100 contracts, the BOX Firm ID would be entitled to an allocation of at least 40% or 40 contracts. If the customer order is sent as multiple small PIPs for 2 contracts, the BOX Participant would receive at least 50% of each PIP sent (2 * .40 = .8, rounded up to 1 contract). Therefore, the total allocation of the original 100 contract order would be at least 50% or 50 contracts, rather than 40% or 40 contracts, a potential over allocation of at least 10 contracts.

Continued

text, if FINRA were to discover manipulative behavior on three (3) or four (4) contracts it would be more difficult to prosecute and deter this manipulative behavior on BOX. The Exchange believes that the removal of the two (2) contracts or less language would help align the rule text with current FINRA surveillance practices and improve the efficacy of the Rule by allowing FINRA and the Exchange to more readily prosecute and deter manipulative behavior in situations where the Initiating Participant [5] submits Primary Improvement Orders [6] into the PIP [7] process for three (3) or four (4) contracts, as well as one (1) or two (2) contracts, for the purpose of manipulating the PIP process.

Rule 7250

BOX Rule 7250 currently states that: ''in order to control the number of quotations the Exchange disseminates, the Exchange shall utilize a mechanism so that newly-received quotations and other changes to the Exchange's best bid and offer are not disseminated for a period of up to, but not more than one second.'' [8] The rule as it currently reads, provides that the Exchange always utilizes a mechanism to control the number of quotations disseminated by the Exchange. The Exchange is now proposing to amend this language to allow the Exchange to utilize the mechanism when appropriate.

BOX's Quote Mitigation mechanism was originally adopted over fifteen years ago as a response to the implementation of the Penny Pilot Program [9] amid concerns that market quality and system capacity would be overwhelmed by the increase in options market data traffic created by the Penny Pilot Program. The Exchange sought to reduce both peak and overall market data traffic by bundling order updates within a certain timeframe. The rule was amended in 2012 to adopt the existing quote mitigation mechanism that systemically limits the dissemination of quotations and other changes to the BOX best bid and offer according to prescribed time criteria (a ''holdback timer'').[10] For example, if there is a change in the price of a security underlying an option, multiple market participants may adjust the price or size of their quotes. Rather than disseminating each individual change, the holdback timer permits BOX to wait until multiple Participants have adjusted their quotes and then disseminates a new quotation.

Through internal review, the Exchange found that, while this mechanism and functionality still exists on the Exchange, it is not always necessary. The Exchange is proposing to amend the rule to replace the ''shall'' with ''may'' and instead provide that ''the Exchange may utilize a mechanism so that newly-received quotations and other changes to the Exchange's best bid and offer are not disseminated for a period of up to, but not more than one second.'' This proposed amendment will modernize the Rule by still allowing the Exchange to control the number of quotations that the Exchange disseminates using the aforementioned mechanism if the need arises but will enable the Exchange to rely on other methods within the overall BOX quote mitigation strategy. For example, BOX actively monitors the quotation activity of its Market Makers. When the Exchange detects that a Market Maker is disseminating an unusual number of quotes, the Exchange contacts that Market Maker and alerts it to such activity. Such monitoring frequently reveals that the Market Maker may have internal system issues or has incorrectly set system parameters that were not immediately apparent. Alerting a Market Maker to possible excessive quoting usually leads the market maker to take steps to reduce the number of its quotes. BOX also has a policy of withdrawing approval of underlying securities with low trading volume, thereby eliminating the quotation traffic attendant to such listings.

The Exchange believes that the rule, as written, is outdated and while the Exchange still has the ability to utilize the quote mitigation mechanism, it is not always necessary to do so. The Exchange believes this proposed change will better align Rule 7250 with current Exchange practices and provide greater efficacy and flexibility to the current quote mitigation strategies in place at the Exchange.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act,[11] in general, and Section 6(b)(5) of the Act,[12] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

Specifically, the Exchange believes that the proposed amendment to IM–7150–1 to remove the language that limits the prohibition for any Initiating Participant to engage in a pattern of conduct where the Initiating Participant submits Primary Improvement Orders into the PIP process for the purpose of manipulating the PIP process to only cover Primary Improvement Orders of two (2) contracts or less will help protect investors and the public interest by allowing greater protection against manipulative behaviors. Although the Rule currently covers orders of two (2) contracts or less, FINRA currently surveils and reviews the submission of four (4) contracts or less for the Exchange. Even though IM–7150–1 as written, notates that a pattern of orders for two (2) contracts may indicate manipulation of the PIP Process, FINRA has identified the potential for manipulation for orders greater than two (2) contracts and now the Exchange seeks to expand the rule language accordingly. This proposed amendment to remove the two (2) contracts or less limitation from IM–7150–1 is designed to 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 aligning the Rule to current surveillance practices and allowing FINRA to prosecute and deter manipulative behavior in violation of this Rule relating to three (3) or four (4) contracts on behalf of the Exchange more effectively. The Exchange believes that the removal of the two (2) contracts or less language would improve the efficacy of FINRA's surveillance by helping FINRA and the Exchange prosecute and deter manipulative behavior in situations where the Initiating Participant submits Primary

Similarly, if the customer order is sent as multiple small PIPs for 4 contracts, the BOX Participant would receive at least 50% of each PIP sent (4 * .40 = 1.6, rounded up to 2 contracts). Therefore, the total allocation of the original 100 contract order would be at least 50% or 50 contracts, rather than 40% or 40 contracts, a potential over allocation of at least 10 contracts.

[5] *See* BOX Rule 7150(f).

[6] *Id.*

[7] *See* BOX Rule 7150.

[8] *See* BOX Rule 7250.

[9] *See* Securities Exchange Act Release Nos. 55073 (January 19, 2007) 72 FR 2047 (January 17, 2007) (SR–BSE–2006–48) (Order Approving BSE Quote Mitigation Plan) *and* 55155 (January 23, 2007) 72 FR 4714 (February 1, 2007) (SR–BSE–2006–49) (Order Approving Penny Pilot Program on BSE).

[10] *See* Securities Exchange Act Release No. 68141 (November 2, 2012) 77 FR 67040 (November 8, 2012) (Notice of Filing and Immediate Effectiveness of a Proposal Regarding Quote Mitigation).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

Improvement Orders into the PIP process for three (3) or four (4) contracts, as well as one (1) or two (2) contracts, for the purpose of manipulating the PIP process. As such, the Exchange believes the proposed rule change is in the public interest, and therefore, consistent with the Act.

The Exchange believes that amending BOX Rule 7250 to provide that the Exchange may utilize a mechanism so that newly-received quotations and other changes to the Exchange's best bid and offer are not disseminated for a period of up to, but not more than one second, will allow the Exchange to control the number of quotations that the Exchange disseminates through the use of the aforementioned mechanism but will enable the Exchange to rely on other methods within the overall BOX quote mitigation strategy, such as monitoring and delisting. The Exchange believes that the current rule, as written, is outdated and while the Exchange still has the ability to utilize the quote mitigation mechanism, it is not always necessary to do so. The Exchange believes this proposed change will better align the Rule with current Exchange practices, provide greater efficacy and flexibility to the current quote mitigation strategies in place at the Exchange, and make the Rule clearer for Participants. As such, the Exchange believes the proposed rule change is in the public interest, and therefore, consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed change will not impose a burden on intermarket or intramarket competition. While the Exchange does not believe that the proposed non-controversial change is a burden on competition, or is competitive in nature, the Exchange believes that proposed updates seek to modernize and improve the operation of the rules.

The proposed amendment to IM–7150–1 is designed to help the Exchange and FINRA more effectively prosecute and deter manipulative behavior in violation of this Rule relating to three (3) or four (4) contracts. This rule change is being proposed to help deter manipulative behaviors on the Exchange and is not intended to address competitive issues. The proposed change to Rule 7250 is intended to modernize and help optimize the quotation mitigation practices on the Exchange and is not intended to address competitive issues. The proposed changes to IM–7150–1 and Rule 7250 will apply equally to all market participants.

For the foregoing reasons, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6)[14] thereunder, the Exchange has designated this proposal as one that effects a change that: (i) does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.[15]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The proposed change raises no novel legal or regulatory issues. Therefore, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[17]

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–BOX–2023–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–BOX–2023–30. 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

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6).

[15] In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–BOX–2023–30 and should be submitted on or before January 11, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28042 Filed 12–20–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–xxx, OMB Control No. 3235–0779]

Submission for OMB Review; Comment Request; Extension: Rule 2a–5

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information described below.

Section 2(a)(41) of the Investment Company Act of 1940 (''Investment Company Act'')[1] requires funds to value their portfolio investments using the market value of their portfolio securities when market quotations for those securities are ''readily available,'' and, when a market quotation for a portfolio security is not readily available, by using the fair value of that security, as determined in good faith by the fund's board.[2] The aggregate value of a fund's investments is the primary determinant of the fund's net asset value (''NAV''), which for many funds determines the price at which their shares are offered and redeemed (or repurchased).[3]

Rule 2a–5 provides requirements for determining in good faith the fair value of the investments of a registered investment company or companies that have elected to be treated as business development companies under the Investment Company Act (''BDCs'' and, collectively, ''funds'') for purposes of section 2(a)(41) of the Investment Company Act and rule 2a–4 thereunder.[4] Under the rule, fair value as determined in good faith requires assessing and managing material risks associated with fair value determinations; selecting, applying, and testing fair value methodologies; and overseeing and evaluating any pricing services used. The rule also permits a fund's board to designate a ''valuation designee'' to perform fair value determinations. The valuation designee can be the adviser of the fund or an officer of an internally managed fund.[5] When a board designates the performance of determinations of fair value to a valuation designee for some or all of the fund's investments under the rule, the rule requires the board to oversee the valuation designee's performance of fair value determinations.

To facilitate the board's oversight, the rule also includes certain reporting and other requirements in the case of designation to a valuation designee.[6] As relevant here, the rule requires, if the board designates performance of fair value determinations to a valuation designee, that the valuation designee report to the board in both periodic and as needed reports on a per-fund basis.

Specifically, on a periodic basis, the valuation designee must provide to the board:

- Quarterly Reports.

At least quarterly, in writing, (1) any reports or materials requested by the board related to the fair value of designated investments or the valuation designee's process for fair valuing fund investments and (2) a summary or description of material fair value matters that occurred in the prior quarter. This summary or description must include (1) any material changes in the assessment and management of valuation risks, including any material changes in conflicts of interest of the valuation designee (and any other service provider), (2) any material changes to, or material deviations from, the fair value methodologies, and (3) any material changes to the valuation designee's process for selecting and overseeing pricing services, as well as any material events related to the valuation designee's oversight of pricing services.

- Annual Reports.

At least annually, in writing, an assessment of the adequacy and effectiveness of the valuation designee's process for determining the fair value of the designated portfolio of investments. At a minimum, this annual report must include a summary of the results of the testing of fair value methodologies required under the rule and an assessment of the adequacy of resources allocated to the process for determining the fair value of designated investments, including any material changes to the roles or functions of the persons responsible for determining fair value.

Further, the rule requires the valuation designee to provide a written notification to the board of the occurrence of matters that materially affect the fair value of the designated portfolio of investments (defined as ''material matters'') within a time period determined by the board, but in no event later than five business days after the valuation designee becomes aware of the material matter. Material matters in this instance include, as examples, a significant deficiency or material weakness in the design or effectiveness of the valuation designee's fair value determination process or of material errors in the calculation of net asset value. The valuation designee must also provide such timely follow-on reports as the board may reasonably determine are appropriate.[7]

The Commission staff estimates that 9,800 funds are subject to rule 2a–5. The internal annual burden estimate is 34 hours for a fund. Based on these estimates, the total annual burden hours associated with the rule is estimated to be 333,200 hours. The estimated burden hours associated with rule 2a–5 have increased by 15,810 hours from the current allocation of 317,390 hours. The external cost associated with this collection of information is approximately $3,674 per fund, and the total annual external cost burden is $36,005,200. The estimated external cost has increased by $6,319,900 from the current estimate of $29,685,300. These increases are due to an increase in the estimated number of affected entities, as well as in the estimated hourly burden and the external cost

[18] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 80a–1 *et seq.*

[2] 15 U.S.C. 80a–2(a)(41). *See also* 17 CFR 270.2a–4.

[3] *See* 15 U.S.C. 80a–22(c) and 23(c). *See also* 17 CFR 270.22c–1(a).

[4] *See* Good Faith Determinations of Fair Value, Investment Company Act Release No. 34128 (Dec. 7, 2020) (''Adopting Release'').

[5] Rule 2a–5(e)(4).

[6] Rule 2a–5(b).

[7] Rule 2a–5(b).

associated with the information collection requirements.

The estimate of average burden hours is made solely for purposes of the Paperwork Reduction Act and is not derived from a comprehensive or even a representative survey or study of the cost of Commission rules. The collection of information required by rule 2a–5 is necessary to obtain the benefits of the rule. Other information provided to the Commission in connection with staff examinations or investigations is kept confidential subject to the provisions of applicable law. If information collected pursuant to rule 2a–5 is reviewed by the Commission's examination staff, it is accorded the same level of confidentiality accorded to other responses provided to the Commission in the context of its examination and oversight program. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by January 22, 2024 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: December 18, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28115 Filed 12–20–23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–418, OMB Control No. 3235–0485]

Submission for OMB Review; Comment Request; Extension: Rule 15c2–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 15c2–1, (17 CFR 240.15c2–1), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 15c2–1 prohibits broker-dealers from commingling under the same lien securities of their margin customers with securities of the broker-dealer and those of other customers without their written consent. The rule also prohibits the re-hypothecation of customers' margin securities for a sum in excess of the customer's aggregate indebtedness. Respondents must collect information necessary to prevent the re-hypothecation of customer securities, issue and retain copies of notices of hypothecation of customer securities, and collect written consents from customers.

There are approximately 59 respondents. Each of these respondents makes an estimated 45 responses per year and each response takes approximately 0.5 hours to complete, resulting in an industry-wide annual burden of approximately 1,327 hours.

The retention period for the recordkeeping requirement under Rule 15c2–1 is not less than two years following the date the notice is submitted. The recordkeeping requirement under this rule is mandatory to assist the Commission in monitoring respondents who fail to collect the information required under the rule. This rule does not involve the collection of confidential information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by January 22, 2024 to

(i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: December 18, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28114 Filed 12–20–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99189; File No. SR–MRX–2023–25]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7, Section 6

December 15, 2023.

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 5, 2023, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Rules at Options 7, Section 6, Ports and Other Services.[3]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/mrx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing changes on November 28, 2023 (SR–MRX–2023–23). On December 5, 2023, the Exchange withdrew that filing and submitted this filing.

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 Options 7, Section 6, Ports and Other Services. Specifically, the Exchange proposes to amend the monthly caps for SQF Ports [4] and SQF Purge Ports.[5] The Exchange also proposes to remove unnecessary rule text from Options 7, Section 6 related to a technology migration. Both changes are explained below.

Today, MRX assesses $1,250 per port, per month for an SQF Port as well as an SQF Purge Port. Today, MRX waives one SQF Port fee per Market Maker per month. Also, today, SQF Ports and SQF Purge Ports are subject to a monthly cap of $17,500, which cap is applicable to Market Makers.

At this time, the Exchange proposes to increase the SQF Port and SQF Purge Port monthly cap fee of $17,500 per month to $27,500 per month. The Exchange is not amending the $1,250 per port, per month SQF Port and SQF Purge Port fees and the Exchange would continue to waive one SQF Port fee per Market Maker per month. As is the case today, the Exchange would not assess a Member an SQF Port or SQF Purge Port fee beyond the monthly cap once the Member has exceeded the monthly cap for the respective month. Despite increasing the monthly cap for SQF Ports and SQF Purge Ports from $17,500 per month to $27,500 per month, the Exchange will continue to offer Members the opportunity to cap their SQF Port and SQF Purge Port fees so that they would not be assessed these fees beyond the cap. Further, an MRX Market Maker requires only one SQF Port to submit quotes in its assigned options series into MRX. An MRX Market Maker may submit all quotes through one SQF Port and utilize one SQF Purge Port to view its purge requests. While a Market Maker may elect to obtain multiple SQF Ports and SQF Purge Ports to organize its business,[6] only one SQF Port and SQF Purge Port is necessary for a Market Maker to fulfill its regulatory quoting obligations.[7]

The Exchange proposes to remove the italicized language in Options 7, Section 6 related to a technology migration that took place in 2022. In 2022, MRX filed a pricing change [8] to permit Members to request certain duplicative ports at no additional cost, from November 1, 2022 through December 30, 2022, to facilitate a technology migration. The rule text related to the 2022 technology migration is no longer necessary because the migration is complete and the pricing is no longer applicable. At this time, the Exchange proposes to remove this rule text.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[10] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed pricing change to increase the monthly cap applicable to SQF Ports and SQF Purge Ports is reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [11]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

Numerous indicia demonstrate the competitive nature of this market. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules.

The proposed pricing change to increase the SQF Port and SQF Purge Port monthly cap from $17,500 per month to $27,500 per month is reasonable because despite the increase in the monthly cap, the Exchange will

[4] ''Specialized Quote Feed'' or ''SQF'' is an interface that allows Market Makers to connect, send, and receive messages related to quotes, Immediate-or-Cancel Orders, and auction responses to the Exchange. Features include the following: (1) options symbol directory messages (*e.g.,* underlying and complex instruments); (2) system event messages (*e.g.,* start of trading hours messages and start of opening); (3) trading action messages (*e.g.,* halts and resumes); (4) execution messages; (5) quote messages; (6) Immediate-or-Cancel Order messages; (7) risk protection triggers and purge notifications; (8) opening imbalance messages; (9) auction notifications; and (10) auction responses. The SQF Purge Interface only receives and notifies of purge requests from the Market Maker. Market Makers may only enter interest into SQF in their assigned options series. Immediate-or-Cancel Orders entered into SQF are not subject to the (i) Order Price Protection, Market Order Spread Protection, and Size Limitation Protection in Options 3, Section 15(a)(1)(A), (1)(B), and (2)(B) respectively, for single leg orders, or (ii) Complex Order Price Protection as defined in Options 3, Section 16(c)(1) for Complex Orders. *See* Supplementary Material .03(c) to Options 3, Section 7.

[5] SQF Purge is a specific port for the SQF interface that only receives and notifies of purge requests from the Market Maker. Dedicated SQF Purge Ports enable Market Makers to seamlessly manage their ability to remove their quotes in a swift manner. The SQF Purge Port is designed to assist Market Makers in the management of, and risk control over, their quotes. Market Makers may utilize a purge port to reduce uncertainty and to manage risk by purging all quotes in their assigned options series. Of note, Market Makers may only enter interest into SQF in their assigned options series. Additionally, the SQF Purge Port may be utilized by a Market Maker in the event that the Member has a system issue and determines to purge its quotes from the order book.

[6] For example, a Market Maker may desire to utilize multiple SQF Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that Member.

[7] MRX Market Makers have various regulatory requirements as provided for in Options 2, Section 4. Additionally, MRX Market Makers have certain quoting requirements with respect to their assigned options series as provided in Options 2, Section 5. SQF Ports are the only quoting protocol available on MRX and only Market Makers may utilize SQF Ports. The same is true for SQF Purge Ports.

[8] *See* Securities Exchange Act Release No. 96120 (October 21, 2022), 87 FR 65105 (October 27, 2022) (SR–MRX–2022–21) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7 in Connection With a Technology Migration).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

[11] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[12] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

continue to offer Members the opportunity to cap their SQF Port and SQF Purge Port fees so that they would not be assessed these fees beyond the cap. Additionally, an MRX Market Maker requires only one SQF Port to submit quotes in its assigned options series into MRX. An MRX Market Maker may submit all quotes through one SQF Port and utilize one SQF Purge Port to view its purge requests. While a Market Maker may elect to obtain multiple SQF Ports and SQF Purge Ports to organize its business,[13] only one SQF Port and SQF Purge Port is necessary for a Market Maker to fulfill its regulatory quoting obligations.[14]

The Exchange's proposed pricing change to increase the SQF Port and SQF Purge Port monthly cap from $17,500 per month to $27,500 per month is equitable and not unfairly discriminatory because the Exchange would uniformly not assess any Market Makers that exceeded the proposed monthly cap any SQF Port and SQF Purge Port fees for that month beyond the cap. Market Makers are the only market participants that are assessed SQF Port and SQF Purge Port fees because they are the only market participants that are permitted to quote on the Exchange.

The Exchange's proposal to remove the italicized language in Options 7, Section 6 related to a technology migration that took place in 2022 is reasonable, equitable and not unfairly discriminatory because the rule text related to the technology migration is no longer necessary because the migration is complete and the fees are no longer applicable. No Member is subject to the pricing described for the 2022 technology migration.

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.

Intermarket Competition

The proposal does not impose an undue burden on intermarket competition. The Exchange believes its proposal remains competitive with other options markets who also offer order entry protocols. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intramarket Competition

The Exchange's proposed pricing change to increase the SQF Port and SQF Purge Port monthly cap from $17,500 per month to $27,500 per month does not impose an undue burden on competition because the Exchange would uniformly not assess any Market Makers that exceeded the proposed monthly cap any SQF Port and SQF Purge Port fees for that month beyond the cap. Market Makers are the only market participants that are assessed SQF Port and SQF Purge Port fees because they are the only market participants that are permitted to quote on the Exchange. The Exchange's proposal to remove the italicized language in Options 7, Section 6 related to a technology migration that took place in 2022 does not impose an undue burden on competition because the rule text related to the technology migration is no longer necessary because the migration is complete and the fees are no longer applicable. No Member is subject to the pricing described for the 2022 technology migration.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[15] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule 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–MRX–2023–25 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–MRX–2023–25. 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All

[13] For example, a Market Maker or may desire to utilize multiple SQF Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that Member.

[14] MRX Market Makers have various regulatory requirements as provided for in Options 2, Section 4. Additionally, MRX Market Makers have certain quoting requirements with respect to their assigned options series as provided in Options 2, Section 5. SQF Ports are the only quoting protocol available on MRX and only Market Makers may utilize SQF Ports.

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

submissions should refer to file number SR–MRX–2023–25 and should be submitted on or before January 11, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28040 Filed 12–20–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–208, OMB Control No. 3235–0213]

Submission for OMB Review; Comment Request; Extension: Rule 17g–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 350l–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 17g–1 (17 CFR 270.17g–1) under the Investment Company Act of 1940 (the ''Act'') (15 U.S.C. 80a–17(g)) governs the fidelity bonding of officers and employees of registered management investment companies (''funds'') and their advisers. Rule 17g–1 requires, in part, the following:

Independent Directors' Approval

The form and amount of the fidelity bond must be approved by a majority of the fund's independent directors at least once annually, and the amount of any premium paid by the fund for any ''joint insured bond,'' covering multiple funds or certain affiliates, must be approved by a majority of the fund's independent directors.

Terms and Provisions of the Bond

The amount of the bond may not be less than the minimum amounts of coverage set forth in a schedule based on the fund's gross assets. The bond must provide that it shall not be cancelled, terminated, or modified except upon 60-days written notice to the affected party and to the Commission. In the case of a joint insured bond, 60-days written notice must also be given to each fund covered by the bond. A joint insured bond must provide that the fidelity insurance company will provide all funds covered by the bond with a copy of the agreement, a copy of any claim on the bond, and notification of the terms of the settlement of any claim prior to execution of that settlement. Finally, a fund that is insured by a joint bond must enter into an agreement with all other parties insured by the joint bond regarding recovery under the bond.

Filings With the Commission

Upon the execution of a fidelity bond or any amendment thereto, a fund must file with the Commission within 10 days: (i) a copy of the executed bond or any amendment to the bond, (ii) the independent directors' resolution approving the bond, and (iii) a statement as to the period for which premiums have been paid on the bond. In the case of a joint insured bond, a fund must also file: (i) a statement showing the amount the fund would have been required to maintain under the rule if it were insured under a single insured bond; and (ii) the agreement between the fund and all other insured parties regarding recovery under the bond. A fund must also notify the Commission in writing within five days of any claim or settlement on a claim under the fidelity bond.

Notices to Directors

A fund must notify by registered mail each member of its board of directors of: (i) any cancellation, termination, or modification of the fidelity bond at least 45 days prior to the effective date; and (ii) the filing or settlement of any claim under the fidelity bond when notification is filed with the Commission.

Rule 17g–1's independent directors' annual review requirements, fidelity bond content requirements, joint bond agreement requirement, and the required notices to directors are designed to ensure the safety of fund assets against losses due to the conduct of persons who may obtain access to those assets. These requirements also seek to facilitate oversight of a fund's fidelity bond. The rule's required filings with the Commission are designed to assist the Commission in monitoring funds' compliance with the fidelity bond requirements.

Based on conversations with representatives in the fund industry, the Commission staff calculates that for each of the estimated 2,543 active funds (respondents),[1] the average annual paperwork burden associated with rule 17g–1's requirements is two hours, one hour each for a compliance attorney and the board of directors as a whole. The time spent by a compliance attorney includes time spent filing reports with the Commission for fidelity losses (if any) as well as paperwork associated with any notices to directors, and managing any updates to the bond and the joint agreement (if one exists). The time spent by the board of directors as a whole includes any time spent initially establishing the bond, as well as time spent on annual updates and approvals. The Commission staff therefore estimates the total ongoing paperwork burden hours per year for all funds required by rule 17g–1 to be 5,086 hours (2,543 funds × 2 hours = 5,086 hours). Commission staff continues to estimate that the filing and reporting requirements of rule 17g–1 do not entail any external cost burdens.

These estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act. These estimates are not derived from a comprehensive or even a representative survey or study of Commission rules. The collection of information required by Rule 17g–1 is mandatory and will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by January 22, 2024 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: December 18, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28119 Filed 12–20–23; 8:45 am]

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[16] 17 CFR 200.30–3(a)(12).

[1] Based on a review of fund filings for the three-year period from January 1, 2020 to December 2022, Commission staff calculates there are 2,186 funds (registered open- and closed-end funds, and business development companies) that must comply with the collections of information under rule 17g–1, and which collectively submit an estimated 2,543 filings on Form 17G annually.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99192; File No. SR–BOX–2023–20]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing of Amendment No. 2 and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 2, To Adopt Rules To Govern FLEX Equity Options and a New Order Type To Trade FLEX Equity Options on the BOX Trading Floor

December 15, 2023.

On September 1, 2023, BOX Exchange LLC (''Exchange'' or ''BOX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt Rules 5055 and 7605 which, among other applicable Exchange rules, will govern the trading of flexible exchange equity options (''FLEX Equity Options'') on the BOX Trading Floor, and make related changes to Rules 100 (Definitions), 7620 (Accommodation Transactions), and 12140 (Imposition of Fines for Minor Rule Violations). The proposed rule change was published for comment in the **Federal Register** on September 19, 2023.[3] On September 27, 2023, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On December 12, 2023, the Exchange submitted Amendment No. 2 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.[6] The Commission is publishing this notice and order to solicit comments on the proposed rule change, as modified by Amendment No. 2, from interested persons, and to institute proceedings pursuant to Section 19(b)(2)(B) of the Act [7] to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 2.

I. Self-Regulatory Organization's Description of the Proposed Rule Change, as Modified by Amendment No. 2 [8]

The Exchange proposes to (1) adopt Rules 5055 and 7605 which will govern the trading of flexible exchange options (''FLEX Equity Options'') on BOX; and (2) make related changes to Rules 100 (Definitions), 7620 (Accommodation Transactions), and 12140 (Imposition of Fines for Minor Rule Violations). The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to (1) adopt Rules 5055 and 7605 which will govern the trading of flexible exchange options (''FLEX Equity Options'') on BOX; and (2) make related changes to Rules 100 (Definitions), 7620 (Accommodation Transactions), and 12140 (Imposition of Fines for Minor Rule Violations). The proposed rule change was published in the **Federal Register** on September 19, 2023 (the ''Original Filing'').[9] The Exchange is proposing Amendment No. 2 to amend and replace the Original Filing in its entirety.[10] This Amendment No. 2 is being filed to better conform to the FLEX rules of other exchanges related to FLEX options position reporting and margin review, and to provide more specificity to the proposed rule change.

Amendment No. 2

This Amendment No. 2 makes the following changes to the Original Filing: (i) clarifies that FLEX Equity Options may not be traded using any other order type or trading mechanism offered by the Exchange; (ii) relocates previously proposed Rule 5055(f)(1) to new proposed Rule 5055(e)(1) and renumbers previously proposed paragraph (e)(1) as (e)(2); (iii) renumbers the remaining text of proposed Rule 5055(f) as proposed Rule 5055(f)(1), (2), and (3); (iv) amends the title of proposed Rule 5055(f); (v) clarifies that exercise settlement is by physical delivery; (vi) includes a requirement for FLEX Equity Option position reporting and margin review; (vii) clarifies the trading procedures that would apply to close a position if a Non-FLEX Equity Option series is added intra-day for a component leg(s) of a Complex FOO Order or Multi-Leg FOO Order; (viii) clarifies the trading procedures that would apply to close a position if a Non-FLEX Equity Option series is added for a component leg(s) of a Complex FOO Order or Multi-Leg FOO Order on a trading day after the position is established; and (ix) makes additional clarifying changes to the description of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 98380 (September 13, 2023), 88 FR 64482 (''Notice''). Comment on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-box-2023-20/srbox202320.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 98568, 86 FR 68237 (October 3, 2023). The Commission designated December 18, 2023, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change.

[6] On December 1, 2023, the Exchange submitted Amendment No. 1 to the proposed rule change. Amendment No. 1 was withdrawn on December 12, 2023. Amendment No. 2 to the proposed rule change revised the proposal to: (i) clarifies that FLEX Equity Options may not be traded using any other order type or trading mechanism offered by the Exchange; (ii) clarifies that exercise settlement is by physical delivery; (iii) includes a requirement for FLEX Equity Option position reporting and margin review; (iv) clarifies the trading procedures that would apply to close a position if a Non-FLEX Equity Option series is added intra-day for a component leg(s) of a Complex FOO Order or Multi-Leg FOO Order; (v) clarifies the trading procedures that would apply to close a position if a Non-FLEX Equity Option series is added for a component leg(s) of a Complex FOO Order or Multi-Leg FOO Order on a trading day after the position is established; (vi) makes technical changes to the location and renumbering of proposed rules; and (vii) makes additional clarifying changes to the description of and statutory basis for the proposed rule change. Amendment No. 2 is available on the Commission's website at: *https://www.sec.gov/comments/sr-box-2023-20/srbox202320-310739-809082.pdf* (''Amendment No. 2'').

[7] 15 U.S.C. 78s(b)(2)(B).

[8] This Section I and II reproduces Amendment No. 2, as filed by the Exchange.

[9] *See* Securities Exchange Act Release No. 98380 (September 13, 2023), 88 FR 64482 (September 19, 2023) (SR–BOX–2023–20) (Notice of Filing of Proposed Rule Change to Adopt Rules to Govern FLEX Equity Options and a New Order Type to Trade FLEX Equity Options on the BOX Trading Floor).

[10] The Exchange withdrew Amendment No. 1 on December 12, 2023.

and statutory basis for the proposed rule change.

The Exchange is amending the rule text to clarify that FLEX Equity Options may not be traded using any other order type or trading mechanism offered by the Exchange. The Exchange is proposing this change to provide greater clarity on how FLEX Equity Options may be traded. The Exchange believes this change is reasonable as it adds more clarity to the rule text by emphasizing that FLEX Equity Options shall not be traded other than as FOO Orders.

The Exchange is amending the rule text to relocate currently proposed Rule 5055(f)(1) to new proposed Rule 5055(e)(1), renumber currently proposed paragraph (e)(1) as (e)(2), and renumber the remaining text of proposed Rule 5055(f) as proposed Rules 5055(f)(1), (2), and (3). The Exchange believes this change will provide greater clarity to the rule text by reorganizing previously proposed text in a more readable, understandable, and user-friendly manner. The Exchange is also amending the title of proposed Rule 5055(f) to ''Fungibility of FLEX Equity Options.'' The Exchange is proposing this change to more appropriately reflect the purpose of the section following these reorganizational changes.

The Exchange is amending rule text by adding proposed Rule 5055(e)(3) to clarify that the exercise settlement of FLEX Equity Options shall be by physical delivery of the underlying security. The Exchange is proposing this change to provide greater clarity on how FLEX Equity Options may be traded and settled. The Exchange believes this change is reasonable as it adds more clarity to the rule text by specifying that the exercise settlement for FLEX Equity Options shall be by physical delivery of the underlying security.

The Exchange is amending the rule text to include a requirement for FLEX Equity Option position reporting and margin review. The Exchange is proposing this change to better align the proposed rules with the already established rules of other exchanges. The Exchange believes this change is reasonable as it conforms the proposed rule with the rest of the industry.

The Exchange is amending the rule text to clarify the trading procedures that would apply to close a position if a Non-FLEX Equity Option series is added intra-day or on a subsequent trading day for a component leg(s) of a Complex FOO Order or Multi-Leg FOO Order. The Exchange is proposing these changes to provide greater clarity on the treatment of FLEX Equity Options after the same Non-FLEX Equity Option is added. The Exchange believes these changes are reasonable as they add more clarity to the rule text on how to close FLEX Equity Option positions.

Summary

The Exchange proposes to adopt rules to govern FLEX Equity Options and a new order type to trade FLEX Equity Options on the BOX Trading Floor.[11] The Exchange also proposes to amend Rules 100 (Definitions), 7620 (Accommodation Transactions), and 12140 (Imposition of Fines for Minor Rule Violations) to reflect the introduction of FLEX Equity Option trading on the Exchange. FLEX Equity Options are options with flexible terms such that Participants [12] can customize expiration date, exercise price, and exercise style. FLEX Equity Options are designed to meet the needs of investors for greater flexibility in selecting the terms of options within the parameters of the Exchange's proposed rules. FLEX Equity Options are not preestablished for trading and are not listed individually for trading on the Exchange. Rather, investors select FLEX Equity Option terms and are limited by the parameters detailed below in their selection of those terms. As a result, FLEX Equity Options allow investors to satisfy more specific, individualized investment objectives than may be available to them in the standardized options market. Specifically, FLEX Equity Options will be subject to proposed Rule 5055 and will be traded as FLEX Open Outcry Orders (''FOO Orders'') on the BOX Trading Floor under proposed Rule 7605. FLEX Equity Options are a type put or call, and allow investors to choose an exercise price of any dollar amount in minimum increments of $0.01,[13] an exercise style of American or European,[14] and an expiration date of any month, business day and year no more than 15 years from the date on which a FLEX Equity Option is executed.[15] As discussed further below, FLEX Equity Options will not be permitted with the same terms as an existing Non-FLEX Equity Option listed on the Exchange.[16] Because of their composition, the Exchange believes that FLEX Equity Options may allow investors to more closely meet their individual investment and hedging objectives by customizing option contracts for the purpose of satisfying particular investment objectives that could not be met by the standardized markets.

Background

The Securities and Exchange Commission (''Commission'') approved the trading of FLEX options in 1993.[17] At the time, the Chicago Board Options Exchange, Inc., now Cboe Exchange, Inc. (''CBOE'') proposed FLEX options based on the Standard and Poor's Corporation 500 and 100 Stock Indexes (referred to as the ''CBOE Order'' herein).[18] These FLEX options were offered as an alternative to an over-the-counter (''OTC'') market in customized equity options.[19] Several years after the initial approval, the Commission approved the trading of additional FLEX options on specified equity securities.[20] In its order, the Commission provided: ''The benefits of the Exchanges' options markets include, but are not limited to, a centralized market center, an auction market with posted transparent market quotations and transaction reporting, parameters and procedures for clearance and settlement, and the guarantee of the OCC [Options Clearing Corporation] for all contracts traded on the Exchange.'' [21]

The Exchange notes that FLEX options are currently traded on CBOE, NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), and Nasdaq PHLX LLC

[11] The term ''Trading Floor'' or ''Options Floor'' means the physical trading floor of the Exchange located in Chicago. The Trading Floor shall consist of one ''Crowd Area'' or ''Pit'' where all option classes will be located. The Crowd Area or Pit shall be marked with specific visible boundaries on the Trading Floor, as determined by the Exchange. A Floor Broker must open outcry an order in the Crowd Area. *See* BOX Rule 100(a)(68).

[12] The term ''Participant'' means a firm, or organization that is registered with the Exchange pursuant to the Rule 2000 Series for purposes of participating in trading on a facility of the Exchange and includes an ''Options Participant'' and ''BSTX Participant.'' *See* BOX Rule 100(a)(42).

[13] *See* proposed Rule 5055(e)(2)(iii).

[14] *See* proposed Rule 5055(e)(2)(iv).

[15] *See* proposed Rule 5055(e)(2)(v).

[16] At least one of the following terms must differ between FLEX Equity Options and Non-FLEX Equity Options on the same underlying security: Exercise price, Exercise style, and Expiration date.

[17] *See* Securities Exchange Act Release No. 31920 (February 24, 1993), 58 FR 12280 (March 3, 1993) (SR–CBOE–92–17) (Order Approving and Notice of Filing and Order Granting Accelerated Approval to Amendment Nos. 1, 2, 3, and 4 to Proposed Rule Changes by the Chicago Board Options Exchange, Inc., Relating to Flexible Exchange Options (''FLEX Options'')).

[18] *Id.*

[19] *Id.*

[20] *See* Securities Exchange Act Release No. 36841 (February 14, 1996), 61 FR 6666 (February 21, 1996) (SR–CBOE–95–43) (SR–PSE–95–24) (Order Approving Proposed Rule Changes and Notice of Filing and Order Granting Accelerated Approval of Amendments by the Chicago Board Options Exchange, Inc. and the Pacific Stock Exchange, Inc., Relating to the Listing of Flexible Exchange Options on Specified Equity Securities).

[21] *Id.* The Exchange notes that the Commission found pursuant to Rule 9b–1 under the Act, that FLEX Options, including FLEX Equity Options, are standardized options for purposes of the options disclosure framework established under Rule 9b–1 of the Act. *Id.*

(''PHLX'').[22] The Exchange notes further that CBOE offers electronic and open outcry FLEX option trading while NYSE American, NYSE Arca, and PHLX offer only open outcry trading of FLEX options.

In August 2017, the Commission approved the Exchange's proposal to adopt rules for an open outcry trading floor.[23] The Exchange based the rules for the BOX Trading Floor on the rules of the options exchanges that had established trading floors at that time. When the BOX Trading Floor was adopted in 2017, it was the first options trading floor to be established since the 1970s.[24] As such, the BOX Trading Floor rules have certain differences to the trading floor rules at the other options exchanges, to account for the unique nature of BOX's Trading Floor and to modernize the existing trading floor rules and surveillance practices. The BOX Trading Floor has been operating since 2017 and is now well-established. The Exchange believes that its unique features for open-outcry trading provide value to Floor Participants. The Exchange now proposes to allow for the trading of FLEX Equity Options as FOO Orders on the BOX Trading Floor.[25]

Proposal

The Exchange proposes to adopt Rule 5055 titled FLEX Equity Options which describes and governs FLEX Equity Options. Rule 5055(a) details the applicability of other Exchange rules with respect to the proposed FLEX Equity Options. Specifically, the trading of FLEX Equity Options is subject to all other Rules applicable to the trading of options on the Exchange, unless otherwise provided in Rules 5055 and 7605.[26] The Exchange has conducted a thorough review of its existing Rules to ensure that the text of proposed Rule 5055(a) appropriately reflects any Rules that (1) would apply to FLEX Equity Options and Non-FLEX Equity Options alike,[27] and (2) would not apply to FLEX Equity Options at all.[28] As described herein, the only means by which the Exchange intends to permit FLEX Equity Options to be traded is via the proposed FOO Order type. To the extent the Exchange proposes to adopt additional rules for the trading of FLEX Equity Options, including electronic trading of FLEX Equity Options, the Exchange would file a separate proposed rule change with the Commission.

The rules proposed by the Exchange are uniquely applicable to FLEX Equity Options in order to accommodate their special characteristics. For example, the BOX Book [29] and the Complex Order Book [30] shall not be available for transactions in FLEX Equity Options because, consistent with other exchanges' FLEX rules, there will be no pre-established series [31] and no electronic trading of FLEX Equity Options.[32] While electronic trading in FLEX options is available on CBOE,[33] the Exchange at this time intends to introduce FLEX Equity Options on the Trading Floor only, consistent with other markets that trade these customized options solely on their trading floors.[34] The Exchange notes that rules that contemplate the operation of or interaction with the BOX Book and the Complex Order Book will not apply to FLEX Equity Options, given that FLEX Equity Options may only be traded as FOO Orders and FOO Orders may not be placed in the BOX Book or the Complex Order Book.[35] Additionally, the Exchange is proposing to codify that Options Exchange Officials have the same duties and ability to enforce rules applicable to the trading of FLEX Equity Options as they do for all other activity on the Trading Floor.[36]

FLEX Equity Options will only be permitted in puts and calls that do not have the same exercise style (American or European), same expiration date and same exercise price as Non-FLEX Equity Options that are already available for trading on the same underlying security.[37] In addition, once, and if, identical option series are listed for trading as Non-FLEX Equity Options, (1) all existing open positions established under the FLEX trading procedures shall be fully fungible with transactions in the respective Non-FLEX Equity Option series, and (2) any further trading in the series would be as Non-FLEX Equity Options subject to the non-FLEX trading procedures and rules.[38] Therefore, FOO Orders, whose terms must be different from options that are already available for trading, would not be fungible with interest resting on the BOX Book or Complex Order Book. Accordingly, the Exchange believes FOO Orders would not be able to trade through interest resting on the BOX Book or Complex Order Book nor would interest resting on the BOX Book or Complex Order Book lose priority to FOO Orders.

The Exchange proposes Rule 5055(b) which defines the following terms: FLEX Equity Option, Non-FLEX Equity Option, FLEX Market Maker, and FLEX Open Outcry Order. Specifically, the term ''FLEX Equity Option'' means an option on a specified underlying security that is subject to Rule 5055.[39] ''Non-FLEX Equity Option'' means an option contract that is not a FLEX Equity Option.[40] ''FLEX Open Outcry Order'' (''FOO Order'') means a FLEX Equity Option order as defined in

[22] *See* CBOE Rules 4.20–4.22 and 5.70–5.75 *and* NYSE American Rules 900G–910G *and* NYSE Arca Rules 5.30–O–5.41–O *and* PHLX Options 8, Section 34.

[23] *See* Securities Exchange Act Release No. 81292 (August 2, 2017), 82 FR 37144 (August 8, 2017) (SR–BOX–2016–48) (Order Approving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Adopt Rules for an Open-Outcry Trading Floor) (finding that the proposed rule change was consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange).

[24] *See https://www.optionsplaybook.com/options-introduction/stock-option-history/.*

[25] The Exchange has received one comment letter in support of the proposed rule change. The commenter believes that permitting BOX to offer FLEX Equity Options will expand competition and capacity and thus drive better execution experiences for the public. *See* Letter from Anish Vora, CEO, FCF Holdings LLC, and Board of Directors of NYSE, to the SEC (September 29, 2023) (*https://www.sec.gov/comments/sr-box-2023-20/srbox202320-638842.htm*).

[26] *See* proposed Rule 5055(a). Proposed Rule 5055(a) is based on CBOE Rule 5.72(a).

[27] *See* proposed Rule 5055(a). For example, Rules 7010 (Fees and Charges), 7020 (Days and Hours of Business), 7030 (Units of Trading), and 7080 (Trading Halts) apply to FLEX Equity Options and Non-FLEX Equity Options alike.

[28] *See,* for example, *infra* note 36, explaining that FLEX Equity Options may not trade using various order mechanisms designed for electronic trading.

[29] The term ''BOX Book'' means the electronic book of orders on each single option series maintained by the BOX Trading Host. *See* BOX Rule 100(a)(10).

[30] The term ''Complex Order Book'' means the electronic book of Complex Orders maintained by the BOX Trading Host. *See* BOX Rule 7240(a)(8).

[31] *See infra* note 52.

[32] *See* proposed Rule 5055(a)(1). Proposed Rule 5055(a)(1) is based on NYSE Arca Rule 5.30–O(c).

[33] *See, e.g.,* CBOE Rules 5.73 and 5.74.

[34] *See, e.g.,* NYSE Arca Rule 5.30–O(c).

[35] The Exchange notes that FLEX Equity Options may not trade via the PIP, COPIP, Facilitation and Solicitation Auctions, or as Qualified Contingent Cross (''QCC''), Complex QCC, Customer Cross, and Complex Customer Cross Orders. If the Exchange intended to allow FLEX Equity Options to trade via the PIP, COPIP, Facilitation and Solicitation Auctions, or as (''QCC''), Complex QCC, Customer Cross, and Complex Customer Cross Orders, the Exchange would be required to file a proposed rule change with the Commission to amend its rules to allow for the inclusion of FLEX Equity Options in the relevant rule text.

[36] *See* proposed Rule 5055(a)(2).

[37] *See* proposed Rule 5055(e)(1). Proposed Rule 5055(e)(1) is based on NYSE Arca Rule 5.32–O, Commentary .01.

[38] *See* proposed Rule 5055(f)(1). Proposed Rule 5055(f)(1) is based on NYSE Arca Rule 5.32–O, Commentary .01.

[39] *See* proposed Rule 5055(b)(1). The Exchange notes that proposed Rule 5055(e)(2)(i) provides that FLEX Equity Options on underlying securities may be authorized pursuant to Rule 5020.

[40] *See* proposed Rule 5055(b)(2). Proposed Rule 5055(b)(2) is based on NYSE Arca Rule 5.30–O(b)(11).

proposed Rule 7605.[41] ''FLEX Market Maker'' means a Market Maker that is qualified by the Exchange to trade FLEX Equity Options and meets the requirements of proposed Rule 5055(k).[42] The proposed functionality for FOO Orders is designed to be similar to the Exchange's existing Qualified Open Outcry (''QOO'') Orders because both order types will be transacted on the Trading Floor and BOX believes they should follow similar procedures, excluding provisions related to the BOX Book, as discussed below.[43] FLEX Equity Options shall not be traded other than as FOO Orders.[44] The Exchange also proposes to specify in proposed Rule 5055(b)(3) that, for the avoidance of doubt, FLEX Equity Options may not be traded using any other order type or trading mechanism offered by the Exchange.

The Exchange proposes Rule 5055(c) which states that certain Exchange rules do not apply to transactions in FLEX Equity Options. Specifically, Rule 7600 ''Qualified Open Outcry Orders—Floor Crossing'' and Rule 7620 ''Accommodation Transactions'' do not apply to transactions in FLEX Equity Options.[45] These rules represent order types that currently apply to Non-FLEX Equity Options on the BOX Trading Floor and are specifically excluded given that the Exchange is proposing the FOO Order type to be used exclusively for trading FLEX Equity Options. However, the Exchange proposes that certain Rule 7600 Interpretive Materials apply to FLEX Equity Options; in particular IM–7600–2 [46] and IM–7600–5.[47] IM–7600–2 and IM–7600–5 relate to tied hedge orders and to compliance with Section 11(a)(1) of the Act, respectively, and will apply to the proposed FOO Orders in the same manner as they currently apply to QOO Orders. Because these provisions would apply equally to FLEX Equity Options as they do to Non-FLEX Equity Options, they need not be duplicated for purposes of the proposed rules.

The Exchange proposes Rule 5055(d) which states that FLEX Equity Options will have no trading rotations.[48] Trading rotations are used to open or reopen a series of options on BOX at a single price.[49] There is a period of time before the market in the underlying security opens during which orders placed on the BOX Book do not generate trade executions but may participate in the Opening Match.[50] FLEX Equity Options will not be placed on the BOX Book, and therefore will not have trading rotations because there will be no requirement for specific FLEX Equity Option series to be quoted or traded each day. FLEX Equity Options are created with terms unique to individual investment objectives. As such, each investor may require FLEX Equity Options with slightly different terms than those already created. These individually defined FLEX Equity Options are customized for each investor and therefore trading rotations may not be useful for other investors who may create their own FLEX Equity Options because trading rotations are designed, in part, to determine a single opening, or reopening, price based on orders and quotes from multiple Participants. With the bespoke nature of FLEX Equity Options there is not the opportunity, nor need, to bring together multiple orders and quotes as part of a trading rotation.

Further, the Exchange proposes Rule 5055(e) which provides that FLEX Equity Options will not be preestablished for trading and, provided the options on an underlying security are otherwise eligible for FLEX trading, FLEX Equity Options shall be permitted in puts and calls that do not have the same exercise style, same expiration date, and same exercise price as Non-FLEX Equity Options that are already available for trading on the same underlying security. Proposed Rule 5055(e) further provides that FLEX Equity Options must include one of each of the terms of a FLEX Equity Option that are described in the proposed Rule.[51] Specifically, (i) the Exchange may authorize for trading a FLEX Equity Option class on any underlying security if it may authorize trading a Non-FLEX Equity Option class on that underlying security pursuant to Rule 5020,[52] and that has Non-FLEX Equity Options on such security listed

[41] *See* proposed Rule 5055(b)(3).

[42] *See* proposed Rule 5055(b)(4).

[43] *See* BOX Rule 7600. *See also* Securities Exchange Act Release No. 81292 (August 2, 2017), 82 FR 37144 (August 8, 2017) (SR–BOX–2016–48) (Order Approving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Adopt Rules for an Open-Outcry Trading Floor).

[44] *See* proposed Rule 5055(b)(3).

[45] *See* proposed Rule 5055(c). Proposed Rule 5055(c) is based on NYSE Arca Rule 5.30–O(d).

[46] BOX IM–7600–2 provides that nothing prohibits a Floor Broker from buying or selling a stock, security futures, or futures position following receipt of an option order, including a Complex Order, provided that prior to announcing such order to the trading crowd: (a) the option order is in a class designated as eligible for ''tied hedge'' transactions (as described below) as determined by the Exchange and is within the designated tied hedge eligibility size parameters, which parameters shall be determined by the Exchange and may not be smaller than 500 contracts per order. Additionally, there shall be no aggregation of multiple orders to satisfy the size parameter, and for Complex Orders involved in a tied hedge transaction at least one leg must meet the minimum size requirement; (b) such Floor Broker shall create an electronic record that it is engaging in a tied hedge transaction in a form and manner prescribed by the Exchange; (c) such hedging position is: (1) comprised of a position designated as eligible for a tied hedge transaction as determined by the Exchange and may include the same underlying stock applicable to the option order, a security future overlying the same stock applicable to the option order or, in reference to an index or Exchange-Traded Fund Shares (''ETF''), a related instrument. A ''related instrument'' means, in reference to an index option, securities comprising ten percent or more of the component securities in the index or a futures contract on any economically equivalent index applicable to the option order. A ''related instrument'' means, in reference to an ETF option, a futures contract on any economically equivalent index applicable to the ETF underlying the option order; (2) brought without undue delay to the trading crowd and announced concurrently with the option order; (3) offered to the trading crowd in its entirety; and (4) offered, at the execution price received by the Floor Broker introducing the option, to any in-crowd Floor Participant who has established parity or priority for the related options; (d) the hedging position does not exceed the option order on a delta basis; (e) all tied hedge transactions (regardless of whether the option order is a simple or Complex Order) are treated the same as Complex Orders for purposes of the Exchange's open outcry allocation and reporting procedures. Tied hedge transactions are subject to the existing NBBO trade-through requirements for options and stock, as applicable, and may qualify for various exceptions; however, when the option order is a simple order, the execution of the option leg of a tied hedge transaction does not qualify for the NBBO trade-through exception for a Complex Trade (defined in Rule 7610(e)); (f) in-crowd Floor Participants that participate in the option transaction must also participate in the hedging position and may not prevent the option transaction from occurring by giving a competing bid or offer for one component of such order; (g) in the event the conditions in the non-options market prevents the execution of the non-option leg(s) at the agreed prices, the trade representing the options leg(s) may be cancelled; and (h) prior to entering tied hedge orders on behalf of Customers, the Floor Broker must deliver to the Customer a written notification informing the Customer that his order may be executed using the Exchange's tied hedge procedures. The written notification must disclose the terms and conditions contained in this Interpretative Material and be in a form approved by the Exchange. *See* BOX IM–7600–2.

[47] BOX IM–7600–5 provides that a Participant shall not utilize the Trading Floor to effect any transaction for its own account, the account of an associated person, or an account with respect to which it or an associated person thereof exercises investment discretion by relying on an exemption under Section 11(a)(1)(G) of the Exchange Act. *See* BOX IM–7600–5.

[48] *See* proposed Rule 5055(d). Proposed Rule 5055(d) is based on NYSE Arca Rule 5.31–O(b).

[49] *See* BOX Rules 7070(e)(2) and (l).

[50] *See* BOX Rules 7070(a) and (e). The Exchange notes that trading rotations are referred to in BOX Rule 7070(e) as the Opening Match.

[51] Proposed Rule 5055(e) is based on NYSE Arca Rule 5.32–O. The Exchange notes that it is not proposing FLEX Index Options and thus has not incorporated applicable provisions as Index Options do not trade on BOX.

[52] Rule 5020 provides criteria for the listing of options on several different underlying types of securities, including securities registered with the SEC under Regulation NMS of the Act (''NMS stock''), Exchange-Traded Fund Shares, and Index-Linked Securities. *See* BOX Rule 5020.

and traded on at least one national securities exchange, even if the Exchange does not list that Non-FLEX Equity Option class for trading; [53] (ii) the option type may be put or call; [54] (iii) the exercise price may be any dollar amount in minimum increments of $0.01; [55] (iv) the exercise style may be American or European; [56] and (v) the expiration date may be any business day (specified to the day, month, and year) no more than 15 years from the date of the FLEX Equity Option transaction.[57] A FLEX Equity Option order may be submitted on any trading day, including the expiration date.[58] Additionally, the exercise settlement of FLEX Equity Options shall be by physical delivery of the underlying security.[59]

Next, the Exchange proposes Rule 5055(f) titled Fungibility of FLEX Equity Options. Proposed Rule 5055(e)(1), described above, limits FLEX Equity Option terms such that options on an underlying security otherwise eligible for FLEX trading will only be permitted in puts and calls that do not have the same exercise style (American or European), same expiration date and same exercise price as Non-FLEX Equity Options that are already available for trading on the same underlying security.[60] Notwithstanding the foregoing, FLEX Equity Options that may in the future have the same terms as Non-FLEX Equity Options will be permitted before the options are listed for trading as Non-FLEX Equity Options. Once and if the identical option series are listed for trading as Non-FLEX Equity Options: (i) all existing open positions established under the FLEX trading procedures shall be fully fungible with transactions in the respective Non-FLEX Equity Option series,[61] and (ii) any further trading in the series would be as Non-FLEX Equity Options subject to the non-FLEX trading procedures and rules,[62] in addition to any other rules that apply to Non-FLEX Equity Options.[63] In the event a Non-FLEX Equity Option series is added intra-day, the holder or writer of a FLEX Equity Option position established under the FLEX trading procedures would be permitted to close such position under the FLEX trading procedures against another closing only FLEX Equity Option position for the balance of the trading day on which the series is added.[64] In the event the Non-FLEX Equity Option series is added on a trading day after the position is established, the holder or writer of a FLEX Equity Option position established under the FLEX trading procedures would be permitted to close such position as a non-FLEX transaction consistent with the requirements of Rule 5055(f)(1).

The Exchange proposes Rule 5055(g) which states that the minimum quoting and trading increment for FLEX Equity Option contracts traded on BOX will be one cent ($0.01) for all series.[65]

The Exchange proposes Rule 5055(h) which states that FLEX Equity Options will be subject to the exercise by exception provisions of Rule 805 of the OCC, titled Expiration Exercise Procedure.[66] Rule 805 provides provisions for the automatic exercise of certain options upon expiration.

The Exchange proposes Rule 5055(i) which details position limits for FLEX Equity Options. Specifically, 5055(i)(1) states that FLEX Equity Options will not be subject to position limits, except as long as the options positions remain open, positions in FLEX Equity Options that expire on a third Friday-of-the-month shall be aggregated with

[53] *See* proposed Rule 5055(e)(2)(i). Proposed Rule 5055(e)(2)(i) is based on NYSE Arca Rule 5.32–O(f)(1).

[54] *See* proposed Rule 5055(e)(2)(ii). Proposed Rule 5055(e)(2)(ii) is based on NYSE Arca Rule 5.32–O(b)(2).

[55] *See* proposed Rule 5055(e)(2)(iii). Proposed Rule 5055(e)(2)(iii) is based on NYSE Arca Rule 5.32–O(f)(2) (exercise prices and premiums may be stated in terms of: (i) a dollar amount; (ii) a method for fixing at the time a FLEX Request for Quote or FLEX Order is traded; or (iii) a percentage of the price of the underlying security at the time of the trade or as of the close of trading on the NYSE Arca on the trade date). The Exchange notes that the proposal only includes exercise, bid, and offer prices in terms of a dollar amount.

[56] *See* proposed Rule 5055(e)(2)(iv). Proposed Rule 5055(e)(2)(iv) is based on NYSE Arca Rule 5.32–O(b)(3).

[57] *See* proposed Rule 5055(e)(2)(v). Proposed Rule 5055(e)(2)(v) is based on NYSE Arca Rules 5.32–O(b)(4) and (6). The Exchange notes that it has omitted the exception for FLEX Index Options because BOX does not list FLEX Index Options and FLEX Index Options are not part of this proposal.

[58] *See* proposed Rule 5055(e)(2)(v)(a). It is the Exchange's understanding from conversations with the Options Clearing Corporation (''OCC'') that the OCC is able to process FLEX transactions that occur on the expiration date. The Exchange notes that NYSE Arca's rules do not contain a similar provision. However, the Exchange believes, based on Participant feedback, that FLEX Option orders on NYSE ARCA are allowed on the expiration date. The Exchange notes that the exercise of options contracts is governed by the Rule 9000 series including exercise cut-off times and contrary exercise advices. The Exchange also notes that, in another context, new series may be listed the day they expire. Specifically, Short Term Option Series may be added up to and including on the Short Term Option Expiration Date for that options series. *See* BOX IM–5050–6(b)(4).

[59] *See* proposed Rule 5055(e)(3). Proposed Rule 5055(e)(3) is based on NYSE Arca Rule 5.32–O(f)(3)(i). The Exchange notes that NYSE Arca Rule 5.32–O(f)(3)(i) includes references to Exchange-Traded Fund Shares and FLEX ByRDs that the Exchange is not including because the Exchange believes it is not necessary to specifically reference Exchange-Traded Fund Shares as they are included under the term underlying security. Additionally, the Exchange notes that FLEX ByRDs are not being proposed on the Exchange.

[60] *See* proposed Rule 5055(e)(1). Proposed Rule 5055(e)(1) is based on NYSE Arca Rule 5.32–O, Commentary .01. The Exchanges notes that its system enforces the requirement that a FLEX Equity Option does not have the same exercise style (American or European), same expiration date and same exercise price as a Non-FLEX Equity Option that is already available for trading on the same underlying security. Specifically, the system will reject an order in a FLEX Equity Option if the order is received with the same exercise style (American or European), same expiration date and same exercise price as a Non-FLEX Equity Option that is already available for trading on the same underlying security on the Exchange.

[61] An open position resulting from a transaction on the Exchange becomes fungible post-trade and is separate from the execution occurring on the Exchange. For example, assume a Participant buys one (1) American style AAPL call option expiring on October 9, 2024, with a strike price of 150, which is a FLEX series because there is no standard option listed with those same terms. Now assume, while holding this position, a standard option with the same terms is listed (American style AAPL call option expiring on October 9, 2024, with a strike price of 150). After this standard option is listed, the Participant purchases one (1) contract in this non-FLEX option series. After this second transaction, the Participant will have an open position of two (2) contracts in the standard AAPL call expiring on October 9, 2024, with a 150 strike price.

[62] This includes all priority and trade-through requirements on the Exchange (*see, e.g.,* Rule 7130).

[63] *See* proposed Rule 5055(f)(1). Proposed Rule 5055(f)(1) is based on NYSE Arca Rule 5.32–O, Commentary .01. The Exchange notes that FLEX Equity Options previously traded as part of a Complex FOO Order or Multi-Leg FOO Order where the respective Non-FLEX Equity Option series is later listed may not be traded as part of a Complex FOO Order or Multi-leg FOO Order except as provided in proposed Rules 5055(f)(2) and 7605(d)(3) and (4) once such Non-FLEX Equity Option series has been listed on the Exchange. *See* proposed Rules 7605(d)(1), (3) and (4). For example, assume a Participant executes a Complex FOO Order to buy strategy A + B where A and B are both FLEX Equity Option series. Now assume that prior to the opening on the next trading day, a Non-FLEX Equity Option series with the same terms (underlying security, type, exercise price, exercise style, and expiration date) as A has been listed on the Exchange. If the Participant decided to close out their open position in strategy A + B, it would need to be done as two separate orders for the component legs of the original order: (i) selling B, a FLEX Equity Option, by submitting a FOO Order, and (ii) selling the corresponding Non-FLEX Equity Option series that has the same terms as A because A has become fungible with the Non-FLEX Equity Option series with the identical terms. Trading in A would be subject to the non-FLEX trading procedures and rules. *See* proposed Rule 5055(f)(1).

[64] *See* proposed Rule 5055(f)(2). Proposed Rule 5055(f)(2) is based on NYSE Arca Rule 5.32–O, Commentary .01. The Exchange notes that Complex FOO Orders and Multi-Leg FOO Orders, discussed below, may be traded with one or more closing only component legs. The Exchange notes that proposed Rule 5055(f) differs from NYSE Arca Rule 5.32–O, Commentary .01 in that it includes proposed Rules 5055(f)(2) and (3), which detail the interaction between proposed Rules 5055(e)(1) and (f)(1).

[65] *See* proposed Rule 5055(g). Proposed Rule 5055(g) is based on CBOE Rule 5.4(c)(4). The Exchange notes that minimum increments in percentage terms have been omitted because they are not part of this proposal.

[66] *See* proposed Rule 5055(h). Proposed Rule 5055(h) is based on NYSE Arca Rule 5.32–O(f)(4).

positions in Non-FLEX Equity Options on the same underlying security and shall be subject to the position and exercise limits set forth in this proposed rule, and in the current BOX rules.[67] Positions in FLEX Equity Options shall not be taken into account when calculating position limits for Non-FLEX Equity Options, other than for positions in FLEX Equity Options that expire on a third Friday-of-the-month, as discussed below.[68]

The Exchange proposes that rather than be subject to FLEX position limits, each Participant (other than a Market Maker) that maintains a position on the same side of the market in excess of the standard position limit for Non-FLEX Equity Options of the same class on behalf of its own account or for the account of a customer shall report information on the FLEX Equity Option position, positions in any related instrument, the purpose or strategy for the position and the collateral used by the account. This report shall be in the form and manner prescribed by the Exchange. In addition, whenever the Exchange determines that a higher margin requirement is necessary in light of the risks associated with a FLEX Equity Option position in excess of the standard position limit for Non-FLEX Equity Options of the same class, the Exchange may, pursuant to its authority under Rule 10130(b), consider imposing additional margin upon the account maintaining such under-hedged position. Additionally, it should be noted that the clearing firm carrying the account will be subject to capital charges under Rule 15c3–1 under the Act[69] to the extent of any margin deficiency resulting from the higher margin requirement.[70]

The Exchange proposes Rule 5055(j) which governs exercise limits for FLEX Equity Options. Specifically, proposed Rule 5055(j) states that exercise limits for FLEX Equity Options shall be equivalent to the position limits established in this proposal; accordingly, there shall be no exercise limits for FLEX Equity Options.[71] FLEX Equity Options will not be taken into account when calculating exercise limits for Non-FLEX Equity Options, except that as long as the option positions remain open, positions in FLEX Equity Options which expire on a third Friday-of-the-month shall be aggregated with positions in Non-FLEX Equity Options on the same underlying security and will be subject to Non-FLEX Equity Option exercise limits as applicable.[72]

The Exchange proposes Rule 5055(k) which details the Letter of Guarantee required for Market Makers to trade FLEX Equity Options. Specifically, proposed Rule 5055(k) states that no Market Maker shall effect any transaction in FLEX Equity Options unless a Letter of Guarantee has been issued by a clearing member organization and filed with the Exchange pursuant to Rule 8070 specifically accepting financial responsibility for all FLEX Equity Option transactions made by such Market Maker and such letter has not been revoked under Rule 8070(c).[73] A Letter of Guarantee will be required for a Market Maker to be qualified to trade FLEX Equity Options.

Similarly, the Exchange proposes Rule 5055(l), which provides that no Floor Broker[74] shall effect any transaction in FLEX Equity Options unless a Letter of Authorization has been issued by a clearing member organization and filed with the Exchange specifically accepting responsibility for the clearance of FLEX Equity Option transactions of the Floor Broker, and that such letter will remain in effect until a written revocation is received by the Exchange.[75]

FLEX Open Outcry (''FOO'') Orders

The Exchange proposes to introduce a new order type to facilitate FLEX Equity Option transactions on the BOX Trading Floor. Specifically, the Exchange proposes to adopt a FOO Order type and to model it after a current order type on the Trading Floor—QOO Orders.[76] Trading FLEX options on an exchange floor in a similar manner as non-FLEX options is consistent with how FLEX orders are traded on another exchange.[77] FOO Orders must consist of options with terms as defined in proposed Rule 5055. Further, FOO Orders are limited solely to FLEX Equity Options.[78] FOO Orders are limited solely to the BOX Trading Floor and may be entered only by Floor Brokers.[79] Floor Brokers must also be registered under Rule 7550. Prior to the announcement of such FOO Orders in the trading crowd, Floor Brokers must record all FOO Orders pursuant to Rule 7580(e)(1).[80] FOO Orders may be traded by FLEX Market Makers, which must be registered under Rule 8000 and must be Floor Market Makers in good standing under Rule 8500.[81] FLEX Market Makers will be subject to Rule 8510, including provisions for the course and conduct of dealings, class assignments, and option priority and parity, unless otherwise specified in proposed Rule 7605. The Exchange shall qualify at least three

[67] *See* BOX Rules 3120 (Position Limits) and 3140 (Exercise Limits). The Exchange notes that Complex FOO Orders and Multi-Leg FOO Orders when executed result in position changes for the individual component legs of the transaction based on the composition of the Complex or Multi-Leg FOO Order.

[68] *See* proposed Rule 5055(i). Proposed Rule 5055(i) is based on NYSE Arca Rules 5.35–O(a)(iii) and (b). The Exchange notes that Index Options and Binary Return Derivatives (''ByRDs'') are not traded on BOX and therefore FLEX Index Options and FLEX ByRDs will not be traded on BOX and are not included in proposed Rule 5055(i). *See also* CBOE Rule 8.35 *and* NYSE American Rule 906G *and* PHLX Options 8, Section 34(e).

[69] *See* 17 CFR 240.15c3–1.

[70] *See* proposed Rule 5055(i)(1). Proposed Rule 5055(i)(1) is based on NYSE Arca Rule 5.35–O(b).

[71] *See* proposed Rule 5055(j). Proposed Rule 5055(j) is based on NYSE Arca Rule 5.36–O. *See also* proposed Rule 5055(i).

[72] *See* proposed Rule 5055(i).

[73] *See* proposed Rule 5055(k). Proposed Rule 5055(k) is based on NYSE Arca Rule 5.41–O(a). The Exchange notes that, while NYSE Arca allows an existing Letter of Guarantee to be amended specifically to include FLEX transactions upon approval by the OCC, the Exchange's proposal does not include such a provision because the Exchange will require a separate Letter of Guarantee. The Exchange notes that a Market Maker's Letter of Guarantee will remain effective until a revocation is received by the Exchange.

[74] A Floor Broker is an individual who is registered with the Exchange for the purpose, while on the Trading Floor, of accepting and handling options orders. A Floor Broker must be registered as an Options Participant prior to registering as a Floor Broker. *See* BOX Rule 7540.

[75] *See* proposed Rule 5055(l). Proposed Rule 5055(l) is based on NYSE Arca Rule 5.41–O(b). The Exchange notes that, while NYSE Arca allows an existing Letter of Authorization to be amended specifically to include FLEX transactions upon approval by the OCC, the Exchange's proposal does not include such a provision because the Exchange will require a separate Letter of Authorization. The Exchange notes that a Floor Broker's Letter of Authorization will remain effective until a written revocation is received by the Exchange.

[76] *See* proposed Rule 7605. *See also* Securities Exchange Act Release No. 81292 (August 2, 2017), 82 FR 37144 (August 8, 2017) (SR–BOX–2016–48) (Order Approving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Adopt Rules for an Open-Outcry Trading Floor) (finding that the proposed rule change was consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange).

[77] CBOE allows a FLEX Order to be represented and executed in the same manner as a non-FLEX Order. *See* CBOE Rule 5.72(d). The Exchange notes that CBOE Rule 5.72(d) also contains provisions that limit the priority rules applicable to FLEX Orders. *Id.* at 5.72(d)(2) and (3).

[78] *See* proposed Rule 7605(a).

[79] *See* proposed Rule 7605(b). Proposed Rule 7605(b) is based on BOX Rules 7600(a)(2) and (3) and NYSE Arca Rule 5.41–O(b). Additionally, the Exchange is proposing to add a statement clarifying that Floor Brokers must record all FOO Orders pursuant to Rule 7580(e)(1) prior to the announcement of such FOO Orders, which is the requirement for all orders on the Trading Floor.

[80] BOX Rule 7580(e)(1) outlines the requirements for a Floor Broker to record and systematize any orders prior to announcement of such order in the trading crowd.

[81] *See* proposed Rule 7605(c). Proposed rule 7605(c) is based on NYSE Arca Rules 5.37–O(a) and 5.41–O(a). The Exchange notes that, while NYSE Arca requires at least three FLEX Qualified Market Makers per class, the Exchange's proposal does not qualify FLEX Market Makers per class.

FLEX Market Makers in accordance with a FLEX-specific qualification process prescribed by the Exchange to perform as Market Makers in FLEX Equity Options on the Trading Floor.[82] The Exchange notes that each FLEX Market Maker will be qualified for all classes of FLEX Equity Options. Additionally, a Floor Broker shall ascertain that at least one FLEX Market Maker is present in the Crowd Area prior to announcing an order for execution.[83] The Exchange notes that the Commission provided in its order approving the BOX Trading Floor that this requirement, among others, is designed to increase the opportunities for another Floor Participant to compete to interact with the orders on the Trading Floor.[84] For FLEX Equity Options, this means that at least one of the FLEX Market Makers, out of the at least three required to be qualified by the Exchange, is present in the Crowd Area when the FOO Order is announced.[85]

On the BOX Trading Floor today, a Floor Broker may bring an unmatched order to the Trading Floor in order to seek liquidity. The Floor Broker may announce the unmatched order (*i.e.,* the initiating side of a QOO Order) to the trading crowd in an attempt to source the contra-side. After finding sufficient quantity to match the initiating side pursuant to Rules 7580(e)(2) and 7600(b), the Floor Broker is then able to submit a two-sided QOO Order to the BOG[86] as required.[87] Floor Brokers may also enter single-sided orders into the BOX Book using BOX's electronic interface. Specifically, a Floor Broker may receive a matched or unmatched order via a telephone call on the Trading Floor[88] or may have the matched or unmatched order sent electronically to the Floor Broker's order entry mechanism on the Trading Floor prior to submitting the QOO Order to the BOG. Similar to how QOO Orders are introduced on the Trading Floor today, FOO Orders may be brought to the floor as matched or unmatched orders with a Floor Broker receiving the matched or unmatched order via the same methods that Floor Brokers receive them currently on the Trading Floor.[89] The Exchange again notes that trading FLEX options on an exchange floor in a similar manner as non-FLEX options is consistent with how FLEX orders are traded on another exchange.[90]

Next, pursuant to proposed Rule 7605(d), FOO Orders may be Complex Orders (''Complex FOO Order'') or Multi-Leg Orders (''Multi-Leg FOO Order'') as defined in Rules 7240(a)(7) and (10) with no more than the applicable number of legs, as determined by the Exchange and communicated to Participants,[91] including tied hedge orders as defined in IM–7600–2.[92] However, the priority provisions of Rules 7240(b)(2) and (3) do not apply to Complex FOO Orders or Multi-Leg FOO Orders because there will be no Complex Order Book for such orders, nor will there be a BOX Book for the individual FLEX Equity Option components of the Complex FOO Orders or Multi-Leg FOO Orders.[93] Each option leg of a Complex FOO Order or Multi-Leg FOO Order must be for a FLEX Equity Option series with the same underlying security and must have the same exercise style (American or European).[94] If a Non-FLEX Equity Option series is added intra-day for a component leg(s) of a Complex FOO Order or Multi-Leg FOO Order, the holder or writer of a position in the component leg(s) resulting from such Complex FOO Order or Multi-Leg FOO Order would be permitted to close its position(s) under the FLEX trading procedures against another closing only FLEX Equity Option position for the balance of the trading day on which the Non-FLEX Equity Option series is added. If a Non-FLEX Equity Option series is added for a component leg(s) of a Complex FOO Order or Multi-Leg FOO Order on a trading day after the position is established, the holder or writer of a position in the component leg(s) resulting from such Complex FOO Order or Multi-Leg FOO Order would be required to execute separate FLEX Equity Option and Non-FLEX Equity Option transactions to close its position(s), such that FLEX Equity Option component leg(s) would trade under the FLEX trading procedures and Non-FLEX Equity Option component leg(s) would trade subject to the non-FLEX trading procedures and rules.[95]

Announcement, Representation, and Execution of a FOO Order

The Exchange proposes Rule 7605(e) which details announcement and representation of FOO Orders on the BOX Trading Floor that is consistent with the current Trading Floor requirements.[96] Specifically, the

[82] *Id.* FLEX Market Maker qualification will include an examination requiring knowledge of FLEX Equity Options, including FLEX Equity Option terms, FLEX Market Maker qualification requirements, FLEX Market Maker quoting obligations, and FOO Order trading procedures.

[83] *See* proposed Rule 7605(e)(3). Proposed Rule 7605(e)(3) is similar to BOX Rule 7580(a), which applies to QOO Orders on the Trading Floor and requires a Floor Broker to ascertain that at least one Floor Market Maker is present in the Crowd Area prior to announcing an order for execution.

[84] *See* Securities Exchange Act Release No. 81292 (August 2, 2017), 82 FR 37144 (August 8, 2017) (SR–BOX–2016–48) (Order Approving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Adopt Rules for an Open-Outcry Trading Floor).

[85] The Exchange notes that the requirement to have at least three qualified FLEX Market Makers is a baseline that must be met in order for any FLEX Equity Option to be traded on the Trading Floor. The requirement that at least one FLEX Market Maker be present when an FOO Order is announced is an additional order-by-order requirement that promotes order competition and is the same requirement for QOO Orders currently.

[86] The BOX Order Gateway (''BOG'') is a component of the Trading Host which enables Floor Brokers and/or their employees to enter transactions on the Trading Floor. *See* BOX Rule 100(b)(2).

[87] *See* BOX IM–7600–4.

[88] When a Floor Broker receives an order, matched or unmatched, via telephone, the Floor Broker must enter the order electronically into the Floor Broker's order entry mechanism.

[89] *See, e.g.,* Securities Exchange Act Release No. 80720 (May 18, 2017), 82 FR 23657, 23666 (May 23, 2017) (SR–BOX–2016–48) (Notice of Filing of Amendment No. 2 to a Proposed Rule Change to Adopt Rules for an Open-Outcry Trading Floor) (''[A] Floor Broker may receive a matched or unmatched order via a telephone call on the Trading Floor or may have the matched or unmatched order sent electronically to the Floor Broker's order entry mechanism on the Trading Floor . . . .'').

[90] CBOE allows a FLEX Order to be represented and executed in a similar manner as a non-FLEX Order. *See* CBOE Rule 5.72(d). The Exchange notes that CBOE Rule 5.72(d) also contains provisions that limit the priority rules applicable to FLEX Orders. *Id.* at 5.72(d)(2) and (3).

[91] The Exchange notes that this process is the same as current Rule 7600(a)(4) for QOO Orders on the BOX Trading Floor. *See* BOX Informational Circular 2022–18 (June 7, 2022), *https://boxoptions.com/assets/IC-2022-18-Upcoming-Enhancements-to-Complex-Orders.pdf* (providing that the maximum number of legs for Complex Orders is currently 16). A separate notice will be issued for Complex FOO Orders and Multi-Leg FOO Orders.

[92] The Exchange notes that tied hedge orders may not be smaller than 500 contracts per order. *See* BOX IM–7600–2(a).

[93] The Exchange notes that, as with a simple FOO Order, the priority and allocation rules applicable to Complex FOO Orders and Multi-Leg FOO Orders are in proposed Rules 7605(i) (allocation of the initiating side of a FOO Order against the contra-side of the FOO Order and interest from the Trading Crowd) and (k) (Floor Broker guarantee when crossing orders) and current Rule 7610 (priority among Floor Participants in the Trading Crowd).

[94] *See* proposed Rule 7605(d). Proposed Rule 7605(d) is based on CBOE Rules 1.1 (definition of ''Complex Order'') and 5.70(b) and BOX Rule 7600(a)(4). The Exchange does not reference FLEX Index Options or related attributes because Index Options are not traded on BOX and FLEX Index Options are not proposed herein.

[95] *See* Proposed Rules 7605(d)(3) and (4). The Exchange is proposing Rules 7605(d)(3) and (4) to clarify the treatment of Complex FOO Orders and Multi-Leg FOO Orders when a Non-FLEX Equity Option is subsequently listed for a component leg.

[96] Proposed Rule 7605(e) is based on BOX Rules 7600(a), (a)(1), (b) and (c). The Exchange notes that the QOO Order provisions related to market conditions, the NBBO, the BOX Book, book sweep, the Complex Order Book, auctions, and away routing have been omitted because there will be no

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Exchange proposes that all FOO Orders must be represented to the trading crowd as provided in Rule 7580(e)(2)[97] prior to submitting the agency FOO Order as part of a two-sided order to the Trading Host. The Exchange notes that Floor Brokers may bring unmatched orders (*i.e.,* the initiating side of a FOO Order) to the Trading Floor in order to seek a contra-side. Once a contra-side is sourced, the Floor Broker shall submit the two-sided FOO Order to the BOG.[98] When a Floor Broker submits a FOO Order for execution, the order will be executed in accordance with the proposed rules. A FOO Order on the Exchange is not deemed executed until it is processed by the Trading Host. All transactions occurring from the Trading Floor must be processed by the Trading Host. Floor Brokers are responsible for handling all orders in accordance with Exchange priority rules.

There will be an initiating side and a contra-side of a FOO Order. The initiating side is the order which must be filled in its entirety. The contra-side must guarantee the full size of the initiating side of the FOO Order and can be composed of multiple firms. When the Floor Broker is soliciting interest from the trading crowd when the initiating side was announced or to the extent the trading crowd offers a better price, the contra-side will be the solicited interest from the trading crowd.[99] If the Floor Broker had sufficient interest to match against the initiating side when the initiating side was announced, such Floor Broker interest will be the contra-side to the initiating side. If Floor Participants[100] responded with interest to the initiating side where the Floor Broker provided sufficient interest to match against the initiating side, the Floor Broker will allocate the initiating side of the FOO Order pursuant to proposed Rule 7605(i).[101] The Exchange notes that this negotiation and agreement that occurs in the trading crowd does not result in a final trade, but rather a ''meeting of the minds'' that is then submitted through the BOG for execution. Consistent with current Trading Floor operations, all FOO Orders must be announced to the trading crowd, as provided in Rule 7580(e)(2), prior to the FOO Order being submitted to the BOG.[102] An Options Exchange Official will certify that the Floor Broker adequately announced the FOO Order to the trading crowd.

The FOO Order is not deemed executed until it is processed by the Trading Host. Once the Floor Broker submits the FOO Order to the BOG there will be no opportunity for the submitting Floor Broker,[103] or anyone else, to alter the terms of the FOO Order. After announcing the FOO Order to the trading crowd, the Floor Broker must submit the FOO Order to the BOG for processing by the Trading Host without undue delay, provided that the executing Floor Broker must give Floor Participants a reasonable amount of time to respond, as provided in Rule 100(b)(5). Additionally, the Exchange shall establish, and announce via Regulatory notice, a minimum period of time (which amount of time must be between three seconds and five minutes) that qualifies as a reasonable amount of time for responses under proposed Rule 7605(e)(2). Such threshold will constitute the minimum possible time that a Floor Broker must give to the trading crowd to respond to a FOO Order; however, based on the characteristics and circumstances of each specific FOO Order, a reasonable amount of time, as provided in Rule 100(b)(5), may require a response interval longer than the minimum threshold. An Options Exchange Official may not waive the minimum threshold established by the Exchange.

The Exchange notes that the proposed floor interaction practice is consistent with the process in BOX Rule 7600 for QOO Orders on the BOX Trading Floor where the main differences are that FOO Orders will not be eligible for the BOX Book or the Complex Order Book, there is no NBBO, and that Floor Brokers must allow Floor Participants a minimum period of time (which amount of time must be between three seconds and five minutes) that qualifies as a reasonable amount of time that a Floor Broker must allow Floor Participants to respond to FOO Orders. Consistent with QOO Orders, a FOO Order is not deemed executed until it is processed by the Trading Host.[104] The Exchange notes that a reasonable amount of time for Floor Participants to respond to a FOO Order, the same as a QOO Order, will be interpreted on a case-by-case basis by an Options Exchange Official based on current market conditions and trading activity on the Trading Floor, provided, for FOO Orders, the minimum threshold discussed above must be satisfied.[105]

NBBO, no BOX Book, no Complex Order Book, no electronic auctions, and no book sweep for FOO Orders. *See* BOX Rules 7600(c)–(e) and (h). A book sweep is the number of contracts, if any, of the initiating side of a QOO Order that the Floor Broker is willing to relinquish to orders and quotes on the BOX Book that have priority pursuant to Rules 7600(d)(1) and (2). *See* BOX Rule 7600(h). Book sweeps will not apply to FOO Orders. As provided in proposed Rules 5055(e)(1) and (f)(1), FOO Orders must have different terms from orders on the BOX Book and, therefore, could not execute against interest on the BOX Book. For the same reason, the Complex Order priority provisions in Rules 7240(b)(2) and (3), which address the priority of Complex Orders and interest on the BOX Book, do not apply to Complex FOO Orders or Multi-Leg FOO Orders. *See* proposed Rule 7605(d). The priority and allocation of FOO Orders will be determined by proposed Rules 7605(i) and (k) and current Rule 7610. *See supra* note 94. The Exchange also notes that proposed Rule 7605(e) requires that Floor Brokers announcing a FOO Order give Floor Participants a reasonable amount of time to respond, as provided in Rule 100(b)(5). Proposed Rule 7605(e) further provides that the Exchange shall establish, and announce via Regulatory Notice, a minimum period of time that qualifies as a reasonable amount of time that a Floor Broker must allow Floor Participants to respond, which must be between three seconds and five minutes. This differs from current Rule 7600(c), which simply states that Floor Brokers must allow adequate time for Floor Participants to participate in the transaction as provided in Rule 100(b)(5).

[97] BOX Rule 7580(e)(2) provides that ''A Floor Broker must announce an agency order that he is representing to the trading crowd before submitting the order to the BOG for execution. This announcement must take place whether the Floor Broker is representing a single-sided order and soliciting contra-side interest, or the Floor Broker has sufficient interest to match against the agency order already. If a Floor Broker is holding two agency orders, he will choose which order is the initiating side.''

[98] *See* proposed IM–7605–1. Proposed IM–7605–1 is based on IM–7600–4.

[99] The Exchange notes that priority of bids and offers from Floor Participants in the trading crowd is determined by Rule 7610.

[100] The term ''Floor Participant'' means Floor Brokers as defined in Rule 7540 and Floor Market Makers as defined in Rule 8510(b). *See* BOX Rule 100(a)(26).

[101] *See* proposed Rule 7605(e)(1). Proposed Rule 7605(e)(1) is based on BOX Rule 7600(a)(1). The Exchange notes that provisions related to market conditions, the NBBO, the BOX Book, book sweep, and the Complex Order Book have been omitted because there will be no NBBO, no BOX Book, no Complex Order Book, and no book sweep for FOO Orders. *See supra* note 97. The priority and allocation of FOO Orders will be determined by proposed Rules 7605(i) and (k) and current Rule 7610. *See supra* note 94.

[102] *See* proposed Rule 7605(e)(2). Proposed Rule 7605(e)(2) is based on BOX Rules 7600(b) and (c). The Exchange notes that provisions related to market conditions, the NBBO, the BOX Book, book sweep, and the Complex Order Book have been omitted because there will be no NBBO, no BOX Book, no Complex Order Book, and no book sweep for FOO Orders. *See supra* note 97. The priority and allocation of FOO Orders will be determined by proposed Rules 7605(i) and (k) and current Rule 7610. *See supra* note 94.

[103] The Exchange notes that trades may be allocated as provided in proposed Rule 7605(j). The Exchange notes further that the Exchange may nullify a transaction or adjust the execution price of a transaction in accordance with Rule 7170 (Nullification and Adjustment of Options Transactions including Obvious Errors). *See also* BOX Rule 7640(b) (relating to trading disputes and adjustment or nullification of transactions on the Trading Floor).

[104] *See* proposed Rule 7605(e).

[105] *See* BOX Rule 100(b)(5). The Exchange notes that an Options Exchange Official takes into account various factors including complexity of the trade, general prevailing market conditions, and activity on the Trading Floor at the time the order is announced.

The Exchange proposes Rule 7605(f) which states that the minimum size for FLEX Equity Options transactions and quotations shall be one (1) contract.[106] The Exchange also proposes Rule 7605(g) which states that there are no maximum differences between the bid and the offer for FLEX Equity Option quotes.[107]

Pursuant to proposed Rule 7605(h), FLEX Market Makers have an obligation to quote a FLEX Equity Option in response to any request for quote by a Floor Broker or Options Exchange Official and must provide a two-sided market.[108]

Allocation of FOO Orders

Next, the Exchange proposes Rule 7605(i) which details the allocation process for FOO Orders. Specifically, the FOO Order will be matched by the Trading Host against the contra-side of the FOO Order, regardless of whether the contra-side order submitted by the Floor Broker is ultimately entitled to receive an allocation pursuant to proposed Rules 7605(i)(1)–(2). If no Floor Participant, other than the executing Floor Broker, is entitled to an allocation, then no further steps are necessary. If however, Floor Participants are entitled to an allocation, the remaining balance of the initiating side of the FOO Order will be allocated as described below.[109]

First, if the FOO Order satisfies the provisions of proposed Rule 7605(k), discussed below, the executing Floor Broker is entitled to 40% of the remaining quantity of the initiating side of the FOO Order.[110] Next, FLEX Market Makers that respond with interest when the Floor Broker announces the FOO Order to the trading crowd, as outlined in Rule 7580(e)(2) and proposed Rule 7605(e), are allocated.[111] When multiple Floor Participants respond with interest, priority in the Trading Crowd is established pursuant to Rule 7610.[112] Last, if interest remains after Floor Participants that responded with interest receive their allocation, the remaining quantity of the initiating side of the FOO Order will be allocated to the executing Floor Broker.[113] The Exchange again notes that similar allocation and priority provisions are already established and apply to responses for QOO Orders on the BOX Trading Floor.[114]

The Exchange proposes that after execution of the FOO Order, the executing Floor Broker is responsible for providing the correct allocations of the initiating side of the FOO Order to an Options Exchange Official or his or her designee, if necessary, who will properly record the order in the Exchange's system.[115] The executing Floor Broker must provide the correct allocations to an Options Exchange Official or his or her designee, in writing, without unreasonable delay.[116] The Exchange notes that the same procedure for recording trade allocations applies to QOO Orders on the BOX Trading Floor today.

Similar to the allocation process in place for QOO Orders, the Exchange proposes to allow for a participation guarantee for certain FOO Orders executed by Floor Brokers on the Trading Floor. Specifically, when a Floor Broker holds an option order of the eligible order size or greater, the Floor Broker is entitled to cross 40% of the remaining contracts of the original order, after all bids or offers at better prices are filled, with other orders that the Floor Broker is holding.[117] The Exchange may determine, on an option by option basis, the eligible size for an order on the Trading Floor to be subject to this guarantee; however, the eligible

[106] *See* proposed Rule 7605(f). Proposed Rule 7605(f) is based on NYSE Arca Rule 5.32–O(b)(7).

[107] *See* proposed Rule 7605(g). Proposed Rule 7605(g) is based on NYSE Arca Rule 5.37–O(d). The Exchange notes that it has omitted the first part of NYSE Arca Rule 5.37–O(d), which provides FLEX Appointed Market Makers need not provide continuous FLEX Quotes and the Exchange has included the second part of NYSE Arca Rule 5.37–O(d), which provides FLEX Appointed Market Makers need not quote a minimum bid-offer spread in FLEX Equity Options. The Exchange has omitted the first part of NYSE Arca Rule 5.37–O(d) because, pursuant to proposed Rule 7605(h), the Exchange is instead proposing that FLEX Market Makers be obligated to quote FLEX Equity Options in response to any request for quote by a Floor Broker or Options Exchange Official and must provide a two-sided market, which the Exchange believes will promote a robust and competitive market for FOO Orders on the Trading Floor and facilitate a fair and orderly market for the trading of FLEX Equity Options on the Exchange. The Exchange further notes that on NYSE Arca, FLEX Appointed Market Makers are appointed in classes of FLEX Index Options. FLEX Qualified Market Makers are appointed in FLEX Equity Options on NYSE Arca. Further, FLEX Appointed Market Makers have an obligation to enter a quote in response to a request for quote in a FLEX Index Option while FLEX Qualified Market Makers do not have a similar obligation for FLEX Equity Options. The Exchange believes that this distinction is the reason why NYSE Arca Rule 5.37–O(d) only specifically exempts FLEX Appointed Market Makers from quoting with a minimum bid-offer spread since they are the only FLEX market makers with the requirement to respond to a request for quote. Similarly, the Exchange is proposing that there be no maximum differences between the bid and offer for FLEX Equity Option quotes that, pursuant to proposed Rule 7605(h), a FLEX Market Maker is required to provide in response to a request for quote by a Floor Broker or Options Exchange Official.

[108] *See* proposed Rule 7605(h). Proposed Rule 7605(h) is based on BOX Rule 8510(c)(2). The Exchange notes that proposed Rule 7605(h) does not include the provisions of current Rule 8510(c)(2) related to quote spread parameter requirements and quotation sizes, which requirements are provided separately in proposed Rules 7605(f) and (g).

[109] *See* proposed Rule 7605(i). Proposed Rule 7605(i) is based on BOX Rule 7600(d)(3). The Exchange notes that provisions of BOX Rules 7600(d)(1)–(2) were omitted from proposed Rule 7605(i) because those provisions are related to the BOX Book, which is inapplicable to FOO Orders.

[110] *See* proposed Rule 7605(i)(1). The Exchange notes that proposed Rule 7605(i)(1) is based on BOX Rule 7600(d)(3)(i).

[111] *See* proposed Rule 7605(i)(2). The Exchange notes that proposed Rule 7605(i)(2) is based on BOX Rule 7600(d)(3)(ii).

[112] *Id.* Priority under Rule 7610 is determined first by price and then by sequence. Specifically, on the Trading Floor, the highest (lowest) bid (offer) shall have priority; when two or more bids (offers) represent the highest (lowest) price, priority shall be afforded to such bids (offers) in the sequence in which they were made. If, however, the bids (offers) of two or more Floor Participants are made simultaneously, or if it is impossible to determine clearly the order of time in which they are made, such bids (offers) will be deemed to be on parity and priority will be afforded to them, insofar as practicable, on an equal basis. The Floor Broker announcing the order is responsible for determining the sequence in which bids or offers are vocalized on the Trading Floor from Floor Participants in response to the Floor Broker's bid, offer, or call for a market. Rule 7610 also provides priority provisions where a Floor Broker requests a market in order to fill a large order and the Floor Participants provide a collective response. *See* BOX Rule 7610.

[113] *See* proposed Rule 7605(i)(3). The Exchange notes that proposed Rule 7605(i)(3) is based on BOX Rule 7600(d)(3)(iii).

[114] The Exchange notes that FOO Order allocation and priority differs from QOO Order provisions related to the priority of orders on the BOX Book. *See* BOX Rules 7600(c)–(e) and (h), and 7600(f)(1) and (3). *See also supra* note 97. In particular, with respect to QOO Order executions BOX Rules 7600(d)(1) and (2) provide priority for better-priced interest on the BOX Book and for Public Customer Orders on the BOX Book at the same price or non-Public Customer Orders ranked ahead of such same-priced Public Customer Orders. As the Exchange noted when it proposed the QOO order type, these priority provisions were designed to provide increased opportunities for orders on the BOX Book to interact with trades on the Trading Floor and to maintain consistency with options trade-through and BOX Book priority rules. *See* Securities Exchange Act Release No. 80720 (May 18, 2017), 82 FR 23657, 23681–82 (May 23, 2017) (SR–BOX–2016–48) (Notice of Filing of Amendment No. 2 to a Proposed Rule Change to Adopt Rules for an Open-Outcry Trading Floor). These priority provisions are not necessary for FOO Orders because there will be no FLEX Equity Option interest on the BOX Book. The Exchange's existing rules for determining priority of bids and offers from Floor Participants in the trading crowd are based on price-time priority without regard to market participant type. *See* BOX Rule 7610. This is consistent with floor priority rules for FLEX options on other options exchanges. *See, e.g.,* PHLX Options 8, Section 34(c)(4), NYSE American Rule 904G(e).

[115] *See* proposed Rule 7605(j). Proposed Rule 7605(j) is based on BOX Rule 7600(d)(4).

[116] *Id.*

[117] *See* proposed Rules 7605(i), 7605(k)(1) and (3). Proposed Rules 7605(k)(1) and (3) are based on BOX Rules 7600(f)(1) and (3). The Exchange notes that the proposed FOO Order guarantee differs from the QOO Order guarantee because BOX Rule 7600(f)(3) contains provisions that pertain to the BOX Book, which is inapplicable to FOO Orders.

order size may not be less than 50 contracts. In determining whether an order satisfies the eligible order size requirement, any Complex FOO Order or Multi-Leg FOO Order must contain one leg alone which is for the eligible order size or greater.[118] Nothing in the proposed rule is intended to prohibit a Floor Broker from trading more than their percentage entitlement if the other Participants of the trading crowd do not choose to trade the remaining portion of the order.[119] The Exchange notes that the proposed guarantee process is similar to the guarantee process currently in place for QOO Orders on the BOX Trading Floor.[120]

The below examples are designed to illustrate the allocation of the initiating side of a FOO Order.

Example 1—Assume a Floor Broker wishes to execute a FOO Order for 500 contracts. When he announces the order, FLEX Market Maker 1 and FLEX Market Maker 2 both respond to the FOO Order for 250 contracts each at the same price as the Floor Broker's contra-side. FLEX Market Maker 1 responded first so he will have time priority over FLEX Market Maker 2. Since the FOO Order is for at least 50 contracts, the Floor Broker is entitled to match at least 40% of the initiating side with the Floor Broker's contra-side.

Result: The initiating side of the FOO Order will match against the Floor Broker's contra-side order for the full 500 contracts. After the execution of the FOO Order, because other Floor Participants are entitled to an allocation, the executing Floor Broker is then responsible for providing an Options Exchange Official or his or her designee the following allocation of the initiating side of the FOO Order:

1. 200 contracts (40%, or 500 * .40) for the contra-side order submitted by the Floor Broker.

2. 250 contracts for FLEX Market Maker 1 with time priority.

3. Remaining 50 contracts to FLEX Market Maker 2.

Example 2—Assume a Floor Broker wishes to execute a FOO Order for 40 contracts. When he announces the order, FLEX Market Maker 1 and FLEX Market Maker 2 both respond to the FOO Order for 20 contracts each at the same price as the Floor Broker's contra-side. FLEX Market Maker 1 responded first so he will have time priority over FLEX Market Maker 2. Since the FOO Order is for less than 50 contracts, the Floor Broker is not entitled to a 40% guarantee.

Result: The initiating side FOO Order will match against the Floor Broker's contra-side for the full 40 contracts. After execution of the FOO Order, because other Floor Participants are entitled to an allocation, the executing Floor Broker is then responsible for providing an Options Exchange Official or his or her designee with the following allocation of the initiating side of the FOO Order:

1. 20 contracts for FLEX Market Maker 1 with time priority.

2. 20 contracts for FLEX Market Maker 2.

3. The initiating side is filled and the executing Floor Broker will receive no allocation.

Example 3—Assume a Floor Broker wishes to execute a FOO Order for 40 contracts in ABC at 1.05 (initiating side is to sell). When he announces the order, FLEX Market Maker 1 and FLEX Market Maker 2 both respond to the FOO Order for 20 contracts each. FLEX Market Maker 1 responded first at an improved price to buy 20 at 1.06 so he will have price priority over FLEX Market Maker 2.[121] Since the FOO Order is for less than 50 contracts, the Floor Broker is not entitled to a 40% guarantee.

Result: The Floor Broker will submit two FOO Orders for 20 contracts each: a FOO Order at 1.06 for 20 contracts and a FOO Order at 1.05 for 20 contracts. The initiating side of each FOO Order will match against the Floor Broker's contra-side orders for the full 20 contracts. After execution of the FOO Orders, the executing Floor Broker is then responsible for providing an Options Exchange Official or his or her designee with the following allocation of the initiating side of the FOO Orders:

1. FOO Order at 1.06—20 contracts for FLEX Market Maker 1.

2. FOO Order at 1.05—20 contracts for FLEX Market Maker 2.

3. The executing Floor Broker will receive no allocation of either FOO Order.

Additional Provisions

The Exchange also proposes that all orders entrusted to a Floor Broker will be considered Not Held Orders, unless otherwise specified by a Floor Broker's client. A Not Held Order is an order marked ''not held'', ''take time'', or which bears any qualifying notation giving discretion as to the price or time at which such order is to be executed.[122]

The Exchange further proposes IM–7605–1 which allows Floor Brokers to bring unmatched orders (*i.e.,* the initiating side of a FOO Order) to the Trading Floor in order to seek contra-side interest. Once a contra-side is sourced pursuant to current Rule 7580(e)(2) and proposed Rule 7605(e), the Floor Broker shall submit the two-sided FOO Order to the BOG.[123] The Exchange notes that this provision is identical to IM–7600–4, with the exception of internal rule references, which applies to QOO Orders on the BOX Trading Floor.

The Exchange proposes IM–7605–2 to guide conduct on the floor.[124] In particular, the Floor Broker must disclose all securities that are components of the Public Customer order which is subject to crossing before requesting bids and offers for the execution of all components of the order. Once the trading crowd has provided a quote, it will remain in effect until a reasonable amount of time has passed, there is a significant change in the price of the underlying security, or the market given in response to the request has been improved. In the case of a dispute, the term ''significant change'' will be interpreted on a case-by-case basis by an Options Exchange Official based upon the extent of recent trading in the option and in the underlying security, and any other relevant factors.[125] The Participants of the trading crowd who established the market will have priority over all other orders that were not announced in the trading crowd at the time that the market was established and will maintain priority over such orders except for orders that improve upon the market. When a Floor Broker announces an order to the trading crowd pursuant

[118] *See* proposed Rule 7605(k)(2). Proposed Rule 7605(k)(2) is based on BOX Rule 7600(f)(2).

[119] *See* proposed Rule 7605(k)(4). Proposed Rule 7605(k)(4) is based on BOX Rule 7600(f)(4).

[120] The Exchange notes that the proposed FOO Order guarantee differs from the QOO Order guarantee because BOX Rule 7600(f)(3) contains provisions that pertain to the BOX Book, which is inapplicable to FOO Orders.

[121] Pursuant to Rule 7610, FLEX Marker Maker 1 would have priority over FLEX Market Maker 2 even if FLEX Market Maker 2 responded first because FLEX Market Maker 1 responded at a better price.

[122] *See* proposed Rule 7605(l). Proposed Rule 7605(l) is based on BOX Rule 7600(g). *See also* NYSE Arca Rules 5.34–O and 6.62–O(f). The Exchange notes that NYSE Arca Rule 5.34–O provides a Floor Broker with additional discretion with respect to the number of FLEX contracts to be purchased or sold. The Exchange is not proposing the same discretion for FOO Orders so that the requirements for Floor Brokers handling FOO Orders are the same as handling QOO Orders currently on the Trading Floor.

[123] *See* proposed IM–7605–1. Proposed IM–7605–1 is based on IM–7600–4.

[124] *See* proposed IM–7605–2. Proposed IM–7605–2 is based on IM–7600–1.

[125] The Exchange believes that, by providing the Options Exchange Official with the ability to consider any other relevant factors, Options Exchange Officials will retain the necessary discretion to perform their duties if a new or unforeseen circumstance arises.

to Rule 7580(e)(2), it shall be the responsibility of the Floor Participant who established the market to alert the Floor Broker of the fact that the Floor Participant has priority. Complex FOO Orders, Multi-Leg FOO Orders or tied hedge orders on opposite sides of the market may be crossed, provided that the Floor Broker holding such orders proceeds in the manner described in proposed Rule 7605 and IM–7600–2 as appropriate. Floor Participants may not prevent a Complex Order from being completed by giving a competing bid or offer for one component of such order.[126] In determining whether an order satisfies the eligible tied hedge order size requirement, any Complex FOO Order or Multi-Leg FOO Order must contain one leg which, standing alone, is for the eligible order size or greater.[127] A Floor Broker crossing a Public Customer FOO Order with an order that is not a Public Customer Order, when providing for a reasonable opportunity [128] for the trading crowd to participate in the transaction, shall disclose the Public Customer Order that is subject to crossing.

The Exchange proposes to amend Rule 100(b)(3) to provide: ''All Exchange options transactions shall be executed automatically by the Trading Host as provided in applicable Exchange Rules.'' [129] The Exchange notes that Rule 100(b)(3) already applies to Non-FLEX Equity Options. The proposed amendment is to replace specific rule references with a more general reference to avoid any unintended ambiguity and permit the Rule to apply in connection with FLEX Equity Options.

The Exchange proposes to amend Rule 7620, titled Accommodation Transactions, and IM–7620–1 to exclude FLEX Equity Options as defined in proposed Rule 5055.[130] The Exchange notes that Rule 7620(b) currently states that it applies to all options except for option classes participating in the Penny Interval Program under Rule 7260, and IM–7620–1(b) currently states that it applies to all options including those in the Penny Interval Program. The proposed amendments will ensure consistency with proposed Rule 5055(c), which provides that Rule 7620 (Accommodation Transactions) shall not apply to transactions in FLEX Equity Options.

The Exchange has not yet determined the fees for FOO transactions executed on the Trading Floor. Prior to commencing trading of the proposed FOO Orders on the Trading Floor, the Exchange intends to submit a proposed rule change to the Commission setting forth the proposed fees.

The Exchange has also analyzed its capacity and represents that it believes the Exchange and the Options Price Reporting Authority (''OPRA'') have the necessary systems capacity to handle the additional message traffic associated with the listing of new series that may result from the introduction of FLEX Equity Options.[131] Additionally, the Exchange will have surveillance coverage in place to monitor issues unique to FLEX trading and has developed FLEX-specific surveillance reports. Further, the Exchange believes it has an adequate surveillance program in place and intends to apply the same program procedures to FLEX Equity Options that it applies to the Exchange's other options products, as applicable. FLEX Equity Options products and their respective symbols will be integrated into the Exchange's existing surveillance system architecture and will be subject to the relevant surveillance processes. The Exchange believes that any potential risk of manipulative activity is mitigated by these existing surveillance technologies, procedures, and reporting requirements, which allow the Exchange to properly identify disruptive and/or manipulative trading activity.

The proposed FLEX Equity Option rules are based predominately on the rules of NYSE Arca. However, the Exchange omitted certain NYSE Arca rules from the proposed rules discussed herein due to differences in the scope and operation of FLEX Option [132] trading at NYSE Arca, compared to the scope and operation of the proposed FLEX Equity Option trading herein. The Exchange is not including NYSE Arca rule provisions that relate to FLEX Index Options as Index Options are not traded on BOX and FLEX Index Options are not proposed herein.[133] In particular, NYSE Arca Rule 5.39–O requires net liquidating equity of $100,000 in an account in which transactions in FLEX Index Options will be conducted. As the Exchange does not trade Index Options, FLEX Index Options are not proposed herein, and the Exchange already imposes minimum net capital requirements,[134] it does not propose additional requirements.

Next, NYSE Arca Rule 5.40–O requires at least $1 million of net liquidating equity in the account of a FLEX Appointed Market Maker. However, FLEX Appointed Market Makers are appointed for FLEX Index Options on NYSE Arca but are not required for FLEX Equity Options.[135] Instead, NYSE Arca only requires FLEX Qualified Market Makers for FLEX Equity Options.[136] And, this subset of Market Makers is not required to have at least $1 million of net liquidating equity. Therefore, the Exchange's proposal does not propose to include additional net liquidating equity requirements for FLEX Market Makers. The Exchange notes that Market Makers, including Floor Market Makers and FLEX Market Makers are still subject to several financial requirements, including net liquidating equity in its Market Maker account of not less than $200,000.[137] Additionally, the Exchange believes that the large infrastructure needed to trade as a Market Maker, including their adequacy of capital and operational capacity is such that current Market Makers are likely to have net liquidating equity well beyond $1 million. In fact, another exchange which trades FLEX Options has removed a net liquidating equity requirement while still requiring market makers to maintain net capital sufficient to comply with the requirements of Rule 15c3–1, under the Act.[138] The Exchange

[126] The Exchange notes that while a Complex Order could be prevented from being completed by competing bids or offers on multiple components of such orders, competing bids or offers in any one of the multiple components may not prevent a Complex Order from being completed and each one is prohibited.

[127] *See* proposed IM–7605–2(d). The eligible tied hedge order size requirement is determined by the Exchange and may not be smaller than 500 contracts per order. *See* BOX IM–7600–2.

[128] The Exchange is proposing that a minimum response period, which must be between three seconds and five minutes, shall be established by the Exchange and announced via Regulatory Notice. *See* proposed Rule 7605(e)(2).

[129] *See* proposed Rule 100(b)(3).

[130] *See* proposed Rule 7620.

[131] The Exchange will report FLEX Equity Option trades and, if necessary, trade cancels to OPRA.

[132] The term ''Flexible Exchange Option'' or ''FLEX Option'' means a customized options contract. *See* NYSE Arca Rule 5.30–O(b)(4) *and* CBOE Rule 1.1 (definition of, ''FLEX Option'').

[133] *See* NYSE Arca Rules 5.39–O and 5.40–O.

[134] *See* BOX Rules 8010, 8080, and 10200.

[135] *See* NYSE Arca Rule 5.37–O(a).

[136] *See id.* The Exchange notes that NYSE Arca allows but does not require appointment of two or more FLEX Appointed Market Makers to FLEX Equity Options in lieu of appointing FLEX Qualified Market Makers.

[137] *See* BOX Rule 8080(a)(1). Rule 8080 also requires Market Makers to maintain net capital sufficient to comply with the requirements of Rule 15c3–1 under the Act and each Market Maker that is a Clearing Participant shall also maintain net capital sufficient to comply with the requirements of the OCC. *See* BOX Rules 8080(a)(2) and (b). *See also* BOX Rule 8010 (''To qualify for registration as a Market Maker, an Options Participant must meet the requirements established in SEC Rule 15c3–1(a)(6)(i) . . .'').

[138] *See* CBOE Rule 11.6 *and* Securities Exchange Act Release No. 87024 (September 19, 2019), 84 FR 50545 (September 25, 2019) (SR–CBOE–2019–059) (Notice of Filing and Immediate Effectiveness of a

Continued

has a similar provision, Rule 10200, that requires each Participant subject to Rule 15c3–1 under the Act to comply with the capital requirements prescribed therein among other requirements.[139]

An additional difference in the appointment of FLEX Market Makers is that NYSE Arca appoints FLEX Qualified Market Makers to each FLEX Equity Option of a given class, while the Exchange will qualify FLEX Market Makers for all FLEX Equity Options. The Exchange believes that the structure of its Trading Floor, with one crowd or trading area, will operate more efficiently without qualifying FLEX Market Makers by class.[140] Accordingly, a Floor Broker or Options Exchange Official may request a FLEX Equity Option quote in any class from a FLEX Market Maker. The Exchange notes that FLEX Market Makers will be subject to Rule 8510, including provisions for the course and conduct of dealings, class assignments, and option priority and parity, unless otherwise specified in proposed Rule 7605.[141]

Further, the Exchange notes differences between the proposed quoting obligations and those applicable on NYSE Arca. Specifically, a NYSE Arca FLEX Qualified Market Maker may, but shall not be obligated to, enter a FLEX Quote in response to a Request for Quotes on a FLEX Equity Option of the class in which he or she is qualified.[142] However, a FLEX Official on NYSE Arca may call upon FLEX Qualified Market Makers appointed in a class of FLEX Equity Options to make FLEX Quotes in response to a specific Request for Quotes in that class of FLEX Equity Options whenever in the opinion of the FLEX Official the interests of a fair, orderly and competitive market are best served by such action and shall make such a call upon FLEX Qualified Market Makers whenever no FLEX Quotes are made in response to a specific Request for Quotes.[143] The Exchange's proposal differs from NYSE Arca's rule in that FLEX Market Makers have an obligation to quote a FLEX Equity Option in response to any request for quote by a Floor Broker or Options Exchange Official and must provide a two-sided market.[144] The Exchange believes that the proposed quoting requirements allow reasonable opportunities for Floor Brokers to get quotes on FOO Orders and notes that the quoting requirements for QOO Orders on the BOX Trading Floor are similar to those proposed for FOO Orders.[145]

Among other NYSE Arca provisions not incorporated by the Exchange, are certain of NYSE Arca's ''Special Terms for FLEX Equity Options.'' [146] Specifically, these special terms include that exercise prices and premiums may be stated in terms of: (i) a dollar amount; (ii) a method for fixing at the time a FLEX Request for Quote or FLEX order is traded; or (iii) a percentage of the price of the underlying security at the time of the trade or as of the close of trading on the NYSE Arca on the trade date. The Exchange will only offer exercise prices and premiums in a dollar amount because the additional methods for fixing prices are a matter of individual preference, and the Exchange believes that the requirements of Participants will be met by pricing exercise prices and premiums in a dollar amount.[147]

Another NYSE Arca provision not adopted by the Exchange in this proposal allows discretionary orders where Floor Brokers have discretion regarding the quantity of FLEX contracts traded.[148] The Exchange prohibits discretion regarding quantity, and other terms, including the choice of the class of options to be bought or sold, and whether any such transaction shall be one of purchase or sale except to any discretionary transactions executed by a Floor Market Maker for an account in which he has an interest.[149] The Exchange believes that proposed Rule 7605(l) combined with current Rule 7590, allowing Floor Brokers to have discretion over some terms of a FOO Order such as price and time while not allowing discretion over terms such as quantity, strikes a balance between allowing Floor Brokers to provide full services to clients and preventing erroneous trades based on differing expectations or miscommunications between Floor Brokers and their clients. The Exchange notes that Rule 7600(g) governing QOO Orders is identical to proposed Rule 7605(l) and believes that consistency of handling between QOO Orders and FOO Orders may reduce confusion and increase efficiency on the Trading Floor.

Another NYSE Arca rule not proposed by the Exchange provides that NYSE Arca may designate FLEX Officials.[150] The Exchange is not proposing a similar rule because Rule 100(b)(6) already provides that any Exchange employee or officer designated as an Options Exchange Official will from time to time as provided in these rules have the ability to recommend and enforce rules and regulations relating to trading access, order, decorum, health, safety and welfare on the Exchange. Specifically, Options Exchange Officials have duties enumerated in Rules 100(b)(5), 7610, 7640, and 8510, as well as in proposed Rule 7605 regarding announcement, quoting, and recording of FOO Orders, priority in the trading crowd, disputes on the trading floor, and obligations and restrictions applicable to Floor Market Makers and FLEX Market Makers. The general authority for Options Exchange Officials under these current Exchange Rules will be the same for FLEX Equity Option transactions on the trading floor as it is for Non-FLEX Equity Option transactions. The Exchange believes that Options Exchange Officials will have the authority necessary to enforce the proposed FLEX Equity Option and FOO Order rules such that designation of a unique FLEX Official would be redundant and unnecessary, as the Exchange's existing Options Exchange Officials will have the ability to perform the same functions as a separately designated FLEX Official. Specifically, the duties of FLEX Officials on NYSE Arca are mainly related to their Request for Quotes (''RFQ'') procedure unique to FLEX Options trading on NYSE Arca.[151]

proposed rule change to amend certain rules relating to market makers upon migration to the trading system used by CBOE affiliated exchanges).

[139] *See* BOX Rule 10200 (Participants must comply with the additional requirements of the Rule 10200 Series and Market Makers must comply with the minimum financial requirements contained in Rule 8010).

[140] Pursuant to BOX Rule 8150(e), whenever a BOX Floor Market Maker enters the trading crowd he must undertake the obligations specified in Rule 8510(d) (In Classes of Option Contracts to Which Assigned—Affirmative Obligations). Since there is only one trading crowd on the BOX Floor, in practice this results in all BOX Floor Market Makers being required to quote all classes on the Trading Floor. The same will apply to FLEX Market Makers.

[141] *See* proposed Rules 7605(f)–(h) (providing FOO Order quoting obligations). The Exchange notes that current Floor Market Maker quoting obligations and restrictions are detailed in Rule 8510.

[142] *See* NYSE Arca Rule 5.37–O(b).

[143] *See* NYSE Arca Rule 5.37–O(c).

[144] *See* proposed Rule 7605(h).

[145] *See* BOX Rule 8510(c)(2). The Exchange notes that proposed Rule 7605(h) and current Rule 8510(c)(2) are similar except that proposed Rule 7605(h) does not include the provisions of current Rule 8510(c)(2) related to quote spread parameter requirements and quotation sizes, which requirements are provided separately in proposed Rules 7605(f) and (g).

[146] *See* NYSE Arca Rule 5.32–O(f)(2).

[147] The Exchange's belief that the requirements of Participants will be met by stating exercise prices and premiums in a dollar amount is based on conversations with Participants regarding their preferences for stating the terms of exercise prices and premiums.

[148] *See* NYSE Arca Rule 5.34–O.

[149] *See* BOX Rule 7590 and proposed Rule 7605(l).

[150] *See* NYSE Arca Rule 5.38–O.

[151] NYSE Arca Rule 5.38–O provides that ''[a] FLEX Official is responsible for: (1) reviewing the

The Exchange has elected not to adopt a similar procedure, as discussed below, instead basing the FOO Order process on the QOO Order process already monitored by Options Exchange Officials. Additionally, the Exchange's system is designed to review the terms of a FLEX Equity Option for compliance with the applicable Rules as opposed to being a requirement of an Options Exchange Official to review.[152] Options Exchange Officials will continue to be responsible for monitoring all open outcry activity on the Trading Floor. Therefore, the Exchange will not require a separate official to govern any unique process for FLEX Equity Options. Additionally, the Exchange represents that Options Exchange Officials will receive appropriate training on the terms of FLEX Equity Options and all rules applicable to FLEX Equity Options and FOO Orders, including their responsibility to certify that a Floor Broker has adequately announced a FOO Order to the trading crowd,[153] consistent with the manner in which they are currently trained with respect to QOO Orders.[154] The Exchange further notes that NYSE Arca's rules do not require the exchange to designate FLEX Officials.[155]

As mentioned above, rather than adopt the NYSE Arca RFQ procedure for FLEX Equity Options,[156] the Exchange instead proposes to utilize the current process used on the BOX Trading Floor for QOO Orders with the addition of a minimum time period that a Floor Broker must allow Floor Participants when responding to FOO Orders.[157] The Exchange believes that using the order announcement and responsive quote process for both QOO Orders and FOO Orders on the BOX Trading Floor will result in less confusion and greater efficiency for all BOX Trading Floor Participants.

The Exchange notes that the manner in which the Exchange has proposed rules with respect to announcement of orders and responsive quotes is similar to how CBOE treats its FLEX Options; specifically, CBOE allows a FLEX Order[158] to be represented and executed in a similar manner as a non-FLEX Option.[159] The Exchange believes CBOE's approach is consistent with the Act and proposes to also require Floor Brokers to allow for a reasonable amount of time to participate in FLEX Equity Option transactions. Further, unlike CBOE, the Exchange proposes to establish and announce, via Regulatory Notice, a minimum period of time that a Floor Broker must allow Floor Participants to respond (which amount of time must be between three seconds and five minutes). The Exchange believes that it is unnecessary to specify a specific maximum time period for responses to FLEX orders as Options Exchange Officials on BOX's Trading Floor will be responsible both to enforce the minimum period of time and to ensure that Floor Participants have a reasonable amount of time to respond to FOO Orders.[160] The Exchange notes that the proposed order announcement procedure for FOO Orders is similar to the rules and procedures currently in place for QOO Orders on the BOX Trading Floor.

Minor Rule Violation Plan

The Exchange's disciplinary rules, including Exchange Rules applicable to ''minor rule violations,'' are set forth in the Rule 12000 Series of the Exchange's current Rules. As described in Rule 12140, the MRVP provides that in lieu of commencing a disciplinary proceeding, the Exchange may, subject to the certain requirements set forth in the Rule, impose a fine, not to exceed $5,000, on any Options Participant, or person associated with or employed by an Options Participant, with respect to any Rule violation listed in Rules 12140(d) or (e) as discussed below. Any fine imposed pursuant to this Rule that (i) does not exceed $2,500 and (ii) is not contested, shall be reported on a periodic basis, except as may otherwise be required by Rule 19d–1 under the Act or by any other regulatory authority. Further, the Rule provides that any person against whom a fine is imposed under the Rule shall be served with a written statement setting forth: (i) the Rule(s) allegedly violated; (ii) the act or omission constituting each such violation; (iii) the fine imposed for each violation; and (iv) the date by which such determination becomes final and such fine must be paid or contested, which date shall be not less than twenty-five (25) calendar days after the date of service of such written statement. Rules 12140 (d) and (e) set forth the list of specific Exchange Rules under which an Options Participant or person associated with or employed by an Options Participant may be subject to a fine for violations of such Rules and the applicable fines that may be imposed by the Exchange. As with all the violations incorporated into its MRVP, the Exchange will proceed under this Rule only for violations that are minor in nature. Any other violation will be addressed pursuant to Rules 12030 (Letters of Consent) or 12040 (Charges).

The Exchange proposes to amend its MRVP to add certain rules relating to FLEX Equity Options to the list of rules eligible for minor rule violation plan treatment by amending Rule 12140. Specifically, the Exchange proposes to amend Rule 12140(e)(3), which covers the failure to properly execute a QOO Order, to include failure to properly execute a FOO Order (proposed Rule 7605).[161] Additionally, the Exchange proposes to amend Rule 12140(e)(9), which covers compliance with quotation requirements for Floor Market Makers as set forth in Rule 8510(c)(2), and is designed to sanction violations thereof, to also include compliance with

conformity of FLEX Requests for Quotes and FLEX Quotes to the terms and specifications contained in Rule 5.32–O [Terms of FLEX Options]; (2) posting FLEX Requests for Quotes for dissemination; (3) determining the BBO; (4) ensuring that FLEX contracts are executed in conformance with the priority principles set forth in Rule 5.33–O; and (5) calling upon FLEX Qualified Market Makers to make FLEX Quotes in specific classes of FLEX Equity Options as provided in paragraph (c) of Rule 5.37–O.'' *See* NYSE Arca Rule 5.38–O.

[152] *See supra* note 61. The Exchange notes that NYSE Arca Rule 5.38–O(b)(1) provides that it is the responsibility of their FLEX Officials to review the terms of a FLEX order.

[153] *See* proposed Rule 7605(e)(2).

[154] BOX Rules currently provide that the President of the Exchange and his or her designated staff shall be responsible for monitoring, among other things, the activities of Floor Participants and their associated persons and shall establish standards and procedures for the training and qualification of Floor Participants and their associated persons active on the Trading Floor. *See* BOX Rule 100(b)(1).

[155] *See* NYSE Arca Rule 5.38–O(a) (''The Exchange *may* at any time designate an Exchange employee to act as a FLEX Official in one or more classes of FLEX Options [emphasis added]. . . .'').

[156] *See* NYSE Arca Rule 5.33–O.

[157] *See* proposed Rule 7605 and current Rule 7600. The minimum time period, which must be between three seconds and five minutes, will be established by the Exchange and communicated via Regulatory Notice. *See* proposed Rule 7605(e)(2). *See also* Securities Exchange Act Release No. 81292 (August 2, 2017), 82 FR 37144 (August 8, 2017) (SR–BOX–2016–48) (Order Approving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Adopt Rules for an Open-Outcry Trading Floor).

[158] ''FLEX Orders'' are orders submitted in FLEX Options. *See* CBOE Rule 5.70.

[159] *See* CBOE Rule 5.72(d). The Exchange notes that CBOE Rule 5.72(d) also contains provisions that limit the priority rules applicable to FLEX Orders. *See* CBOE Rules 5.72(d)(2) and (3).

[160] *See supra* note 158 and accompanying text.

[161] *See* proposed Rule 12140(e)(3). The Exchange notes that adding proposed Rule 7605 for FOO Orders to current Rule 12140(e)(3) is consistent with the existing provision to enforce current Rule 7600 for QOO Orders because Floor Participants have the same general requirements for executing FOO and QOO Orders on the Trading Floor. The Exchange notes further that fines defined under Rule 12140(e)(3) may apply to any failure to properly execute a FOO Order in accordance with applicable provisions of proposed Rule 7605 governing such execution requirements. Proposed Rule 7605(h), however, which relates to a FLEX Market Maker's quoting obligation, is specifically proposed for inclusion in proposed Rule 12140(e)(9).

the quotation requirements for FLEX Market Makers set forth in proposed Rule 7605(h) and sanction violations of such requirements.[162]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [163] in general, and furthers the objectives of Section 6(b)(5) of the Act [164] in particular, in that it is designed 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. Specifically, the Exchange believes the adoption of the proposed rules allowing FLEX Equity Options to trade on the BOX Trading Floor as FOO Orders is consistent with the goals of the Act to remove the impediments to and perfect the mechanism of a free and open market because it will benefit Participants by providing an additional venue for Participants to provide and seek liquidity for customized, large, or complex FLEX option orders. As the Commission noted in its order granting FLEX Equity Option trading on CBOE and what was then the Pacific Stock Exchange (now NYSE Arca), trading FLEX Equity Options on an exchange is an alternative to trading customized options in OTC markets and carries with it the advantages of exchange markets such as transparency, parameters and procedures for clearance and settlement, and a centralized counterparty clearing agency.[165] Therefore, the Exchange believes the proposed rule change will promote these same benefits for the market as a whole by providing an additional venue for market participants to seek liquidity for customized, large-sized, or complex FLEX option orders. The Exchange believes that providing an additional venue for these FLEX orders will benefit investors, the national market system, Participants, and BOX by increasing competition for order flow and executions, and thereby spur product enhancements and potentially result in lower prices for exchange services related to FLEX Equity Options.

The Exchange further believes that the proposal is designed to prevent fraudulent and manipulative acts and practices as the Exchange will review all current surveillance in light of any changes required, including surveillance and technology to detect disruptive or manipulative trading activity for FOO Orders on the Trading Floor, and will modify or add any surveillance as appropriate. As described above, the Exchange will apply its existing surveillance program to FLEX Equity Options and has developed FLEX-specific surveillance reports.

As described below, the Exchange also believes the proposed changes to Rule 12140(e) are consistent with Section 6(b)(6) of the Act,[166] 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. The Exchange further believes the proposed changes to Rule 12140(e) are 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.[167]

General

The Exchange believes that proposed Rule 5055(a) stating that the trading of FLEX Equity Options is subject to all other Rules applicable to the trading of options on the Exchange, unless otherwise provided in Rules 5055 and 7605, is consistent with the Act because it will ensure that, except where otherwise provided in Rules 5055 and 7605, the Exchange's existing rules will continue to apply to FLEX Equity Options, which will provide increased consistency for Participants trading FLEX Equity Options and Non-FLEX Equity Options on BOX. The Exchange reiterates that rules which contemplate the operation of or interaction with the BOX Book and the Complex Order Book will not apply to FLEX Equity Options, given that FLEX Equity Options may only be traded as FOO Orders and FOO Orders may not be placed in the BOX Book or the Complex Order Book.[168] Specifically, proposed Rule 5055(a) will specify that the BOX Book and the Complex Order Book shall not be applicable for transactions in FLEX Equity Options and thereby provide clarity for market participants that FLEX Equity Options may only be traded on the Trading Floor. As described above, while electronic trading in FLEX options is available on one market today, the Exchange at this time intends to introduce FLEX Equity Options on the Trading Floor only, consistent with other markets that trade these customized options solely on their trading floors. The Exchange also believes that providing further detail about rules that shall not apply in proposed Rule 5055(c) is consistent with the Act because it will provide clarity for market participants about existing rules that will not be applicable to FLEX Equity Options on BOX. In particular, specifying that Rules 7600 and 7620 will not apply to FLEX Equity Options will avoid potential confusion about which order types apply to FLEX Equity Options on BOX, as the Exchange is instead proposing Rule 7605 to apply to transactions in FLEX Equity Options. Specifically, Rule 7600 contains priority provisions related to the BOX Book and the Complex Order Book neither of which are applicable to transactions in FLEX Equity Options. The Exchange notes that another exchange excludes similar rules from application to transactions in FLEX Equity Options.[169] However, proposed Rule 5055(c) also specifies that IM–7600–2 and IM–7600–5 shall apply to FLEX Equity Options. The Exchange believes that expressly applying these provisions is consistent with the Act because, although the remainder of Rule 7600 will not apply to FOO Orders, IM–7600–2, and IM–7600–5 relate, respectively, to tied hedge orders and to compliance with Section 11(a)(1) of the Act and should apply to the proposed FOO Orders in the same manner as they currently apply to QOO Orders. Specifically, tied hedge orders are a combination of an option and hedging position that must follow the procedures set forth in IM–7600–2 which is designed to protect investors and the public interest with provisions that limit the types of combinations considered to be tied hedge orders as well as prescribing Floor Broker duties

[162] *See* proposed Rule 12140(e)(9). The Exchange notes that proposed Rule 7605(h) and current Rule 8510(c)(2) are similar except that proposed Rule 7605(h) does not include the provisions of current Rule 8510(c)(2) related to quote spread parameter requirements and quotation sizes, which requirements are provided separately in proposed Rules 7605(f) and (g). However, the Exchange believes it is appropriate to include proposed Rule 7605(h) with Rule 8510(c)(2) in the MRVP given the similar nature of the underlying requirement to provide quotations.

[163] 15 U.S.C. 78f(b).

[164] 15 U.S.C. 78f(b)(5).

[165] *See* Securities Exchange Act Release No. 36841 (February 14, 1996), 61 FR 6666 (February 21, 1996) (SR–CBOE–95–43) (SR–PSE–95–24) (Order Approving the Trading of Flexibly Structured Equity Options by CBOE and PSE).

[166] 15 U.S.C. 78f(b)(6).

[167] 15 U.S.C. 78f(b)(7) and 78f(d).

[168] *See supra* notes 94 and 97 and accompanying text.

[169] *See* NYSE Arca Rules 5.30–O(c) and (d).

for the handling of such orders. The Exchange believes that expressly applying IM–7600–2 to FOO Orders is consistent with the Act, as this will provide greater consistency between the trading of FLEX Equity Options and Non-FLEX Equity Options on the BOX Trading Floor and reduce the potential for market participant confusion. Next, IM–7600–5 prevents Participants from utilizing the Trading Floor to effect any transactions for their own account, the account of an associated person, or an account with respect to which the Participant or an associated person thereof exercises investment discretion by relying on an exemption under Section 11(a)(1)(G) of the Act (''G Exemption''). IM–7600–5 thereby provides notice to Floor Participants that when utilizing the trading floor to effect transactions in covered accounts, they cannot rely on the G Exemption and must rely on other available exemptions to the prohibition in Section 11(a)(1) of the Act.[170] In this manner, IM–7600–5 provides increased clarity to Floor Participants about their ability to comply with Section 11(a)(1) of the Act and it is therefore consistent with the Act and would protect investors and the public interest to continue to apply this rule to FOO Orders.

The Exchange believes that the definitions proposed in Rule 5055(b) will provide increased clarity to market participants which will protect investors and the public interest by specifying definitions for FLEX Equity Options and Non-FLEX Equity Options, and by specifying that FLEX Equity Option transactions will be governed as proposed in Rule 7605 and shall not be traded other than as FOO Orders. The Exchange believes further that the term ''FLEX Market Maker'' will clarify the difference between Floor Market Makers and FLEX Market Makers, where the latter are qualified for trading FLEX Equity Options and have an obligation to provide quotes in response to FOO Orders. The Exchange also believes that specifying that FLEX Equity Options may not be traded using any other order type or trading mechanism offered by the Exchange will provide increased clarity to Participants that the only means by which the Exchange intends to permit FLEX Equity Options to be traded is via the proposed FOO order type. The Exchange notes that, should it decide to propose additional order types or electronic trading for FLEX Equity Options, it will revise the defined term ''FLEX Open Outcry Order'' accordingly.

The Exchange believes that proposed Rule 5055(d) which specifies that there shall be no trading rotations in FLEX Equity Options is designed to promote just and equitable principles of trade and to remove impediments to and perfect the mechanism of a free and open market and a national market system because it provides notice to Participants regarding the mechanisms applicable to FLEX trading, which will not include trading rotations due to the customized nature of FLEX Equity Options and the fact that there will be no requirement for specific FLEX Equity Option series to be quoted or traded each day.[171] The Exchange notes that QOO Orders on the Trading Floor can only participate in a trading rotation if entered into the BOX Book and as discussed herein FLEX Equity Options will not be eligible to be placed on the BOX Book.[172] The Exchange also notes that another exchange does not hold trading rotations for FLEX Equity Options.[173]

FLEX Equity Option Terms

The Exchange believes that the terms of FLEX Equity Options pursuant to proposed Rule 5055(e) serve to perfect the mechanism of a free and open market and a national market system because they will permit investors to customize some of the terms of their FLEX Equity Options to implement more precise trading strategies and hedges which may not be possible using Non-FLEX Equity Options.[174] These investors may have improved capability to execute strategies to meet their specific investment objectives by using customized FLEX Equity Options. However, only certain terms are subject to flexible structuring by the parties to FLEX Equity Option transactions, and most of such terms have a specified number of alternative configurations. The Exchange believes that these restrictions are reasonable and designed to further the objectives of the Act and to promote just and equitable principles of trade because limiting FLEX Equity Option terms enables the efficient, centralized clearance and settlement and active secondary trading of opened FLEX Equity Options. Further, these terms are consistent with those currently offered at another exchange.[175]

Proposed rule 5055(e)(2)(v)(a) allowing a FLEX Equity Option order to be submitted on any trading day, including the expiration date, serves to perfect the mechanism of a free and open market and a national market system because it will allow investors to execute FLEX Equity Options at a time of their choosing. These investors may have improved capability to execute strategies to meet their specific investment objectives. Further, this rule is designed to provide clarity about when FLEX Equity Options may be executed. The Exchange believes that Floor Participants benefit from increased flexibility and clarity. The Exchange notes that, in another context, new series may be listed the day they expire. Specifically, Short Term Option Series may be added up to and including on the Short Term Option Expiration Date for that options series.[176]

The Exchange also believes that proposed Rule 5055(e)(1) to prevent FLEX Equity Options and Non-FLEX Equity Options with the same terms from trading concurrently is designed to promote just and equitable principles of trade and prevent fraudulent and manipulative acts and practices.[177] In particular, a Non-FLEX Equity Option trading pursuant to Rule 7600 as a QOO Order has different priority rules than a FOO Order trading pursuant to proposed Rule 7605.[178] Allowing an option with the same terms to trade under both rules concurrently would result in inconsistent order handling and could allow the order priority of QOO Orders to be circumvented. Therefore, the Exchange proposes to prevent this situation by permitting FLEX Equity Option transactions only in options with a different term (exercise style, expiration date, or exercise price) than Non-FLEX Equity Options that otherwise meet the requirements of proposed Rule 5055(e). This is designed to prevent FLEX Equity

[170] *See infra* note 245 and accompanying text (describing the Section 11(a)(1) prohibition and defining ''covered accounts'').

[171] *See* Securities Exchange Act Release No. 31920 (February 24, 1993), 58 FR 12280, 12284 (March 3, 1993) (SR–CBOE–92–17) (Order Approving Proposed Rule Change by the Chicago Board Options Exchange, Inc. Relating to the Listing and Trading of Flexible Exchange Options Based on the Nasdaq 100 Index).

[172] *See* BOX Rule 7070(d).

[173] *See* NYSE Arca Rule 5.31–O(b).

[174] *See* proposed Rule 5055(e)(1) (providing that FLEX Equity Options shall be permitted in puts and calls that do not have the same exercise style, same expiration date, and same exercise price as Non-FLEX Equity Options that are already available for trading on the same underlying security).

[175] *See* NYSE Arca Rule 5.32–O.

[176] *See* BOX IM–5050–6(b)(4).

[177] *See* proposed Rule 5055(e)(1).

[178] For example, the BOX Book will be inapplicable to FOO Orders and thus certain priority provisions applicable to QOO Orders are not applicable to FOO Orders. Specifically, FOO Order priority differs from QOO Order provisions related to the priority of orders on the BOX Book. *See* BOX Rules 7600(c)–(e) and (h). The priority of FOO Orders will be determined by proposed Rules 7605(i) and (k) and BOX Rule 7610.

Options from being surrogates for Non-FLEX Equity Options. Additionally, in the event that a Non-FLEX Equity Option series is added intra-day, the holder or writer of a FLEX Equity Option position established under the FLEX trading procedures would be permitted to close such position under the FLEX trading procedures against another closing only FLEX Equity Option position for the balance of the trading day on which the series is added. In the event that the Non-FLEX Equity Option series is added on a trading day after the position is established, the holder or writer of a FLEX Equity Option position established under the FLEX trading procedures would be permitted to close such position as a non-FLEX transaction consistent with the requirements of proposed Rule 5055(f)(1). This proposed rule will prevent an option with the same terms from trading as both a FLEX Equity Option and a Non-FLEX Equity Option concurrently, while providing a narrow exception for closing positions.[179] Further opening trades in such options would be as Non-FLEX Equity Options subject to the Non-FLEX Equity Option trading procedures and rules, including Rule 7600 for Trading Floor transactions.[180] The Exchange believes that enforcing consistent handling and priority for identical and fungible options prevents fraudulent and manipulative acts and practices, and promotes just and equitable principles of trade to protect investors and the public interest by ensuring consistent treatment of these options. The Exchange further believes that providing a narrow exception to permit the closing of a FLEX Equity Option position for the balance of the trading day on which the fungible Non-FLEX Equity Option is added perfects the mechanism of a free and open market and a national market system because it provides investors the ability to close their open FLEX Equity Option positions the same day as the identical Non-FLEX Equity Option is added.[181] As noted herein, these requirements are consistent with those at another exchange.[182]

Further, the Exchange believes that allowing FLEX Equity Options to trade in minimum increments of $0.01 [183] perfects the mechanism of a free and open market and a national market system because it provides investors with increased ability to meet their specific investment objectives and allows for increased opportunities for price improvement through a finer trading increment. The Exchange notes that another exchange currently trades FLEX Equity Options in minimum increments of $0.01.[184]

The Exchange further believes that subjecting FLEX Equity Options to the exercise by exception provisions of Rule 805 of the OCC [185] fosters cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities.[186] Specifically, OCC Rule 805 provides that, unless contrary instructions are given, option contracts that are in-the-money by specified amounts shall be automatically exercised. Application of Rule 805 to FLEX Equity Options provides consistency with Non-FLEX Equity Options and prevents confusion in the clearing process with respect to exercise instructions. The Exchange notes that another exchange provides that FLEX Equity Options shall be subject to the exercise by exception provisions of OCC Rule 805.[187]

Position Limits

Position and exercise limits are designed to address potential manipulative schemes and adverse market impacts surrounding the use of options, such as disrupting the market in the security underlying the options. While position and exercise limits should address and discourage the potential for manipulative schemes and adverse market impact, if such limits are set too low, participation in the options market may be discouraged. The Exchange believes that any decision regarding imposing position and exercise limits for FLEX Equity Options must therefore be balanced between mitigating concerns of any potential manipulation and the cost of inhibiting potential hedging activity that could be used for legitimate economic purposes.[188]

Similar to the other exchanges that trade FLEX Equity Options, the Exchange believes that eliminating position and exercise limits for FLEX Equity Options, while requiring positions in FLEX Equity Options that expire on a third Friday-of-the-month to be aggregated with positions in Non-FLEX Equity Options on the same underlying security,[189] removes impediments to and perfects the mechanism of a free and open market and a national market system because it allows BOX to create a product and market that is an improved but comparable alternative to the OTC market in customized options. OTC transactions occur through bilateral agreements, the terms of which are not publicly disclosed to the marketplace. As such, OTC transactions do not contribute to the price discovery process that exists on a public exchange.

The Exchange believes that the proposed elimination of position and exercise limits for FLEX Equity Options may encourage market participants to transfer their liquidity demands from OTC markets to exchanges and enable liquidity providers to provide additional liquidity to BOX through transactions in FLEX Equity Options. The Exchange notes that the Commission previously approved the elimination of position and exercise limits for FLEX Equity

[179] *See* proposed Rule 5055(f)(2). *See also* proposed Rules 7605(d)(3) and (4). *See* Exchange Act Release Nos. 62321 (June 17, 2010), 75 FR 36130 (June 24, 2010) (SR–NYSEArca–2010–46) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Commentary .01 to Rule 5.32 To Permit Certain FLEX Options To Trade Under the FLEX Trading Procedures for a Limited Time on a Closing Only Basis) *and* 62870 (September 8, 2010), 75 FR 56147 (September 15, 2010) (SR–CBOE–2010–078) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Permit Certain FLEX Options To Trade Under the FLEX Trading Procedures for a Limited Time on a Closing Only Basis).

[180] *See* proposed Rule 5055(f)(1). *See also* Exchange Act Release Nos. 59417 (February 18, 2009), 74 FR 8591 (February 25, 2009) (SR–CBOE–2008–115) (Notice of Filing of Amendments No. 1 and 2 and Order Granting Accelerated Approval to a Proposed Rule Change, as Modified by Amendments No. 1 And 2 Thereto, Relating to FLEX Options Expirations); 60548 (August 20, 2009), 74 FR 43191 (August 26, 2009) (SR–NYSEAmex–2009–44) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change by NYSE AMEX LLC Amending the Permissible Expiration Dates for Flexible Exchange Options); 60549 (August 20, 2009), 74 FR 44415 (August 28, 2009) (SR–NYSE–Arca–2009–75) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change by NYSE Arca, Inc. Amending Permissible Expiration Dates for Flexible Exchange Options); *and* 60549 (September 16, 2009), 74 FR 48619 (September 23, 2009) (SR–Phlx–2009–81) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to FLEX Option Expirations).

[181] The Exchange notes that investors will be able to close any such positions utilizing Non-FLEX Equity Option trading procedures beginning the next trading day.

[182] *See* NYSE Arca Rule 5.32–O, Commentary .01.

[183] *See* proposed Rule 5055(g).

[184] *See* CBOE Rule 5.4(c)(4). The Exchange notes that minimum increments in percentage terms are not part of this proposal.

[185] *See* proposed Rule 5055(h).

[186] The Exchange notes that Rule 805 of the OCC currently applies to Non-FLEX Equity Options on BOX. *See* BOX Rule 9000(b).

[187] *See* NYSE Arca Rule 5.32–O(f)(4).

[188] The Exchange notes that although no position limits are proposed for FLEX Equity Options, there are several mitigating factors, which include aggregation of FLEX Equity Option and Non-FLEX Equity Option positions that expire on a third Friday-of-the-month and subjecting those positions to position and exercise limits, and daily monitoring of market activity.

[189] *See* proposed Rules 5055(i) and (j). *See also* NYSE Arca Rules 5.35–O(a)(iii), (b) and 5.36–O *and* CBOE Rules 8.35 and 8.42 *and* NYSE American Rules 906G and 907G *and* PHLX Options 8, Section 34(e) and (f).

Options, finding that such elimination would allow exchanges ''to better compete with the growing OTC market in customized equity options, thereby encouraging fair competition among brokers and dealers and exchange markets.'' [190] The Commission has also stated that the elimination of position and exercise limits for FLEX Equity Options ''could potentially expand the depth and liquidity of the FLEX equity market without significantly increasing concerns regarding intermarket manipulations or disruptions of the options or the underlying securities.'' [191]

Additionally, the Exchange believes that requiring positions in FLEX Equity Options that expire on a third Friday-of-the-month to be aggregated with positions in Non-FLEX Equity Options on the same underlying security subjects FLEX Equity Options and Non-FLEX Equity Options to the same position and exercise limits on third Friday-of-the-month expirations. These limitations are intended to serve as a safeguard against potential adverse effects of large FLEX Equity Option positions expiring on the same day as Non-FLEX Equity Option positions. The Exchange notes that another exchange has the same requirement.[192]

The Exchange believes that any potential risk of manipulative activity is mitigated by existing surveillance technologies, procedures, and reporting requirements at the Exchange, which allows the Exchange to properly identify disruptive and/or manipulative trading activity. In addition to its own surveillance programs, the Exchange also works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG'') [193] the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange also notes that Financial Industry Regulatory Authority, Inc. (''FINRA''), conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement.[194] The Exchange also represents that it is reviewing its procedures to detect potential manipulation in light of any changes required for FLEX Equity Options to confirm appropriate surveillance coverage. These procedures utilize daily monitoring of market activity via automated surveillance techniques to identify unusual activity in both options and their underlying securities and are designed to protect investors and the public interest by ensuring that the Exchange has an adequate surveillance program in place.

The Exchange believes that proposed Rule 5055(i)(1) further mitigates concerns for potential market manipulation and/or disruption in the underlying markets and thus protects investors and the public interest because position reporting will be required (other than for a Market Maker) and the Exchange may determine that a higher margin requirement is necessary in light of the risks associated with a FLEX Equity Option position in excess of the standard limit for Non-FLEX Equity Options of the same class. The Exchange may, pursuant to its authority under Rule 10130(b), impose additional margin upon the account maintaining such under-hedged position as a safeguard against potential adverse effects of large FLEX Equity Option positions. The Exchange notes that the clearing firm carrying the account will be subject to capital charges under SEC Rule 15c3–1 to the extent of any margin deficiency resulting from a higher margin requirement imposed by the Exchange. The Exchange also notes that other exchanges currently trading FLEX options have similar position and exercise limits.[195]

Letters of Guarantee and Authorization

Pursuant to proposed Rule 5055(k), the Exchange will require FLEX Market Makers to provide a Letter of Guarantee issued by a clearing member organization and filed with the Exchange specifically accepting financial responsibility for all FLEX Equity Option transactions made by such person as long as such letter has not been revoked under Rule 8070(c).[196] Market Makers that are qualified by the Exchange and have provided such a Letter of Guarantee will be permitted to trade FLEX Equity Options on BOX.[197] The Exchange believes that requiring a Letter of Guarantee specific to FLEX Equity Options protects investors and the public interest because it signifies that the clearing member has specifically accepted financial responsibility for transactions in FLEX Equity Options entered into by the Market Maker which will protect the counterparties of those trades and such protections will flow to other clearing members and ultimately to the OCC as the central counterparty and guarantor of both FLEX Equity Option and Non-FLEX Equity Option transactions. The Exchange notes that another exchange requires a Letter of Guarantee for FLEX transactions.[198]

Pursuant to proposed Rule 5055(l), prior to effecting any transaction in FLEX Equity Options, Floor Brokers are required to provide a Letter of Authorization issued by a clearing member organization and filed with the Exchange specifically accepting financial responsibility for all FLEX Equity Option transactions made by such person, and such letter remains in effect until a written revocation is received by the Exchange.[199] Floor Brokers that have provided such a Letter of Authorization and are qualified by the Exchange will be permitted to trade FLEX Equity Options on BOX.[200] The Exchange believes that requiring a Letter of Authorization specific to FLEX Equity Options protects investors and the public interest because it signifies that the clearing member has accepted financial responsibility for transactions in FLEX Equity Options entered into by the Floor Broker which will protect the counterparties of those trades and such protections will flow to other clearing members and ultimately to the OCC as the central counterparty and guarantor of both FLEX Equity Option and Non-FLEX Equity Option transactions. The Exchange notes that another exchange requires a separate Letter of Authorization for Floor Brokers to trade FLEX Equity Options.[201]

[190] *See* Securities Exchange Act Release No. 42223 (December 10, 1999), 64 FR 71158, 71159 (December 20, 1999) (SR–Amex–99–40) (SR–PCX–99–41) (SR–CBOE–99–59) (Order Granting Accelerated Approval to Proposed Rule Change Relating to the Permanent Approval of the Elimination of Position and Exercise Limits for FLEX Equity Options).

[191] *See id.*

[192] *See* NYSE Arca Rule 5.35–O(b)(i).

[193] ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by cooperatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[194] The Exchange notes that it is responsible for FINRA's performance under this regulatory services agreement.

[195] *See* NYSE Arca Rules 5.35–O(a)(iii), (b) and 5.36–O *and* CBOE Rules 8.35 and 8.42 *and* NYSE American Rules 906G and 907G *and* PHLX Options 8, Section 34(e) and (f).

[196] *See* proposed Rule 5055(k).

[197] *See* proposed Rule 7605(c). The Exchange notes that Market Makers are subject to the qualifications in Exchange rules including net capital and financial requirements. *See* BOX Rule 8000 series.

[198] *See* NYSE Arca Rule 5.41–O(a).

[199] *See* proposed Rules 5055(l) and 7605(b).

[200] The Exchange notes that Floor Brokers are subject to registration requirements in Exchange rules including a Floor Broker examination and other factors deemed appropriate by the Exchange. *See* BOX Rule 7550.

[201] *See* NYSE Arca Rule 5.41–O(b).

FOO Orders

The Exchange believes that the proposed rule change to adopt a new order type [202] for FLEX Equity Option transactions on the BOX Trading Floor is consistent with the Act. The Exchange modeled its proposed rule governing FOO Orders after Rule 7600 applicable to QOO Orders to harmonize current procedures on BOX's Trading Floor, which the Exchange believes will reduce investor confusion and thus remove impediments to and perfect the mechanism of a free and open market and a national market system.[203] Specifically, the proposed elements of a FOO Order are designed to aid Floor Brokers in their duties and to maintain order and structure on the Trading Floor. For example, as with a QOO Order, the rules applicable to FOO Orders will ensure that all FLEX Equity Option transactions executed on the Trading Floor by Floor Brokers are systematized before they are represented to the trading crowd and provide an accurate timestamp of when the order was executed by the Floor Broker.[204] As described above, the main differences from QOO Orders are that FOO Orders will not interact with the BOX Book or the Complex Order Book and that Floor Brokers must allow Floor Participants a minimum period of time to respond to FOO Orders.

Under this proposal, Floor Brokers will continue to allow a reasonable amount of time for Floor Participants to participate in a FOO Order. Additionally, the Exchange will establish and communicate via Regulatory Notice a minimum time that Floor Brokers must provide for Floor Participants to respond to FOO Orders, which amount of time must be between three seconds and five minutes. While other exchanges have adopted RFQ processes for FLEX Equity Options,[205] the Exchange has proposed to follow a similar approach for trading FLEX Equity Options as CBOE, which does not have a different open outcry process for FLEX Option transactions as compared to non-FLEX Option transactions, but does establish a different order announcement process that requires a reasonable amount of time for traders to respond to a FLEX Order.[206] In fact, the Exchange notes that CBOE recently changed its process for FLEX Option transactions from conducting a RFQ process to utilizing the same process as for a non-FLEX Option on its trading floor.[207] In its rule filing, CBOE stated that aligning the open outcry process for FLEX Options with that of non-FLEX Options may reduce confusion regarding how FLEX Orders may trade in open outcry and encourage the submission of FLEX Orders for execution.[208]

The Exchange similarly proposes to align its open outcry process for FLEX Equity Options with that of Non-FLEX Equity Options and to establish a minimum time for responses to FOO Orders. The Exchange also believes that, in addition to the required minimum time, it is appropriate to continue to have Options Exchange Officials determine whether Floor Participants have been provided a reasonable amount of time to respond to a FOO Order, which is consistent with the current procedure on the BOX Trading Floor for QOO Orders.[209] The Options Exchange Official will make this determination on a case-by-case basis based on the current market conditions and trading activity on the Trading Floor.[210] Options Exchange Officials are employees of the Exchange, reporting to the Chief Regulatory Officer, and are trained and qualified to enforce the Exchange's rules. The Exchange believes that Options Exchange Officials will ensure that FOO Orders follow the Exchange's rules, including that FLEX Market Makers are provided a reasonable amount of time to respond.[211] FLEX Market Makers that do not believe a reasonable amount of time to respond was provided may appeal any related determination of an Options Exchange Official to the Exchange's Chief Regulatory Officer.[212] Additionally, Floor Brokers have a general responsibility to use due diligence to cause orders to be executed at the best price or prices available to them in accordance with the Rules of the Exchange.[213] Further, it shall be considered conduct inconsistent with just and equitable principles of trade for any Floor Broker to intentionally disrupt the open outcry process.[214] Thus, the Exchange believes that the proposed process promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system because the proposed process provides substantially similar opportunities for Floor Participants to respond to FOO Orders as an RFQ process while maintaining consistency with existing Exchange processes for transactions on the Trading Floor. As noted herein, the proposed open outcry process is safeguarded by enforcement of the Exchange's rules by Options Exchange Officials. The Exchange again notes that, except for the inclusion of a minimum time period that a Floor Broker must allow Floor Participants to respond to FOO Orders, the proposed open outcry process for FOO Orders is similar to the current process for QOO Orders. Therefore, the Exchange believes the proposal will serve to avoid confusion

[202] *See* proposed Rule 7605.

[203] *See* Securities Exchange Act Release No. 81292 (August 2, 2017), 82 FR 37144 (August 8, 2017) (SR–BOX–2016–48) (Order Approving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Adopt Rules for an Open-Outcry Trading Floor) (''After careful review and consideration of the comments received, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1 and 2, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.'').

[204] *See* proposed Rule 7605(e). The Exchange notes that in order to execute a FOO Order on the Trading Floor, it must be sent from a Floor Broker's system to the BOG. This requires that the Floor Broker adequately systematized the FOO Order. An order is systematized when a Floor Broker creates an electronic record of the order. As the Exchange described when it originally proposed the QOO order type, in order to execute a QOO Order from the Trading Floor, it must be sent from a Floor Broker's system to the BOG—which requires that the Floor Broker adequately systemized the QOO Order. *See* Securities Exchange Act Release No. 80720 (May 18, 2017), 82 FR 23657, 23682 n.259 (May 23, 2017) (SR–BOX–2016–48) (Notice of Filing of Amendment No. 2 to a Proposed Rule Change to Adopt Rules for an Open-Outcry Trading Floor).

[205] *See* NYSE Arca Rule 5.33–O *and* PHLX Options 8, Section 34(c) *and* NYSE American Rule 904G.

[206] *See* CBOE Rule 5.72(d)(1) (providing that FLEX Traders have a reasonable amount of time (which amount of time must be between three seconds and five minutes) from the time a FLEX Trader requests a quote in a FLEX Option series or represents a FLEX Order (including announcing a crossing transaction pursuant to Rule 5.87) to respond with bids and offers). The Exchange notes that PHLX has also taken a similar approach to CBOE. *See* Securities Exchange Act Release No. 97658 (June 7, 2023), 88 FR 38562 (June 13, 2023) (SR–Phlx–2023–22) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Various Options 8 Rules).

[207] *See* Securities Exchange Act Release No. 87235 (October 4, 2019), 84 FR 54671 (October 10, 2019) (SR–CBOE–2019–084) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Operation of its Flexible Exchange Options (''FLEX Options'') Pilot Program Regarding Permissible Exercise Settlement Values for FLEX Index Options).

[208] *Id.*

[209] *See supra* note 158 (describing that the minimum time period, which must be between three seconds and five minutes, will be established by the Exchange and communicated via Regulatory Notice).

[210] The Exchange has a Minor Rule Violation Program (''MRVP'') pursuant to Rule 12140 (Imposition of Fines for Minor Rule Violations). The MRVP provides in part that improper vocalization of a trade may result in sanction. *See* BOX Rule 12140.

[211] *See supra* note 158 (describing that the minimum time period, which must be between three seconds and five minutes, will be established by the Exchange and communicated via Regulatory Notice).

[212] *See* BOX Rule 7640(e).

[213] *See* BOX Rule 7570.

[214] *See* BOX IM–7580–4.

and increase efficiency on the BOX Trading Floor.

Proposed Rule 7605(b) states that FOO Orders will be limited solely to the Trading Floor. The Exchange believes that limiting FOO Orders to the Trading Floor is consistent with the Act because, due to their unique and customizable nature, FLEX Equity Option transactions are well suited for a trading floor environment where the terms of such options can be effectively negotiated. The Exchange notes that other exchanges limit FLEX Equity Options trading to their respective trading floors.[215] To the extent the Exchange determines to adopt an electronic mechanism for the trading of FLEX Equity Options, it will file a subsequent proposed rule change with the Commission.

Proposed Rule 7605(c) provides that FLEX Market Makers must be registered under Rule 8000 and must be Floor Market Makers in good standing under Rule 8500, which protects investors and the public interest by ensuring that Market Makers are qualified to perform their duties, including filing an application, demonstrating knowledge of FLEX Equity Options, and providing additional information as the Exchange may consider necessary. The Exchange shall qualify at least three FLEX Market Makers in accordance with a FLEX-specific qualification process prescribed by the Exchange to provide competition for FOO Orders and reasonable opportunities for Participants to get quotes on FLEX Equity Options. The requirement to qualify at least three FLEX Market Makers is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system. Similarly to Floor Market Makers, FLEX Market Makers will also be subject to Rule 8510, including provisions for the course and conduct of dealings, class assignments, and option priority and parity, unless otherwise specified in proposed Rule 7605.[216] Specifically, Rule 8510 provides that transactions of a Floor Market Maker should constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, quoting obligations, restrictions on trading in certain circumstances, and restrictions on conduct related to the allocation of trades. These rules are designed to protect investors and the public interest and are therefore consistent with the Act.

Proposed Rule 7605(d) states that FOO Orders may be Complex FOO Orders or Multi-Leg FOO Orders, including as tied hedge orders, and that these orders may be crossed.[217] However, the priority provisions of Rules 7240(b)(2) and (3) do not apply to Complex FOO Orders or Multi-Leg FOO Orders because there will be no pre-established series and no electronic trading.[218] Further, only FLEX Equity Options on the same underlying and of the same exercise style (American or European) may be part of a Complex FOO Order or Multi-Leg FOO Order. Additionally, if a Non-FLEX Equity Option series is added intra-day for a component leg(s) of a Complex FOO Order or Multi-Leg FOO Order, the holder or writer of a FLEX Equity Option position in the component leg(s) resulting from such Complex FOO Order or Multi-Leg FOO Order would be permitted to close its position(s) under the FLEX trading procedures against another closing only FLEX Equity Option position for the balance of the trading day on which the Non-FLEX Equity Option series is added. If a Non-FLEX Equity Option series is added for a component leg(s) of a Complex FOO Order or Multi-Leg FOO Order on a trading day after the position is established, the holder or writer of a FLEX Equity Option position in the component leg(s) resulting from such Complex FOO Order or Multi-Leg FOO Order would be required to execute separate FLEX Equity Option and Non-FLEX Equity Option transactions to close its position(s), such that FLEX Equity Option component leg(s) would trade under the FLEX trading procedures and Non-FLEX Equity Option component leg(s) would trade subject to the non-FLEX trading procedures and rules. These proposed rules are designed to maintain order and structure, to detail the operation of Complex FOO Order and Multi-Leg FOO Order trading on the Trading Floor, and are similar to BOX's current Rule 7600(a)(4). The Exchange is proposing to use similar procedures for the trading of Complex QOO Orders, multi-leg QOO Orders, Complex FOO Orders, and Multi-Leg FOO Orders on the BOX Trading Floor because it will reduce investor confusion and increase efficiency. Additionally, offering order functionality such as Complex FOO Orders, Multi-Leg FOO Orders, and tied hedge orders provides investors with the flexibility and capability to meet their investment and hedging objectives. For these reasons, the Exchange believes that allowing Complex FOO Orders, Multi-Leg FOO Orders, and tied hedge orders removes impediments to and perfects the mechanism of a free and open market and a national market system and is therefore consistent with the Act. The Exchange notes that another exchange allows complex orders and tied hedge orders for FLEX Equity Options.[219]

Another provision designed to maintain order and structure on the Trading Floor is the Exchange's proposal that FOO Orders entrusted to a Floor Broker will be considered a Not Held Order, unless otherwise specified by a Floor Broker's client.[220] In particular, considering orders as Not Held will aid Floor Brokers in their duties on the Trading Floor because it provides clarity to both Floor Brokers and their clients regarding how each order is to be handled. Additionally, this rule is consistent with the current handling of QOO Orders on the BOX Trading Floor which will avoid confusion, increase efficiency, and ensure consistent treatment of orders on the Trading Floor. The Exchange further believes that this proposed rule protects investors and the public interest by clarifying order handling duties and expectations between Floor Brokers and Participants.

Additionally, the requirement, in proposed IM–7605–2, that Participants disclose Public Customer Orders subject to crossing with an order that is not a

[215] *See* NYSE American Rule 904G *and* NYSE Arca Rule 5.33–O *and* PHLX Options 8, Section 34(c).

[216] Pursuant to proposed Rule 7605(h), FLEX Market Makers have an obligation to quote a FLEX Equity Option in response to any request for quote by a Floor Broker or Options Exchange Official and must provide a two-sided market.

[217] *See* proposed Rule 7605(d), proposed IM–7605–2(d) and current IM–7600–2.

[218] BOX Rules 7240(b)(2) and (3) provide priority provisions for Complex Orders that take into consideration the prices of orders on the BOX Book and the Complex Order Book. Because there will be no BOX Book or Complex Book for Complex FOO Orders, there is no priority of orders on the BOX Book or Complex Book applicable to Complex FOO Orders. This is a distinction from Rule 7600(c), which, for purposes of QOO Orders, excludes the priority rules for Complex Orders contained in Rules 7240(b)(2) and (3) only from multi-leg QOO Orders that are not Complex Orders.

[219] *See* CBOE Rules 5.70(b) and 1.1 (definition of, ''Complex Order'') (providing that the term ''complex order'' means an order involving the concurrent execution of two or more different series in the same underlying security or index (the ''legs'' or ''components'' of the complex order), for the same account, occurring at or near the same time and for the purpose of executing a particular investment strategy with no more than the applicable number of legs (which number CBOE determines on a class-by-class basis)). The Exchange notes that the term ''complex order'' on CBOE includes both Complex Orders and Multi-Leg Orders, as those terms are defined on BOX. *See also* CBOE Rule 5.87 Interpretations and Policies .07 *and* Securities Exchange Act Release No. 93122 (September 24, 2021), 86 FR 54269 (September 30, 2021) (Order Granting Approval of SR–CBOE–2021–041).

[220] *See* proposed Rule 7605(l). *See also* NYSE Arca Rules 5.34–O and 6.62–O(f).

Public Customer Order and all securities that are components of the Public Customer Order is designed to maintain order and structure on the Trading Floor.[221] The rule also clarifies that Complex FOO Orders, Multi-Leg FOO Orders, or tied hedge orders on opposite sides of the market may be crossed subject to limitations.[222] The Exchange believes that providing clarity will remove impediments to and perfect the mechanism of a free and open market and a national market system and that full disclosure will prevent fraudulent and manipulative acts and practices by providing complete information to Participants which may prompt them to improve upon the Floor Broker's proposed crossing price. Additionally, rules governing how long a response is in effect and the effect of an established market on priority create order and structure on the Trading Floor.[223] The Exchange believes that such order and structure protects investors and the public and notes that the same rules apply to QOO Orders.[224]

Proposed Rule 7605(e) is designed to aid Floor Brokers in their duties and to maintain structure and order on the Trading Floor. For example, by providing that a FOO Order is not executed until it is processed by the Trading Host,[225] the Exchange is providing an accurate timestamp of when the order was actually executed by the Floor Broker and not just when it was submitted to the Exchange.[226] Additionally, the process whereby Floor Brokers are required to systematize orders in their systems is designed to provide a complete and accurate audit trail and minimize the occurrence of disputes and regulatory violations.[227] After systematization, a Floor Broker's system will then be required to send an order to the BOG. Further, Floor Brokers are responsible for providing the correct allocations of the initiating side of the FOO Order to an Options Exchange Official or his or her designee, if necessary, after order execution.[228] Floor Brokers will also be required to ascertain that at least one FLEX Market Maker is present in the Crowd Area prior to announcing a FOO Order for execution, which is designed to increase competition for FLEX Equity Option interest on the Trading Floor.[229] The Exchange notes that these rules are substantially similar to those currently in place for QOO Orders on the BOX Trading Floor.[230] The Exchange believes that having substantially similar rules for all orders on the BOX Trading Floor will avoid any potential confusion and increase efficiency on the BOX Trading Floor, which will further the objectives and goals of the Act by helping to prevent fraudulent and manipulative acts and practices, promoting just and equitable principles of trade, and removing impediments to and perfecting the mechanisms of a free and open market and a national market system.

FLEX Market Maker Requirements

The Exchange believes that the proposed rules applicable to FLEX Market Makers are reasonable and will foster cooperation and coordination with persons engaged in facilitating transactions in securities, promote just and equitable principles of trade, and remove impediments to and perfect the mechanism of a free and open market and a national market system. Specifically, proposed Rules 7605(f), (g) and (h) state: (1) that the minimum size for FLEX Equity Option transactions and quotations shall be 1 contract; (2) that there are no maximum bid to ask spread differentials for FLEX Equity Option quotes; and (3) that FLEX Market Makers have an obligation to quote a FLEX Equity Option in response to any request for quote by a Floor Broker or Options Exchange Official and must provide a two-sided market.[231] The Exchange believes that these rules reflect the unique nature of FLEX Equity Option trading which occurs relatively infrequently and with option premiums that can vary widely because any exercise price (in minimum increments of $0.01) and any expiration date on a business day within 15 years of trade date may be traded.[232] The Exchange believes that these requirements strike a balance between the complexity of quoting customized options and the need to ensure that Floor Brokers are able to get a quote for any FLEX Equity Option selected by their clients. Further, these requirements remove impediments to and perfect the mechanism of a free and open market and a national market system by ensuring that there is a procedure in place to receive a two-sided quote for each FOO Order brought to the BOX Trading Floor. The Exchange notes that these requirements are similar to those currently in place at BOX and another options exchange.[233]

Priority of Orders and Allocation of Trades

The Exchange believes that the proposed rule to provide a Floor Broker with a guarantee or entitlement to cross 40% of the remaining contracts of the original order, after all bids or offers at better prices are filled, with other orders that he is holding,[234] is reasonable and is consistent with the Act. Specifically, proposed Rules 7605(i) and (k) will reward Floor Brokers who bring orders of an eligible size determined by the Exchange but not less than 50 contracts to the Exchange by guaranteeing them the ability to cross 40% of the remaining contracts of those orders after any better priced interest has been filled. The Exchange believes that establishing an eligible size for such guarantee for at least 50 contracts will encourage larger negotiated transactions while providing Floor Participants with a reasonable opportunity to participate. The Exchange notes that other options exchanges provide a guarantee for FLEX Equity Options on their trading floors.[235] Additionally, the Exchange

[221] *See* proposed IM–7605–2(a) and (e).

[222] *See* proposed IM–7605–2(d).

[223] *See* proposed IM–7605–2(b) and (c).

[224] *See* BOX IM–7600–1. The Exchanges notes that the portion of IM–7600–1 that references BOX Book Priority is not included in proposed IM–7605–2 because, as discussed, the BOX Book is not available for transactions in FLEX Equity Options.

[225] *See* proposed Rule 7605(e)(2).

[226] FOO Orders will be submitted by Floor Brokers to the BOG, which is a component of the Trading Host. A Floor Broker will have a connection to the BOG giving the Floor Broker the ability to submit FOO Orders to the Trading Host.

[227] In order to execute a FOO Order on the Trading Floor, it must be sent from a Floor Broker's system to the BOG. This requires that the Floor Broker adequately systematized the FOO Order prior to announcing the FOO Order to the trading crowd. *See* proposed Rule 7605(b).

[228] *See* proposed Rule 7605(j).

[229] *See* proposed Rule 7605(e)(3).

[230] *See* BOX Rule 7600(d)(4). *See also* BOX Rule 7580(a).

[231] *See* proposed Rules 7605(f)–(h).

[232] *See* proposed Rule 5055(e).

[233] *See* NYSE Arca Rules 5.32–O(b)(7) and 5.37–O(d) *and* BOX Rule 8510(c)(2).

[234] *See* proposed Rules 7605(i) and (k).

[235] *See* NYSE American Rule 904G(e)(iii) (providing that ''[i]n the case of FLEX Equity Options only and notwithstanding [Rules 904G(e)(i) and (ii)], whenever the Submitting Member has indicated an intention to cross or act as principal on the trade and has matched or improved the BBO during the BBO Improvement Interval, the Submitting Member will be permitted to execute the contra side of the trade that is the subject of the Request for Quotes, to the extent of at least 40% of the trade'') *and* PHLX Rule Options 8, Section 34(c)(5) (''In the case of FLEX equity options only and notwithstanding [Section 34(c)(4)], whenever the Requesting Member has indicated an intention to cross or act as principal on the trade and has matched or improved the BBO during the BBO Improvement Interval, the Requesting Member will be permitted to execute the contra side of the trade that is the subject of the RFQs, to the extent of at least 40% of the trade, provided the order is a Public Customer order or an order respecting the Requesting Member's firm proprietary account.''). *See also* NYSE American Rule 904G(f) (''A Submitting Member may effect crossing transactions only on public customer orders or orders respecting the Submitting Member's firm proprietary account.''). The Exchange notes differences between the guarantees on NYSE American and PHLX and the guarantee on BOX.

currently provides a similar guarantee with respect to QOO Orders executed on the BOX Trading Floor.[236] Allowing a similar guarantee for QOO Orders and FOO Orders is intended to maintain consistency and increase efficiency for the different order types offered on the BOX Trading Floor. The Exchange believes that allowing a guarantee will promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system by encouraging Floor Brokers to bring orders to the Trading Floor while maintaining the ability of other Floor Participants to participate in floor transactions and compete for such orders.

The Exchange believes that, after the allocation of any bids and offers at better prices and any eligible Floor Broker guarantee, allocating FLEX Equity Option trades between Floor Participants pursuant to the priority provisions of Rule 7610 is reasonable and promotes just and equitable principles of trade. The Exchange notes that, pursuant to Rule 7610, bids and offers are considered in order of the highest bid/lowest offer and priority shall be afforded to such bids and offers in the sequence in which they are made. In situations where the sequence cannot be determined, Floor Participants are treated on an equal basis and receive an equal number of contracts to the extent mathematically possible.[237] The Exchange believes that Rule 7610 is designed to be a fair and impartial method of trade allocation, to promote competition between Floor Participants, and to encourage quick responses of bids and offers at the best available prices. Additionally, consistent and objective trade allocation on the BOX Trading Floor may encourage FLEX Market Makers to provide liquidity which may improve the quality of responses to FOO Orders. The Exchange notes that Rule 7610 is currently applicable to QOO Orders on the BOX Trading Floor[238] and that other exchanges use a similar procedure.[239] Further, if interest remains after Floor Participants that responded with interest receive their allocation, the remaining quantity of the initiating side of the FOO Order will be allocated to the executing Floor Broker. This allocation is designed to further incentivize Floor Brokers after first allowing Floor Participants an opportunity to participate in the trade.

The Exchange believes that the proposed rule change to add certain proposed rules as eligible for a minor rule fine disposition under its MRVP 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. In particular, the Exchange believes that the proposed rule changes to Rule 12140(e) are consistent with Section 6(b)(6) of the Act,[240] 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 adds certain rules as eligible for a minor rule fine disposition under the Exchange's MRVP. The Exchange believes violations of proposed Rules 7605 and 7605(h) to be minor in nature and will be more appropriately disciplined through the Exchange's MRVP, and therefore proposes to add them to the list of rules in Rule 12140(e) eligible for a minor rule fine disposition. 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.[241] Rule 12140, currently and as amended, does not preclude a Participant or person associated with or employed by a Participant from contesting an alleged violation and receiving a hearing on the matter with the same procedural rights through a litigated disciplinary proceeding. Further, the Exchange will be able to carry out its regulatory responsibility more quickly and efficiently by incorporating these violations into the MRVP. The Exchange notes that these violations are consistent with violations at other options exchanges.[242] The Exchange also notes that the proposed additional violations are similar to minor rule violations already designated in the Exchange's MRVP for activities related to the Trading Floor.

In requesting the proposed additions to BOX Rule 12140(e), the Exchange in no way minimizes the importance of compliance with Exchange Rules and all other rules subject to the imposition of fines under the MRVP. Minor rule fines provide a meaningful sanction for minor or technical violations of rules when the conduct at issue does not warrant stronger, immediately reportable disciplinary sanctions. The inclusion of a rule in the Exchange's MRVP does not minimize the importance of compliance with the rule, nor does it preclude the Exchange from choosing to pursue violations of eligible rules through a Letter of Consent if the nature of the violations or prior disciplinary history warrants more significant sanctions. Rather, the Exchange believes that the proposed rule change will strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities in cases where full disciplinary proceedings are unwarranted in view of the minor nature of the particular violation. Rather, the option to impose a minor rule sanction gives the Exchange

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First, neither PHLX nor NYSE American set an eligible order size and BOX proposes an eligible order size, determined by the Exchange, of 50 or more contracts. Further, both NYSE American and PHLX require the contra side of a crossing order subject to the 40% guaranteed allocation to be either a Public Customer order or an order respecting the submitting firm's proprietary account whereas BOX does not impose such limitations. The Exchange notes that not limiting contra side participant types is consistent with current BOX rules on the Trading Floor for QOO Orders.

[236] *See* BOX Rule 7600(f).

[237] *See* BOX Rule 7610.

[238] The Exchange notes that split-price priority applicable to QOO Orders is not applicable to FOO Orders. Split-price priority allows a Participant effecting a trade that betters the market to have priority on the balance of that trade at the next pricing increment, even if there are orders in the book at the same price. BOX Book will not be applicable to FOO Orders and thus there is no need for split-price priority. Accordingly, the Exchange does not propose to adopt provisions analogous to Rule 7600(i), IM–7600–6, or IM–7600–7 in proposed Rule 7605.

[239] CBOE Rule 5.72(d)(2) provides that FLEX Orders are allocated only to responses from the trading crowd pursuant to Rules 5.85(a)(1) and (2)(C). Rule 5.85(a)(1) provides that bids and offers with the highest bid and lowest offer have priority and (2)(C) establishes priority between in-crowd market participants at the same price. The Exchange believes that these rules are similar to BOX Rule 7610 and are appropriate for FLEX Equity Option trading. *But see* NYSE Arca Rules 5.30–O(d) (providing that priority and order allocation procedures for open outcry do not apply to FLEX Equity Options) and 5.33–O (providing a RFQ procedure for FLEX transactions including priority provisions that provide priority in certain instances to FLEX Qualified Market Makers and limited priority to the submitting firm if it has matched or improved the market on NYSE Arca). As discussed herein, the Exchange does not believe that a RFQ procedure is necessary for FLEX Equity Option trading on BOX. Similarly, CBOE does not have a specific open outcry procedure for FLEX transactions. *See* CBOE Rule 5.72(d) (providing that a submitting FLEX Trader may represent and execute a FLEX Order on the Exchange's trading floor in the same manner as a Trading Permit Holder may represent and execute an order for a non-FLEX Option).

[240] 15 U.S.C. 78f(b)(6).

[241] 15 U.S.C. 78f(b)(7) and 78f(d).

[242] *See, e.g.,* NYSE Arca Rule 10.12(h) *and* CBOE Rule 13.15(g)(9).

additional flexibility to administer its enforcement program in the most effective and efficient manner while still fully meeting the Exchange's remedial objectives in addressing violative conduct. Specifically, the proposed rule change is designed to prevent fraudulent and manipulative acts and practices because it will provide the Exchange the ability to issue a minor rule fine for violations relating to FOO Orders and FLEX Market Maker quoting of FLEX Equity Options where a more formal disciplinary action may not be warranted or appropriate. Finally, the Exchange believes that the proposed rule change will reinforce its surveillance and enforcement functions.

The Exchange believes that amending Rule 7620 and IM–7620–1 to exclude FLEX Equity Options is consistent with proposed Rule 5055(c) which provides that Rule 7620 shall not apply to transactions in FLEX Equity Options. The amendment is designed to provide clarity by adding FLEX Equity Options to the exclusion list in Rule 7620 and IM–7620–1 to clarify that neither Cabinet orders nor Sub-Penny Cabinet orders will be available for FLEX Equity Options. The Exchange believes further that this amendment will protect investors and the public interest by removing potential ambiguity between Rule 7620 and proposed Rules 5055 and 7605 and is therefore consistent with the Act.

Lastly, the amendment of Rule 100(b)(3) to remove specific rule references is designed to clarify that all Exchange options transactions shall be executed automatically by the Trading Host as provided in applicable Exchange Rules. The Exchange believes that this amendment will protect investors and the public interest by removing potential ambiguity created by a list of specific rule references that may not be complete and is therefore consistent with the Act.

The Exchange reiterates that FLEX Equity Options are currently traded on four other options exchanges currently conducting options trading.[243] Therefore, the proposed rules perfect the mechanism of a free and open market and protect investors and the public interest by establishing FLEX Equity Options and FOO Orders on the BOX Trading Floor, which would provide market participants an additional execution venue to provide and seek liquidity for their customized orders, thereby increasing the opportunities to execute such orders to the benefit of all market participants.

Section 11(a) Analysis

The proposed rule change is consistent with Section 11(a) of the Act and the rules thereunder. Section 11(a)(1) of the Act[244] prohibits a member of a national securities exchange from effecting transactions on that exchange for its own account, the account of an associated person, or an account over which it or its associated person exercises investment discretion (collectively, ''covered accounts''), unless an exception applies. Sections 11(a)(1)(A)–(I) of the Act[245] and the rules thereunder provide certain exemptions from this general prohibition, including the exemption set forth in Rule 11a2–2(T) under the Act.[246] The proposed rule change would not limit in any way the obligation of a Participant, while acting as a Floor Broker or otherwise, to comply with Section 11(a) of the Act or the rules thereunder.[247]

As described above, the Exchange proposes to apply existing IM–7600–5 to FLEX Equity Options,[248] which states that a Participant shall not utilize the Trading Floor to effect any transaction for a covered account by relying on the G Exemption.[249] Because no covered account transactions utilizing the Trading Floor may rely on the G Exemption, Participants utilizing the Trading Floor to effect transactions for covered accounts may only rely upon other exemptions to the Section 11(a)(1) prohibition.[250]

In addition to statutory exemptions, Rule 11a2–2(T) under the Act,[251] known as the ''effect versus execute'' rule, provides Participants with an exemption from the Section 11(a)(1) prohibition. Rule 11a2–2(T) permits a Participant, subject to certain conditions, to effect transactions for covered accounts by arranging for an unaffiliated Participant, acting as a Floor Broker, to execute transactions on the Exchange. To comply with Rule 11a2–2(T)'s conditions, the initiating Participant: (i) must transmit the order from off the Trading Floor; (ii) may not participate in the execution of the transaction once the order has been transmitted to the Participant performing the execution; [252] (iii) may not be affiliated with the executing Participant; and (iv) with respect to an account over which the Participant or an associated person has investment discretion, neither the Participant nor an associated person may retain any compensation in connection with effecting the transaction except as provided in the Rule. For the reasons set forth below, the Exchange believes that Participants utilizing FOO Orders on the Trading Floor may comply with the conditions of Rule 11a2–2(T) under the Act.[253]

[243] FLEX options are currently traded on CBOE, NYSE American, NYSE Arca, and PHLX.

[244] 15 U.S.C. 78k(a)(1).

[245] 15 U.S.C. 78k(a)(1)(A)–(I).

[246] 17 CFR 240.11a2–2(T).

[247] A Floor Broker may utilize the Trading Floor to effect a transaction for a covered account only pursuant to Rule 7540 and for purposes of liquidating error positions.

[248] *See* proposed Rule 5055(c) (stating that IM–7600–5 shall apply to FLEX Equity Options).

[249] 15 U.S.C. 78k(a)(1)(G). Section 11(a)(1)(G) of the Act provides an exemption from the general prohibition in Section 11(a)(1) of the Act for any transaction for a member's own account, provided that: (i) such member is primarily engaged in the business of underwriting and distributing securities issued by other persons, selling securities to customers, and acting as broker, or any one or more of such activities, and whose gross income normally is derived principally from such business and related activities; and (ii) such transaction is effected in compliance with rules of the Commission which, as a minimum, assure that the transaction is not inconsistent with the maintenance of fair and orderly markets and yields priority, parity, and precedence in execution to orders for the account of persons who are not members or associated with members of the exchange. *See also* 17 CFR 240.11a1–1(T) (setting forth requirements for relying on the G Exemption).

[250] Section 11(a) of the Act and the rules thereunder provide other exemptions to the Section 11(a)(1) prohibition, including, for example, the ''effect versus execute'' exemption (as discussed below), the exemption for transactions by a dealer acting in the capacity of a market maker, and the exemption for transactions to offset a transaction made in error.

[251] 17 CFR 240.11a2–2(T).

[252] This prohibition also applies to associated persons of the initiating Participant. The Participant may, however, participate in clearing and settling the transaction.

[253] The Commission has previously found that the all-electronic transactions effected through the Trading Host are consistent with the requirements of Section 11(a) of the Act and Rule 11a2–2(T) thereunder. *See, e.g.,* Securities Exchange Act Release Nos. 72848 (August 14, 2014), 79 FR 49361 (August 20, 2014) (SR–BOX–2014–16) (order approving the Exchange's proposal to adopt new trade allocation algorithms for matching trades at the conclusion of the PIP and the COPIP); and 66871 (April 27, 2012), 77 FR 26323 (May 3, 2012) (order granting the Exchange's application for registration as a national securities exchange). The Commission has also found that transactions effected by Participants through the Trading Floor are consistent with the requirements of Section 11(a) of the Act and Rule 11a2–2(T) thereunder. *See* Securities Exchange Act Release No. 81292 (August 2, 2017), 82 FR 37144 (August 8, 2017) (SR–BOX–2016–48) (order approving the Exchange's proposal to adopt rules for an open-outcry Trading Floor).

Rule 11a2–2(T)'s first requirement is that orders for covered accounts be transmitted from off the Trading Floor. The Commission has found that the off-floor transmission requirement is met if a covered account order is transmitted from a remote location directly to an exchange's floor by electronic means.[254] Floor Brokers will receive matched or unmatched orders either via telephone, or electronically to the Floor Broker's order entry mechanism. A Participant could submit an order for a covered account from off the Trading Floor to an unaffiliated Floor Broker for representation on the Trading Floor and use the ''effect versus execute'' exemption (assuming the other conditions of the rule are satisfied). A Participant that submits a FOO Order for a covered account utilizing the Trading Floor, and who wishes to rely on the ''effect versus execute'' exemption, must submit the order from off the Trading Floor.

Second, Rule 11a2–2(T) requires that neither the initiating Participant nor an associated person of the initiating Participant participate in the execution of the transaction at any time after the order for the transaction has been transmitted. At no time following the submission of a FOO Order utilizing the Trading Floor will the submitting Participant or any associated person of such Participant acquire control or influence over the result or timing of the order's execution.[255] In addition, once a Floor Broker submits a FOO order to the BOG for execution, neither the Floor Broker nor anyone else may alter the terms of the order.[256] Moreover, when a Floor Broker submits a FOO Order for execution, the order will be executed in accordance with Exchange rules and based on market conditions of when the order is received by the Trading Host.[257] Accordingly, a Participant and its associated persons would not participate in the execution of a FOO Order submitted for execution utilizing the Trading Floor.

Third, Rule 11a2–2(T) requires that the order be executed by a Participant that is not associated with the Participant initiating the order. To rely on the exemption in Rule 11a2–2(T), a Participant could submit a FOO Order for a covered account from off the Trading Floor to an unaffiliated Floor Broker. A Participant relying on Rule 11a2–2(T) could not submit a FOO Order for a covered account to its ''house'' Floor Broker on the Trading Floor for execution. If a Participant sends its FOO Order from off the floor to an affiliated Participant that is on the floor, who then directs the order into the Trading Host for execution, the off-floor Participant may not rely on the exemption in Rule 11a2–2(T).

Fourth, in the case of a transaction effected for an account with respect to which the initiating Participant or an associated person thereof exercises investment discretion, neither the initiating Participant nor any associated person may retain any compensation in connection with effecting the transaction, unless the person authorized to transact business for the account has expressly provided otherwise by written contract referring to Section 11(a) of the Act and Rule 11a2–2(T) thereunder.[258] Participants and their associated persons trading for covered accounts over which they exercise investment discretion must comply with this condition in order to rely on the rule's exemption.

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 notes that other exchanges currently offer FLEX option trading on their respective trading floors. The Exchange believes that the proposed rules will allow BOX to compete with these other exchanges and provide an additional execution venue for these transactions for market participants. Thus, the proposed rules will promote intermarket competition by increasing the number of exchanges where FLEX Equity Options can be traded. The proposal also promotes intermarket competition by providing another alternative, exchange markets, to bilateral OTC trading of options with flexible terms. Exchange markets, in contrast with bilateral OTC trading, are centralized, transparent, and have the guarantee of the OCC for options traded.

Additionally, the Exchange believes that this proposal does not impose an undue burden on intramarket competition because Participants are not required to trade FLEX Equity Options and those that choose to trade FLEX Equity Options may do so on the same terms and pursuant to the same rules. To the extent that the proposed rules differ for FLEX Market Makers and Floor Brokers, these differences are based on the unique roles and obligations of Floor Brokers (*e.g.,* systemization, announcement, and allocation of orders) and FLEX Market Makers (*e.g.,* quoting in response to orders). Additionally, any burden on intramarket competition imposed by providing Floor Brokers with a guaranteed trade allocation on certain trades is mitigated by the facts that FLEX Market Maker quotes at better prices are allocated first and FLEX Market Makers may still participate after the Floor Broker's guarantee at the same price. Further, the Exchange notes that Floor Brokers source liquidity for the contra side of a two-sided order that may otherwise be unavailable on the Trading Floor due to the size and complexity of the order. The proposed guarantee provides greater opportunity for the contra-side to participate in the trade which facilitates Floor Brokers in their generation of contra-side interest and increases the likelihood of securing sufficient contra-side interest. FLEX Market Makers do not construct two-sided orders and thus are not provided a guarantee. However, FLEX Market Makers may benefit from the Floor Broker guarantee as the guarantee is designed to incentivize Floor Brokers to bring their FLEX orders to the BOX Trading Floor where FLEX Market Makers have the ability to interact with these orders. The Exchange also does not believe the proposed rule change imposes any undue burden on intramarket competition between Participants that trade FLEX Equity Options and those that trade Non-FLEX

[254] *See, e.g.,* Securities Exchange Act Release Nos. 15533 (January 29, 1979), 44 FR 6084 (January 31, 1979) (''1979 Release''); and 14563 (March 14, 1978), 43 FR 11542 (March 17, 1978) (''1978 Release'').

[255] A Participant may cancel or modify the FOO Order, or modify the instructions for executing the FOO Order. The Commission has stated that the nonparticipation requirement is satisfied under such circumstances so long as the modifications or cancellations are also transmitted from off the floor. *See* 1978 Release, *supra* note 248, at 11547 (stating that the ''non-participation requirement does not prevent initiating members from canceling of modifying orders (or the instructions pursuant to which the initiating member wishes orders to be executed) after the orders have been transmitted to the executing member, provided that any such instructions are also transmitted from off the floor'').

[256] *See* proposed Rule 7600(c).

[257] *See* proposed Rule 7600(a).

[258] In addition, Rule 11a2–2(T)(d) requires that, if a Participant or associated person is authorized by written contract to retain compensation in connection with effecting transactions for covered accounts over which the Participant or associated person thereof exercises investment discretion, the Participant or associated person must furnish at least annually to the person authorized to transact business for the account a statement setting forth the total amount of compensation retained by the Participant or any associated person thereof in connection with effecting transactions for the account during the period covered by the statement. *See* 17 CFR 240.11a2–2(T)(d). *See also* 1978 Release, *supra* note 248, at 11548 (stating that ''[t]he contractual and disclosure requirements are designed to assure that accounts electing to permit transaction-related compensation do so only after deciding that such arrangements are suitable to their interests'').

Equity Options. As described above, the Exchange has proposed to use substantially similar procedures for the trading of QOO Orders and FOO Orders, with any modifications designed to reflect the unique nature of customizable FLEX Equity Options. The Exchange notes further that proposed Rule 5055(f) would prevent any FLEX Equity Options and Non-FLEX Equity Options with the same terms from trading concurrently on the Exchange, with a narrow exception for closing only orders.[259]

Lastly, the proposed MRVP changes are not intended to address competitive issues but rather are concerned solely with updating the Exchange's MRVP in connection with the proposed rules eligible for a minor rule fine disposition. Further, the proposal relates to the Exchange's role and responsibilities as a self-regulatory organization and the manner in which it disciplines its Participants and associated persons for violations of its rules. The Exchange believes the proposed MRVP changes, overall, will strengthen the Exchange's ability to carry out its oversight and enforcement functions and deter potential violative conduct.

Based on the foregoing, the Exchange believes that the proposed rule changes discussed herein do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Proceedings To Determine Whether To Approve or Disapprove SR–BOX–2023–20, as Modified by Amendment No. 2, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[260] to determine whether the proposed rule change, as modified by Amendment No. 2, should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change, as modified by Amendment No. 2.

Pursuant to Section 19(b)(2)(B) of the Act,[261] the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange proposes to adopt Rules 5055 and 7605 which, among other applicable Exchange rules, will govern the trading of FLEX Equity Options on the BOX Trading Floor and make corresponding rule changes. The Commission received one comment letter in support of the proposed rule change as originally proposed.[262] On December 12, 2023, the Exchange filed Amendment No. 2 that replaced and superseded its original proposal.[263] The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the proposed rule change's consistency, as modified by Amendment No. 2, with the Act, and in particular, Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to 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.[264] The Commission is also seeking additional comment on the proposed rule change in order to provide the public with an opportunity to consider and comment on Amendment No. 2, which was filed with the Commission on December 12, 2023.

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization ['SRO'] that proposed the rule change.'' [265] 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,[266] 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 Exchange Act and the applicable rules and regulations.[267]

For these reasons, the Commission believes it is appropriate to institute proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act to determine whether the proposal should be approved or disapproved.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(5) of the Act [268] or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,[269] any request for an opportunity to make an oral presentation.[270]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change, as modified by Amendment No. 2, should be approved or disapproved by January 11, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by January 25, 2024.

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in Amendment No. 2,[271] in addition to any other comments they may wish to submit about the proposed rule change.

[259] *See supra* note 61.

[260] 15 U.S.C. 78s(b)(2)(B).

[261] *Id.*

[262] *See supra* note 3.

[263] *See supra* note 6.

[264] 15 U.S.C. 78f(b)(5).

[265] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[266] *See id.*

[267] *See id.*

[268] 15 U.S.C. 78f(b)(5).

[269] 17 CFR 240.19b–4.

[270] Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Pub. L. 94–29 (June 4, 1975), grants to 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 Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[271] *See* Amendment No. 2, *supra* note 6.

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–BOX–2023–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–BOX–2023–20. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–BOX–2023–20 and should be submitted on or before January 11, 2024. Rebuttal comments should be submitted by January 25, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[272]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28043 Filed 12–20–23; 8:45 am]

BILLING CODE 8011–01–P

[272] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99190; File No. SR–GEMX–2023–19]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7, Section 6

December 15, 2023.

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 5, 2023, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Rules at Options 7, Section 6, C, Ports and Other Services.[3]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/gemx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing changes on November 28, 2023 (SR–GEMX–2023–16). On December 5, 2023, the Exchange withdrew that filing and submitted this filing.

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 Options 7, Section 6, C, Ports and Other Services. Specifically, the Exchange proposes to amend the monthly caps for SQF Ports [4] and SQF Purge Ports.[5]

Today, GEMX assesses $1,250 per port, per month for an SQF Port as well as an SQF Purge Port.[6] Also, today, SQF Ports and SQF Purge Ports are subject to a monthly cap of $17,500, which cap is applicable to Market Makers.

At this time, the Exchange proposes to increase the SQF Port and SQF Purge Port monthly cap fee of $17,500 per month to $27,500 per month. The Exchange is not amending the $1,250 per port, per month SQF Port and SQF Purge Port. As is the case today, the Exchange would not assess a Member an SQF Port or SQF Purge Port fee beyond the monthly cap once the Member has exceeded the monthly cap for the respective month. Despite increasing the monthly cap for SQF Ports and SQF Purge Ports from $17,500 per month to

[4] ''Specialized Quote Feed'' or ''SQF'' is an interface that allows Market Makers to connect, send, and receive messages related to quotes, Immediate-or-Cancel Orders, and auction responses to the Exchange. Features include the following: (1) options symbol directory messages (*e.g.,* underlying instruments); (2) System event messages (*e.g.,* start of trading hours messages and start of opening); (3) trading action messages (*e.g.,* halts and resumes); (4) execution messages; (5) quote messages; (6) Immediate-or-Cancel Order messages; (7) risk protection triggers and purge notifications; (8) opening imbalance messages; (9) auction notifications; and (10) auction responses. The SQF Purge Interface only receives and notifies of purge requests from the Market Maker. Market Makers may only enter interest into SQF in their assigned options series. Immediate-or-Cancel Orders entered into SQF are not subject to the Order Price Protection, Market Order Spread Protection, and Size Limitation Protection in Options 3, Section 15(a)(1)(A), (1)(B), and (2)(B) respectively. *See* Supplementary Material .03(c) to Options 3, Section 7.

[5] SQF Purge is a specific port for the SQF interface that only receives and notifies of purge requests from the Market Maker. Dedicated SQF Purge Ports enable Market Makers to seamlessly manage their ability to remove their quotes in a swift manner. The SQF Purge Port is designed to assist Market Makers in the management of, and risk control over, their quotes. Market Makers may utilize a purge port to reduce uncertainty and to manage risk by purging all quotes in their assigned options series. Of note, Market Makers may only enter interest into SQF in their assigned options series. Additionally, the SQF Purge Port may be utilized by a Market Maker in the event that the Member has a system issue and determines to purge its quotes from the order book.

[6] The Exchange proposes to add a comma between ''per port'' and ''per month'' in the Options 7, Section 6, C, SQF Port and SQF Purge Port Fee rule text. The Exchange also proposes to remove an extraneous period in Options 7, Section 6, C, in the second paragraph.

$27,500 per month, the Exchange will continue to offer Members the opportunity to cap their SQF Port and SQF Purge Port fees so that they would not be assessed these fees beyond the cap. Further, a GEMX Market Maker requires only one SQF Port to submit quotes in its assigned options series into GEMX. A GEMX Market Maker may submit all quotes through one SQF Port and utilize one SQF Purge Port to view its purge requests. While a Market Maker may elect to obtain multiple SQF Ports and SQF Purge Ports to organize its business,[7] only one SQF Port and SQF Purge Port is necessary for a Market Maker to fulfill its regulatory quoting obligations.[8]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[10] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed pricing change to increase the monthly cap applicable to SQF Ports and SQF Purge Ports is reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [11]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

Numerous indicia demonstrate the competitive nature of this market. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules.

The proposed pricing change to increase the SQF Port and SQF Purge Port monthly cap from $17,500 per month to $27,500 per month is reasonable because despite the increase in the monthly cap, the Exchange will continue to offer Members the opportunity to cap their SQF Port and SQF Purge Port fees so that they would not be assessed these fees beyond the cap. Additionally, a GEMX Market Maker requires only one SQF Port to submit quotes in its assigned options series into GEMX. A GEMX Market Maker may submit all quotes through one SQF Port and utilize one SQF Purge Port to view its purge requests. While a Market Maker may elect to obtain multiple SQF Ports and SQF Purge Ports to organize its business,[13] only one SQF Port and SQF Purge Port is necessary for a Market Maker to fulfill its regulatory quoting obligations.[14]

The Exchange's proposed pricing change to increase the SQF Port and SQF Purge Port monthly cap from $17,500 per month to $27,500 per month is equitable and not unfairly discriminatory because the Exchange would uniformly not assess any Market Makers that exceeded the proposed monthly cap any SQF Port and SQF Purge Port fees for that month beyond the cap. Market Makers are the only market participants that are assessed SQF Port and SQF Purge Port fees because they are the only market participants that are permitted to quote on the Exchange.

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.

Intermarket Competition

The proposal does not impose an undue burden on intermarket competition. The Exchange believes its proposal remains competitive with other options markets who also offer order entry protocols. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intramarket Competition

The Exchange's proposed pricing change to increase the SQF Port and SQF Purge Port monthly cap from $17,500 per month to $27,500 per month does not impose an undue burden on competition because the Exchange would uniformly not assess any Market Makers that exceeded the proposed monthly cap any SQF Port and SQF Purge Port fees for that month beyond the cap. Market Makers are the only market participants that are assessed SQF Port and SQF Purge Port fees because they are the only market participants that are permitted to quote on the Exchange.

[7] For example, a Market Maker may desire to utilize multiple SQF Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that Member.

[8] GEMX Market Makers have various regulatory requirements as provided for in Options 2, Section 4. Additionally, GEMX Market Makers have certain quoting requirements with respect to their assigned options series as provided in Options 2, Section 5. SQF Ports are the only quoting protocol available on GEMX and only Market Makers may utilize SQF Ports. The same is true for SQF Purge Ports.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

[11] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[12] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[13] For example, a Market Maker or may desire to utilize multiple SQF Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that Member.

[14] GEMX Market Makers have various regulatory requirements as provided for in Options 2, Section 4. Additionally, GEMX Market Makers have certain quoting requirements with respect to their assigned options series as provided in Options 2, Section 5. SQF Ports are the only quoting protocol available on GEMX and only Market Makers may utilize SQF Ports.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[15] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule 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–GEMX–2023–19 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–GEMX–2023–19. 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–GEMX–2023–19 and should be submitted on or before January 11, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28041 Filed 12–20–23; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–222, OMB Control No. 3235–0233]

Submission for OMB Review; Comment Request; Extension: Form 2–E

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 609 (17 CFR 230.609) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) requires small business investment companies and business development companies that have engaged in offerings of securities that are exempt from registration pursuant to Regulation E under the Securities Act of 1933 (17 CFR 230.601 to 610a) to report semi-annually on Form 2–E (17 CFR 239.201) the progress of the offering. The form solicits information such as the dates an offering commenced and was completed (if completed), the number of shares sold and still being offered, amounts received in the offering, and expenses and underwriting discounts incurred in the offering. The information provided on Form 2–E assists the staff in monitoring the progress of the offering and in determining whether the offering has stayed within the limits set for an offering exempt under Regulation E.

Although there have been no filings of Form 2–E since 2017, for administrative purposes the Commission estimates that, on average, approximately one respondent submits a Form 2–E filing each year. The Commission further estimates that this information collection imposes an annual burden of four hours and imposes no annual external cost burden.

The collection of information under Form 2–E is mandatory. The information provided by the form will not be kept confidential. 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.

Written comments continue to be invited on: (a) whether this 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 imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by January 22, 2024 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*.

Dated: December 18, 2023.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28116 Filed 12–20–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99187; File No. SR–NASDAQ–2023–054]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7, Section 3

December 15, 2023.

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 5, 2023, The Nasdaq Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend The Nasdaq Options Market LLC's (''NOM'') Rules at Options 7, Section 3, Nasdaq Options Market—Ports and Other Services.[3]

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 Exchange proposes to amend Options 7, Section 3, Nasdaq Options Market—Ports and Other Services. Specifically, the Exchange proposes to amend Options 7, Section 3(i) to increase the per port, per month SQF Port[4] and SQF Purge[5] Port Fees for all ports over 20 ports (21 and above) from $500 to $750.[6]

Today, NOM assesses SQF Ports and SQF Purge Ports a per port, per month fee based on a tiered fee schedule. Specifically, NOM assesses an SQF Port and an SQF Purge Port fee of $1,500 per port, per month for the first 5 ports (1–5), a $1,000 per port, per month fee for the next 15 ports (6–20), and a $750 per port, per month fee for all ports over 20 ports (21 and above).

The Exchange proposes to amend the per port, per month fee for SQF Ports and SQF Ports above 20 ports (21 and above) from $500 to $750 per port, per month. The Exchange is not amending the SQF Port and SQF Purge Port fees for ports below 20 ports. SQF Ports and SQF Purge Ports over 20 ports are unnecessary for a NOM Market Maker to fulfill its regulatory requirements.[7] A NOM Market Maker requires only one SQF Port to submit quotes in its assigned options series into NOM. A NOM Market Maker may submit all quotes through one SQF Port and utilize one SQF Purge Port to view its purge requests. While a NOM Market Maker may elect to obtain multiple SQF Ports and SQF Purge Ports to organize its business,[8] only one SQF Port and SQF Purge Port is necessary for a NOM Market Maker to fulfill its regulatory quoting obligations.[9]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange's proposed pricing change to increase fees for certain SQF Ports and SQF Purge Ports is reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [12]

The Commission and the courts have repeatedly expressed their preference

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing changes on November 28, 2023 (SR–NASDAQ–2023–050). On December 5, 2023, the Exchange withdrew that filing and submitted this filing.

[4] ''Specialized Quote Feed'' or ''SQF'' is an interface that allows Market Makers to connect, send, and receive messages related to quotes and Immediate-or-Cancel Orders into and from the Exchange. Features include the following: (1) options symbol directory messages (*e.g.,* underlying instruments); (2) system event messages (*e.g.,* start of trading hours messages and start of opening); (3) trading action messages (*e.g.,* halts and resumes); (4) execution messages; (5) quote messages; (6) Immediate-or-Cancel Order messages; (7) risk protection triggers and purge notifications; and (8) opening imbalance messages. The SQF Purge Interface only receives and notifies of purge requests from the Market Maker. Market Makers may only enter interest into SQF in their assigned options series. Immediate-or-Cancel Orders entered into SQF are not subject to the Order Price Protection, Market Order Spread Protection, or Size Limitation in Options 3, Section 15(a)(1) and (a)(2), and (b)(2), respectively. *See* Options 3, Section 7(e)(1)(B).

[5] SQF Purge is a specific port for the SQF interface that only receives and notifies of purge requests from the NOM Market Maker.

[6] The Exchange also proposes a technical amendment to remove an extraneous period in Options 7, Section 3 in the second paragraph.

[7] *See* NOM Options 2, Sections 4 and 5.

[8] For example, a NOM Market Maker may desire to utilize multiple SQF Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that NOM Participant.

[9] NOM Market Makers have various regulatory requirements as provided for in Options 2, Section 4. Additionally, NOM Market Makers have certain quoting requirements with respect to their assigned options series as provided in Options 2, Section 5. The Exchange notes that SQF Ports are the only quoting protocol available on NOM and only NOM Market Makers may utilize SQF Ports. The same is true for SQF Purge Ports.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [13]

Numerous indicia demonstrate the competitive nature of this market. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules.

The Exchange believes that increasing the fee for SQF Ports and SQF Purge Ports over 20 ports (21 and above) from $500 to $750 per port, per month is reasonable because SQF Ports and SQF Purge Ports over 20 ports are unnecessary for a NOM Market Maker to fulfill its regulatory requirements.[14] A NOM Market Maker requires only one SQF Port to submit quotes in its assigned options series into NOM. A NOM Market Maker may submit all quotes through one SQF Port and utilize one SQF Purge Port to view its purge requests. While a NOM Market Maker may elect to obtain multiple SQF Ports and SQF Purge Ports to organize its business,[15] only one SQF Port and SQF Purge Port is necessary for a NOM Market Maker to fulfill its regulatory quoting obligations.

The Exchange believes that increasing the fee for SQF Ports and SQF Purge Ports over 20 ports (21 and above) from $500 to $750 per port, per month is equitable and not unfairly discriminatory because all NOM Market Makers would be assessed the same fees for SQF Ports and SQF Purge Ports to the extent that these NOM Market Makers have subscribed to more than 20 SQF Ports or SQF Purge Ports. NOM Market Makers are the only market participants that are assessed SQF Port and SQF Purge Port fees because they are the only market participants that are permitted to quote on the Exchange.

[13] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[14] *See* NOM Options 2, Sections 4 and 5.

[15] For example, a NOM Market Maker may desire to utilize multiple SQF Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that Participant.

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.

Intermarket Competition

The proposal does not impose an undue burden on intermarket competition. The Exchange believes its proposal remains competitive with other options markets who also offer order entry protocols. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intramarket Competition

The Exchange believes that increasing the fee for SQF Ports and SQF Purge Ports over 20 ports (21 and above) from $500 to $750 per port, per month does not impose an undue burden on competition because all NOM Market Makers would be assessed the same fees for SQF Ports and SQF Purge Ports to the extent that these NOM Market Makers have subscribed to more than 20 SQF Ports or SQF Purge Ports. NOM Market Makers are the only market participants that are assessed SQF Port and SQF Purge Port fees because they are the only market participants that are permitted to quote on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[16] 15 U.S.C. 78s(b)(3)(A)(ii).

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–2023–054 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2023–054. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All

submissions should refer to file number SR–NASDAQ–2023–054 and should be submitted on or before January 11, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–28039 Filed 12–20–23; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20131 and #20132; Tennessee Disaster Number TN–20009]

Presidential Declaration of a Major Disaster for the State of Tennessee

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Tennessee (FEMA–4751–DR), dated 12/13/2023.

Incident: Severe Storms and Tornadoes.

Incident Period: 12/09/2023.

DATES: Issued on 12/13/2023.

Physical Loan Application Deadline Date: 02/12/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 09/13/2024.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 12/13/2023, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Davidson, Dickson, Montgomery, Sumner.

Contiguous Counties (Economic Injury Loans Only):

Tennessee: Cheatham, Hickman, Houston, Humphreys, Macon, Robertson, Rutherford, Stewart, Trousdale, Williamson, Wilson

Kentucky: Christian, Simpson, Allen, Todd

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 20131C and for economic injury is 201320.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2023–28150 Filed 12–20–23; 8:45 am]

BILLING CODE 8026–09–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2023–0046]

Privacy Act of 1974; Matching Program

AGENCY: Social Security Administration (SSA).

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the provisions of the Privacy Act, as amended, this notice announces a new matching program with Office of Personnel Management (OPM). This matching program sets forth the terms, conditions, and safeguards under which SSA uses identifying information (*e.g.,* name, Social Security number (SSN), and date of birth) concerning United States Postal Service (Postal Service) annuitants and their family members as part of a process to verify eligibility to enroll in Medicare Part B during the Postal Service Reform Act of 2022 (PSRA) Medicare special enrollment period (SEP).

DATES: Submit comments on the proposed matching program no later than January 22, 2024.

The matching program will be applicable on January 20, 2024, or once a minimum of 30 days after publication of this notice has elapsed, whichever is later. The matching program will be in effect for a period of 9 months.

ADDRESSES: You may submit comments by any one of three methods—internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2023–0046 so that we may associate your comments with the correct regulation. CAUTION: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov.* Use the *Search* function to find docket number SSA–2023–0046 and then submit your comments. The system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each submission manually. It may take up to a week for your comments to be viewable.

2. *Fax:* Fax comments to (410) 966–0869.

3. *Mail:* Matthew Ramsey, Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, or emailing *Matthew.Ramsey@ssa.gov.* Comments are also available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Interested parties may submit general questions about the matching program to Cynthia Scott, Division Director, Office of Privacy and Disclosure, Office of the General Counsel, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, at telephone: (410) 965–1416, or send an email to *Cynthia.Scott@ssa.gov.*

[17] 17 CFR 200.30–3(a)(12).

SUPPLEMENTARY INFORMATION: None.

Matthew Ramsey,

Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.

Participating Agencies: SSA and OPM.

Authority for Conducting the Matching Program: This Agreement is executed under the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act (CMPPA) of 1988, Public Law 100–503, 102 Stat. 2507 (1988), as amended, and the Computer Matching and Privacy Protection Amendments of 1990 (Privacy Act), (Pub. L. 101–508, 104 Stat. 143 (1990)), and the regulations and guidance promulgated thereunder.

Legal authority for OPM's disclosures under this agreement are the Privacy Act (5 U.S.C. 552a(b)(1) & (3)) and section 101(c) of the PSRA (Pub. L. 117–108, Title I, 101(c); 5 U.S.C. 8903c note).

Section 1837(o) of the Social Security Act (42 U.S.C. 1395p(o)) authorizes a one-time Medicare Part B PSRA SEP for certain eligible Postal Service annuitants and their family members.

Purpose(s): This matching program sets forth the terms, conditions, and safeguards under which SSA uses identifying information (*e.g.,* name, SSN, and date of birth) concerning Postal Service annuitants and their family members as part of a process to verify eligibility to enroll in Medicare Part B during the PSRA SEP. This one-time PSRA SEP will occur during a 6-month period beginning on April 1, 2024, and ending on September 30, 2024.

Categories of Individuals: The individuals whose information is involved in this matching program are Postal Service annuitants and their family members.

Categories of Records: SSA will maintain an OPM SEP reference list, which includes Postal Service annuitants' and family members' SSN, name, and date of birth who are not enrolled in Medicare Part B.

System(s) of Records: SSA will maintain the information concerning Postal Service annuitants and family members in the Claims Folders System, 60–0089, last fully published at 84 FR 58422 (October 31, 2019) for the period needed to support the PSRA SEP.

[FR Doc. 2023–28104 Filed 12–20–23; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 12235]

RIN 1400–AF79

Pilot Program To Resume Renewal of H–1B Nonimmigrant Visas in the United States for Certain Qualified Noncitizens

AGENCY: Department of State.

ACTION: Notice of pilot program.

SUMMARY: The Department of State (the ''Department'') is announcing a pilot program to resume domestic visa renewal for qualified H–1B nonimmigrant visa applicants who meet certain requirements. This notice describes the requirements for participation in the pilot and provides information on how those falling within the bounds of the pilot program may apply for domestic visa renewal.

DATES: The pilot program will accept applications from January 29 to April 1, 2024. Applicants who meet the requirements may choose to participate during the application window by applying online at *https://travel.state.gov/content/travel/en/us-visas/employment/domestic-renewal.html.* Written comments and related materials must be received on or before midnight April 15, 2024.

ADDRESSES: Interested parties may submit comments, identified by Department docket number DOS–2023–0042 or RIN 1400–AF79, through the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the website instructions for submitting comments. A summary of this rule is also available at *www.regulations.gov* by searching for ''1400–AF79'' from the home page.

Comments submitted in a manner other than the one listed above, including emails or letters sent to Department officials, will not be considered comments on the Notice, and may not be considered by the Department.

FOR FURTHER INFORMATION CONTACT: Jami Thompson, Senior Regulatory Coordinator, Visa Services, Bureau of Consular Affairs, Department of State; email: *VisaRegs@state.gov.*

SUPPLEMENTARY INFORMATION: *Public Participation:* The Department invites all interested parties to submit written data, views, comments, and arguments on all aspects of this Notice. Comments must be submitted in English, or an English translation must be provided. Comments that will provide the most assistance to the Department should comment on the proposal to provide for renewal of visas within the United States. Do not submit case inquiries, case numbers, bar code numbers, or photographs from any vias application. The Department does not intend to address comments as part of this pilot, but will consider relevant comments in deciding on any future rulemaking.

Instructions: If you submit a comment, you must include the agency name and the RIN 1400–AF79 for this Notice in the title or body of the comment. Submitted comments will be publicly posted to the Federal eRulemaking Portal at *www.regualtions.gov.* Therefore, you may wish to consider limiting the amount of personal information that you provide. The Department may withhold from public viewing information provided in comments that it determines offensive. For additional information, please read the Privacy Act notice available in the footer at *www.regulations.gov.*

Docket: For access to the docket and to read background documents or comments received, go to *www.regulations.gov,* referencing RIN 1400–AF79. You may also sign up for email alerts on the online docket to be notified when comments are posted.

I. Background

In 2004, the Department discontinued the domestic renewal of non-diplomatic nonimmigrant visas primarily because of the passage of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Pub. L. 107–173), which required that U.S. visas issued after October 26, 2004, include biometric identifiers [1] (69 FR 35121). Then, as now, the State Department did not possess the capacity to collect fingerprints in the United States, so all non-diplomatic visa applicants were required to apply for new visas outside of the United States where fingerprints can be collected at a U.S. embassy, consulate or, for certain posts, at an offsite contract facility. For purposes of implementing this pilot, however, those prior concerns are overcome, as participation in the pilot is limited to individuals who have previously submitted fingerprints in connection with the application for the prior visa, are eligible for a waiver of the in-person interview requirement and meet other applicable requirements. The

[1] In 2004, the Department, in coordination with the Department of Homeland Security, determined that biometric identifiers should include two fingerprints and a photograph (69 FR 78515). In 2010, the standard was changed to ten fingerprints and a photograph (75 FR 39323). Certain individuals under the age of 14 and those age 80 or over are exempt from the fingerprint requirement.

goal of this pilot is to test the Department's technical and operational ability to resume domestic visa renewals for specific nonimmigrant classifications and to assess the efficacy of this program in reducing worldwide visa wait times by shifting certain workloads from overseas posts to the United States.

II. Pilot Program and Requirements for Participation

Pursuant to 22 CFR 41.111(b)(3), the Deputy Assistant Secretary for Visa Services (VO DAS) and Department officials designated by them, are authorized to issue, in their discretion, nonimmigrant visas in the United States, to qualified applicants who meet specific criteria. Based on this discretionary authority, the VO DAS sets the limitations and parameters of the domestic renewal pilot, including establishing parameters that limit the types of applications that fall within the pilot's scope. Consequently, applicants that fall outside of this scope are not eligible to apply for, nor be issued, a visa domestically.

Participation in this pilot will be limited to applicants who(se):

1. Are seeking to renew an H–1B visa; during the pilot phase, the Department will not process any other visa classifications;
2. Prior H–1B visa that is being renewed was issued by Mission Canada with an *issuance* date from January 1, 2020, through April 1, 2023; or by Mission India with an *issuance* date of February 1, 2021, through September 30, 2021;
3. Are not subject to a nonimmigrant visa issuance fee (Note: this is commonly referred to as a ''reciprocity fee'');
4. Are eligible for a waiver of the in-person interview requirement;
5. Have submitted ten fingerprints to the Department in connection with a previous visa application;
6. Prior visa does not include a ''clearance received'' annotation;
7. Do not have a visa ineligibility that would require a waiver prior to visa issuance;
8. Have an approved and unexpired H–1B petition;
9. Were most recently admitted to the United States in H–1B status;
10. Are currently maintaining H–1B status in the United States;
11. Period of authorized admission in H–1B status has not expired; and
12. Intend to reenter the United States in H–1B status after a temporary period abroad.

Some of these requirements are mandated by statute or regulation. Others are discretionary requirements and are designed to limit the pilot population to a size that is manageable and consistent with available resources, and control the costs of conducting the pilot, while still testing the efficacy of a domestic renewals program.

Specifically, the Department is limiting the scope of the pilot to applicants who were previously issued visas within specified dates by Missions Canada or India to properly assess the performance and capabilities of contractors who manage the majority of the Department's worldwide visa processing. The population of visa applicants in India and Canada is sufficiently representative of the global population and visa issuances during the referenced periods provide enough cases to make the pilot results meaningful, without overwhelming available resources.

Additionally, the Department is limiting the scope of the pilot to include only H–1B applicants. After careful consideration, the Visa Office determined that including other visa categories, including H–4s (dependents of H–1B principal applicants), created additional technical and operational challenges that cannot be resolved before the pilot launch date. For instance, developing standard operating procedures and training staff to recommence domestic renewals is a time-consuming process that requires months of practice currently underway for H–1B adjudications. Developing processes to adjudicate additional visa categories will continue concurrent with the pilot, leveraging real time data and feedback to expand the program.

Limiting the pilot to only H–1B principal applicants will also maximize the Department's direct impact on U.S. industry partners, whose H–1B employees may need to travel abroad for work purposes and risk being unable to immediately return if their visa is expired.

As the Department does not conduct in-person nonimmigrant visa interviews or collect fingerprints domestically, a key requirement for participation in the pilot is that applicants for domestic visa renewal must qualify for a waiver of the in-person interview requirement under section 222(h) of the Immigration and Nationality Act (INA) and have fingerprints on file with the Department that may be used for biometric vetting. Just like any individual applying for a nonimmigrant visa overseas, including those whose in-person interview is waived, all applicants for domestic visa renewal must undergo screening and vetting. With certain exceptions set out in the law, most applicants seeking to renew their H–1B visas, whether overseas or domestically, within 48 months of the expiration of their prior visa in the same classification, will be eligible for a waiver of the in-person interview requirement. Based on statutory requirements for an interview waiver under INA section 222(h)(2), applicants for domestic visa renewal must reside in the United States. Applicants are not required to submit evidence of residence in the United States at the time they submit their application beyond the information requested in the visa application; however, additional information may be requested at any time prior to visa issuance.

Some applicants may not be fully aware of the facts that caused them to be ineligible for interview waiver, even though the reasons are tied to a specific statutory ground. For example, applicants requiring a Department clearance are ineligible for interview waiver, but such clearance requirements are not public information. Any such requirement would be based on the applicant's individual circumstances. Applicants who do not meet the requirements for domestic adjudication as published in this notice, including eligibility for a waiver of the in-person interview requirement, are not eligible to apply for, nor be issued a visa domestically. Fees will not be refunded and these applicants must submit a new application, pay the associated fee, and apply overseas where they have a residence or are physically present if they wish to pursue a new visa. Participation in the pilot is voluntary. Individuals who do not wish to participate in this pilot may continue to apply overseas at a U.S. embassy or consulate where they have a residence or are physically present.

The pilot aligns with the Administration's commitment to transform federal customer experience and service delivery to rebuild trust in government, as outlined in Executive Order 14058, signed on December 13, 2021 (*https://www.whitehouse.gov/briefing-room/presidential-actions/2021/12/13/executive-order-on-transforming-federal-customer-experience-and-service-delivery-to-rebuild-trust-in-government/*). By designing and delivering services with a focus on innovative solutions and the user experience of American industry partners, the Department is looking to alleviate the uncertainty often experienced by U.S. companies that employ temporary workers requiring petition-based visas, as well as the uncertainty experienced by their impacted workers. This pilot will also

support implementation of the Chips and Science Act and Executive Order 14110, issued on October 30, 2023, which outlines the administration's commitment to the safe, secure, and trustworthy development and use of artificial intelligence (*https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence*).

III. Procedures for Participation

a. Application Period

The Department will begin accepting online applications January 29, 2024 via *https://travel.state.gov/content/travel/en/us-visas/employment/domestic-renewal.html.* In order to control the number of applications received, the Department will, each week, release approximately 2,000 application slots for applicants whose most recent H–1B visas were issued by Mission Canada, and approximately 2,000 application slots for those whose most recent H–1B visas were issued by Mission India (approximately 4,000 total each week) on the following dates:

- January 29
- February 5
- February 12
- February 19
- February 26

Every application received will be counted against an approximate 2,000 maximum weekly limit for each participating Mission. Once the limit is reached, the online portal will be locked until the next tranche of slots are released for each participating Mission group on the next application date. Applicants who are unable to apply on one application date may attempt to apply on any of the remaining application dates during the entry period. The application period for the pilot will close when all application slots are filled or on April 1, 2024, whichever comes first.

b. Completing the Online Application for the Pilot

To complete an application, applicants must navigate to the dedicated domestic visa renewal website available at *https://travel.state.gov/content/travel/en/us-visas/employment/domestic-renewal.html.* On this site, applicants will be directed to select the host-country post of their most recent H–1B visa issuance (either Canada or India). From there, applicants will be taken through a navigator tool, which will assist applicants in assessing their qualifications for participation in the pilot, as discussed in Section II, 1–12 above. Applicant responses to questions in the navigator tool will not be retained by the Department. After completing the self-assessment, qualified applicants must electronically complete and submit Form DS–160. Qualified applicants will also receive instructions through the portal on how to pay the required, non-refundable, non-transferrable Machine-Readable Visa (MRV) application processing fee and where to mail their passports and other required documents for processing. The navigator is not capable of screening out all unqualified applicants. Consequently, it is possible the application subsequently will be returned unadjudicated for failure to satisfy the requirements for pilot participation or adjudicated and refused based on failure to qualify for an interview waiver. The MRV application processing fee payment will not be refunded in either case.

c. Application Processing

Applications will be considered in the order received. The Department will not provide non-automated status reports on individual applications, other than the return of the application, issuance of the visa, or refusal, nor will it expedite applications. Applicants may check the status of their application at: *https://ceac.state.gov/CEACStatTracker/Status.aspx?App=NIV.*

The application processing is as follows:

After online submission of the DS–160 and payment of the *non-refundable, non-transferrable* MRV fee, applicants will receive instructions through the portal to send their passports and other required documents (as specified in section d. Required Documents of this notice) via the U.S. Postal Service or commercial courier service to the Department (see section f, below). Applications will then be sorted to determine whether they fall within the scope of the pilot. Applications and passports that do not pass this initial sorting process will be returned to applicants unadjudicated, as described below, but the fee will be retained to cover processing costs. Applications that satisfy the initial sorting requirements are forwarded to a location where authorized Department employees will adjudicate those applications.

The average processing time for a domestic visa renewal application is expected to be six to eight weeks from the time that the passport and other required documents are received by the Department. The Department aims to complete processing of all applications no later than May 1, 2024. The Department will not consider requests for expedited processing. If an applicant anticipates urgent travel, the applicant may wish to apply for visa renewal overseas where they have a residence or are physically present. If an applicant applies for domestic visa renewal and learns that they must travel urgently, the applicant may withdraw their application and request through the online portal that their passport be returned to them. If the applicant withdraws their application during the adjudication process, it will be refused under INA 221(g) and the MRV fee will *not* be refunded. The INA 221(g) refusal will not prejudice any future application. With this notice and other Department publications, visa applicants are made aware of the limited scope of this pilot program and the requirements for participation, as detailed in Section II, 1–12 above.

Domestic issuance of a visa through the pilot program is *not* guaranteed. If the application is adjudicated but does not satisfy the requirements for domestic visa renewal under this pilot program for any reason, including a determination that the applicant requires an interview, resulting in a refusal under INA 221(g), the applicant may reapply by filing a new visa application at a U.S. consulate or embassy abroad where they have a residence or are physically present, and pay a new MRV fee.

d. Required Documents

Each applicant for a domestic H–1B visa renewal must submit the following documentation:

- A properly completed [2] and electronically filed DS–160, Online Nonimmigrant Visa Application.
- One photograph (taken within the last six months), which meets the specifications at: *https://travel.state.gov/content/travel/en/passports/how-apply/photos.html.*
- A passport valid for travel to the United States, which is valid for at least six months beyond the visa application date, and contains a blank, unmarked page for placement of a visa foil.
- The original or a copy of the applicant's current Form I–797, Notice of Action.
- The original or a copy of the applicant's Form I–94, Arrival-Departure Record (available at *https://i94.cbp.dhs.gov/I94/#/home* or on the Form I–797).

[2] A properly completed application is one that is completed in accordance with the instructions provided on the DS–160.

e. Fee Payment

After completing their DS–160, applicants must pay the required $205.00 *non-refundable and non-transferable* MRV fee via the online portal. Fee payment may only be made using a major debit or credit card. Payment confirmation will be provided at that time.

f. Where To Send Passport and Other Required Documents

After completing the DS–160 and paying the MRV fee, applicants will be provided information via the portal on where and how to send their passports and required documentation.

g. Visa and Documentation Return

Issued visas, passports, and other documents submitted by the applicant will be returned via U.S. Postal Service or a commercial courier. It is important to note that issuance of a visa in the United States is *NOT* a grant of nonimmigrant status, does not constitute an extension of current nonimmigrant status, and does not constitute an admission to the United States. The visa only permits the applicant to seek entry at a U.S. port of entry after overseas travel and is not a guarantee of admission. Any foreign nationals seeking to extend or maintain their status while in the United States should contact U.S. Citizenship and Immigration Services (USCIS) per usual practice.

h. Out-of-Scope Case Returns

The Department will return the following out-of-scope cases *without* an adjudication and *without* a refund of the MRV fee:

- Any application that seeks to renew a visa other than an H–1B visa.
- Any application where the prior H–1B visa was not issued by Mission Canada with an *issuance* date of January 1, 2020, through April 1, 2023; or by Mission India with an *issuance* date of February 1, 2021, through September 30, 2021.
- Any application which is subject to a nonimmigrant visa issuance fee (reciprocity fee). An applicant may research reciprocity fees by country and visa class here: U.S. Visa: Reciprocity and Civil Documents by Country (*state.gov*).
- Any application where the prior visa includes a ''clearance received'' annotation.

i. Visa Refusals

Visa applications will be refused under section 221(g) of the INA if the application is accepted for domestic adjudication, but the applicant is subsequently found to be ineligible for a waiver of the in-person interview requirement under section 222(h) of the INA, or otherwise fails to satisfy the requirements for domestic renewal set out above in Section II, 9–12. In such cases, any applicant seeking to pursue a visa application will have to do so by filing a new DS–160 with a new MRV fee payment at an embassy or consulate overseas. The Department will not transfer applications to an overseas embassy or consulate or refund the MRV fee for applications returned or refused under the pilot program.

The Department also will refuse an application under section 221(g) of the INA if the applicant fails to provide required documentation or information but is expected to overcome the refusal before the end of the pilot. In such instances, the Department will provide specific instructions to the applicant with an opportunity to provide any outstanding documents or information, or correct any minor errors in the application, by April 15, 2024, before completing adjudication. Applicants who are instructed to provide such documentation or information, or those who are instructed to correct minor errors in their application, will not be required to pay an additional MRV fee. If the applicant provides the requested information by April 15, 2024, and the Department can issue the visa through the pilot program, the Department will overcome the 221(g) refusal and issue the visa. As the pilot concludes on May 1, 2024, any refusal due to missing documents or information will not be able to be overcome after that time. Some examples of additional information or documents that may be required include:

- Properly completed Form DS–160,
- Photograph meeting Department standards, and
- Evidence the applicant is resident in the United States.

Julie M. Stufft,

Deputy Assistant Secretary for Visa Services, Bureau of Consular Affairs, Department of State.

[FR Doc. 2023–28160 Filed 12–20–23; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice 12244]

RIN: 1400–AF75

Continental Shelf and Maritime Boundaries; Notice of Limits

SUMMARY: This notice provides updated information pertaining to the outer limits of the U.S. continental shelf.

DATES: These limits are in effect as of December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Brian Van Pay, Executive Director, U.S. Extended Continental Shelf Project, Department of State, *vanpaybj@state.gov.*

SUPPLEMENTARY INFORMATION: By Presidential Proclamation No. 2667 made on September 28, 1945, the United States asserted jurisdiction and control over the natural resources of its continental shelf. Subsequent to that Presidential Proclamation and through its domestic laws, the United States has exercised sovereign rights and jurisdiction over its continental shelf, consistent with international law.

The Department of State on behalf of the Government of the United States hereby announces the outer limits of the continental shelf of the United States of America. The coordinates in this notice describe the outer limits of the continental shelf of the United States in areas beyond 200 nautical miles from the baseline from which the breadth of the territorial sea is measured, in accordance with international law.[1] In other areas, the outer limits of the continental shelf of the United States are the same as the limits of the exclusive economic zone of the United States set forth in Public Notice 12243 or any subsequent Public Notice pertaining to the limits of the U.S. exclusive economic zone in such areas that supersedes that notice.

The limits set forth in this notice are subject to future revision, including with respect to maritime boundary delimitation with neighboring countries. The Government of the United States has been, is, and will be engaged in consultations and negotiations with governments of neighboring countries concerning the delimitation of areas subject to the respective jurisdiction of the United States and of these countries. The outer limits of the continental shelf of the United States as set forth in this notice are without prejudice to any negotiations with these countries or to any positions that may have been or may be adopted respecting the limits of maritime jurisdiction in such areas.

The coordinates in this notice are expressed in decimal degrees and have six decimal places. All coordinates use the World Geodetic System 1984 (''WGS 84'') datum, unless otherwise noted.

[1] For more information on the outer limits of the U.S. continental shelf in areas beyond 200 nautical miles from the baseline from which the breadth of the territorial sea is measured, see the U.S. Extended Continental Shelf Project on the website of the Department of State (*https://www.state.gov/u-s-extended-continental-shelf-project/*).

Some coordinates in this notice were derived from treaties that use a different datum or were expressed in degrees, minutes, and seconds. In the case of a discrepancy, the relevant treaties take precedence over the contents of this notice.

The term ''straight line'' means a geodesic line, which is the shortest distance between two points on the referenced ellipsoid and is the most common method of linking coordinates defining maritime limits and boundaries.

This notice is exempt from the requirements of 5 U.S.C. 553, to the extent those requirements apply, as it relates to a foreign affairs function of the United States. (See Title 5 U.S.C. 553 (a)(1).) This notice '''clearly and directly' involve[s] activities or actions characteristic of the conduct of international relations,'' *E.B.* v. *U.S. Dep't of State,* 583 F. Supp. 3d 58, 66 (D.D.C. 2022), because it announces the locations of maritime boundaries agreed between the United States and other countries and the geographic limits within which the United States may exercise sovereign rights and jurisdiction in accordance with international law. See, *e.g., City of New York* v. *Permanent Mission of India to United Nations,* 618 F.3d 172, 201 (2d Cir. 2010). Since it is exempt from Section 553, the provisions of 5 U.S.C 553(d) do not apply, and this notice is in effect upon publication.

Arctic

In the Arctic, the outer limits of the continental shelf are defined by straight lines connecting the following fixed points:

Outer limit point	Latitude	Longitude
ARC–OL–001	75.648860	–136.778228
ARC–OL–002	75.649727	–136.786746
ARC–OL–003	75.652854	–136.817738
ARC–OL–004	75.655966	–136.848638
ARC–OL–005	75.659063	–136.879692
ARC–OL–006	75.662145	–136.910654
ARC–OL–007	75.665212	–136.941770
ARC–OL–008	75.668264	–136.972792
ARC–OL–009	75.671301	–137.003969
ARC–OL–010	75.674323	–137.035052
ARC–OL–011	75.677330	–137.066290
ARC–OL–012	75.680322	–137.097433
ARC–OL–013	75.683299	–137.128730
ARC–OL–014	75.686261	–137.159933
ARC–OL–015	75.689208	–137.191290
ARC–OL–016	75.692140	–137.222552
ARC–OL–017	75.695056	–137.253967
ARC–OL–018	75.697958	–137.285288
ARC–OL–019	75.700844	–137.316762
ARC–OL–020	75.703715	–137.348140
ARC–OL–021	75.706571	–137.379672
ARC–OL–022	75.709412	–137.411108
ARC–OL–023	75.712237	–137.442697
ARC–OL–024	75.715048	–137.474189
ARC–OL–025	75.717842	–137.505835
ARC–OL–026	75.720623	–137.537384
ARC–OL–027	75.723387	–137.569086
ARC–OL–028	75.726137	–137.600691
ARC–OL–029	75.728870	–137.632448
ARC–OL–030	75.731590	–137.664109
ARC–OL–031	75.734292	–137.695921
ARC–OL–032	75.736981	–137.727636
ARC–OL–033	75.739653	–137.759503
ARC–OL–034	75.742311	–137.791272
ARC–OL–035	75.744952	–137.823192
ARC–OL–036	75.747580	–137.855015
ARC–OL–037	75.750190	–137.886989
ARC–OL–038	75.752786	–137.918865
ARC–OL–039	75.755366	–137.950892
ARC–OL–040	75.757932	–137.982820
ARC–OL–041	75.760480	–138.014899
ARC–OL–042	75.763015	–138.046879
ARC–OL–043	75.765532	–138.079009
ARC–OL–044	75.768036	–138.111041
ARC–OL–045	75.770522	–138.143222
ARC–OL–046	75.772996	–138.175304
ARC–OL–047	75.775451	–138.207536
ARC–OL–048	75.777893	–138.239669
ARC–OL–049	75.780317	–138.271950
ARC–OL–050	75.782728	–138.304132
ARC–OL–051	75.785120	–138.336463
ARC–OL–052	75.787500	–138.368694
ARC–OL–053	75.789862	–138.401074
ARC–OL–054	75.792210	–138.433353
ARC–OL–055	75.794540	–138.465781
ARC–OL–056	75.796858	–138.498108
ARC–OL–057	75.799157	–138.530584
ARC–OL–058	75.801443	–138.562958
ARC–OL–059	75.803710	–138.595480
ARC–OL–060	76.093986	–142.486996
ARC–OL–061	76.096584	–142.519768
ARC–OL–062	76.099168	–142.552439
ARC–OL–063	76.101734	–142.585264
ARC–OL–064	76.104287	–142.617989
ARC–OL–065	76.106822	–142.650869
ARC–OL–066	76.109343	–142.683648
ARC–OL–067	76.111791	–142.715763
ARC–OL–068	76.114285	–142.748714
ARC–OL–069	76.114427	–142.750588
ARC–OL–070	76.116899	–142.783574
ARC–OL–071	76.119359	–142.816458
ARC–OL–072	76.121800	–142.849495
ARC–OL–073	76.124228	–142.882431
ARC–OL–074	76.126639	–142.915518
ARC–OL–075	76.128423	–142.940046
ARC–OL–076	76.129255	–142.951562
ARC–OL–077	76.131634	–142.984702
ARC–OL–078	76.133999	–143.017740
ARC–OL–079	76.136346	–143.050930
ARC–OL–080	76.138680	–143.084017
ARC–OL–081	76.140995	–143.117257
ARC–OL–082	76.143297	–143.150394
ARC–OL–083	76.145581	–143.183682
ARC–OL–084	76.147852	–143.216868
ARC–OL–085	76.150103	–143.250205
ARC–OL–086	76.152343	–143.283438
ARC–OL–087	76.154563	–143.316822
ARC–OL–088	76.156771	–143.350103
ARC–OL–089	76.158959	–143.383535
ARC–OL–090	76.161135	–143.416862
ARC–OL–091	76.163291	–143.450340
ARC–OL–092	76.165436	–143.483714
ARC–OL–093	76.167560	–143.517237
ARC–OL–094	76.169673	–143.550656
ARC–OL–095	76.171765	–143.584225
ARC–OL–096	76.173846	–143.617689
ARC–OL–097	76.175907	–143.651302
ARC–OL–098	76.177956	–143.684810
ARC–OL–099	76.179985	–143.718467
ARC–OL–100	76.182002	–143.752018
ARC–OL–101	76.183998	–143.785719
ARC–OL–102	77.081172	–145.626830
ARC–OL–103	77.088872	–145.613031
ARC–OL–104	77.096586	–145.599388
ARC–OL–105	77.104314	–145.585902
ARC–OL–106	77.112057	–145.572574
ARC–OL–107	77.119814	–145.559403
ARC–OL–108	77.127585	–145.546391
ARC–OL–109	77.135370	–145.533538
ARC–OL–110	77.143168	–145.520845
ARC–OL–111	77.150980	–145.508311
ARC–OL–112	77.158805	–145.495939
ARC–OL–113	77.166643	–145.483728
ARC–OL–114	77.174494	–145.471679
ARC–OL–115	77.182358	–145.459792
ARC–OL–116	77.190234	–145.448069
ARC–OL–117	77.197518	–145.437389
ARC–OL–118	77.203850	–145.428219
ARC–OL–119	77.211759	–145.416930
ARC–OL–120	77.219679	–145.405807
ARC–OL–121	77.227612	–145.394848
ARC–OL–122	77.235556	–145.384056
ARC–OL–123	77.243511	–145.373431
ARC–OL–124	77.251478	–145.362973
ARC–OL–125	77.259456	–145.352682
ARC–OL–126	77.267444	–145.342560
ARC–OL–127	77.275444	–145.332607
ARC–OL–128	77.283453	–145.322823
ARC–OL–129	77.291473	–145.313210
ARC–OL–130	77.299503	–145.303766
ARC–OL–131	77.307544	–145.294494
ARC–OL–132	77.315593	–145.285393
ARC–OL–133	77.627479	–144.928204
ARC–OL–134	77.635532	–144.918930
ARC–OL–135	77.641988	–144.911629
ARC–OL–136	77.648285	–144.904572
ARC–OL–137	77.656359	–144.895690
ARC–OL–138	77.664442	–144.886987
ARC–OL–139	77.672534	–144.878461
ARC–OL–140	77.680635	–144.870114
ARC–OL–141	77.688744	–144.861946
ARC–OL–142	77.696861	–144.853957
ARC–OL–143	77.704987	–144.846149
ARC–OL–144	77.713121	–144.838522
ARC–OL–145	77.721262	–144.831076
ARC–OL–146	77.727624	–144.825389
ARC–OL–147	77.729863	–144.823410
ARC–OL–148	77.732101	–144.821444
ARC–OL–149	77.736368	–144.817682
ARC–OL–150	77.744526	–144.810632
ARC–OL–151	77.752691	–144.803766
ARC–OL–152	77.760864	–144.797083
ARC–OL–153	77.769043	–144.790584
ARC–OL–154	77.777228	–144.784269
ARC–OL–155	77.785421	–144.778140
ARC–OL–156	77.793619	–144.772196
ARC–OL–157	77.801823	–144.766438
ARC–OL–158	77.810034	–144.760867
ARC–OL–159	77.818250	–144.755483
ARC–OL–160	77.826471	–144.750287
ARC–OL–161	77.834698	–144.745279
ARC–OL–162	77.842930	–144.740459
ARC–OL–163	77.851166	–144.735828
ARC–OL–164	77.859408	–144.731387
ARC–OL–165	77.867654	–144.727136
ARC–OL–166	77.875904	–144.723076
ARC–OL–167	77.884158	–144.719207
ARC–OL–168	77.892416	–144.715529
ARC–OL–169	77.900678	–144.712043
ARC–OL–170	77.908944	–144.708749
ARC–OL–171	77.917212	–144.705649
ARC–OL–172	77.925484	–144.702742

Outer limit point	Latitude	Longitude
ARC–OL–173	77.933759	–144.700029
ARC–OL–174	77.942036	–144.697510
ARC–OL–175	77.950316	–144.695185
ARC–OL–176	77.958598	–144.693056
ARC–OL–177	77.966883	–144.691123
ARC–OL–178	77.975169	–144.689386
ARC–OL–179	77.983457	–144.687845
ARC–OL–180	77.991746	–144.686501
ARC–OL–181	78.000037	–144.685355
ARC–OL–182	78.008329	–144.684406
ARC–OL–183	78.016622	–144.683656
ARC–OL–184	78.024915	–144.683105
ARC–OL–185	78.033209	–144.682753
ARC–OL–186	78.041503	–144.682600
ARC–OL–187	78.049797	–144.682647
ARC–OL–188	78.058091	–144.682895
ARC–OL–189	78.214671	–144.687776
ARC–OL–190	78.222965	–144.688114
ARC–OL–191	78.565309	–144.706873
ARC–OL–192	78.573602	–144.707487
ARC–OL–193	78.581894	–144.708312
ARC–OL–194	78.590186	–144.709347
ARC–OL–195	78.598476	–144.710593
ARC–OL–196	78.604872	–144.711699
ARC–OL–197	78.612234	–144.713127
ARC–OL–198	78.620520	–144.714935
ARC–OL–199	78.628805	–144.716956
ARC–OL–200	78.637087	–144.719189
ARC–OL–201	78.645366	–144.721636
ARC–OL–202	78.653644	–144.724297
ARC–OL–203	78.661918	–144.727171
ARC–OL–204	78.670190	–144.730261
ARC–OL–205	78.678458	–144.733565
ARC–OL–206	78.686723	–144.737085
ARC–OL–207	78.694984	–144.740820
ARC–OL–208	78.703242	–144.744772
ARC–OL–209	78.710574	–144.748464
ARC–OL–210	78.716839	–144.751738
ARC–OL–211	78.725086	–144.756241
ARC–OL–212	78.733328	–144.760961
ARC–OL–213	78.741565	–144.765899
ARC–OL–214	78.749798	–144.771055
ARC–OL–215	78.758025	–144.776429
ARC–OL–216	78.766247	–144.782023
ARC–OL–217	78.774463	–144.787835
ARC–OL–218	78.780698	–144.792395
ARC–OL–219	78.788153	–144.798008
ARC–OL–220	78.796353	–144.804396
ARC–OL–221	78.804547	–144.811005
ARC–OL–222	78.812734	–144.817834
ARC–OL–223	78.820914	–144.824883
ARC–OL–224	78.829087	–144.832154
ARC–OL–225	78.837253	–144.839646
ARC–OL–226	78.845411	–144.847360
ARC–OL–227	79.591391	–145.604936
ARC–OL–228	79.599527	–145.613824
ARC–OL–229	79.607655	–145.622950
ARC–OL–230	79.615774	–145.632316
ARC–OL–231	79.623885	–145.641922
ARC–OL–232	79.637744	–145.658571
ARC–OL–233	79.645847	–145.668403
ARC–OL–234	79.652143	–145.676217
ARC–OL–235	79.659768	–145.685816
ARC–OL–236	79.667848	–145.696233
ARC–OL–237	79.675918	–145.706892
ARC–OL–238	79.683515	–145.717160
ARC–OL–239	79.690498	–145.726786
ARC–OL–240	79.698540	–145.738111
ARC–OL–241	79.706571	–145.749678
ARC–OL–242	79.714591	–145.761488
ARC–OL–243	79.722600	–145.773541
ARC–OL–244	79.730598	–145.785836
ARC–OL–245	79.738585	–145.798374
ARC–OL–246	79.746559	–145.811156
ARC–OL–247	79.754522	–145.824182
ARC–OL–248	79.762472	–145.837451
ARC–OL–249	79.770410	–145.850964
ARC–OL–250	79.778335	–145.864721
ARC–OL–251	79.786248	–145.878723
ARC–OL–252	79.794147	–145.892969
ARC–OL–253	79.802033	–145.907459
ARC–OL–254	79.809905	–145.922194
ARC–OL–255	79.817763	–145.937174
ARC–OL–256	79.825608	–145.952400
ARC–OL–257	79.833438	–145.967870
ARC–OL–258	79.841253	–145.983585
ARC–OL–259	79.849054	–145.999546
ARC–OL–260	79.856840	–146.015752
ARC–OL–261	79.864611	–146.032204
ARC–OL–262	79.872366	–146.048901
ARC–OL–263	79.880106	–146.065844
ARC–OL–264	79.887830	–146.083033
ARC–OL–265	79.895537	–146.100468
ARC–OL–266	79.903229	–146.118148
ARC–OL–267	79.910904	–146.136074
ARC–OL–268	79.918562	–146.154246
ARC–OL–269	79.926203	–146.172664
ARC–OL–270	79.933826	–146.191327
ARC–OL–271	79.941433	–146.210237
ARC–OL–272	79.949021	–146.229392
ARC–OL–273	79.956592	–146.248793
ARC–OL–274	79.964144	–146.268440
ARC–OL–275	79.970680	–146.285680
ARC–OL–276	79.976923	–146.302352
ARC–OL–277	79.984426	–146.322657
ARC–OL–278	79.991909	–146.343208
ARC–OL–279	79.999374	–146.364004
ARC–OL–280	80.006819	–146.385046
ARC–OL–281	80.014244	–146.406333
ARC–OL–282	80.020394	–146.424194
ARC–OL–283	80.027257	–146.444343
ARC–OL–284	80.034629	–146.466280
ARC–OL–285	80.041980	–146.488463
ARC–OL–286	80.049311	–146.510889
ARC–OL–287	80.056621	–146.533561
ARC–OL–288	80.063909	–146.556476
ARC–OL–289	80.071176	–146.579636
ARC–OL–290	80.078421	–146.603040
ARC–OL–291	80.085645	–146.626688
ARC–OL–292	80.092846	–146.650579
ARC–OL–293	80.100025	–146.674714
ARC–OL–294	80.107181	–146.699091
ARC–OL–295	80.114315	–146.723712
ARC–OL–296	80.121425	–146.748575
ARC–OL–297	80.128512	–146.773681
ARC–OL–298	80.135576	–146.799028
ARC–OL–299	80.142616	–146.824617
ARC–OL–300	80.149632	–146.850448
ARC–OL–301	80.156624	–146.876520
ARC–OL–302	80.163591	–146.902833
ARC–OL–303	80.189175	–147.000611
ARC–OL–304	80.196104	–147.027360
ARC–OL–305	80.203008	–147.054349
ARC–OL–306	80.209886	–147.081579
ARC–OL–307	80.216739	–147.109049
ARC–OL–308	80.223566	–147.136758
ARC–OL–309	80.230367	–147.164705
ARC–OL–310	80.237142	–147.192892
ARC–OL–311	80.243891	–147.221316
ARC–OL–312	80.250614	–147.249979
ARC–OL–313	80.257309	–147.278878
ARC–OL–314	80.263978	–147.308014
ARC–OL–315	80.270619	–147.337387
ARC–OL–316	80.277233	–147.366995
ARC–OL–317	80.283819	–147.396839
ARC–OL–318	80.290377	–147.426917
ARC–OL–319	80.296908	–147.457229
ARC–OL–320	80.303409	–147.487775
ARC–OL–321	80.309883	–147.518555
ARC–OL–322	80.316327	–147.549567
ARC–OL–323	80.322743	–147.580811
ARC–OL–324	80.329129	–147.612286
ARC–OL–325	80.335486	–147.643992
ARC–OL–326	80.341813	–147.675928
ARC–OL–327	80.348111	–147.708094
ARC–OL–328	80.354378	–147.740488
ARC–OL–329	80.360615	–147.773111
ARC–OL–330	80.366822	–147.805961
ARC–OL–331	80.372998	–147.839039
ARC–OL–332	80.379143	–147.872342
ARC–OL–333	80.385257	–147.905871
ARC–OL–334	80.391339	–147.939625
ARC–OL–335	80.397390	–147.973602
ARC–OL–336	80.403409	–148.007803
ARC–OL–337	80.409396	–148.042226
ARC–OL–338	80.415351	–148.076871
ARC–OL–339	80.421274	–148.111737
ARC–OL–340	80.427164	–148.146823
ARC–OL–341	80.433021	–148.182129
ARC–OL–342	80.438845	–148.217653
ARC–OL–343	80.444636	–148.253394
ARC–OL–344	80.450394	–148.289352
ARC–OL–345	80.456118	–148.325526
ARC–OL–346	80.461808	–148.361915
ARC–OL–347	80.467464	–148.398519
ARC–OL–348	80.473085	–148.435335
ARC–OL–349	80.478673	–148.472364
ARC–OL–350	80.484225	–148.509603
ARC–OL–351	80.489743	–148.547054
ARC–OL–352	80.495226	–148.584714
ARC–OL–353	80.500674	–148.622582
ARC–OL–354	80.506086	–148.660657
ARC–OL–355	80.511462	–148.698939
ARC–OL–356	80.516803	–148.737427
ARC–OL–357	80.522108	–148.776119
ARC–OL–358	80.527376	–148.815014
ARC–OL–359	80.532608	–148.854111
ARC–OL–360	80.537804	–148.893410
ARC–OL–361	80.542963	–148.932908
ARC–OL–362	80.548084	–148.972606
ARC–OL–363	80.553169	–149.012502
ARC–OL–364	80.558216	–149.052594
ARC–OL–365	80.563226	–149.092882
ARC–OL–366	80.568198	–149.133364
ARC–OL–367	80.573132	–149.174040
ARC–OL–368	80.578028	–149.214908
ARC–OL–369	80.582886	–149.255966
ARC–OL–370	80.587706	–149.297215
ARC–OL–371	80.592486	–149.338651
ARC–OL–372	80.597228	–149.380276
ARC–OL–373	80.601931	–149.422086
ARC–OL–374	80.606595	–149.464080
ARC–OL–375	80.611220	–149.506259
ARC–OL–376	80.615805	–149.548619
ARC–OL–377	80.619239	–149.580709
ARC–OL–378	80.622709	–149.613419
ARC–OL–379	80.627198	–149.656216
ARC–OL–380	80.631647	–149.699192
ARC–OL–381	80.636055	–149.742343
ARC–OL–382	80.640423	–149.785670
ARC–OL–383	80.644751	–149.829170
ARC–OL–384	80.649037	–149.872842
ARC–OL–385	80.653283	–149.916685
ARC–OL–386	80.657488	–149.960698
ARC–OL–387	80.661652	–150.004878
ARC–OL–388	80.665774	–150.049225
ARC–OL–389	80.669854	–150.093737
ARC–OL–390	80.673893	–150.138413
ARC–OL–391	80.677890	–150.183251
ARC–OL–392	80.681845	–150.228249
ARC–OL–393	80.685758	–150.273407
ARC–OL–394	80.689629	–150.318722

Outer limit point	Latitude	Longitude
ARC–OL–395	80.693457	–150.364193
ARC–OL–396	80.697242	–150.409819
ARC–OL–397	80.700985	–150.455598
ARC–OL–398	80.704685	–150.501529
ARC–OL–399	80.708342	–150.547609
ARC–OL–400	80.711955	–150.593837
ARC–OL–401	80.715526	–150.640213
ARC–OL–402	80.719052	–150.686733
ARC–OL–403	80.722536	–150.733397
ARC–OL–404	80.725975	–150.780203
ARC–OL–405	80.729371	–150.827149
ARC–OL–406	80.732722	–150.874233
ARC–OL–407	80.736030	–150.921455
ARC–OL–408	80.739293	–150.968812
ARC–OL–409	80.742512	–151.016302
ARC–OL–410	80.745686	–151.063924
ARC–OL–411	80.748816	–151.111676
ARC–OL–412	80.751901	–151.159557
ARC–OL–413	80.754941	–151.207565
ARC–OL–414	80.757936	–151.255697
ARC–OL–415	80.760886	–151.303953
ARC–OL–416	80.763791	–151.352330
ARC–OL–417	80.766650	–151.400826
ARC–OL–418	80.769464	–151.449441
ARC–OL–419	80.772232	–151.498172
ARC–OL–420	80.774954	–151.547017
ARC–OL–421	80.777631	–151.595975
ARC–OL–422	80.780262	–151.645043
ARC–OL–423	80.782847	–151.694221
ARC–OL–424	80.785386	–151.743505
ARC–OL–425	80.787878	–151.792895
ARC–OL–426	80.790324	–151.842388
ARC–OL–427	80.792724	–151.891982
ARC–OL–428	80.795077	–151.941676
ARC–OL–429	80.797384	–151.991468
ARC–OL–430	80.799644	–152.041356
ARC–OL–431	80.801857	–152.091337
ARC–OL–432	80.804024	–152.141411
ARC–OL–433	80.806143	–152.191575
ARC–OL–434	80.808215	–152.241827
ARC–OL–435	80.810240	–152.292166
ARC–OL–436	80.812218	–152.342589
ARC–OL–437	80.814149	–152.393094
ARC–OL–438	80.816032	–152.443680
ARC–OL–439	80.817868	–152.494344
ARC–OL–440	80.819657	–152.545085
ARC–OL–441	80.821397	–152.595901
ARC–OL–442	80.823090	–152.646789
ARC–OL–443	80.824736	–152.697748
ARC–OL–444	80.826333	–152.748776
ARC–OL–445	80.827883	–152.799870
ARC–OL–446	80.829385	–152.851029
ARC–OL–447	80.830839	–152.902251
ARC–OL–448	80.832244	–152.953533
ARC–OL–449	80.833602	–153.004874
ARC–OL–450	80.834912	–153.056272
ARC–OL–451	80.836173	–153.107724
ARC–OL–452	80.837386	–153.159229
ARC–OL–453	80.838551	–153.210785
ARC–OL–454	80.839667	–153.262389
ARC–OL–455	80.840735	–153.314039
ARC–OL–456	80.841754	–153.365734
ARC–OL–457	80.842725	–153.417472
ARC–OL–458	80.843648	–153.469249
ARC–OL–459	80.844522	–153.521065
ARC–OL–460	80.845347	–153.572918
ARC–OL–461	80.846124	–153.624804
ARC–OL–462	80.846852	–153.676723
ARC–OL–463	80.847531	–153.728671
ARC–OL–464	80.848162	–153.780648
ARC–OL–465	80.848744	–153.832650
ARC–OL–466	80.849277	–153.884676
ARC–OL–467	80.849761	–153.936724
ARC–OL–468	80.850196	–153.988791
ARC–OL–469	80.850583	–154.040876
ARC–OL–470	80.850921	–154.092977
ARC–OL–471	80.851210	–154.145091
ARC–OL–472	80.851450	–154.197216
ARC–OL–473	80.851641	–154.249351
ARC–OL–474	80.851783	–154.301492
ARC–OL–475	80.851877	–154.353639
ARC–OL–476	80.851921	–154.405788
ARC–OL–477	80.851917	–154.457939
ARC–OL–478	80.851863	–154.510088
ARC–OL–479	80.851761	–154.562234
ARC–OL–480	80.851610	–154.614374
ARC–OL–481	80.851410	–154.666507
ARC–OL–482	80.851161	–154.718630
ARC–OL–483	80.850863	–154.770742
ARC–OL–484	80.850517	–154.822840
ARC–OL–485	80.850121	–154.874922
ARC–OL–486	80.849677	–154.926986
ARC–OL–487	80.849184	–154.979030
ARC–OL–488	80.848642	–155.031052
ARC–OL–489	80.848051	–155.083050
ARC–OL–490	80.847412	–155.135021
ARC–OL–491	80.846723	–155.186965
ARC–OL–492	80.845987	–155.238877
ARC–OL–493	80.845201	–155.290758
ARC–OL–494	80.844367	–155.342604
ARC–OL–495	80.843484	–155.394413
ARC–OL–496	80.842553	–155.446183
ARC–OL–497	80.841573	–155.497913
ARC–OL–498	80.840545	–155.549600
ARC–OL–499	81.380045	–160.923666
ARC–OL–500	81.387954	–160.940313
ARC–OL–501	81.395849	–160.957254
ARC–OL–502	81.403730	–160.974489
ARC–OL–503	81.411598	–160.992020
ARC–OL–504	81.419452	–161.009846
ARC–OL–505	81.427291	–161.027967
ARC–OL–506	81.435116	–161.046384
ARC–OL–507	81.442927	–161.065097
ARC–OL–508	81.450722	–161.084106
ARC–OL–509	81.458502	–161.103411
ARC–OL–510	81.466267	–161.123013
ARC–OL–511	81.474016	–161.142913
ARC–OL–512	81.481749	–161.163109
ARC–OL–513	81.489467	–161.183602
ARC–OL–514	81.497167	–161.204393
ARC–OL–515	81.504851	–161.225482
ARC–OL–516	81.512519	–161.246868
ARC–OL–517	81.520169	–161.268553
ARC–OL–518	81.527802	–161.290535
ARC–OL–519	81.535417	–161.312815
ARC–OL–520	81.543015	–161.335394
ARC–OL–521	81.550594	–161.358271
ARC–OL–522	81.558156	–161.381447
ARC–OL–523	81.565699	–161.404921
ARC–OL–524	81.573223	–161.428694
ARC–OL–525	81.580728	–161.452765
ARC–OL–526	81.588214	–161.477135
ARC–OL–527	81.595680	–161.501804
ARC–OL–528	81.603127	–161.526772
ARC–OL–529	81.610553	–161.552038
ARC–OL–530	81.617960	–161.577602
ARC–OL–531	81.625346	–161.603466
ARC–OL–532	81.632712	–161.629628
ARC–OL–533	81.640057	–161.656088
ARC–OL–534	81.647380	–161.682847
ARC–OL–535	81.654682	–161.709905
ARC–OL–536	81.661963	–161.737261
ARC–OL–537	81.669222	–161.764914
ARC–OL–538	81.676458	–161.792866
ARC–OL–539	81.683673	–161.821116
ARC–OL–540	81.690865	–161.849664
ARC–OL–541	81.698034	–161.878509
ARC–OL–542	81.705180	–161.907651
ARC–OL–543	81.712302	–161.937091
ARC–OL–544	81.719402	–161.966828
ARC–OL–545	81.726477	–161.996861
ARC–OL–546	81.733529	–162.027191
ARC–OL–547	81.740556	–162.057817
ARC–OL–548	81.747559	–162.088739
ARC–OL–549	81.754537	–162.119957
ARC–OL–550	81.761490	–162.151470
ARC–OL–551	81.768418	–162.183278
ARC–OL–552	81.775321	–162.215381
ARC–OL–553	81.782198	–162.247778
ARC–OL–554	81.789049	–162.280470
ARC–OL–555	81.795874	–162.313455
ARC–OL–556	81.846851	–162.563618
ARC–OL–557	81.853632	–162.597286
ARC–OL–558	81.860386	–162.631249
ARC–OL–559	81.867112	–162.665506
ARC–OL–560	81.873812	–162.700056
ARC–OL–561	81.880484	–162.734900
ARC–OL–562	81.887128	–162.770036
ARC–OL–563	81.893744	–162.805464
ARC–OL–564	81.897623	–162.826441
ARC–OL–565	81.903539	–162.858724
ARC–OL–566	81.910086	–162.894871
ARC–OL–567	81.916604	–162.931308
ARC–OL–568	81.928118	–162.995926
ARC–OL–569	81.934624	–163.032555
ARC–OL–570	81.941100	–163.069474
ARC–OL–571	81.947547	–163.106682
ARC–OL–572	81.953965	–163.144179
ARC–OL–573	81.960352	–163.181965
ARC–OL–574	81.966710	–163.220038
ARC–OL–575	81.973038	–163.258397
ARC–OL–576	81.979335	–163.297043
ARC–OL–577	81.985601	–163.335974
ARC–OL–578	81.991837	–163.375189
ARC–OL–579	81.998041	–163.414689
ARC–OL–580	82.004214	–163.454472
ARC–OL–581	82.010355	–163.494536
ARC–OL–582	82.015663	–163.529562
ARC–OL–583	82.021157	–163.566201
ARC–OL–584	82.027210	–163.607042
ARC–OL–585	82.033230	–163.648161
ARC–OL–586	82.039218	–163.689559
ARC–OL–587	82.045173	–163.731234
ARC–OL–588	82.051095	–163.773186
ARC–OL–589	82.056983	–163.815413
ARC–OL–590	82.062838	–163.857915
ARC–OL–591	82.068660	–163.900691
ARC–OL–592	82.074447	–163.943739
ARC–OL–593	82.080200	–163.987059
ARC–OL–594	82.085918	–164.030649
ARC–OL–595	82.091052	–164.070243
ARC–OL–596	82.096573	–164.113284
ARC–OL–597	82.102193	–164.157634
ARC–OL–598	82.107778	–164.202251
ARC–OL–599	82.113328	–164.247133
ARC–OL–600	82.118841	–164.292279
ARC–OL–601	82.124319	–164.337689
ARC–OL–602	82.129761	–164.383360
ARC–OL–603	82.135166	–164.429292
ARC–OL–604	82.140535	–164.475483
ARC–OL–605	82.145867	–164.521933
ARC–OL–606	82.151162	–164.568639
ARC–OL–607	82.156420	–164.615602
ARC–OL–608	82.161641	–164.662818
ARC–OL–609	82.166824	–164.710288
ARC–OL–610	82.171969	–164.758010
ARC–OL–611	82.177077	–164.805981
ARC–OL–612	82.182146	–164.854202
ARC–OL–613	82.187177	–164.902671
ARC–OL–614	82.192169	–164.951385
ARC–OL–615	82.197123	–165.000345
ARC–OL–616	82.202037	–165.049548

Outer limit point	Latitude	Longitude
ARC–OL–617	82.225057	–165.281850
ARC–OL–618	82.229906	–165.331576
ARC–OL–619	82.234717	–165.381543
ARC–OL–620	82.239487	–165.431749
ARC–OL–621	82.244218	–165.482191
ARC–OL–622	82.248909	–165.532869
ARC–OL–623	82.253559	–165.583781
ARC–OL–624	82.258169	–165.634925
ARC–OL–625	82.262738	–165.686300
ARC–OL–626	82.267267	–165.737904
ARC–OL–627	82.271754	–165.789736
ARC–OL–628	82.276200	–165.841793
ARC–OL–629	82.280605	–165.894074
ARC–OL–630	82.284968	–165.946577
ARC–OL–631	82.338352	–166.600594
ARC–OL–632	82.342592	–166.654048
ARC–OL–633	82.346791	–166.707719
ARC–OL–634	82.350947	–166.761605
ARC–OL–635	82.355060	–166.815704
ARC–OL–636	82.357659	–166.850288
ARC–OL–637	82.361563	–166.902798
ARC–OL–638	82.365568	–166.957432
ARC–OL–639	82.369529	–167.012272
ARC–OL–640	82.373447	–167.067317
ARC–OL–641	82.377321	–167.122564
ARC–OL–642	82.381152	–167.178013
ARC–OL–643	82.384938	–167.233660
ARC–OL–644	82.388681	–167.289504
ARC–OL–645	82.392379	–167.345543
ARC–OL–646	82.395905	–167.399788
ARC–OL–647	82.397903	–167.430800
ARC–OL–648	82.401499	–167.487285
ARC–OL–649	82.405051	–167.543958
ARC–OL–650	82.408557	–167.600817
ARC–OL–651	82.412019	–167.657859
ARC–OL–652	82.415435	–167.715083
ARC–OL–653	82.418806	–167.772487
ARC–OL–654	82.422131	–167.830068
ARC–OL–655	82.425411	–167.887824
ARC–OL–656	82.428645	–167.945753
ARC–OL–657	82.431833	–168.003852
ARC–OL–658	82.434975	–168.062120
ARC–OL–659	82.438071	–168.120555
ARC–OL–660	82.441121	–168.179153
ARC–OL–661	82.444124	–168.237913
ARC–OL–662	82.447081	–168.296833
ARC–OL–663	82.449991	–168.355909
ARC–OL–664	82.452854	–168.415141
ARC–OL–665	82.455670	–168.474525
ARC–OL–666	82.458440	–168.534058
ARC–OL–667	82.461162	–168.593740
ARC–OL–668	82.463836	–168.653567
ARC–OL–669	82.466464	–168.713537
ARC–OL–670	82.469044	–168.773647
ARC–OL–671	82.471576	–168.833895
ARC–OL–672	82.474060	–168.894280
ARC–OL–673	82.476497	–168.954797
ARC–OL–674	82.477370	–168.976944

ARC–OL–001 is located on the 200 nautical mile limit of Canada. ARC–OL–674 is located on the maritime boundary set forth in the U.S.-Russia maritime boundary agreement of 1990.[2] From ARC–OL–674, the outer limits of the U.S. continental shelf extend south along the 168°58′37″ W meridian, consistent with the U.S.-Russia maritime boundary agreement of 1990.

Atlantic (East Coast)

In the Atlantic (East Coast), the outer limits of the continental shelf are defined by straight lines connecting the following fixed points:

Outer limit point	Latitude	Longitude
ATL–OL–001	38.905000	–64.392292
ATL–OL–002	38.626417	–64.620030
ATL–OL–003	38.331444	–65.557815
ATL–OL–004	37.877221	–66.116298
ATL–OL–005	37.260735	–66.992063
ATL–OL–006	37.081071	–67.431569
ATL–OL–007	37.019608	–67.621243
ATL–OL–008	36.644833	–68.758685
ATL–OL–009	36.181790	–69.314812
ATL–OL–010	35.509520	–70.078668
ATL–OL–011	34.931101	–70.828741
ATL–OL–012	34.206847	–71.497220
ATL–OL–013	33.385252	–72.029324
ATL–OL–014	33.276756	–71.999232
ATL–OL–015	32.364559	–72.413228
ATL–OL–016	31.403007	–72.082675
ATL–OL–017	31.196463	–71.776196
ATL–OL–018	30.447158	–71.520658
ATL–OL–019	29.919863	–72.351233
ATL–OL–020	29.914941	–72.358940
ATL–OL–021	29.910001	–72.366672
ATL–OL–022	29.905097	–72.374394
ATL–OL–023	29.900175	–72.382141
ATL–OL–024	29.895289	–72.389876
ATL–OL–025	29.890386	–72.397638
ATL–OL–026	29.885518	–72.405388
ATL–OL–027	29.880633	–72.413164
ATL–OL–028	29.875784	–72.420929
ATL–OL–029	29.870917	–72.428719
ATL–OL–030	29.866086	–72.436498
ATL–OL–031	29.861238	–72.444303
ATL–OL–032	29.856425	–72.452095
ATL–OL–033	29.851595	–72.459915
ATL–OL–034	29.846801	–72.467722
ATL–OL–035	29.841990	–72.475555
ATL–OL–036	29.837214	–72.483376
ATL–OL–037	29.832421	–72.491224
ATL–OL–038	29.827664	–72.499059
ATL–OL–039	29.822889	–72.506920
ATL–OL–040	29.818150	–72.514770
ATL–OL–041	29.813395	–72.522645
ATL–OL–042	29.808674	–72.530508
ATL–OL–043	29.803937	–72.538398
ATL–OL–044	29.799235	–72.546275
ATL–OL–045	29.794517	–72.554178
ATL–OL–046	29.789834	–72.562069
ATL–OL–047	29.785134	–72.569987
ATL–OL–048	29.780469	–72.577891
ATL–OL–049	29.775788	–72.585822
ATL–OL–050	29.771142	–72.593741
ATL–OL–051	29.766479	–72.601686
ATL–OL–052	29.761852	–72.609618
ATL–OL–053	29.757208	–72.617576
ATL–OL–054	29.752600	–72.625522
ATL–OL–055	29.747975	–72.633494
ATL–OL–056	29.743385	–72.641453
ATL–OL–057	29.738779	–72.649439
ATL–OL–058	29.734208	–72.657411
ATL–OL–059	29.729621	–72.665411
ATL–OL–060	29.725069	–72.673397
ATL–OL–061	29.720501	–72.681410
ATL–OL–062	29.715967	–72.689409
ATL–OL–063	29.711418	–72.697435
ATL–OL–064	29.706903	–72.705448
ATL–OL–065	29.702373	–72.713487
ATL–OL–066	29.697878	–72.721513
ATL–OL–067	29.693366	–72.729566
ATL–OL–068	29.688890	–72.737605
ATL–OL–069	29.684397	–72.745671
ATL–OL–070	29.679940	–72.753723
ATL–OL–071	29.675466	–72.761802
ATL–OL–072	29.671027	–72.769867
ATL–OL–073	29.666573	–72.777960
ATL–OL–074	29.662154	–72.786038
ATL–OL–075	29.657718	–72.794143
ATL–OL–076	29.653318	–72.802234
ATL–OL–077	29.648902	–72.810353
ATL–OL–078	29.644521	–72.818456
ATL–OL–079	29.640124	–72.826588
ATL–OL–080	29.635762	–72.834704
ATL–OL–081	29.631384	–72.842849
ATL–OL–082	29.627041	–72.850978
ATL–OL–083	29.622682	–72.859135
ATL–OL–084	29.618359	–72.867277
ATL–OL–085	29.614019	–72.875447
ATL–OL–086	29.609715	–72.883602
ATL–OL–087	29.605395	–72.891784
ATL–OL–088	29.601110	–72.899952
ATL–OL–089	29.596809	–72.908147
ATL–OL–090	29.592543	–72.916327
ATL–OL–091	29.588262	–72.924534
ATL–OL–092	29.584015	–72.932727
ATL–OL–093	29.579753	–72.940947
ATL–OL–094	29.575526	–72.949152
ATL–OL–095	29.571283	–72.957384
ATL–OL–096	29.567076	–72.965602
ATL–OL–097	29.562852	–72.973847
ATL–OL–098	29.558664	–72.982076
ATL–OL–099	29.554460	–72.990333
ATL–OL–100	29.550291	–72.998575
ATL–OL–101	29.546107	–73.006845
ATL–OL–102	29.541958	–73.015098
ATL–OL–103	29.537793	–73.023380
ATL–OL–104	29.533663	–73.031646
ATL–OL–105	29.529518	–73.039940
ATL–OL–106	29.525408	–73.048218
ATL–OL–107	29.521282	–73.056524
ATL–OL–108	29.517191	–73.064814
ATL–OL–109	29.513085	–73.073132
ATL–OL–110	29.509014	–73.081434
ATL–OL–111	29.504928	–73.089764
ATL–OL–112	29.500876	–73.098078
ATL–OL–113	29.496810	–73.106420
ATL–OL–114	29.492777	–73.114745
ATL–OL–115	29.488731	–73.123099
ATL–OL–116	29.484718	–73.131437
ATL–OL–117	29.480691	–73.139802
ATL–OL–118	29.476698	–73.148151
ATL–OL–119	29.472691	–73.156529
ATL–OL–120	29.468718	–73.164889
ATL–OL–121	29.464731	–73.173278
ATL–OL–122	29.460777	–73.181651
ATL–OL–123	29.456810	–73.190051
ATL–OL–124	29.452876	–73.198435
ATL–OL–125	29.448928	–73.206847
ATL–OL–126	29.445015	–73.215242
ATL–OL–127	29.441087	–73.223666
ATL–OL–128	29.437193	–73.232072
ATL–OL–129	29.433285	–73.240508
ATL–OL–130	29.429411	–73.248925
ATL–OL–131	29.425523	–73.257372
ATL–OL–132	28.521200	–73.746301
ATL–OL–133	28.513049	–73.744375
ATL–OL–134	28.504870	–73.742443
ATL–OL–135	28.496714	–73.740545

[2] Agreement between the United States of America and the Union of Soviet Socialist Republics on the Maritime Boundary, signed June 1, 1990, Senate Treaty Doc. 102–22, and applied provisionally by agreement, effective June 15, 1990, TIAS 11451. (The Russian Federation is the successor of the USSR with respect to the 1990 Agreement and the agreement to provisionally apply it.)

Outer limit point	Latitude	Longitude
ATL–OL–136	28.488530	–73.738640
ATL–OL–137	28.480369	–73.736768
ATL–OL–138	28.472180	–73.734890
ATL–OL–139	28.464015	–73.733045
ATL–OL–140	28.455821	–73.731194
ATL–OL–141	28.447651	–73.729376
ATL–OL–142	28.439453	–73.727552
ATL–OL–143	28.431279	–73.725760
ATL–OL–144	28.423076	–73.723963
ATL–OL–145	28.414896	–73.722199
ATL–OL–146	28.406689	–73.720428
ATL–OL–147	28.398505	–73.718691
ATL–OL–148	28.390293	–73.716947
ATL–OL–149	28.382105	–73.715237
ATL–OL–150	28.373889	–73.713520
ATL–OL–151	28.365697	–73.711836
ATL–OL–152	28.357476	–73.710147
ATL–OL–153	28.349279	–73.708490
ATL–OL–154	28.341054	–73.706827
ATL–OL–155	28.332853	–73.705197
ATL–OL–156	28.324624	–73.703561
ATL–OL–157	28.316419	–73.701958
ATL–OL–158	28.308186	–73.700349
ATL–OL–159	28.299977	–73.698772
ATL–OL–160	28.291740	–73.697191
ATL–OL–161	28.283527	–73.695641
ATL–OL–162	28.275285	–73.694086
ATL–OL–163	28.267068	–73.692563
ATL–OL–164	28.258823	–73.691036
ATL–OL–165	28.250602	–73.689540
ATL–OL–166	28.242353	–73.688039
ATL–OL–167	28.234128	–73.686569
ATL–OL–168	28.225875	–73.685095
ATL–OL–169	28.217647	–73.683653
ATL–OL–170	28.209390	–73.682206
ATL–OL–171	28.201158	–73.680791
ATL–OL–172	28.192898	–73.679370
ATL–OL–173	28.184663	–73.677982
ATL–OL–174	28.176399	–73.676589
ATL–OL–175	28.168160	–73.675227
ATL–OL–176	28.160232	–73.673917

ATL–OL–001 is located on a seaward extension of the maritime boundary between the United States and Canada delimited by a chamber of the International Court of Justice in 1984.[3] ATL–OL–176 is located on the 200 nautical mile limit of The Bahamas.

Bering Sea

In the Bering Sea, the outer limits of the continental shelf are defined by lines and arcs connecting the following fixed points:

Outer limit point	Latitude	Longitude
BER–OL–001	60.194167	–179.780278
BER–OL–002	59.972778	–179.681944
BER–OL–003	58.955000	178.566389
BER–OL–004	58.970556	178.251389
BER–OL–005	58.966111	178.243611
BER–OL–006	58.801667	177.970556
BER–OL–007	58.636667	177.698056
BER–OL–008	58.471111	177.426111
BER–OL–009	58.304722	177.155000
BER–OL–010	58.137500	176.884444
BER–OL–011	57.969722	176.614444
BER–OL–012	57.801111	176.345278
BER–OL–013	57.631667	176.076389
BER–OL–014	57.461667	175.808611
BER–OL–015	57.291111	175.541111
BER–OL–016	57.119722	175.274167
BER–OL–017	56.947500	175.008056
BER–OL–018	56.774722	174.742222
BER–OL–019	56.601111	174.477222
BER–OL–020	56.426944	174.212778
BER–OL–021	56.251944	173.948889

Outer limit points BER–OL–001 to BER–OL–021 correspond to boundary points 36 to 56 of the U.S.-Russia boundary agreement of 1990.[4] Consistent with that agreement:

- Between BER–OL–001 and BER–OL–002, the outer limit ''extends along an arc with a radius of 200 nautical miles and a center at 60°38′23″ N, 173°06′54″ W.''
- Between BER–OL–002 and BER–OL–003, the outer limit ''extends . . . along the rhumb line, defined by the following points: 64°05′08″ N, 172°00′00″ W, 53°43′42″ N, 170°18′31″ E.''
- Between BER–OL–003 and BER–OL–004, the outer limit ''extends along an arc with a radius of 200 nautical miles and a center at 62°16′09″ N, 179°05′34″ E.''
- Outer limit points BER–OL–004 to BER–OL–021 are connected by straight lines.

Eastern Gulf of Mexico

In the Eastern Gulf of Mexico, the outer limits of the continental shelf are defined by straight lines connecting the following fixed points:

Outer limit point	Latitude	Longitude
GME–OL–001	25.699417	–88.384894
GME–OL–002	25.698383	–88.334067
GME–OL–003	25.685397	–88.171717
GME–OL–004	25.667461	–87.952567
GME–OL–005	25.613831	–87.325197
GME–OL–006	25.590275	–87.051397
GME–OL–007	25.487900	–87.013733
GME–OL–008	25.207300	–86.553308

Outer limit points GME–OL–001 to GME–OL–007 correspond to boundary points 1 to 7 of the 2017 U.S.-Mexico maritime boundary treaty.[5] Outer limit points GME–OL–008 and GME–OL–007 correspond to boundary points 1 and 2 of the 2017 U.S.-Cuba maritime boundary treaty.[6]

Western Gulf of Mexico

In the Western Gulf of Mexico, the outer limits of the continental shelf are defined by straight lines connecting the following fixed points:

Outer limit point	Latitude	Longitude
GMW–OL–001	25.997028	–93.445139
GMW–OL–002	25.907611	–93.252750
GMW–OL–003	25.864167	–93.167500
GMW–OL–004	25.812556	–93.066361
GMW–OL–005	25.776083	–92.994861
GMW–OL–006	25.710333	–92.954444
GMW–OL–007	25.674250	–92.932222
GMW–OL–008	25.667556	–92.779111
GMW–OL–009	25.656611	–92.537139
GMW–OL–010	25.656194	–92.527889
GMW–OL–011	25.637056	–92.133139
GMW–OL–012	25.630750	–92.009861
GMW–OL–013	25.617000	–91.738639
GMW–OL–014	25.612833	–91.658167
GMW–OL–015	25.661972	–91.342000
GMW–OL–016	25.703917	–91.090278

Outer limit points GMW–OL–001 to GMW–OL–016 correspond to the 16 boundary points set forth in the 2000 U.S.-Mexico maritime boundary treaty.[7] Coordinates are in North American Datum 1983 (NAD 83), which are considered equivalent to WGS 84 for purposes of delineating the outer limits of the U.S. continental shelf.

Mariana Islands

In the area northeast of the Mariana Islands, the outer limits of the continental shelf are defined by a straight line connecting the following fixed points:

Outer limit point	Latitude	Longitude
MAR–OL–001	24.316155	145.120626
MAR–OL–002	23.816920	145.683481

Outer limit point MAR–OL–001 is located on the 200 nautical mile limit of Japan. Outer limit point MAR–OL–002 is located on the 200 nautical mile (exclusive economic zone) limit of the United States.

[3] Delimitation of the Maritime Boundary in the Gulf of Maine Area, 1984 I.C.J. Reports 246 (Judgment of Oct. 12, 1984). The boundary delimited by a chamber of International Court of Justice does not extend beyond 200 nautical miles from the baseline from which the breadth of the U.S. territorial sea is measured. For purposes of delineating its continental shelf limits in areas beyond 200 nautical miles, the United States has computed a seaward extension of the Chamber's delimitation line in the area beyond 200 nautical miles from the U.S. baseline, maintaining the same southeasterly trajectory.

[4] For U.S.-Russia maritime boundary agreement, see note 2.

[5] Treaty between the Government of the United States of America and the Government of the United Mexican States on the Delimitation of the Maritime Boundary in the Eastern Gulf of Mexico, signed January 18, 2017, not in force.

[6] Treaty between the United States of America and the Republic of Cuba on the Delimitation of the Continental Shelf in the Eastern Gulf of Mexico beyond 200 Nautical Miles, signed January 18, 2017, and applied provisionally by agreement, effective January 18, 2017.

[7] Treaty between the Government of the United States of America and the Government of the United Mexican States on the Delimitation of the Continental Shelf in the Western Gulf of Mexico beyond 200 Nautical Miles, signed June 9, 2000, Treaty Doc. 106–39, entered into force January 17, 2001, TIAS 01–117.

Pacific (West Coast)

In the Pacific (West Coast), the outer limits of the continental shelf are defined by straight lines connecting the following fixed points:

Outer limit point	Latitude	Longitude
PAC–OL–001	41.422234	–128.787324
PAC–OL–002	41.356271	–129.353869
PAC–OL–003	41.354928	–129.364791
PAC–OL–004	41.353516	–129.375696
PAC–OL–005	41.352034	–129.386585
PAC–OL–006	41.350483	–129.397457
PAC–OL–007	41.348862	–129.408311
PAC–OL–008	41.347173	–129.419146
PAC–OL–009	41.345414	–129.429961
PAC–OL–010	41.343587	–129.440756
PAC–OL–011	41.341691	–129.451530
PAC–OL–012	41.339726	–129.462282
PAC–OL–013	41.337693	–129.473011
PAC–OL–014	41.335592	–129.483716
PAC–OL–015	41.333422	–129.494397
PAC–OL–016	41.331185	–129.505053
PAC–OL–017	41.328879	–129.515684
PAC–OL–018	41.326506	–129.526287
PAC–OL–019	41.324065	–129.536863
PAC–OL–020	41.321558	–129.547412
PAC–OL–021	41.318983	–129.557931
PAC–OL–022	41.316341	–129.568420
PAC–OL–023	41.313632	–129.578879
PAC–OL–024	41.310857	–129.589307
PAC–OL–025	41.308015	–129.599703
PAC–OL–026	41.305107	–129.610066
PAC–OL–027	41.302134	–129.620396
PAC–OL–028	41.299094	–129.630692
PAC–OL–029	41.295989	–129.640953
PAC–OL–030	41.292819	–129.651178
PAC–OL–031	41.289584	–129.661367
PAC–OL–032	41.286284	–129.671518
PAC–OL–033	41.282919	–129.681632
PAC–OL–034	41.279490	–129.691707
PAC–OL–035	41.275997	–129.701743
PAC–OL–036	41.272440	–129.711739
PAC–OL–037	41.268819	–129.721694
PAC–OL–038	41.265135	–129.731608
PAC–OL–039	41.261389	–129.741479
PAC–OL–040	41.257579	–129.751308
PAC–OL–041	41.253707	–129.761093
PAC–OL–042	41.249772	–129.770834
PAC–OL–043	41.245776	–129.780530
PAC–OL–044	41.241718	–129.790181
PAC–OL–045	41.237599	–129.799784
PAC–OL–046	41.233418	–129.809341
PAC–OL–047	41.229177	–129.818851
PAC–OL–048	41.224876	–129.828312
PAC–OL–049	41.220514	–129.837723
PAC–OL–050	41.216092	–129.847085
PAC–OL–051	41.211611	–129.856397
PAC–OL–052	41.207071	–129.865658
PAC–OL–053	41.202472	–129.874867
PAC–OL–054	41.197814	–129.884023
PAC–OL–055	41.193098	–129.893127
PAC–OL–056	41.188325	–129.902177
PAC–OL–057	41.183494	–129.911172
PAC–OL–058	41.178605	–129.920113
PAC–OL–059	41.173660	–129.928998
PAC–OL–060	41.168658	–129.937827
PAC–OL–061	41.163601	–129.946599
PAC–OL–062	41.158487	–129.955314
PAC–OL–063	41.153319	–129.963971
PAC–OL–064	41.148095	–129.972569
PAC–OL–065	41.142816	–129.981108
PAC–OL–066	41.137484	–129.989587
PAC–OL–067	41.132097	–129.998005
PAC–OL–068	41.126657	–130.006363
PAC–OL–069	41.121164	–130.014659
PAC–OL–070	41.115619	–130.022892
PAC–OL–071	41.110021	–130.031063
PAC–OL–072	41.104371	–130.039171
PAC–OL–073	41.098670	–130.047214
PAC–OL–074	41.092917	–130.055193
PAC–OL–075	41.087115	–130.063107
PAC–OL–076	41.081261	–130.070956
PAC–OL–077	41.075358	–130.078738
PAC–OL–078	41.069406	–130.086454
PAC–OL–079	41.063404	–130.094103
PAC–OL–080	41.057355	–130.101683
PAC–OL–081	41.051257	–130.109196
PAC–OL–082	41.045111	–130.116640
PAC–OL–083	41.038918	–130.124014
PAC–OL–084	41.032678	–130.131319
PAC–OL–085	41.026392	–130.138553
PAC–OL–086	41.020060	–130.145717
PAC–OL–087	41.013683	–130.152809
PAC–OL–088	41.007261	–130.159830
PAC–OL–089	41.000794	–130.166778
PAC–OL–090	40.994283	–130.173654
PAC–OL–091	40.987729	–130.180456
PAC–OL–092	40.981131	–130.187185
PAC–OL–093	40.974491	–130.193840
PAC–OL–094	40.967808	–130.200420
PAC–OL–095	40.961084	–130.206925
PAC–OL–096	40.954319	–130.213354
PAC–OL–097	40.947513	–130.219708
PAC–OL–098	40.940667	–130.225985
PAC–OL–099	40.933780	–130.232186
PAC–OL–100	40.926855	–130.238310
PAC–OL–101	40.919891	–130.244355
PAC–OL–102	40.912888	–130.250323
PAC–OL–103	40.905848	–130.256213
PAC–OL–104	40.898771	–130.262024
PAC–OL–105	40.891656	–130.267755
PAC–OL–106	40.884506	–130.273407
PAC–OL–107	40.877319	–130.278980
PAC–OL–108	40.870098	–130.284472
PAC–OL–109	40.862841	–130.289883
PAC–OL–110	40.855551	–130.295213
PAC–OL–111	40.848226	–130.300462
PAC–OL–112	40.840869	–130.305629
PAC–OL–113	40.833479	–130.310714
PAC–OL–114	40.826056	–130.315717
PAC–OL–115	40.818602	–130.320637
PAC–OL–116	40.811117	–130.325474
PAC–OL–117	40.803602	–130.330228
PAC–OL–118	40.796056	–130.334898
PAC–OL–119	40.788481	–130.339484
PAC–OL–120	40.780877	–130.343986
PAC–OL–121	40.773244	–130.348403
PAC–OL–122	40.765584	–130.352736
PAC–OL–123	40.524405	–130.486030
PAC–OL–124	40.516695	–130.490195
PAC–OL–125	40.508959	–130.494274
PAC–OL–126	40.501198	–130.498268
PAC–OL–127	40.493410	–130.502176
PAC–OL–128	40.485599	–130.505998
PAC–OL–129	40.477763	–130.509734
PAC–OL–130	40.469903	–130.513384
PAC–OL–131	40.462020	–130.516946
PAC–OL–132	40.454115	–130.520422
PAC–OL–133	40.446188	–130.523810
PAC–OL–134	40.438240	–130.527112
PAC–OL–135	40.430270	–130.530325
PAC–OL–136	40.422281	–130.533451
PAC–OL–137	40.414271	–130.536489
PAC–OL–138	40.406243	–130.539439
PAC–OL–139	40.398196	–130.542300
PAC–OL–140	40.390131	–130.545073
PAC–OL–141	40.382048	–130.547758
PAC–OL–142	40.373948	–130.550353
PAC–OL–143	40.365833	–130.552860
PAC–OL–144	40.357701	–130.555277
PAC–OL–145	40.349554	–130.557606
PAC–OL–146	40.341393	–130.559845
PAC–OL–147	40.333217	–130.561994
PAC–OL–148	40.325029	–130.564054
PAC–OL–149	40.316827	–130.566024
PAC–OL–150	40.308613	–130.567905
PAC–OL–151	40.300387	–130.569695
PAC–OL–152	40.292150	–130.571395
PAC–OL–153	40.283902	–130.573006
PAC–OL–154	40.275644	–130.574526
PAC–OL–155	40.267377	–130.575956
PAC–OL–156	40.259101	–130.577296
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PAC–OL–158	40.242525	–130.579704
PAC–OL–159	40.234226	–130.580772
PAC–OL–160	40.225920	–130.581750
PAC–OL–161	40.217609	–130.582637
PAC–OL–162	40.209292	–130.583434
PAC–OL–163	40.200970	–130.584140
PAC–OL–164	40.192644	–130.584755
PAC–OL–165	40.184314	–130.585280
PAC–OL–166	40.175981	–130.585714
PAC–OL–167	40.167646	–130.586058
PAC–OL–168	40.159309	–130.586311
PAC–OL–169	40.150970	–130.586473
PAC–OL–170	40.142631	–130.586545
PAC–OL–171	40.134291	–130.586527
PAC–OL–172	40.125952	–130.586417
PAC–OL–173	40.117614	–130.586218
PAC–OL–174	40.109277	–130.585927
PAC–OL–175	40.100943	–130.585547
PAC–OL–176	40.092611	–130.585076
PAC–OL–177	40.084283	–130.584515
PAC–OL–178	40.075958	–130.583864
PAC–OL–179	40.067638	–130.583122
PAC–OL–180	40.059323	–130.582291
PAC–OL–181	40.051013	–130.581369
PAC–OL–182	40.042710	–130.580358
PAC–OL–183	40.034413	–130.579257
PAC–OL–184	40.026124	–130.578067
PAC–OL–185	40.017842	–130.576787
PAC–OL–186	40.009569	–130.575417
PAC–OL–187	40.001305	–130.573959
PAC–OL–188	39.993051	–130.572411
PAC–OL–189	39.984807	–130.570774
PAC–OL–190	39.976573	–130.569049
PAC–OL–191	39.968351	–130.567234
PAC–OL–192	39.960141	–130.565332
PAC–OL–193	39.951943	–130.563340
PAC–OL–194	39.943758	–130.561261
PAC–OL–195	39.935587	–130.559094
PAC–OL–196	39.927430	–130.556838
PAC–OL–197	39.919288	–130.554495
PAC–OL–198	39.911160	–130.552065
PAC–OL–199	39.903049	–130.549547
PAC–OL–200	39.894954	–130.546943
PAC–OL–201	39.886876	–130.544251
PAC–OL–202	39.878815	–130.541473
PAC–OL–203	39.870773	–130.538608
PAC–OL–204	39.862749	–130.535657
PAC–OL–205	39.854744	–130.532621
PAC–OL–206	39.846759	–130.529498
PAC–OL–207	39.838794	–130.526290
PAC–OL–208	39.830850	–130.522997
PAC–OL–209	39.822927	–130.519619
PAC–OL–210	39.815026	–130.516156
PAC–OL–211	39.807148	–130.512608
PAC–OL–212	39.799292	–130.508977
PAC–OL–213	39.791460	–130.505261
PAC–OL–214	39.783652	–130.501462
PAC–OL–215	39.775868	–130.497580

Outer limit point	Latitude	Longitude
PAC–OL–216	39.768110	–130.493615
PAC–OL–217	39.760377	–130.489566
PAC–OL–218	39.752670	–130.485436
PAC–OL–219	39.744990	–130.481223
PAC–OL–220	39.737337	–130.476929
PAC–OL–221	39.729712	–130.472553
PAC–OL–222	39.722115	–130.468095
PAC–OL–223	39.714547	–130.463557
PAC–OL–224	39.707009	–130.458939
PAC–OL–225	39.699499	–130.454240
PAC–OL–226	39.692021	–130.449462
PAC–OL–227	39.684573	–130.444604
PAC–OL–228	39.677156	–130.439667
PAC–OL–229	39.669771	–130.434651
PAC–OL–230	39.662419	–130.429557
PAC–OL–231	39.655099	–130.424385
PAC–OL–232	39.647813	–130.419135
PAC–OL–233	39.640560	–130.413808
PAC–OL–234	39.633342	–130.408404
PAC–OL–235	39.626159	–130.402924
PAC–OL–236	39.619010	–130.397367
PAC–OL–237	39.611898	–130.391735
PAC–OL–238	39.604822	–130.386028
PAC–OL–239	39.597783	–130.380245
PAC–OL–240	39.590780	–130.374389
PAC–OL–241	39.583816	–130.368458
PAC–OL–242	39.576890	–130.362454
PAC–OL–243	39.570002	–130.356376
PAC–OL–244	39.563153	–130.350226
PAC–OL–245	39.556344	–130.344004
PAC–OL–246	39.549575	–130.337709
PAC–OL–247	39.542847	–130.331343
PAC–OL–248	39.536159	–130.324907
PAC–OL–249	39.529513	–130.318399
PAC–OL–250	39.522909	–130.311822
PAC–OL–251	39.516347	–130.305175
PAC–OL–252	39.509827	–130.298459
PAC–OL–253	39.503351	–130.291674
PAC–OL–254	39.496919	–130.284822
PAC–OL–255	39.490530	–130.277901
PAC–OL–256	39.484186	–130.270913
PAC–OL–257	39.477887	–130.263859
PAC–OL–258	39.471633	–130.256739
PAC–OL–259	39.465425	–130.249552
PAC–OL–260	39.459263	–130.242301
PAC–OL–261	39.453148	–130.234984
PAC–OL–262	39.447080	–130.227604
PAC–OL–263	39.441059	–130.220160
PAC–OL–264	39.435086	–130.212653
PAC–OL–265	39.429161	–130.205083
PAC–OL–266	39.423284	–130.197451
PAC–OL–267	39.417457	–130.189757
PAC–OL–268	39.411679	–130.182002
PAC–OL–269	39.405951	–130.174187
PAC–OL–270	39.400273	–130.166312
PAC–OL–271	39.394646	–130.158377
PAC–OL–272	39.389070	–130.150384
PAC–OL–273	39.383545	–130.142332
PAC–OL–274	39.378071	–130.134223
PAC–OL–275	39.372650	–130.126056
PAC–OL–276	39.367281	–130.117832
PAC–OL–277	39.361965	–130.109553
PAC–OL–278	39.356702	–130.101218
PAC–OL–279	39.351493	–130.092828
PAC–OL–280	39.346337	–130.084383
PAC–OL–281	39.341235	–130.075885
PAC–OL–282	39.336189	–130.067333
PAC–OL–283	39.331196	–130.058729
PAC–OL–284	39.326260	–130.050073
PAC–OL–285	39.321378	–130.041366
PAC–OL–286	39.316553	–130.032607
PAC–OL–287	39.311784	–130.023799
PAC–OL–288	39.307071	–130.014940
PAC–OL–289	39.302415	–130.006033
PAC–OL–290	39.297816	–129.997077
PAC–OL–291	39.293275	–129.988073
PAC–OL–292	39.288791	–129.979022
PAC–OL–293	39.284365	–129.969925
PAC–OL–294	39.279998	–129.960781
PAC–OL–295	39.275689	–129.951592
PAC–OL–296	39.271440	–129.942359
PAC–OL–297	39.267249	–129.933081
PAC–OL–298	39.263118	–129.923759
PAC–OL–299	39.259047	–129.914395
PAC–OL–300	39.255036	–129.904989
PAC–OL–301	39.251085	–129.895541
PAC–OL–302	39.247195	–129.886052
PAC–OL–303	39.243365	–129.876522
PAC–OL–304	39.239597	–129.866953
PAC–OL–305	39.235890	–129.857345
PAC–OL–306	39.232244	–129.847699
PAC–OL–307	39.228661	–129.838015
PAC–OL–308	39.225139	–129.828294
PAC–OL–309	39.221680	–129.818536
PAC–OL–310	39.218283	–129.808743
PAC–OL–311	39.214949	–129.798914
PAC–OL–312	39.211678	–129.789051
PAC–OL–313	39.208471	–129.779154
PAC–OL–314	39.205326	–129.769224
PAC–OL–315	39.202245	–129.759262
PAC–OL–316	39.199229	–129.749268
PAC–OL–317	39.196276	–129.739243
PAC–OL–318	39.193387	–129.729187
PAC–OL–319	39.190563	–129.719101
PAC–OL–320	39.187803	–129.708987
PAC–OL–321	39.185109	–129.698844
PAC–OL–322	39.182479	–129.688673
PAC–OL–323	39.179914	–129.678475
PAC–OL–324	39.177415	–129.668251
PAC–OL–325	39.174981	–129.658001
PAC–OL–326	39.172613	–129.647726
PAC–OL–327	39.170310	–129.637427
PAC–OL–328	39.168074	–129.627104
PAC–OL–329	39.165904	–129.616759
PAC–OL–330	39.163800	–129.606391
PAC–OL–331	39.161762	–129.596001
PAC–OL–332	39.159791	–129.585591
PAC–OL–333	39.157887	–129.575160
PAC–OL–334	39.156049	–129.564710
PAC–OL–335	39.154278	–129.554241
PAC–OL–336	39.152575	–129.543754
PAC–OL–337	39.150938	–129.533250
PAC–OL–338	39.149369	–129.522729
PAC–OL–339	39.147867	–129.512192
PAC–OL–340	39.146433	–129.501640
PAC–OL–341	39.145066	–129.491073
PAC–OL–342	39.143766	–129.480492
PAC–OL–343	39.142535	–129.469899
PAC–OL–344	39.141371	–129.459292
PAC–OL–345	39.140275	–129.448674
PAC–OL–346	39.139248	–129.438045
PAC–OL–347	39.138288	–129.427406
PAC–OL–348	39.137396	–129.416757
PAC–OL–349	39.136573	–129.406099
PAC–OL–350	39.135817	–129.395433
PAC–OL–351	39.135130	–129.384759
PAC–OL–352	39.134511	–129.374079
PAC–OL–353	39.133961	–129.363392
PAC–OL–354	39.133479	–129.352700
PAC–OL–355	39.133065	–129.342004
PAC–OL–356	39.132720	–129.331303
PAC–OL–357	39.132444	–129.320600
PAC–OL–358	39.132235	–129.309893
PAC–OL–359	39.132096	–129.299185
PAC–OL–360	39.132025	–129.288476
PAC–OL–361	39.132022	–129.277767
PAC–OL–362	39.132088	–129.267058
PAC–OL–363	39.132222	–129.256349
PAC–OL–364	39.132425	–129.245643
PAC–OL–365	39.132697	–129.234939
PAC–OL–366	39.133036	–129.224238
PAC–OL–367	39.133445	–129.213542
PAC–OL–368	39.133921	–129.202849
PAC–OL–369	39.134466	–129.192162
PAC–OL–370	39.135080	–129.181481
PAC–OL–371	39.135762	–129.170807
PAC–OL–372	39.136512	–129.160141
PAC–OL–373	39.137330	–129.149482
PAC–OL–374	39.138216	–129.138832
PAC–OL–375	39.139171	–129.128192
PAC–OL–376	39.140194	–129.117562
PAC–OL–377	39.141284	–129.106943
PAC–OL–378	39.142443	–129.096336
PAC–OL–379	39.143669	–129.085741
PAC–OL–380	39.144963	–129.075160
PAC–OL–381	39.146324	–129.064592
PAC–OL–382	39.194329	–128.479047

PAC–OL–001 and PAC–OL–382 are located on the 200 nautical mile (exclusive economic zone) limit of the United States.

Elizabeth Kim,

Director, Office of Ocean and Polar Affairs, Department of State.

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DEPARTMENT OF STATE

[Public Notice 12243]

RIN 1400–AF74

Exclusive Economic Zone and Maritime Boundaries; Notice of Limits

SUMMARY: This notice provides updated information pertaining to the outer limits of the U.S. exclusive economic zone.

DATES: These limits are in effect as of December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Amanda Williams, Maritime Geographer, Department of State, *williamsac3@state.gov.*

SUPPLEMENTARY INFORMATION: By Presidential Proclamation No. 5030 made on March 10, 1983, the United States established an exclusive economic zone, within which the United States may exercise its sovereign rights and jurisdiction as permitted under international law. The outer limit of the exclusive economic zone extends to a maximum distance of 200 nautical miles from the baseline from which the breadth of the territorial sea is measured.

The Department of State on behalf of the Government of the United States hereby announces updated information pertaining to the outer limits of the exclusive economic zone of the United States of America. The Government of

the United States has been, is, and will be engaged in consultations and negotiations with governments of neighboring countries concerning the delimitation of areas subject to the respective jurisdiction of the United States and of these countries. The outer limits of the exclusive economic zone of the United States as set forth in this notice are without prejudice to any negotiations with these countries or to any positions that may have been or may be adopted respecting the limits of maritime jurisdiction in such areas. Further, the limits of the exclusive economic zone set forth in this notice are without prejudice to the outer limits of the continental shelf of the United States where that shelf extends beyond 200 nautical miles from the baseline from which the breath of the territorial sea is measured in accordance with international law.

This Public Notice supersedes all limits defined in the following Public Notices that variously defined the outer limits of the U.S. fishery conservation zone before 1984 and the U.S. exclusive economic zone beginning in 1983: Public Notice 506, 41 FR 48619 (November 4, 1976); Public Notice 526, 42 FR 12937 (March 7, 1977); Public Notice 544, 42 FR 24134 (May 12, 1977); Public Notice 4710–01, 43 FR 1658 (January 11, 1978); Public Notice 585, 43 FR 1978 (January 11, 1978); Public Notice 910, 49 FR 31973 (August 9, 1984); and Public Notice 2237, 60 FR 43825 (August 23, 1995). This Public Notice incorporates the limits agreed to in treaties that entered into force or are being provisionally applied since publication of Public Notice 2237, is based on more recent survey data, and corrects typographical errors.

The coordinates in this notice use the World Geodetic System 1984 (''WGS 84'') datum, unless otherwise noted. For the purpose of this notice, the North American 1983 Datum (''NAD 83'' (1986)) is considered equivalent to WGS 84. Some coordinates in this notice were derived from coordinates that used the North American Datum 1927 (''NAD 27'') or the World Geodetic System 1972 (''WGS 72'') datum. For those coordinates, the conversions to the WGS 84 datum were done using the National Geospatial-Intelligence Agency's Mensuration Services Program (MSP) Geographic Translator (GEOTRANS) version 3.8 and are noted in the relevant footnotes. In the case of a discrepancy, treaties and the judgment given by a Chamber of the International Court of Justice take precedence over the contents of this notice.

The term ''straight line'' means a geodesic line, which is the shortest distance between two points on the referenced ellipsoid and is the most common method of linking coordinates defining maritime limits and boundaries.

This notice is exempt from the requirements of 5 U.S.C. 553, to the extent those requirements apply, as it relates to a foreign affairs function of the United States. (See Title 5 U.S.C. 553 (a)(1).) This notice '' 'clearly and directly' involve[s] activities or actions characteristic of the conduct of international relations,'' *E.B.* v. *U.S. Dep't of State,* 583 F. Supp. 3d 58, 66 (D.D.C. 2022), because it announces the locations of maritime boundaries agreed between the United States and other countries and the geographic limits within which the United States may exercise sovereign rights and jurisdiction in accordance with international law. See, *e.g., City of New York* v. *Permanent Mission of India to United Nations,* 618 F.3d 172, 201 (2d Cir. 2010). Since it is exempt from Section 553, the provisions of 5 U.S.C. 553(d) do not apply, and this notice is in effect upon publication.

Atlantic Ocean and Gulf of Mexico

Gulf of Maine

In the Gulf of Maine area, the outer limit of the exclusive economic zone is defined by straight lines connecting the following points: [1]

1. 44°46′35.6″ N, 66°54′09.2″ W
2. 44°44′41″ N, 66°56′15″ W
3. 44°43′56″ N, 66°56′24″ W
4. 44°39′18″ N, 66°57′27″ W
5. 44°36′58″ N, 67°00′34″ W
6. 44°33′27″ N, 67°02′55″ W
7. 44°30′38″ N, 67°02′36″ W
8. 44°29′03″ N, 67°03′40″ W
9. 44°25′27″ N, 67°02′14″ W
10. 44°21′43″ N, 67°02′31″ W
11. 44°14′06″ N, 67°08′36″ W
12. 44°11′12″ N, 67°16′44″ W
13. 42°53′14″ N, 67°44′33″ W
14. 42°31′08″ N, 67°28′03″ W
15. 40°27′05″ N, 65°41′57″ W

Atlantic Ocean

Between points 15 (seaward of the Gulf Maine) and 16 (north of the Straits of Florida), the outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured.

From north of the Straits of Florida to the eastern Gulf of Mexico, the outer limit of the exclusive economic zone is defined by straight lines connecting the following points: [2]

16. 28°17′11″ N, 76°36′44″ W
17. 28°17′11″ N, 79°11′23″ W
18. 27°52′55″ N, 79°28′35″ W
19. 27°26′01″ N, 79°31′37″ W
20. 27°16′13″ N, 79°34′17″ W
21. 27°11′54″ N, 79°34′55″ W
22. 27°05′59″ N, 79°35′18″ W
23. 27°00′28″ N, 79°35′16″ W
24. 26°55′16″ N, 79°34′38″ W
25. 26°53′58″ N, 79°34′26″ W
26. 26°45′46″ N, 79°32′40″ W
27. 26°44′30″ N, 79°32′22″ W
28. 26°43′40″ N, 79°32′19″ W
29. 26°41′12″ N, 79°32′00″ W
30. 26°38′13″ N, 79°31′32″ W
31. 26°36′30″ N, 79°31′06″ W
32. 26°35′21″ N, 79°30′49″ W
33. 26°34′51″ N, 79°30′45″ W
34. 26°34′11″ N, 79°30′37″ W
35. 26°31′12″ N, 79°30′14″ W
36. 26°29′05″ N, 79°29′52″ W
37. 26°25′31″ N, 79°29′57″ W
38. 26°23′29″ N, 79°29′54″ W
39. 26°23′21″ N, 79°29′53″ W
40. 26°18′57″ N, 79°31′54″ W
41. 26°15′26″ N, 79°33′16″ W
42. 26°15′13″ N, 79°33′22″ W
43. 26°08′09″ N, 79°35′52″ W
44. 26°07′47″ N, 79°36′08″ W
45. 26°06′59″ N, 79°36′34″ W
46. 26°02′52″ N, 79°38′21″ W
47. 25°59′30″ N, 79°40′02″ W
48. 25°59′16″ N, 79°40′07″ W
49. 25°57′48″ N, 79°40′37″ W
50. 25°56′18″ N, 79°41′05″ W
51. 25°54′04″ N, 79°41′37″ W
52. 25°53′24″ N, 79°41′45″ W
53. 25°51′54″ N, 79°41′58″ W
54. 25°49′33″ N, 79°42′15″ W
55. 25°48′24″ N, 79°42′22″ W

[1] Point 1 is from the Canada-U.S. International Boundary Commission (Point TP 15 of the official geographical coordinates of the boundary points in Passamaquoddy Bay, Section 1, in NAD 83). Points 1 to 10 are landward of the U.S. exclusive economic zone and define the limits of the U.S. territorial sea. The U.S. maritime limits from points 1 to 12 in areas adjacent to Canada do not correspond to limits of the maritime zones claimed by Canada, due to the dispute between the United States and Canada relating to the sovereignty over Machias Seal Island and North Rock. The line defined by points 12 to 15 reflects the judgment of a chamber of the International Court of Justice establishing a U.S.-Canada maritime boundary in the Gulf of Maine. Case Concerning Delimitation of the Maritime Boundary in the Gulf of Maine Area, 1984 I.C.J. Reports 246 (Judgment of Oct. 12, 1984). The coordinates in the judgment have been converted from NAD 27 to WGS 84 for the purpose of this Notice.

[2] Points 113 to 138 correspond to the boundary points set forth in the Maritime Boundary Agreement between the United States of America and the Republic of Cuba, signed December 16, 1977, Senate Treaty Doc. 96–8. The treaty has been applied provisionally since January 1, 1978. The coordinates in the treaty have been converted from NAD 27 to WGS 84 for the purpose of this Notice. Point 139 corresponds to boundary point 1 set forth in the Treaty between the United States of America and the Republic of Cuba on the Delimitation of the Continental Shelf in the Eastern Gulf of Mexico beyond 200 Nautical Miles, signed January 18, 2017. The treaty has been applied provisionally since January 18, 2017.

56. 25°48′20″ N, 79°42′23″ W
57. 25°46′26″ N, 79°42′43″ W
58. 25°46′16″ N, 79°42′44″ W
59. 25°43′40″ N, 79°42′58″ W
60. 25°42′31″ N, 79°42′47″ W
61. 25°40′37″ N, 79°42′26″ W
62. 25°37′24″ N, 79°42′26″ W
63. 25°37′08″ N, 79°42′26″ W
64. 25°31′03″ N, 79°42′11″ W
65. 25°27′59″ N, 79°42′10″ W
66. 25°24′05″ N, 79°42′11″ W
67. 25°22′22″ N, 79°42′19″ W
68. 25°21′30″ N, 79°42′07″ W
69. 25°16′53″ N, 79°41′23″ W
70. 25°15′58″ N, 79°41′30″ W
71. 25°10′40″ N, 79°41′30″ W
72. 25°09′52″ N, 79°41′35″ W
73. 25°09′04″ N, 79°41′44″ W
74. 25°03′55″ N, 79°42′29″ W
75. 25°03′00″ N, 79°42′56″ W
76. 25°00′30″ N, 79°44′05″ W
77. 24°59′03″ N, 79°44′48″ W
78. 24°55′28″ N, 79°45′57″ W
79. 24°44′18″ N, 79°49′24″ W
80. 24°43′04″ N, 79°49′38″ W
81. 24°42′36″ N, 79°50′50″ W
82. 24°41′47″ N, 79°52′57″ W
83. 24°38′32″ N, 79°59′58″ W
84. 24°36′27″ N, 80°03′51″ W
85. 24°33′18″ N, 80°12′43″ W
86. 24°33′05″ N, 80°13′21″ W
87. 24°32′13″ N, 80°15′16″ W
88. 24°31′27″ N, 80°16′55″ W
89. 24°30′57″ N, 80°17′47″ W
90. 24°30′14″ N, 80°19′21″ W
91. 24°30′06″ N, 80°19′44″ W
92. 24°29′38″ N, 80°21′05″ W
93. 24°28′18″ N, 80°24′35″ W
94. 24°28′06″ N, 80°25′10″ W
95. 24°27′23″ N, 80°27′20″ W
96. 24°26′30″ N, 80°29′30″ W
97. 24°25′07″ N, 80°32′22″ W
98. 24°23′30″ N, 80°36′09″ W
99. 24°22′33″ N, 80°38′56″ W
100. 24°22′07″ N, 80°39′51″ W
101. 24°19′31″ N, 80°45′21″ W
102. 24°19′16″ N, 80°45′47″ W
103. 24°18′38″ N, 80°46′49″ W
104. 24°18′35″ N, 80°46′54″ W
105. 24°09′51″ N, 80°59′47″ W
106. 24°09′48″ N, 80°59′51″ W
107. 24°08′58″ N, 81°01′07″ W
108. 24°08′30″ N, 81°01′51″ W
109. 24°08′26″ N, 81°01′57″ W
110. 24°07′28″ N, 81°03′06″ W
111. 24°02′20″ N, 81°09′05″ W
112. 24°00′00″ N, 81°11′15″ W
113. 23°55′32″ N, 81°12′54″ W
114. 23°53′52″ N, 81°19′43″ W
115. 23°50′52″ N, 81°29′59″ W
116. 23°50′02″ N, 81°39′59″ W
117. 23°49′05″ N, 81°50′00″ W
118. 23°49′05″ N, 82°00′12″ W
119. 23°49′42″ N, 82°10′00″ W
120. 23°51′14″ N, 82°25′00″ W
121. 23°51′14″ N, 82°40′00″ W
122. 23°49′42″ N, 82°48′54″ W
123. 23°49′32″ N, 82°51′12″ W
124. 23°49′24″ N, 83°00′00″ W
125. 23°49′52″ N, 83°15′00″ W
126. 23°51′22″ N, 83°25′50″ W
127. 23°52′27″ N, 83°33′02″ W
128. 23°54′04″ N, 83°41′36″ W
129. 23°55′47″ N, 83°48′12″ W
130. 23°58′38″ N, 84°00′00″ W
131. 24°09′37″ N, 84°29′28″ W
132. 24°13′20″ N, 84°38′40″ W
133. 24°16′41″ N, 84°46′08″ W
134. 24°23′30″ N, 85°00′00″ W
135. 24°26′37″ N, 85°06′20″ W
136. 24°38′57″ N, 85°31′55″ W
137. 24°44′17″ N, 85°43′12″ W
138. 24°53′57″ N, 86°00′00″ W
139. 25°12′26.28″ N, 86°33′11.91″ W

Gulf of Mexico

In the eastern Gulf of Mexico, between points 139 and 140, the outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured. The 200 nautical mile exclusive economic zone limit in this area intersects with the line connecting points 138 and 139 and with the line connecting points 140 and 141.

In the central Gulf of Mexico, the outer limit of the exclusive economic zone is determined by straight lines connecting the following points: [3]

140. 25°41′54.18″ N, 88°20′02.64″ W
141. 25°41′57.90″ N, 88°23′05.62″ W
142. 25°46′53.47″ N, 90°29′41.37″ W
143. 25°42′14.1″ N, 91°05′25.0″ W

In the western Gulf of Mexico, between points 143 and 144, the outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured. The 200 nautical mile exclusive economic zone limit in this area intersects with the line connecting points 142 and 143 and with the line connecting points 144 and 145.

To the west, the outer limit is defined by straight lines connecting the following points: [4]

144. 25°59′49.3″ N, 93°26′42.5″ W
145. 26°00′31.42″ N, 95°39′26.89″ W
146. 26°00′32.41″ N, 96°48′30.01″ W
147. 25°58′31.98″ N, 96°55′28.39″ W

From point 147 westward, the limit of United States jurisdiction is the territorial sea boundary with Mexico.[5]

Caribbean Sea

Commonwealth of Puerto Rico and the United States Virgin Islands

The outer limit of the exclusive economic zone around the Commonwealth of Puerto Rico and the Virgin Islands of the United States is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured, except that to the east, south, and west, the limit is defined by straight lines connecting the following points: [6]

1. 21°48′33″ N, 65°50′31″ W
2. 21°41′20″ N, 65°49′13″ W
3. 20°58′05″ N, 65°40′30″ W
4. 20°46′56″ N, 65°38′14″ W
5. 19°57′29″ N, 65°27′21″ W
6. 19°37′29″ N, 65°20′57″ W
7. 19°12′25″ N, 65°06′08″ W
8. 18°45′14″ N, 65°00′22″ W
9. 18°41′14″ N, 64°59′33″ W
10. 18°29′22″ N, 64°53′50″ W
11. 18°27′36″ N, 64°53′22″ W
12. 18°25′22″ N, 64°52′39″ W
13. 18°24′31″ N, 64°52′19″ W
14. 18°23′51″ N, 64°51′50″ W

[3] Points 140 and 141 corresponds to boundary points 2 and 1, respectively, set forth in the Treaty between the Government of the United States of America and the Government of the United Mexican States on the Delimitation of the Maritime Boundary in the Eastern Gulf of Mexico, signed January 18, 2017, not in force. Point 142 corresponds to boundary point GM.E–2 set forth in the Treaty on Maritime Boundaries Between the United States of America and the United Mexican States, signed May 4, 1978, entered into force November 13, 1997, TIAS 97–1113 (''U.S.-Mexico Treaty of 1978''). This point has been converted from NAD 27 to WGS 84 for the purpose of this Notice. Point 143 corresponds to boundary point 1 set forth in the Treaty between the Government of the United States of America and the Government of the United Mexican States on the Delimitation of the Continental Shelf in the Western Gulf of Mexico beyond 200 Nautical Miles, signed June 9, 2000, entered into force January 17, 2001 (''U.S.-Mexico Treaty of 2000''). Coordinates in this treaty are expressed in NAD 83.

[4] Point 144 corresponds to boundary point 16 set forth in the U.S.-Mexico Treaty of 2000 (footnote 3 of this Notice). Points 145 to 147 correspond to boundary points GM.W–3 to GM.W–1 set forth in the U.S.-Mexico Treaty of 1978 (footnote 3 of this Notice) and have been converted from NAD 27 to WGS 84 for the purpose of this Notice.

[5] Treaty to Resolve Pending Boundary Differences and Maintain the Rio Grande and Colorado River as the International Boundary Between the United States of America and the United Mexican States, article V(A) and annexes, signed November 23, 1970, entered into force April 18, 1972, TIAS 7313, 23 UST 371, 830 UNTS 57 (''U.S.-Mexico Treaty of 1970'').

[6] Points 1 to 50 correspond to the boundary points set forth in the Treaty between the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of the United States of America on the Delimitation in the Caribbean of a Maritime Boundary relating to Puerto Rico/U.S. Virgin Islands and the British Virgin Islands, signed November 5, 1993, entered into force on June 1, 1995, 1913 UNTS 67. Points 50 to 51 correspond to the boundary points set forth in the Treaty between the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of the United States of America on the Delimitation in the Caribbean of a Maritime Boundary relating to the U.S. Virgin Islands and Anguilla signed November 4, 1993, entered into force June 1, 1995, 1913 UNTS 59. Coordinates in these treaties are expressed in NAD 83. Points 57 to 78 correspond to the boundary points set forth in the Maritime Boundary Treaty between the United States of America and the Republic of Venezuela, signed March 28, 1978, entered into force November 24, 1980, TIAS 9890, 32 UST 3100, 1273 UNTS 25. Coordinates in this treaty are expressed in NAD 27 and have been converted to WGS 84 for the purpose of this Notice.

15. 18°23′43″ N, 64°51′23″ W
16. 18°23′37″ N, 64°50′18″ W
17. 18°23′48″ N, 64°49′42″ W
18. 18°24′11″ N, 64°49′01″ W
19. 18°24′29″ N, 64°47′57″ W
20. 18°24′18″ N, 64°47′00″ W
21. 18°23′14″ N, 64°46′37″ W
22. 18°22′38″ N, 64°45′21″ W
23. 18°22′40″ N, 64°44′42″ W
24. 18°22′42″ N, 64°44′36″ W
25. 18°22′37″ N, 64°44′24″ W
26. 18°22′40″ N, 64°43′42″ W
27. 18°22′30″ N, 64°43′36″ W
28. 18°22′25″ N, 64°42′58″ W
29. 18°22′27″ N, 64°42′28″ W
30. 18°22′16″ N, 64°42′03″ W
31. 18°22′23″ N, 64°40′59″ W
32. 18°21′58″ N, 64°40′15″ W
33. 18°21′51″ N, 64°38′22″ W
34. 18°21′22″ N, 64°38′16″ W
35. 18°20′39″ N, 64°38′32″ W
36. 18°19′16″ N, 64°38′13″ W
37. 18°19′07″ N, 64°38′16″ W
38. 18°17′24″ N, 64°39′37″ W
39. 18°16′43″ N, 64°39′41″ W
40. 18°11′34″ N, 64°38′58″ W
41. 18°03′03″ N, 64°38′03″ W
42. 18°02′57″ N, 64°29′35″ W
43. 18°02′52″ N, 64°27′03″ W
44. 18°02′30″ N, 64°21′08″ W
45. 18°02′31″ N, 64°20′08″ W
46. 18°02′01″ N, 64°15′39″ W
47. 18°00′12″ N, 64°02′29″ W
48. 17°59′58″ N, 64°01′02″ W
49. 17°58′47″ N, 63°57′00″ W
50. 17°57′51″ N, 63°53′53″ W
51. 17°56′37″ N, 63°53′20″ W
52. 17°39′50″ N, 63°54′52″ W
53. 17°37′17″ N, 63°55′09″ W
54. 17°30′31″ N, 63°55′55″ W
55. 17°11′46″ N, 63°57′58″ W
56. 17°05′10″ N, 63°58′40″ W
57. 16°44′52″ N, 64°01′06″ W
58. 16°43′25″ N, 64°06′29″ W
59. 16°43′13″ N, 64°06′57″ W
60. 16°42′43″ N, 64°08′04″ W
61. 16°41′46″ N, 64°10′05″ W
62. 16°35′22″ N, 64°23′37″ W
63. 16°23′33″ N, 64°45′52″ W
64. 15°39′34″ N, 65°58′39″ W
65. 15°30′13″ N, 66°07′07″ W
66. 15°14′09″ N, 66°19′55″ W
67. 14°55′51″ N, 66°34′28″ W
68. 14°56′09″ N, 66°51′38″ W
69. 14°58′30″ N, 67°04′17″ W
70. 14°58′48″ N, 67°05′15″ W
71. 14°59′01″ N, 67°06′09″ W
72. 14°59′13″ N, 67°06′58″ W
73. 15°02′35″ N, 67°23′38″ W
74. 15°05′10″ N, 67°36′21″ W
75. 15°10′41″ N, 68°03′44″ W
76. 15°11′09″ N, 68°09′19″ W
77. 15°12′36″ N, 68°27′30″ W
78. 15°12′54″ N, 68°28′54″ W
79. 15°46′49″ N, 68°26′02″ W
80. 17°21′33″ N, 68°17′51″ W
81. 17°38′04″ N, 68°16′44″ W
82. 17°50′26″ N, 68°16′09″ W
83. 17°58′09″ N, 68°15′50″ W
84. 18°02′30″ N, 68°15′38″ W
85. 18°06′12″ N, 68°15′25″ W
86. 18°07′29″ N, 68°15′31″ W
87. 18°09′14″ N, 68°14′51″ W
88. 18°17′08″ N, 68°11′26″ W
89. 18°19′22″ N, 68°09′38″ W
90. 18°22′44″ N, 68°06′55″ W
91. 18°24′41″ N, 68°04′56″ W
92. 18°25′27″ N, 68°04′07″ W
93. 18°28′10″ N, 68°00′57″ W
94. 18°31′29″ N, 67°56′55″ W
95. 18°33′00″ N, 67°55′05″ W
96. 18°34′36″ N, 67°52′51″ W
97. 18°54′39″ N, 67°46′19″ W
98. 19°00′44″ N, 67°44′23″ W
99. 19°10′02″ N, 67°41′22″ W
100. 19°19′05″ N, 67°38′17″ W
101. 19°21′22″ N, 67°37′59″ W
102. 19°59′47″ N, 67°31′50″ W
103. 20°01′01″ N, 67°31′33″ W
104. 20°01′19″ N, 67°31′27″ W
105. 20°02′51″ N, 67°31′02″ W
106. 20°03′32″ N, 67°30′50″ W
107. 20°09′30″ N, 67°29′09″ W
108. 20°48′20″ N, 67°17′48″ W
109. 21°22′50″ N, 67°02′32″ W
110. 21°30′20″ N, 66°59′03″ W
111. 21°33′49″ N, 66°57′28″ W
112. 21°51′26″ N, 66°49′28″ W

Navassa Island

The outer limits of the exclusive economic zone around Navassa Island remain to be determined.

Pacific Ocean (Washington, Oregon, and California)

In the area seaward of the Strait of Juan de Fuca (Washington), the outer limit of the exclusive economic zone is defined by straight lines connecting the following points: [7]

1. 48°29′36.4″ N, 124°43′38.1″ W
2. 48°30′10″ N, 124°47′18″ W
3. 48°30′21″ N, 124°50′26″ W
4. 48°30′13″ N, 124°54′57″ W
5. 48°29′56″ N, 124°59′19″ W
6. 48°29′43″ N, 125°00′11″ W
7. 48°28′08″ N, 125°05′52″ W
8. 48°27′09″ N, 125°08′30″ W
9. 48°26′46″ N, 125°09′17″ W
10. 48°20′15″ N, 125°22′53″ W
11. 48°18′21″ N, 125°30′03″ W
12. 48°11′04″ N, 125°53′53″ W
13. 47°49′14″ N, 126°41′02″ W
14. 47°36′46″ N, 127°12′03″ W
15. 47°21′59″ N, 127°41′28″ W
16. 46°42′04″ N, 128°52′01″ W
17. 46°31′46″ N, 129°07′44″ W

Between point 17 (seaward of the Strait of Juan de Fuca) and 18 (off the southern California coast), the outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured.

In the area off the southern California coast, the outer limit of the exclusive economic zone is defined by straight lines connecting the following points: [8]

18. 30°32′31.50″ N, 121°52′01.77″ W
19. 31°07′58.32″ N, 118°36′21.14″ W
20. 32°37′37.18″ N, 117°49′34.12″ W
21. 32°35′22.30″ N, 117°27′52.50″ W

From point 21 to the coast, the limit of United States jurisdiction is the territorial sea boundary with Mexico.[9]

Arctic Ocean and Pacific Ocean (Alaska)

Beaufort Sea

Off the coast of Alaska, in the Beaufort Sea, the outer limit of exclusive economic zone is defined by straight lines connecting the following points: [10]

1. 69°38′47.810″ N, 141°00′02.129″ W
2. 69°38′51″ N, 141°00′01″ W
3. 69°39′36″ N, 140°59′11″ W
4. 69°40′09″ N, 140°58′44″ W
5. 69°41′29″ N, 140°57′10″ W
6. 69°46′24″ N, 140°49′55″ W
7. 69°47′53″ N, 140°47′17″ W
8. 69°51′39″ N, 140°42′47″ W
9. 70°09′25″ N, 140°19′32″ W
10. 70°11′29″ N, 140°18′19″ W
11. 70°29′07″ N, 140°10′01″ W
12. 70°29′19″ N, 140°09′55″ W
13. 70°37′31″ N, 140°02′57″ W
14. 70°48′25″ N, 139°52′42″ W
15. 70°58′02″ N, 139°47′27″ W
16. 71°01′15″ N, 139°44′35″ W
17. 71°11′58″ N, 139°34′09″ W
18. 71°23′10″ N, 139°21′57″ W
19. 72°12′18″ N, 138°26′30″ W
20. 72°46′39″ N, 137°30′13″ W
21. 72°56′49″ N, 137°34′19″ W

Beaufort Sea, Chukchi Sea, and Bering Sea

Between point 21 (Beaufort Sea) and point 22 (Chukchi Sea), the outer limit

[7] The U.S. maritime limits in areas adjacent to Canada seaward of the Strait of Juan de Fuca do not correspond to limits of the maritime zones claimed by Canada. Point 1 is from the Canada-U.S. International Boundary Commission (Point TP 12 of the official geographical coordinates of the boundary points for the Straits of Georgia and Juan de Fuca, Section 26, in NAD 83). Points 1 to 6 are landward of the U.S. exclusive economic zone and define the limits of the U.S. territorial sea.

[8] Points 18 to 21 correspond to the boundary points set forth in the U.S.-Mexico Treaty of 1978 (footnote 3 of this Notice). Coordinates in this treaty are expressed in NAD 27 and have been converted to WGS 84 for the purpose of this Notice.

[9] U.S.-Mexico Treaty of 1970 (footnote 5 of this Notice), article V(B) and annexes.

[10] The U.S. maritime limits in areas adjacent to Canada in the Beaufort Sea do not correspond to limits of the maritime zones claimed by Canada. Point 1 is from the Canada-U.S. International Boundary Commission (Point SITE MON 1 of the official geographical coordinates of the boundary points for the 141st Meridian, Section 29, in NAD 83). Points 1 to 7 are landward of the U.S. exclusive economic zone and define the limits of the U.S. territorial sea.

of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured.

From the Chukchi Sea through the Bering Strait to the northern Bering Sea, the outer limit of the exclusive economic zone is defined by straight lines connecting the following points: [11]

22. 72°46′29″ N, 168°58′37″ W
23. 65°30′00″ N, 168°58′37″ W
24. 65°19′58″ N, 169°21′38″ W
25. 65°09′51″ N, 169°44′34″ W
26. 64°59′41″ N, 170°07′23″ W
27. 64°49′26″ N, 170°30′06″ W
28. 64°39′08″ N, 170°52′43″ W
29. 64°28′46″ N, 171°15′14″ W
30. 64°18′20″ N, 171°37′40″ W
31. 64°07′50″ N, 172°00′00″ W
32. 63°59′27″ N, 172°18′39″ W
33. 63°51′01″ N, 172°37′13″ W
34. 63°42′33″ N, 172°55′42″ W
35. 63°34′01″ N, 173°14′07″ W
36. 63°25′27″ N, 173°32′27″ W
37. 63°16′50″ N, 173°50′42″ W
38. 63°08′11″ N, 174°08′52″ W
39. 62°59′29″ N, 174°26′58″ W
40. 62°50′44″ N, 174°44′59″ W
41. 62°41′56″ N, 175°02′56″ W
42. 62°33′06″ N, 175°20′48″ W
43. 62°24′13″ N, 175°38′36″ W
44. 62°15′17″ N, 175°56′19″ W
45. 62°06′19″ N, 176°13′59″ W
46. 61°57′18″ N, 176°31′34″ W
47. 61°48′14″ N, 176°49′04″ W
48. 61°39′08″ N, 177°06′31″ W
49. 61°29′59″ N, 177°23′53″ W
50. 61°20′47″ N, 177°41′11″ W
51. 61°11′33″ N, 177°58′26″ W
52. 61°02′17″ N, 178°15′36″ W
53. 60°52′57″ N, 178°32′42″ W
54. 60°43′35″ N, 178°49′45″ W
55. 60°34′11″ N, 179°06′44″ W
56. 60°24′44″ N, 179°23′38″ W
57. 60°15′14″ N, 179°40′30″ W
58. 60°11′39″ N, 179°46′49″ W

Bering Sea and North Pacific Ocean

In the Bering Sea, between points 58 and 59, the outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured.

In the southern Bering Sea and North Pacific Ocean, the outer limit of the exclusive economic zone is defined by straight lines connecting the following points: [12]

59. 56°16′50.52″ N, 173°59′31.30″ E
60. 56°15′07″ N, 173°56′56″ E
61. 56°04′34″ N, 173°41′08″ E
62. 55°53′59″ N, 173°25′22″ E
63. 55°43′22″ N, 173°09′37″ E
64. 55°32′42″ N, 172°53′55″ E
65. 55°21′59″ N, 172°38′14″ E
66. 55°11′14″ N, 172°22′36″ E
67. 55°00′26″ N, 172°06′59″ E
68. 54°49′36″ N, 171°51′24″ E
69. 54°38′43″ N, 171°35′51″ E
70. 54°27′48″ N, 171°20′20″ E
71. 54°16′50″ N, 171°04′50″ E
72. 54°05′50″ N, 170°49′22″ E
73. 53°54′47″ N, 170°33′56″ E
74. 53°43′42″ N, 170°18′31″ E
75. 53°32′46″ N, 170°05′29″ E
76. 53°21′48″ N, 169°52′32″ E
77. 53°10′49″ N, 169°39′40″ E
78. 52°59′48″ N, 169°26′53″ E
79. 52°48′46″ N, 169°14′12″ E
80. 52°37′43″ N, 169°01′36″ E
81. 52°26′38″ N, 168°49′05″ E
82. 52°15′31″ N, 168°36′39″ E
83. 52°04′23″ N, 168°24′17″ E
84. 51°53′14″ N, 168°12′01″ E
85. 51°42′03″ N, 167°59′49″ E
86. 51°30′51″ N, 167°47′42″ E
87. 51°22′13.88″ N, 167°38′27.40″ E

In the North Pacific Ocean, between points 87 and 88, the outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured.

From point 88, the limit of the exclusive economic zone off the coast of Alaska, seaward of the Dixon Entrance, is defined by straight lines connecting the following points: [13]

88. 53°28′25″ N, 138°45′26″ W
89. 53°59′59″ N, 135°46′03″ W
90. 54°07′28″ N, 134°56′29″ W
91. 54°12′43″ N, 134°25′08″ W
92. 54°12′55″ N, 134°23′52″ W
93. 54°15′38″ N, 134°10′54″ W
94. 54°20′31″ N, 133°49′26″ W
95. 54°21′59″ N, 133°44′29″ W
96. 54°30′04″ N, 133°17′03″ W
97. 54°31′00″ N, 133°14′05″ W
98. 54°30′40″ N, 133°11′33″ W
99. 54°30′08″ N, 133°07′48″ W
100. 54°30′01″ N, 133°07′05″ W
101. 54°28′30″ N, 132°56′33″ W
102. 54°28′23″ N, 132°55′59″ W
103. 54°27′21″ N, 132°50′47″ W
104. 54°27′05″ N, 132°49′40″ W
105. 54°25′58″ N, 132°44′17″ W
106. 54°24′52″ N, 132°39′51″ W
107. 54°24′32″ N, 132°38′21″ W
108. 54°24′37″ N, 132°26′56″ W
109. 54°24′39″ N, 132°24′40″ W
110. 54°24′39″ N, 132°24′34″ W
111. 54°24′50″ N, 132°23′44″ W
112. 54°21′49″ N, 132°02′59″ W
113. 54°26′40″ N, 131°49′33″ W
114. 54°28′17″ N, 131°45′25″ W
115. 54°30′31″ N, 131°38′06″ W
116. 54°29′52″ N, 131°33′53″ W
117. 54°36′52″ N, 131°19′27″ W
118. 54°39′08″ N, 131°16′22″ W
119. 54°40′51″ N, 131°13′59″ W
120. 54°42′10″ N, 131°13′05″ W
121. 54°46′15″ N, 131°04′48″ W
122. 54°45′38″ N, 131°03′11″ W
123. 54°44′11″ N, 130°59′49″ W
124. 54°43′45″ N, 130°59′00″ W
125. 54°42′59″ N, 130°57′46″ W
126. 54°42′33″ N, 130°57′14″ W
127. 54°42′26″ N, 130°56′23″ W
128. 54°41′25″ N, 130°53′44″ W
129. 54°41′20″ N, 130°53′23″ W
130. 54°41′04″ N, 130°49′22″ W
131. 54°41′05″ N, 130°48′36″ W
132. 54°40′45″ N, 130°45′56″ W
133. 54°40′40″ N, 130°45′04″ W
134. 54°40′41″ N, 130°44′48″ W
135. 54°40′02″ N, 130°42′27″ W
136. 54°39′47″ N, 130°41′40″ W
137. 54°39′13″ N, 130°39′23″ W
138. 54°39′53″ N, 130°39′03″ W
139. 54°41′08″ N, 130°39′03″ W
140. 54°42′21″ N, 130°38′31″ W
141. 54°42′46″ N, 130°38′11″ W
142. 54°42′57″ N, 130°38′02″ W
143. 54°42′59″ N, 130°38′00″ W
144. 54°43′14″ N, 130°37′49″ W
145. 54°43′23″ N, 130°37′44″ W
146. 54°43′29.0″ N, 130°37′43.1″ W

Special Areas Pertaining to the U.S.-Russia Maritime Boundary

The 1990 Agreement between the United States of America and the Union of Soviet Socialist Republics on the Maritime Boundary (U.S.-Russia Agreement of 1990) recognizes areas on the east side (*i.e.,* U.S. side) of the U.S.-Russia maritime boundary that are within 200 nautical miles of the

[11] Point 22 is located at a distance of 200 nautical miles from the territorial sea baselines of the United States on the U.S.-Russia maritime boundary established by the Agreement between the United States of America and The Union of Soviet Socialist Republics on the Maritime Boundary (''U.S.-Russia Agreement of 1990''), signed June 1, 1990, Senate Treaty Doc. 101–22, and applied provisionally, pending its entry into force, by an exchange of notes effective June 15, 1990, TIAS 11451. (The Russian Federation is the successor of the USSR with respect to the 1990 Agreement and the agreement to provisionally apply it.) Points 23 to 58 correspond to boundary points 1 to 36 set forth in the U.S.-Russia Agreement of 1990. The coordinates set forth in the U.S.-Russia Agreement of 1990 are expressed in WGS 84.

[12] Point 59 is located at a distance of 200 nautical miles from the territorial sea baselines of the United States between points 55 and 56 of the U.S.-Russia maritime boundary (footnote 11 of this Notice). Points 60 to 86 correspond to boundary points 56 to 82. Point 87 is located at a distance of 200 nautical miles from the territorial sea baselines of the United States on the U.S.-Russia maritime boundary, between boundary points 82 and 83.

[13] The U.S. maritime limits in areas adjacent to Canada in, and seaward of, the Dixon Entrance do not correspond to the limits of maritime zones claimed by Canada. Points 117 to 146 are landward of the U.S. exclusive economic zone and define the limits of the U.S. territorial sea. Point 146 is from the Canada-U.S. International Boundary Commission (Point TP 1 of the official geographical coordinates of the boundary points for the Portland Canal, Section 27, in NAD 83). Where the claimed limits published by the United States and Canada leave an unclaimed area within Dixon Entrance, the United States will exercise fishery management jurisdiction to the Canadian claimed line where that line is situated southward of the United States claimed line, until such time as a maritime boundary with Canada is established in the Dixon Entrance.

baselines from which the breadth of the territorial sea of the Russian Federation is measured but beyond 200 nautical miles of the baseline from which the breadth of the territorial sea of the United States is measured (''Eastern Special Areas'').[14] Pursuant to article 3 of the U.S.-Russia Agreement of 1990, within Eastern Special Areas the United States may exercise the sovereign rights and jurisdiction derived from exclusive economic zone jurisdiction that the Russian Federation would otherwise be entitled to exercise under international law in the absence of the agreement of the two countries on the maritime boundary. The exercise of sovereign rights or jurisdiction by the United States in the three Eastern Special Areas described in this notice derives from the U.S.-Russia Agreement of 1990 and does not constitute an extension of the U.S. exclusive economic zone under international law.

Pacific Ocean (Hawaii and U.S. Territories)

Hawaii and Midway Islands [15]

The outer limit of the exclusive economic zone is 200 nautical miles from the baselines from which the breadth of the territorial sea is measured.

Northern Mariana Islands and Guam

The outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured, except that to the north of the Northern Mariana Islands, the limit is defined by straight lines connecting the following points: [16]

1. 23°53′35″ N, 145°05′46″ E
2. 23°44′32″ N, 144°54′05″ E
3. 23°33′52″ N, 144°40′23″ E
4. 23°16′11″ N, 144°17′47″ E
5. 22°50′13″ N, 143°44′57″ E
6. 22°18′13″ N, 143°05′02″ E
7. 21°53′58″ N, 142°35′03″ E
8. 21°42′14″ N, 142°20′39″ E
9. 21°40′08″ N, 142°18′05″ E
10. 21°28′21″ N, 142°03′45″ E
11. 20°58′24″ N, 141°27′33″ E
12. 20°52′51″ N, 141°20′54″ E

and, except that to the south of Guam, the limit is defined by straight lines connecting the following points: [17]

13. 13°05′51.5″ N, 141°13′07.5″ E
14. 12°55′00.6″ N, 141°20′49.9″ E
15. 12°33′14.0″ N, 141°39′56.5″ E
16. 11°37′33.8″ N, 142°28′23.2″ E
17. 11°10′41.6″ N, 142°51′38.2″ E
18. 10°57′54.8″ N, 143°02′39.7″ E
19. 10°57′14.3″ N, 143°28′21.4″ E
20. 11°08′29.1″ N, 144°29′55.2″ E
21. 11°13′19.3″ N, 144°56′45.7″ E
22. 11°17′36.6″ N, 145°23′45.1″ E
23. 11°22′08.6″ N, 145°52′47.4″ E
24. 11°28′05.6″ N, 146°31′35.8″ E
25. 11°31′12.0″ N, 146°52′07.4″ E
26. 11°33′58.8″ N, 147°11′37.9″ E
27. 11°36′51.1″ N, 147°31′56.6″ E
28. 11°38′03.0″ N, 147°44′32.6″ E

Johnston Atoll

The outer limit of the exclusive economic zone is 200 nautical miles from the baselines from which the breadth of the territorial sea is measured.

American Samoa

The outer limit of the exclusive economic zone is defined by straight lines connecting the following points: [18]

1. 11°02′17″ S, 173°44′47″ W
2. 10°46′15″ S, 173°03′52″ W
3. 10°25′26″ S, 172°11′00″ W
4. 10°17′50″ S, 171°50′57″ W
5. 10°15′17″ S, 171°15′31″ W
6. 10°10′18″ S, 170°16′09″ W
7. 10°07′52″ S, 169°46′49″ W
8. 10°01′26″ S, 168°31′24″ W
9. 10°12′44″ S, 168°31′01″ W
10. 10°12′49″ S, 168°31′01″ W
11. 10°52′31″ S, 168°29′41″ W
12. 11°02′40″ S, 168°29′20″ W
13. 11°43′53″ S, 168°27′57″ W
14. 12°01′55″ S, 168°10′23″ W
15. 12°28′40″ S, 167°25′19″ W
16. 12°41′22″ S, 167°11′00″ W
17. 12°57′51″ S, 166°52′20″ W
18. 13°11′25″ S, 166°37′01″ W
19. 13°14′03″ S, 166°34′02″ W
20. 13°21′25″ S, 166°25′41″ W
21. 13°35′44″ S, 166°09′18″ W
22. 13°44′56″ S, 165°58′43″ W
23. 14°03′30″ S, 165°37′19″ W
24. 15°00′09″ S, 165°22′06″ W
25. 15°14′04″ S, 165°18′28″ W
26. 15°38′47″ S, 165°12′02″ W
27. 15°44′58″ S, 165°16′35″ W
28. 16°08′42″ S, 165°34′11″ W
29. 16°18′30″ S, 165°41′28″ W
30. 16°23′29″ S, 165°45′10″ W
31. 16°45′30″ S, 166°01′38″ W
32. 17°33′28″ S, 166°38′34″ W
33. 17°33′18″ S, 166°38′31″ W
34. 17°32′55″ S, 166°39′38″ W
35. 17°23′55″ S, 167°06′38″ W
36. 17°10′49″ S, 167°45′27″ W
37. 17°04′39″ S, 168°03′34″ W
38. 17°01′07″ S, 168°13′55″ W
39. 16°47′47″ S, 168°52′31″ W
40. 16°39′00″ S, 169°17′32″ W
41. 16°38′12″ S, 169°19′47″ W
42. 16°38′01″ S, 169°22′25″ W
43. 16°37′04″ S, 169°36′12″ W
44. 16°35′39″ S, 169°55′57″ W
45. 16°36′16″ S, 169°59′13″ W
46. 16°37′23″ S, 170°05′15″ W
47. 16°41′39″ S, 170°28′26″ W
48. 16°43′16″ S, 170°37′28″ W
49. 16°43′49″ S, 170°40′35″ W
50. 16°49′33″ S, 171°13′23″ W
51. 16°50′25″ S, 171°18′19″ W
52. 16°31′48.11″ S, 171°28′51.47″ W
53. 16°07′52.80″ S, 171°42′21.77″ W
54. 15°58′43.10″ S, 171°47′17.22″ W
55. 15°52′35.12″ S, 171°50′44.54″ W
56. 15°18′05.61″ S, 171°38′27.74″ W
57. 15°17′34.11″ S, 171°38′12.88″ W
58. 15°13′02.61″ S, 171°36′04.46″ W
59. 14°52′33.06″ S, 171°26′23.50″ W
60. 14°49′23.43″ S, 171°24′55.36″ W
61. 14°41′10.56″ S, 171°21′06.52″ W
62. 14°38′41.65″ S, 171°19′57.44″ W
63. 14°31′56.96″ S, 171°16′49.84″ W
64. 14°22′44.27″ S, 171°12′34.00″ W
65. 14°19′55.29″ S, 171°11′16.44″ W
66. 14°16′44.35″ S, 171°09′48.69″ W
67. 14°15′05.69″ S, 171°09′03.36″ W
68. 14°13′05.27″ S, 171°08′08.11″ W
69. 14°11′49.35″ S, 171°07′32.78″ W
70. 14°10′03.02″ S, 171°06′43.31″ W
71. 14°05′49.83″ S, 171°04′45.75″ W
72. 14°05′15.40″ S, 171°04′29.77″ W
73. 14°04′51.25″ S, 171°04′18.53″ W
74. 14°04′04.11″ S, 171°03′51.30″ W
75. 14°03′04.48″ S, 171°03′16.90″ W
76. 14°02′41.88″ S, 171°03′05.11″ W
77. 14°01′14.02″ S, 171°02′20.01″ W
78. 13°58′43.31″ S, 171°01′02.79″ W
79. 13°57′50.38″ S, 171°00′35.30″ W
80. 13°56′02.44″ S, 170°59′39.21″ W
81. 13°54′38.87″ S, 170°58′57.53″ W
82. 13°49′58.34″ S, 170°56′41.76″ W

[14] U.S.-Russia Agreement of 1990 (footnote 11 of this Notice), article 3.

[15] This description covers all islands that are part of the U.S. state of Hawaii, including the Northwestern Hawaiian Islands.

[16] Points 1 to 12 correspond to the points defining the line of delimitation between the United States and Japan as set forth in an Exchange of Notes dated July 5, 1994. Points 1 to 12 are expressed in WGS 84. In this regard, users should be aware that the Government of Japan defines points 1 to 12 on the Tokyo Datum, and the location of those points may differ from those published in this Notice.

[17] Points 13 to 28 correspond to the boundary points set forth in the Treaty between the Government of the United States of America and the Government of the Federated States of Micronesia on the Delimitation of a Maritime Boundary, signed August 1, 2014, entered into force July 18, 2019, TIAS 19–718.

[18] Points 1 to 8 correspond to the boundary points set forth in the Treaty between the United States of America and New Zealand on the Delimitation of the Maritime Boundary between Tokelau and the United States of America, signed December 2, 1980, entered into force September 3, 1983, TIAS 10775. Points 8 to 32 correspond to the boundary points set forth in the Treaty between the United States of America and the Cook Islands on Friendship and Delimitation of the Maritime Boundary between the United States of America and the Cook Islands, signed June 11, 1980, entered into force September 8, 1983, TIAS 10774. For points 1 to 32, the coordinates set forth in the treaties were expressed in WGS 72 and have been converted to WGS 84 for the purpose of this Notice. Points 33 to 51 correspond to the boundary points set forth in the Treaty between the Government of the United States of America and the Government of Niue on the Delimitation of a Maritime Boundary, signed May 13, 1997, entered into force August 1, 2002, TIAS 14–1007.

83. 13°46′00.69″ S, 170°55′27.61″ W
84. 13°22′23.46″ S, 170°48′06.12″ W
85. 13°15′34.29″ S, 170°45′57.09″ W
86. 12°43′02.25″ S, 170°34′49.21″ W
87. 12°41′37.51″ S, 170°34′20.28″ W
88. 12°39′25.61″ S, 170°33′26.97″ W
89. 12°36′22.90″ S, 170°32′13.05″ W
90. 12°36′12.20″ S, 170°33′16.15″ W
91. 12°33′42.24″ S, 170°47′35.41″ W
92. 12°32′19.75″ S, 170°55′27.52″ W
93. 12°32′13.78″ S, 170°56′01.58″ W
94. 12°31′59.59″ S, 170°57′22.76″ W
95. 12°31′20.77″ S, 171°01′03.71″ W
96. 12°31′11.41″ S, 171°01′56.87″ W
97. 12°30′11.49″ S, 171°07′37.16″ W
98. 12°29′58.93″ S, 171°08′48.36″ W
99. 12°28′44.85″ S, 171°13′36.05″ W
100. 12°28′23.09″ S, 171°14′59.96″ W
101. 12°27′46.86″ S, 171°17′19.68″ W
102. 12°24′27.18″ S, 171°24′04.14″ W
103. 12°24′18.70″ S, 171°24′21.24″ W
104. 12°24′03.21″ S, 171°24′52.41″ W
105. 12°21′52.31″ S, 171°29′15.86″ W
106. 12°21′05.10″ S, 171°30′50.63″ W
107. 12°19′38.25″ S, 171°33′44.38″ W
108. 12°17′50.68″ S, 171°37′19.43″ W
109. 12°17′35.87″ S, 171°37′48.62″ W
110. 12°15′14.29″ S, 171°42′27.60″ W
111. 12°13′49.06″ S, 171°45′15.04″ W
112. 12°13′08.10″ S, 171°46′34.61″ W
113. 12°12′59.62″ S, 171°46′51.09″ W
114. 12°11′46.51″ S, 171°49′13.22″ W
115. 12°08′10.03″ S, 171°56′11.05″ W
116. 12°05′49.99″ S, 172°00′41.53″ W
117. 12°05′18.21″ S, 172°01′42.91″ W
118. 12°04′36.43″ S, 172°03′03.74″ W
119. 12°03′47.50″ S, 172°04′38.40″ W
120. 12°03′24.47″ S, 172°05′23.02″ W
121. 12°03′13.83″ S, 172°05′43.64″ W
122. 12°00′40.99″ S, 172°10′39.77″ W
123. 11°59′01.54″ S, 172°13′52.46″ W
124. 11°58′09.61″ S, 172°15′32.95″ W
125. 11°58′02.36″ S, 172°15′46.98″ W
126. 11°55′29.21″ S, 172°20′43.52″ W
127. 11°54′47.01″ S, 172°22′05.19″ W
128. 11°54′44.15″ S, 172°22′10.72″ W
129. 11°54′01.01″ S, 172°23′33.80″ W
130. 11°53′42.35″ S, 172°24′09.75″ W
131. 11°46′47.48″ S, 172°37′25.33″ W
132. 11°43′08.82″ S, 172°44′24.37″ W
133. 11°41′14.97″ S, 172°48′02.30″ W
134. 11°40′58.96″ S, 172°48′32.96″ W
135. 11°38′07.51″ S, 172°52′46.28″ W
136. 11°37′52.55″ S, 172°53′08.38″ W
137. 11°26′47.70″ S, 173°09′29.10″ W
138. 11°24′37.04″ S, 173°12′41.58″ W
139. 11°23′37.32″ S, 173°14′09.18″ W
140. 11°22′09.47″ S, 173°16′18.03″ W
141. 11°20′04.25″ S, 173°19′21.79″ W
142. 11°02′21.75″ S, 173°45′13.09″ W

Palmyra Atoll and Kingman Reef

The outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured, except that to the southeast and south of Palmyra Atoll and Kingman Reef the limit is defined by straight lines connecting the following points: [19]

1. 2°39′34.8″ N, 163°03′53.0″ W
2. 3°56′06.0″ N, 162°11′14.4″ W
3. 5°52′03.0″ N, 160°47′48.1″ W
4. 7°46′18.5″ N, 159°25′30.9″ W
5. 7°52′44.6″ N, 159°19′52.9″ W

Wake Island

The outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured, except that to the south of Wake Island the limit is defined by straight lines connecting the following points:

1. 17°56′14″ N, 169°54′07″ E
2. 17°46′01″ N, 169°31′25″ E
3. 17°37′46″ N, 169°13′00″ E
4. 17°11′17″ N, 168°13′37″ E
5. 16°41′30″ N, 167°07′46″ E
6. 16°02′45″ N, 165°43′37″ E

Jarvis Island

The outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured, except that to the north and east of Jarvis Island the limit is defined by straight lines connecting the following points: [20]

1. 1°58′59.8″ N, 162°22′43.6″ W
2. 2°02′31.6″ N, 161°38′46.0″ W
3. 1°43′16.3″ N, 159°39′22.2″ W
4. 0°45′21.7″ N, 158°46′44.3″ W
5. 0°16′35.9″ N, 158°20′58.3″ W
6. 0°01′30.1″ S, 158°05′53.7″ W
7. 1°30′55.4″ S, 156°59′50.8″ W
8. 3°10′47.0″ S, 158°11′08.6″ W
9. 3°16′18.3″ S, 158°18′14.3″ W
10. 3°16′55.3″ S, 158°19′01.7″ W

Howland and Baker Islands

The outer limit of the exclusive economic zone is 200 nautical miles from the baseline from which the breadth of the territorial sea is measured, except that to the southeast and south of Howland and Baker Islands the limit is defined by straight lines connecting the following points: [21]

1. 3°01′15.0″ S, 177°28′06.9″ W
2. 3°00′53.4″ S, 177°27′10.7″ W
3. 2°56′48.9″ S, 177°17′04.6″ W
4. 0°43′47.1″ S, 173°45′17.4″ W
5. 0°15′54.9″ N, 173°08′34.7″ W
6. 0°16′46.3″ N, 173°08′03.0″ W

Elizabeth Kim,

Director, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2023–28158 Filed 12–20–23; 8:45 am]

BILLING CODE 4710–09–P

[19] Points 1 to 5 correspond to the boundary points set forth in the Treaty between the Government of the United States of America and the Government of the Republic of Kiribati on the Delimitation of Maritime Boundaries (''U.S.-Kiribati Treaty of 2013''), signed September 6, 2013, entered into force July 19, 2019, TIAS 19–719.

[20] Points 1 to 10 correspond to the boundary points set forth in the U.S.-Kiribati Treaty of 2013 (footnote 19 of this Notice).

[21] Points 1 to 6 correspond to the boundary points set forth in the U.S.-Kiribati Treaty of 2013 (footnote 19 of this Notice).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Approval of Noise Compatibility Program Update; Westfield-Barnes Regional Airport (BAF), Westfield, Massachusetts

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the Noise Compatibility Program (NCP) Update submitted by the City of Westfield, Massachusetts, through its Aviation Department, for Westfield-Barnes Regional Airport. The Final Noise Compatibility Program (NCP) was submitted to FAA for review and approval on May 26, 2023. The NCP was found to be sufficient for consideration by the FAA, and a **Federal Register** noticed appeared on July 11, 2023. The required 60-day public comment period expired on September 9, 2023. The NEM was previously determined to be in compliance on June 13, 2019, and is still valid. The NCP contained 10 noise abatement measures, nine land use measures, and four program management measures. Of the 23 measures proposed, 12 were approved, 9 were approved as voluntary, one requires no action at this time, and one was disapproved for purposes of part 150.

DATES: The applicable start date of the FAA's approval is December 14, 2023.

FOR FURTHER INFORMATION CONTACT: Cheryl Quaine, Federal Aviation Administration, New England Regional Office Environmental Protection Specialist, Airports Division, Federal Aviation Administration, 1200 District Avenue, Burlington, Massachusetts 01803. Phone number: 781–238–7613.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA's approval of the NCP Update for the Westfield-Barnes Regional Airport. Per United States Code section 47504 (49 U.S.C. 47504) and Title 14, Code of Federal Regulations (CFR) part 150, an airport sponsor who previously

submitted a noise exposure map (NEM) may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport sponsor for the reduction of existing non-compatible land uses and prevention of additional non-compatible land uses within the area covered by the NEMs. As required by 49 U.S.C. 47504, such programs must be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and the FAA. The FAA does not substitute its judgment for that of the airport sponsor with respect to which measures should be recommended for action. The FAA approval or disapproval of an airport sponsor's recommendations in their noise compatibility program are made in accordance with the requirements and standards pursuant to 49 U.S.C. 47504 and 14 CFR part 150, which is limited to the following determinations:

a. The noise compatibility program was developed in accordance with the provisions and procedures of 14 CFR 150.23;

b. Program measures are reasonably consistent with achieving the goals of reducing existing non-compatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations of FAA's approval of NCPs are delineated in 14 CFR 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the noise compatibility program nor a determination that all measures covered by the NCP are eligible for grant-in-aid funding from the FAA. Where federal funding is sought, requests must be submitted to the FAA New England Regional Office at 1200 District Ave., Burlington, MA 01803.

The City of Westfield submitted the noise exposure maps, descriptions, and other documentation produced during the noise compatibility planning study to the FAA and the FAA determined that the NEMs for BAF were in compliance with applicable requirements under 14 CFR 150, effective June 3, 2019 (Noise Exposure Map Notice; Westfield-Barnes Regional Airport, Westfield, Massachusetts, volume 84, **Federal Register**, pages 35177–8, July 22, 2019). The airport operator requested that the FAA review the submitted material and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as an NCP. The formal review period, limited by law to a maximum of 180 days, was initiated on May 26, 2023. Notice of the intent to review the NCP was published in the **Federal Register** on July 11, 2023 (Notice of Receipt of Noise Compatibility Program Update and Request for Review, volume 88, **Federal Register**, pages 44182–3, July 11, 2023). The **Federal Register** Notice also announced the start of a 60- day period of public review for the NCP documentation. The FAA received no comments during the public review.

It was requested that the FAA evaluate and approve this material as a noise compatibility program as described in 49 U.S.C. 47504. The FAA began its review and was required by a provision of 49 U.S.C. 47504 to approve or disapprove the program within 180 days, other than the use of new or modified flight procedures for noise control. The submitted program contained 23 proposed measures to minimize impacts of aviation noise on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the 49 U.S.C. 47504 and 14 CFR part 150 were satisfied. A Record of Approval for the overall program was issued by the FAA effective December 14, 2023.

The specific program elements and their individual determinations are as follows:

NA–1—Maintain Runway Heading to East Mountain Ridge after Departing Runway 15. Approved as voluntary.

NA–2—Prohibit the Use of Intersection Departures on Runway 33. Approved as voluntary.

NA–3—Turn to 360-degrees Heading after Departing Runway 02. No action at this time.

NA–4—Barnes ANG Preferential Runway Use Program. Approved as voluntary.

NA–5: Barnes ANG Fighter Aircraft ''High Initial'' Approach Procedures. Disapproved for Purposes of Part 150.

NA–6: Barnes ANG Noise Abatement Departure Procedures. Approved as voluntary.

NA–7: Helicopter Noise Abatement Approach Procedures to Runway 02. Approved as voluntary.

NA–8: Helicopter Noise Abatement Departure Procedures from Runway 02. Approved as voluntary.

NA–9: Helicopter Noise Abatement Approach Procedures to Runways 15 and 33. Approved as voluntary.

NA–10: Helicopter Noise Abatement Departure Procedures to Runways 15 and 33. Approved as voluntary.

LU–1: Sound Insulate Noise-Sensitive Structures. Approved.

LU–2: Acquire Non-Compatible Residential Property. Approved.

LU–3: Acquire Avigation Easements. Approved.

LU–4: Modify Local Land Use Zoning. Approved.

LU–5: Modify Local Subdivision Regulations. Approved.

LU–6: Review Proposed Land Use Development within the 65 dB DNL Contour and Higher Contours. Approved.

LU–7: Voluntary Acquisition of Undeveloped Land. Approved.

LU–8: Real Estate Disclosure. Approved.

LU–9: Acquire the Arbor Mobile Home Park. Approved.

PM–1: Re-establish and Maintain a Noise Mitigation Advisory Committee. Approved.

PM–2: Continue the Community Awareness Program. Approved.

PM–3: Expand the Fly Quiet Program. Approved as Voluntary.

PM–4: Periodically Evaluate Noise Exposure. Approved.

These determinations are set forth in detail in the Record of Approval signed by the FAA Airports New England Deputy Director on December 14, 2023. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above. The Record of Approval will also be available on the internet on the FAA's website at *http://www.faa.gov/airports/environmental/airport_noise/part_150/states/* and the City of Westfield Airport's website at *www.barnesairport.com.*

Issued in New England Regional Office, Burlington, MA, on December 14, 2023.

Julie Seltsam-Wilps,

Deputy Director, ANE–600.

[FR Doc. 2023–28148 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2013–0259]

Random Drug and Alcohol Testing Percentage Rates of Covered Aviation Employees for the Period January 1, 2024 to December 31, 2024; Correction

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Random drug and alcohol testing percentage rates of covered aviation employees for the period January 1, 2024 to December 31, 2024; correction.

SUMMARY: On December 15, 2023, the Federal Aviation Administration (FAA) published a correction to the Random Drug and Alcohol Testing Percentage Rates of Covered Aviation Employees for the Period January 1, 2024 to December 31, 2024. In that document, the FAA inadvertently provided the incorrect docket number in the heading and corrections sections. This document corrects that error.

DATES: This correction is effective December 21, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Vicky Dunne, Federal Aviation Administration, Office of Aerospace Medicine, Drug Abatement Division, Program Policy Branch; Email *drugabatement@faa.gov;* Telephone (202) 267–8442.

SUPPLEMENTARY INFORMATION: On December 15, 2023, the Federal Aviation Administration (FAA) published the Random Drug and Alcohol Testing Percentage Rates of Covered Aviation Employees for the Period January 1, 2024 to December 31, 2024; Correction. In the heading and corrections section of the document, the docket number appeared as ''Docket Number FAA–2023–25488'' instead of ''Docket No. FAA–2013–0259.'' This document corrects that error.

Correction

On page 87046 of the **Federal Register**, Vol. 88 No. 240, published December 15, 2023, in the second and third columns, the following correction is made to the second line of the Heading and thirteenth line of the Corrections section.

Docket No. FAA–2013–0259

Issued in Washington, DC.

Nancy Rodriguez Brown,

Director, Drug Abatement Division.

[FR Doc. 2023–28124 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[[Docket No. FHWA–2023–0056]

Agency Information Collection Activities: Notice of Request for Renewal of Currently Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for extension of currently approved information collection.

SUMMARY: The FHWA has forwarded the information collection request described in this notice to the Office of Management and Budget (OMB) for approval of a renewal of information collection. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on October 17, 2023. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by January 22, 2024.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 0056 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: John Berg, (202) 740–4602, Office of Freight Management and Operations, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Certification of Enforcement of Vehicle Size and Weight Laws.

OMB Control #: 2125–0034.

Background: Title 23, U.S.C., section 141, requires each State, the District of Columbia and Puerto Rico to file an annual certification that they are enforcing their size and weight laws on Federal-aid highways and that their Interstate System weight limits are consistent with Federal requirements to be eligible to receive an apportionment of Federal highway trust funds. Failure of a State to file a certification, adequately enforce its size and weight laws, and enforce weight laws on the Interstate System that are consistent with Federal requirements, could result in a specified reduction of its Federal highway fund apportionment for the next fiscal year. In addition, section 123 of the Surface Transportation Assistance Act of 1978 (Pub. L. 95–599, 92 Stat.2689, 2701) requires each jurisdiction to inventory annually (1) its penalties for violation of its size and weight laws, and (2) the term and cost of its oversize and overweight permits.

Section 141 also authorizes the Secretary to require States to file such information as is necessary to verify that their certifications are accurate. To determine whether States are adequately enforcing their size and weight limits, FHWA requires that each State submit to the FHWA an updated plan for enforcing their size and weight limits. The plan goes into effect at the beginning of each Federal fiscal year. At the end of the fiscal year, States must submit their certifications and sufficient information to verify that their enforcement goals established in the plan have been met.

Respondents: The State Departments of Transportation (or equivalent) in the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico.

Frequency: Annually in separate collections: one certification and one plan.

Estimated Average Burden per Response: Each response will take approximately 40 hours.

Estimated Total Annual Burden Hours: Total estimated average annual burden is 4,160 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of

electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued On: December 18, 2023.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2023–28134 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2006–25854;FMCSA–2013–0106; FMCSA–2013–0107; FMCSA–2013–0108; FMCSA–2015–0117; FMCSA–2015–0119; FMCSA–2017–0178; FMCSA–2018–0052; FMCSA–2019–0028]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 11 individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before January 22, 2024.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA–2006–25854, Docket No. FMCSA–2013–0106, Docket No. FMCSA–2013–0107, Docket No. FMCSA–2013–0108, Docket No. FMCSA–2015–0117, Docket No. FMCSA–2015–0119, Docket No. FMCSA–2017–0178, Docket No. FMCSA–2018–0052, or Docket No. FMCSA–2019–0028 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/,* insert the docket number (FMCSA–2006–25854, FMCSA–2013–0106, FMCSA–2013–0107, FMCSA–2013–0108, FMCSA–2015–0117, FMCSA–2015–0119, FMCSA–2017–0178, FMCSA–2018–0052, or FMCSA–2019–0028) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–4001, *fmcsamedical@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket numbers for this notice (Docket No. FMCSA–2006–25854, Docket No. FMCSA–2013–0106, Docket No. FMCSA–2013–0107, Docket No. FMCSA–2013–0108, Docket No. FMCSA–2015–0117, Docket No. FMCSA–2015–0119, Docket No. FMCSA–2017–0178, Docket No. FMCSA–2018–0052, or Docket No. FMCSA–2019–0028), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *www.regulations.gov/,* insert the docket number (FMCSA–2006–25854, FMCSA–2013–0106, FMCSA–2013–0107, FMCSA–2013–0108, FMCSA–2015–0117, FMCSA–2015–0119, FMCSA–2017–0178, FMCSA–2018–0052, or FMCSA–2019–0028) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number (FMCSA–2006–25854, FMCSA–2013–0106, FMCSA–2013–0107, FMCSA–2013–0108, FMCSA–2015–0117, FMCSA–2015–0119, FMCSA–2017–0178, FMCSA–2018–0052, or FMCSA–2019–0028) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov.* As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at *https://www.transportation.gov/*

individuals/privacy/privacy-act-system-records-notices, the comments are searchable by the name of the submitter.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statutes also allow the Agency to renew exemptions at the end of the 5-year period. However, FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria [1] to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

The 11 individuals listed in this notice have requested renewal of their exemptions from the epilepsy and seizure disorders prohibition in § 391.41(b)(8), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

[1] These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. *Epilepsy:* § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 11 applicants has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition. The 11 drivers in this notice remain in good standing with the Agency, have maintained their medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period. In addition, for commercial driver's license (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of December and are discussed below. As of December 16, 2023, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers:

Eric Barnwell (MI)
Christopher Bird (OH)
Scott DeJarnette (KY)
Curtis Alan Hartman (MD)
Wendell Headley (MO)
Jason Kirkham (WI)
Dannie Kuck (MT)

The drivers were included in docket numbers FMCSA–2013–0106, FMCSA–2013–0107, FMCSA–2015–0117, FMCSA–2015–0119, FMCSA–2017–0178, or FMCSA–2018–0052. Their exemptions are applicable as of December 16, 2023 and will expire on December 16, 2025.

As of December 23, 2023, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following four individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers:

Gary Freeman (WI)
Aaron Gillette (SD)
David Kestner (VA)
Brent Mapes (IL)

The drivers were included in docket numbers FMCSA–2006–25854, FMCSA–2013–0108, or FMCSA–2019–0028. Their exemptions are applicable as of December 23, 2023 and will expire on December 23, 2025.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) each driver must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified ME, as defined by § 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based on its evaluation of the 11 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the epilepsy and seizure disorders prohibition in § 391.41(b)(8). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023–28038 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2010–0043]

Northern Indiana Commuter Transportation District's Request To Amend Its Positive Train Control Safety Plan and Positive Train Control System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on December 12, 2023, the Northern Indiana Commuter Transportation District (NICD) submitted a request for amendment (RFA) to its FRA-approved Positive Train Control Safety Plan (PTCSP). As this RFA requests FRA's approval of NICD's proposed material modifications to its FRA-certified positive train control (PTC) system, FRA is publishing this notice and inviting public comment on the railroad's RFA to its PTCSP.

DATES: FRA will consider comments received by January 10, 2024. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES:

Comments: Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA–2010–0043. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/research-development/program-areas/train-control/ptc/railroads-ptc-dockets.* All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: In general, title 49 United States Code (U.S.C.) section 20157(h) requires FRA to certify that a host railroad's PTC system complies with title 49 Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated in revenue service. Before making certain changes to an FRA-certified PTC system or the associated FRA-approved PTCSP, a host railroad must submit, and obtain FRA's approval of, an RFA to its PTCSP under 49 CFR 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal or train control system. Accordingly, this notice informs the public that, on December 12, 2023, NICD submitted an RFA to its PTCSP for its Interoperable Electronic Train Management System, which seeks FRA's approval to implement the Railcomm Back Office System and its new Computer Aided Dispatching program. That RFA is available in Docket No. FRA–2010–0043.

Interested parties are invited to comment on NICD's RFA to its PTCSP by submitting written comments or data. During FRA's review of this railroad's RFA, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to a PTC system. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny a railroad's RFA to its PTCSP at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of regulations.gov. To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2023–28008 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2016–0086]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letter dated December 13, 2022, Union Pacific Railroad Company (UPRR) and Canadian National Railway Co. (CN) petitioned the Federal Railroad Administration (FRA) to join an existing waiver of compliance in Docket Number FRA–2016–0086.[1] The existing relief in this docket provides CSX Transportation (CSX), BNSF Railway (BNSF), and Kansas City Southern Railway (now known as CPKC) conditional relief from certain provisions of the Federal railroad safety regulations contained at 49 CFR parts 232 (Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment; End-Of-Train Devices), and 229 (Railroad Locomotive Safety Standards). Specifically, the existing relief allows the railroads to test extending the air flow method (AFM) test intervals from 92 days to 184 days on locomotives equipped with the New York Air Brake (NYAB) CCB–II and Fastbrake air brake systems.

UPRR and CN seek to form test waiver teams operating under the current test committee overseeing the relief in this docket to test UPRR's 2,113 NYAB CCBII-equipped and 660 Fastbrake-equipped locomotives and CN's 772 NYAB CCB–2 equipped locomotives.

This document also provides the public notice that BNSF, who is already a party to the relief in this docket, petitioned FRA to extend the existing relief and make the relief permanent.[2] Subsequently, however, BNSF recognized existing implementation issues that could impact the validity of data being gathered under the terms of the existing relief in this docket and

[1] UPRR's petition is available at *https://www.regulations.gov/document/FRA-2016-0086-0024,* and CN's petition is available at *https://www.regulations.gov/document/FRA-2016-0086-0022.* Notice of CN's petition was previously published on November 16, 2022. *See https://www.regulations.gov/document/FRA-2016-0086-0021.*

[2] *https://www.regulations.gov/document/FRA-2016-0086-0016.*

asked FRA to suspend its field investigation of BNSF's extension request until the railroad reviewed and addressed the issues through the Test Committee established per the terms of the existing relief in this docket.[3] Given BNSF's request, on October 6, 2022, FRA dismissed BNSF's petition to allow the railroad time to correct the identified issues.[4] In a letter dated June 14, 2023, BNSF notified FRA that it had addressed the issues identified and BNSF reiterated its requests to extend and make permanent the existing relief in this docket.[5]

A copy of the petitions from UPRR, CN, and BNSF, as well as any written communications concerning the petitions, are available for review online at *www.regulations.gov.*

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted at *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Communications received by February 20, 2024 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.*

[3] *https://www.regulations.gov/document/FRA-2016-0086-0019.*

[4] *https://www.regulations.gov/document/FRA-2016-0086-0020.*

[5] *https://www.regulations.gov/document/FRA-2016-0086-0025.*

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2023–28110 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Decommissioning and Disposition of the National Historic Landmark Nuclear Ship Savannah; Notice of Public Meeting

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: The Maritime Administration (MARAD) announces a public meeting of the Peer Review Group (PRG). The PRG was established pursuant to the requirements of the National Historic Preservation Act (NHPA) and its implementing regulations to plan for the decommissioning and disposition of the Nuclear Ship Savannah (NSS). PRG membership is comprised of officials from the U.S. Department of Transportation, MARAD, the U.S. Nuclear Regulatory Commission (NRC), the Advisory Council on Historic Preservation (ACHP), and the Maryland State Historic Preservation Officer (SHPO) and other consulting parties. The public meeting affords the public an opportunity to participate in PRG activities, including reviewing and providing comments on draft deliverables. MARAD encourages public participation and provides the PRG meeting information below.

DATES: The meeting will be held on Tuesday, January 16, 2024, from 2:30 p.m. to 4:00 p.m. Eastern Standard Time (EST). Requests to attend the meeting must be received by 5:00 p.m. EST one week before the meeting, Tuesday, January 9, 2024, to facilitate entry or to receive instructions to participate online. Requests for accommodations for a disability must also be received one week before the meeting, Tuesday, January 9, 2024.

ADDRESSES: The meeting will be held onboard the NSS, online, or by phone. The NSS is located at Pier 13 Canton Marine Terminal, 4601 Newgate Avenue, Baltimore, MD 21124. To attend onboard the NSS or attend the meeting online, members of the public must submit a request to attend as described in the Public Participation section below. Online information will be provided to members of the public in response to their requests to attend. Members of the public may call-in using the following number: 312–600–3163 and entering conference ID: 930 866 814#.

FOR FURTHER INFORMATION CONTACT: Erhard W. Koehler, (202) 680–2066 or via email at *marad.history@dot.gov.* You may send mail to N.S. Savannah/Savannah Technical Staff, Pier 13 Canton Marine Terminal, 4601 Newgate Avenue, Baltimore, MD 21224, ATTN: Erhard Koehler.

SUPPLEMENTARY INFORMATION:

I. Background

The decommissioning and disposition of the NSS is an Undertaking under Section 106 of the NHPA. Section 106 requires that federal agencies consider views of the public regarding their Undertakings; therefore, in 2020, MARAD established a Federal docket at *https://www.regulations.gov/docket/MARAD-2020-0133* to provide public notice about the NSS Undertaking. The federal docket was also used in 2021 to solicit public comments on the future uses of the NSS. MARAD is continuing to use this same docket to take in public comment, share information, and post agency actions.

The NHPA Programmatic Agreement (PA) for the Decommissioning and Disposition of the NSS is available on the MARAD docket located at *www.regulations.gov* under docket id ''MARAD–2020–0133.'' The PA stipulates a deliberative process by which MARAD will consider the disposition of the NSS. This process requires MARAD to make an affirmative, good-faith effort to preserve the NSS. The PA also establishes the PRG in Stipulation II. The PRG is the mechanism for continuing consultation during the effective period of the PA and its members consist of the signatories and concurring parties to the PA, as well as other consulting parties. The PRG members will provide individual input and guidance to MARAD regarding the implementation of stipulations in the PA. PRG members and members of the public are invited to provide input by attending bi-monthly meetings and reviewing and commenting on deliverables developed as part of the PA.

II. Agenda

The agenda will include (1) welcome and introductions; (2) program update; (3) status of PA stipulations; (4) other business; and (5) date of next meeting. The agenda topic titled PA stipulations involves deliverables identified in the PA. MARAD will provide status updates for the following items: the Disposition

Alternatives Study; the Notice of Availability/Request for Information; and the License Termination Plan. The agenda will also be posted on MARAD's website at *https://www.maritime.dot.gov/outreach/history/maritime-administration-history-program* and on the MARAD docket located at *www.regulations.gov* under docket id ''MARAD–2020–0133.''

III. Public Participation

The meeting will be open to the public. Members of the public who wish to attend in person or online must submit a request to attend to the person listed in the **FOR FURTHER INFORMATION CONTACT** section with your name and affiliation. Members of the public may also call-in using the following number: 312–600–3163 and conference ID: 930 866 814#.

Special services. The NSS is not compliant with the Americans with Disabilities Act (ADA). The ship has some capability to accommodate persons with impaired mobility. If you require accommodations to attend PRG meetings in-person, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The U.S. Department of Transportation is committed to providing all participants equal access to this meeting. If you need alternative formats or services such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

(Authority: 49 CFR 1.81 and 1.93, 36 CFR part 800, 5 U.S.C. 552b.)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–28099 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans and Community Oversight and Engagement Board, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act (FACA), 5 U.S.C. ch. 10, that the Veterans and Community Oversight and Engagement Board (Board) will meet on January 31–February 1, 2024, at the VA Greater Los Angeles Healthcare System (VAGLAHS), 11301 Wilshire Boulevard, Building 500, Room 1281, Los Angeles, CA. The meeting sessions will begin and end as follows:

Date(s):	Time(s):	Location(s):	Open session
January 31, 2024	8:30 a.m. to 12:00 p.m.—Pacific Daylight Time (PDT).	VAGLAHS Facility/WEBEX link and call-in information below.	Yes.
January 31, 2024	12:00 p.m. to 5:00 p.m.—Pacific Daylight Time (PDT).	VAGLAHS Facility	No.
February 1, 2024	8:30 a.m. to 3:00 p.m.—PDT	VAGLAHS Facility/WEBEX link and call-in information below.	Yes.

The meetings are open to the public and will be recorded. Sessions are open to the public, except during the time the Board is conducting tours of VA facilities. Tours of VA facilities are closed, to protect Veterans' privacy and personal information, in accordance with 5 U.S.C 552b(c)(6).

The Board was established by the West Los Angeles Leasing Act of 2016 on September 29, 2016. The purpose of the Board is to provide advice and make recommendations to the Secretary of Veterans Affairs on identifying the goals of the community and Veteran partnership; improving services and outcomes for Veterans, members of the Armed Forces, and the families of such Veterans and members; and on the implementation of the Draft Master Plan approved by VA Secretary on January 28, 2016, and on the creation and implementation of any successor master plans.

On Wednesday, January 31, 2024, from 8:30 a.m. to 12:00 p.m. PDT, the Board will meet in open session with key staff of VAGLAHS. The Advisory Committee Management Office will present, FACA 101 training. The agenda will include opening remarks from the Committee Chair, Executive Sponsor, and other VA officials. There will be a general update from the Director of VAGLAHS. The Designated Federal Officer will provide an update on the status of recommendation packages. The Board will receive an overview of matters associated with the new Hospital Construction from Office of Construction and Facilities Management. From 12:30 p.m. to 5:00 p.m. PDT, the Board will convene with a closed tour of VAGLAHS. Tours of VA facilities are closed to protect Veterans' privacy and personal information, in accordance with 5 U.S.C 552b(c)(6).

On Thursday February 1, 2024, the Board will reconvene in open session from 8:30 a.m. to 3:00 p.m. PDT, at the VAGLAHS facility. The Office of Asset Enterprise Management will provide a comprehensive presentation on the Principal Developer's contractual relationships, terms, conditions, and commitments for permanent supportive housing to include any negotiations regarding Town Center development construction. The Office of General Counsel, Real Property Group will provide an overview of policies that govern the rights to public access on VA medical and residential facilities.

Time will be allocated for receiving public comments on February 1, at 1:45 p.m. PDT. Individuals wishing to make public comments should contact Chihung Szeto at (562) 708–9959 or at *Chihung.Szeto@va.gov* and are requested to submit a 1–2-page summary of their comments for inclusion in the official meeting record. Only those members of the public (first 12 public comment registrants) who have confirmed registrations to provide public comment will be allowed to provide public comment. In the interest of time, each speaker will be held to 5-minute time limit. The Committee will accept written comments from interested parties on issues outlined in the meeting agenda, from February 2 through February 9, 2024. Members of the public not able to attend in person can attend the meeting via WEBEX by joining from the meeting link below. The link will be active from 8:00 a.m. to 12:00 p.m. PDT on January 31, 2024, and from 8:00 a.m. to 2:30 p.m. PDT on February 1, 2024.

Day 1

Veteran Community Oversight and Engagement Board (VCOEB) Meeting (January 31–February 1, 2024)

Hosted by Walsh, Margaret K. (ERPI)

https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m58910f86b693a33153cc01165f45e6c2

Wednesday, January 31, 2024 11:00

a.m. | 4 hours | (UTC–05:00) Eastern Time (U.S. & Canada)
Meeting number: 2761 648 5320
Password: CvkBYhd*482
Agenda: TBD
Join by video system
Dial *27616485320@veteransaffairs.webex.com*
You can also dial 207.182.190.20 and enter your meeting number.
Join by phone
14043971596 USA Toll Number
Access code: 276 164 85320

Day 2

Veteran Community Oversight and Engagement Board (VCOEB) Meeting (January 31–February 1, 2024)
Hosted by Walsh, Margaret K. (ERPI)
https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=med643bde1cdf2d501fac1d2a5a3236d8
Thursday, February 1, 2024 11:00 a.m. | 9 hours | (UTC–05:00) Eastern Time (U.S. & Canada)
Meeting number: 2760 511 3108
Password: GpDAyH24k*5
Agenda: TBD
Join by video system
Dial *27605113108@veteransaffairs.webex.com*
You can also dial 207.182.190.20 and enter your meeting number.
Join by phone
14043971596 USA Toll Number
Access code: 276 051 13108

Any member of the public seeking additional information should contact Mr. Eugene W. Skinner Jr. at (202) 631–7645 or at *Eugene.Skinner@va.gov.*

Dated: December 18, 2023.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2023–28136 Filed 12–20–23; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 88 Thursday,

No. 244 December 21, 2023

Part II

Department of the Treasury

Internal Revenue Service

Department of Labor

Employee Benefits Security Administration

Department of Health and Human Services

26 CFR Part 54

29 CFR Part 2590

45 CFR Part 149

Federal Independent Dispute Resolution (IDR) Process Administrative Fee and Certified IDR Entity Fee Ranges; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9985]

RIN 1545–BQ94

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AC24

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 149

[CMS–9890–F]

RIN 0938–AV39

Federal Independent Dispute Resolution (IDR) Process Administrative Fee and Certified IDR Entity Fee Ranges

AGENCY: Internal Revenue Service (IRS), Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services (HHS).

ACTION: Final rules.

SUMMARY: This document finalizes rules related to the fees established by the No Surprises Act for the Federal independent dispute resolution (IDR) process, as established by the Consolidated Appropriations Act, 2021 (CAA). These final rules amend existing regulations to provide that the administrative fee amount charged by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (the Departments) to participate in the Federal IDR process, and the ranges for certified IDR entity fees for single and batched determinations, will be set by the Departments through notice and comment rulemaking. The preamble to these final rules also sets forth the methodology used to calculate the administrative fee and the considerations used to develop the certified IDR entity fee ranges. This document also finalizes the amount of the administrative fee for disputes initiated on or after the effective date of these rules. Finally, this document finalizes the certified IDR entity fee ranges for disputes initiated on or after the effective date of these rules.

DATES: These final rules are effective on January 22, 2024.

FOR FURTHER INFORMATION CONTACT: Shira B. McKinlay or William Fischer, Internal Revenue Service, Department of the Treasury, 202–317–5500;

Shannon Hysjulien or Rebecca Miller, Employee Benefits Security Administration, Department of Labor, 202–693–8335; and

Jacquelyn Rudich or Nora Simmons, Centers for Medicare & Medicaid Services, Department of Health and Human Services, 301–492–5211.

SUPPLEMENTARY INFORMATION:

I. Background

A. Preventing Surprise Medical Bills and Establishing the Federal IDR Process Under the Consolidated Appropriations Act, 2021

On December 27, 2020, the CAA was enacted.[1] Title I, also known as the No Surprises Act, and title II (Transparency) of Division BB of the CAA amended chapter 100 of the Internal Revenue Code (Code), part 7 of the Employee Retirement Income Security Act (ERISA), and title XXVII of the Public Health Service Act (PHS Act). The No Surprises Act provides Federal protections against surprise billing by limiting out-of-network cost sharing and prohibiting balance billing in many of the circumstances in which surprise bills most frequently arise. In particular, the No Surprises Act added new provisions applicable to group health plans and health insurance issuers offering group or individual health insurance coverage. Section 102 of the No Surprises Act added section 9816 of the Code,[2] section 716 of ERISA,[3] and section 2799A–1 of the PHS Act,[4] which contain limitations on cost sharing and requirements regarding the timing of initial payments and notices of denial of payment by plans and issuers for emergency services furnished by nonparticipating providers and nonparticipating emergency facilities, and for non-emergency services furnished by nonparticipating providers for patient visits to participating health care facilities, generally defined as hospitals, hospital outpatient departments, critical access hospitals, and ambulatory surgical centers.[5]

Section 103 of the No Surprises Act established a Federal IDR process that plans and issuers and nonparticipating providers and facilities may utilize to resolve certain disputes regarding out-of-network rates under section 9816 of the Code,[6] section 716 of ERISA,[7] and section 2799A–1 of the PHS Act.[8] Section 9816(c)(8) of the Code,[9] section 716(c)(8) of ERISA,[10] and section 2799A–1(c)(8) of the PHS Act[11] provide that each party to a determination under the Federal IDR process shall pay a fee for participating in the Federal IDR process, and the amount of the fee is an amount established by the Departments in a manner such that the total amount of fees paid by all parties is estimated to be equal to the amount of expenditures estimated to be made by the Departments for the year in carrying out the Federal IDR process.

Section 105 of the No Surprises Act added section 9817 of the Code,[12] section 717 of ERISA,[13] and section 2799A–2 of the PHS Act.[14] These sections contain limitations on cost sharing and requirements for the timing of initial payments and notices of denial of payment by plans and issuers for air ambulance services furnished by nonparticipating providers of air ambulance services, and allow plans and issuers and nonparticipating providers of air ambulance services to utilize the Federal IDR process.

The No Surprises Act also added provisions to title XXVII of the PHS Act in a new part E[15] that apply to health care providers, facilities, and providers of air ambulance services, such as prohibitions on balance billing for certain items and services and requirements related to disclosures about balance billing protections.

The Departments, along with the Office of Personnel Management (OPM), have issued rules in 2021 and 2022 to implement various provisions of the No Surprises Act. More specifically relevant to this rulemaking, the Departments and OPM issued interim final rules (July 2021 interim final

[1] Public Law 116–260 (Dec. 27, 2020).

[2] 26 U.S.C. 9816, *et seq.*

[3] 29 U.S.C. 1185e, *et seq.*

[4] 42 U.S.C. 300gg–111, *et seq.*

[5] Section 102(d)(1) of the No Surprises Act amended the Federal Employees Health Benefits (FEHB) Act, 5 U.S.C. 8901 *et seq.,* by adding a new subsection (p) to 5 U.S.C. 8902. Under this new provision, each FEHB Program contract must require a carrier to comply with requirements described in sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A–1 and 2799A–2 of the PHS Act (as applicable) in the same manner as these provisions apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.

[6] 26 U.S.C. 9816.

[7] 29 U.S.C. 1185e, *et seq.*

[8] 42 U.S.C. 300gg–111, *et seq.*

[9] 26 U.S.C. 9816(c)(8).

[10] 29 U.S.C. 1185e(c)(8).

[11] 42 U.S.C. 300gg–111(c)(8).

[12] 26 U.S.C. 9817.

[13] 29 U.S.C. 1185f, *et seq.*

[14] 42 U.S.C. 300gg–112, *et seq.*

[15] 42 U.S.C. 300gg–131–139.

rules [16] and October 2021 interim final rules) [17] and final rules (August 2022 final rules) [18] implementing provisions of sections 9816 and 9817 of the Code,[19] sections 716 and 717 of ERISA,[20] and sections 2799A–1 and 2799A–2 of the PHS Act.[21] Those rules implement provisions to protect consumers from surprise medical bills for emergency services, non-emergency services furnished by nonparticipating providers for patient visits to participating facilities [22] in certain circumstances, and air ambulance services furnished by nonparticipating providers of air ambulance services. Those rules also implement provisions to establish a Federal IDR process to determine payment amounts when there is a dispute between plans or issuers and providers, facilities, or providers of air ambulance services about the out-of-network rate for these services if a specified State law as defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30 or an applicable All-Payer Model Agreement under section 1115A of the Social Security Act does not provide a method for determining the total amount payable.

The July 2021 interim final rules and October 2021 interim final rules generally apply to plans and issuers (including grandfathered health plans) for plan years (in the individual market, policy years) beginning on or after January 1, 2022, and to health care providers, facilities, and providers of air ambulance services for items and services furnished during plan years (in the individual market, policy years) beginning on or after January 1, 2022.[23] The August 2022 final rules became effective October 25, 2022, and are applicable for items or services provided or furnished on or after October 25, 2022, for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

B. October 2021 Interim Final Rules and Related Guidance

The October 2021 interim final rules implement the Federal IDR process under sections 9816(c) and 9817(b) of the Code,[24] sections 716(c) and 717(b) of ERISA,[25] and sections 2799A–1(c) and 2799A–2(b) of the PHS Act.[26] The rules apply to emergency services, non-emergency services furnished by nonparticipating providers for patient visits to certain types of participating health care facilities [27] (unless an individual has been provided notice and waived the individual's surprise billing protections, in accordance with 45 CFR 149.410 or 149.420, as applicable), and air ambulance services furnished by nonparticipating providers of air ambulance services, for situations in which neither a specified State law as defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30 nor an All-Payer Model Agreement under section 1115A of the Social Security Act applies.

To implement the Federal IDR process, the October 2021 interim final rules include requirements governing the costs of the Federal IDR process. Under section 9816(c)(5)(F)(i) of the Code,[28] section 716(c)(5)(F)(i) of ERISA,[29] section 2799A–1(c)(5)(F)(i) of the PHS Act,[30] and the October 2021 interim final rules, the party whose offer is not selected is responsible for the payment of the fee charged by the certified IDR entity (certified IDR entity fee).[31] Under the October 2021 interim final rules, as a condition of certification, the certified IDR entity must notify the Departments of the amount of the certified IDR entity fees it intends to charge for payment determinations, which is limited to a fixed certified IDR entity fee amount for single determinations and a separate fixed certified IDR entity fee amount for batched determinations.[32] Each of these fixed certified IDR entity fees must be within a range set forth in guidance by the Departments, unless the certified IDR entity receives written approval from the Departments to charge a certified IDR entity fee outside that range.[33] The October 2021 interim final rules describe the considerations that the Departments will use to develop the certified IDR entity fee ranges, including the anticipated time and resources needed for certified IDR entities to meet the requirements of those interim final rules, the volume of payment determinations, and the capacity of the Federal IDR process to efficiently handle the volume of IDR initiations and payment determinations, and provide that the Departments will review and update the allowable fee ranges annually based on these factors, the impact of inflation, and other cost increases. Those rules also provide that on an annual basis, the certified IDR entity may update its certified IDR entity fees within the ranges set forth in current guidance and seek approval from the Departments to charge fixed certified IDR entity fees beyond the upper or lower limits for certified IDR entity fees.[34]

Additionally, pursuant to section 9816(c)(8) of the Code,[35] section 716(c)(8) of ERISA,[36] and section 2799A–1(c)(8) of the PHS Act,[37] and under the October 2021 interim final rules, each party must pay an administrative fee for participating in the Federal IDR process. The administrative fee is established in guidance in a manner so that, in accordance with the requirements of section 9816(c)(8)(B) of the Code,[38] section 716(c)(8)(B) of ERISA,[39] and section 2799A–1(c)(8)(B) of the PHS Act,[40] the total administrative fees paid for a year are estimated to be equal to the amount of expenditures estimated to be made by the Departments in carrying

[16] 86 FR 36872 (July 13, 2021).

[17] 86 FR 55980 (October 7, 2021).

[18] 87 FR 52618 (August 26, 2022).

[19] 26 U.S.C. 9816 and 26 U.S.C. 9817.

[20] 29 U.S.C. 1185e, *et seq.* and 29 U.S.C. 1185f, *et seq.*

[21] 42 U.S.C. 300gg–111, *et seq.* and 42 U.S.C. 300gg–112, *et seq.*

[22] References to a ''participating facility'' in this preamble mean a ''participating health care facility,'' as defined at 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30.

[23] The interim final rules also include interim final regulations under 5 U.S.C. 8902(p) issued by OPM that specify how certain provisions of the No Surprises Act apply to health benefit plans offered by carriers under the FEHB Act. These provisions apply to carriers in the FEHB Program with respect to contract years beginning on or after January 1, 2022. The disclosure requirements at 45 CFR 149.430 regarding patient protections against balance billing are applicable as of January 1, 2022.

[24] 26 U.S.C. 9816(c) and 26 U.S.C. 9817(b).

[25] 29 U.S.C. 1185e(c) and 29 U.S.C. 1185f(b).

[26] 42 U.S.C. 300gg–111(c) and 42 U.S.C. 300gg–112(b).

[27] A health care facility, in the context of non-emergency services, is defined as (1) a hospital (as defined in section 1861(e) of the Social Security Act), (2) a hospital outpatient department, (3) a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act), or (4) an ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act. Code section 9816(b)(2)(A)(ii), ERISA section 716(b)(2)(A)(ii), and PHS Act section 2799A–1(b)(2)(A)(ii). 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30.

[28] 26 U.S.C. 9816(c)(5)(F)(i).

[29] 29 U.S.C. 1185e(c)(5)(F)(i).

[30] 42 U.S.C. 300gg–111(c)(5)(F)(i).

[31] In the case of a batched dispute, the party with fewest determinations in its favor is considered the non-prevailing party and is responsible for paying the certified IDR entity fee. In the event that each party prevails in an equal number of determinations, the certified IDR entity fee will be split evenly between the parties. 86 FR 55980, 56001.

[32] 26 CFR 54.9816–8T(e)(2)(vii), 29 CFR 2590.716–8(e)(2)(vii), and 45 CFR 149.510(e)(2)(vii).

[33] *Id.*

[34] *Id.*

[35] 26 U.S.C. 9816(c)(8).

[36] 29 U.S.C. 1185e(c)(8).

[37] 42 U.S.C. 300gg–111(c)(8).

[38] 26 U.S.C. 9816(c)(8)(B).

[39] 29 U.S.C. 1185e(c)(8)(B).

[40] 42 U.S.C. 300gg–111(c)(8)(B).

out the Federal IDR process for that year.[41]

Contemporaneously with the October 2021 interim final rules, the Departments released the Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act (October 2021 guidance), setting the administrative fee for both parties to a dispute at $50 per party.[42] The October 2021 guidance also established the range for fixed certified IDR entity fees for single determinations as $200–$500, and the range for fixed certified IDR entity fees for batched determinations as $268–$670, unless the Departments otherwise grant approval for the certified IDR entity to charge a fee outside these ranges. In October 2022, the Departments released the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act (October 2022 guidance), again setting the administrative fee for both parties to a dispute at $50 per party.[43] The October 2022 guidance explained that the data available regarding usage of the Federal IDR process was not sufficiently reliable to support a change to either the estimated number of payment determinations for which administrative fees would be paid or the estimated ongoing program costs for 2023; therefore, the 2023 administrative fee amount due from each party for participating in the Federal IDR process would remain the same as the 2022 administrative fee amount. The October 2022 guidance permits certified IDR entities to charge a fee between $200 and $700 for single determinations and between $268 and $938 for batched determinations, unless the Departments otherwise grant approval for the certified IDR entity to charge a fee outside of these ranges. In addition, to account for the heightened workload for batched determinations, the October 2022 guidance permits a certified IDR entity to charge the following percentage of its approved certified IDR entity batched determination fee (''batching percentage'') for batched determinations, which are based on the number of line items initially submitted in the batch:

- 2–20 line items: 100 percent of the approved batched determination fee;
- 21–50 line items: 110 percent of the approved batched determination fee;
- 51–80 line items: 120 percent of the approved batched determination fee; and
- 81 line items or more: 130 percent of the approved batched determination fee.

In December 2022, the Departments released the Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act: Change in Administrative Fee (December 2022 guidance), which amended the $50 per party administrative fee set in the October 2022 guidance to $350 for calendar year 2023.[44] The change in the administrative fee for 2023 reflected the additional costs to the Departments to carry out the Federal IDR process as a result of the Departments' enhanced role in calendar year 2023 in conducting pre-eligibility reviews to allow the certified IDR entities to complete their eligibility determinations more efficiently,[45] as well as systemic improvements that allowed for the aggregation of data needed to estimate the rate at which disputes were determined eligible for the Federal IDR process and the rate at which one or both parties paid the administrative fee for purposes of calculating the administrative fee. The December 2022 guidance did not amend the certified IDR entity fee ranges provided in the October 2022 guidance.

C. Recent Litigation

On November 30, 2022, the Texas Medical Association, Tyler Regional Hospital, and a Texas physician filed a lawsuit (*TMA III*)[46] against the Departments and OPM, asserting that the July 2021 interim final rules,[47] including the regulations governing how the qualifying payment amount (QPA) should be calculated, and certain related guidance documents conflicted with the statutory language. On August 24, 2023, the U.S. District Court for the Eastern District of Texas (District Court) issued a memorandum opinion and order[48] that vacated certain portions of the July 2021 interim final rules and associated regulatory provisions[49] and portions of guidance documents,[50] including portions that provided the methodology for calculating the QPA and interpretations for certified IDR entities related to the processing of disputes for air ambulance services.

On January 30, 2023, the Texas Medical Association, Houston Radiology Associated, Texas Radiological Society, Tyler Regional Hospital, and a Texas physician filed a lawsuit (*TMA IV*)[51] against the Departments and OPM, asserting that the December 2022 guidance[52] that set the $350 per party administrative fee amount for 2023 was unlawfully issued without notice and comment rulemaking.[53] On August 3, 2023, the District Court issued a memorandum opinion and order[54] vacating the portion of the December 2022 guidance[55] that increased the

[41] 26 CFR 54.9816–8T(d)(2)(ii), 29 CFR 2590.716–8(d)(2)(ii), and 45 CFR 149.510(d)(2)(ii).

[42] Centers for Medicare & Medicaid Services (September 30, 2021). *Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Technical-Guidance-CY2022-Fee-Guidance-Federal-Independent-Dispute-Resolution-Process-NSA.pdf.*

[43] Centers for Medicare & Medicaid Services (October 31, 2022). *Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.*

[44] Centers for Medicare & Medicaid Services (December 23, 2022). *Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act: Change in Administrative Fee. https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/amended-cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.*

[45] Centers for Medicare & Medicaid Services (November 21, 2022). *Notice of the Federal Independent Dispute Resolution (IDR) Team Technical Assistance to Certified Independent Dispute Resolution Entities (IDREs) in the Dispute Eligibility Determination Process. https://www.cms.gov/files/document/idre-eligibility-support-guidance-11212022-final-updated.pdf.*

[46] Complaint, *Tex. Med. Ass'n* v. *U. S. Dep't of Health and Human Servs.,* No. 6:22–cv–00450–JDK (E.D. Tex. Nov. 30, 2022) (ECF No. 1).

[47] 86 FR 36872 (July 13, 2021).

[48] *See* Memorandum Opinion and Order, *Tex. Med. Ass'n.* v. *U.S. Dep't of Health & Hum. Servs.,* No. 6:22–cv–00450–JDK, 2023 WL 5489028 (E.D. Tex. Aug. 24, 2023).

[49] Specifically, the District Court vacated certain provisions of 26 CFR 54.9816–6T and 54.9817–1T, 29 CFR 2590.716–6 and 2590.717–1, and 45 CFR 149.130 and 149.140. The District Court also vacated 5 CFR 890.114(a), insofar as it requires compliance with the vacated regulations and guidance.

[50] Specifically, the District Court vacated FAQs 14 and 15 of *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55* (August 19, 2022), as well as portions of *Technical Guidance for Certified IDR Entities* at 2–3 (August 18, 2022).

[51] Complaint, *Tex. Med. Ass'n.* v. *U. S. Dep't of Health and Human Servs.,* No. 6:23–cv–00059–JDK (E.D. Tex. Jan. 30, 2023) (ECF No. 1).

[52] Centers for Medicare & Medicaid Services (December 23, 2022). *Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act: Change in Administrative Fee. https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/amended-cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.*

[53] Complaint, *Tex. Med. Ass'n.* v. *U. S. Dep't of Health and Human Servs.,* No. 6:23–cv–00059–JDK (E.D. Tex. Jan. 30, 2023) (ECF No. 1).

[54] *See* Memorandum Opinion and Order, *Tex. Med. Ass'n.* v. *U.S. Dep't of Health & Hum. Servs.,* No. 6:23–cv–00059–JDK, 2023 WL 4977746 (E.D. Tex. Aug. 3, 2023).

[55] Centers for Medicare & Medicaid Services (December 23, 2022). *Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the*

administrative fee for the Federal IDR process to $350 per party for disputes initiated during the calendar year beginning January 1, 2023. The District Court also vacated certain provisions of the October 2021 interim final rules setting forth the batching criteria under which multiple IDR items or services may be considered jointly as part of a single IDR dispute.[56] On August 11, 2023, the Departments released guidance [57] to reflect the *TMA IV* opinion and order related to the administrative fee to clarify that the $50 per party per dispute administrative fee amount established in the October 2022 guidance applies for disputes initiated on or after August 3, 2023, and until the Departments take action to set a new administrative fee amount.

On October 6, 2023, the Departments and OPM released ''FAQs About Consolidated Appropriations Act, 2021 Implementation Part 62'' [58] to provide guidance related to the *TMA III* opinion and order. On November 28, 2023, the Departments released guidance in accordance with the *TMA III* and *TMA IV* opinions and orders [59] to clarify how certified IDR entities should determine whether a dispute is appropriately batched and how to submit single and batched air ambulance disputes.[60]

D. Federal Independent Dispute Resolution Operations Proposed Rules

On November 3, 2023, the Departments published the Federal Independent Dispute Resolution Operations proposed rules [61] (IDR Operations proposed rules). Those proposed rules included new proposed requirements for disclosing information when initiating the Federal IDR process and the provision of certain claims codes with paper or electronic remittances. Additionally, those proposed rules would amend certain requirements related to the open negotiation period, initiation of the Federal IDR process, eligibility determinations, batched disputes, extensions due to extenuating circumstances, and the collection of administrative fees and certified IDR entity fees. Lastly, those proposed rules would require plans and issuers to register with the Federal IDR portal.

With respect to the administrative fee, the Departments proposed in the IDR Operations proposed rules to collect the administrative fee directly from the parties rather than having the certified IDR entities collect the administrative fee on the Departments' behalf. The Departments also proposed required timeframes for the initiating and non-initiating parties to pay the administrative fee and proposed to establish consequences for non-payment of the administrative fee for each party. Finally, to ensure that the Federal IDR process is accessible to all parties, the Departments proposed to charge both parties a reduced administrative fee when the highest offer made during open negotiation by either party was less than a predetermined threshold and proposed to charge the non-initiating party a reduced administrative fee when the dispute is determined ineligible by either the certified IDR entity or the Departments, as applicable.

To align with these proposals, the Departments also set forth the methodology inputs used to calculate the proposed administrative fee amounts in the preamble to the IDR Operations proposed rules that would be effective for disputes initiated on or after January 1, 2025. The Departments proposed that the full administrative fee amount would be $150 per party per dispute, the reduced administrative fee for both parties when the highest offer made by either party during open negotiation was less than the threshold would be $75 per party per dispute (50 percent of the full administrative fee amount), and the reduced administrative fee for non-initiating parties in ineligible disputes would be $30 per non-initiating party per ineligible dispute (20 percent of the full administrative fee amount).

The inputs to the methodology set forth in this preamble and the administrative fee amount the Departments are finalizing in these final rules are effective for disputes initiated on or after the effective date of these final rules. In contrast, the proposed administrative fee structure and administrative fee amounts based on inputs to the methodology set forth in the IDR Operations proposed rules, if finalized, would be effective for disputes initiated on or after January 1, 2025. The administrative fee policies finalized in these final rules are effective, and unchanged by the proposals in the IDR Operations proposed rules, unless and until superseding administrative fee policies in the IDR Operations proposed rules are adopted.

E. Public Comments Received in Response to Proposed Rules

In the September 26, 2023 **Federal Register**, the Departments published the Federal Independent Dispute Resolution (IDR) Process Administrative Fee and Certified IDR Entity Fee Ranges proposed rules (IDR Fees proposed rules),[62] which proposed to amend existing regulations to provide that the administrative fee amount charged by the Departments to participate in the Federal IDR process, and the ranges for certified IDR entity fees for single and batched determinations, would be set by the Departments through notice and comment rulemaking. The IDR Fees proposed rules also discussed the methodology used to calculate the administrative fee and the considerations used to develop the certified IDR entity fee ranges. Finally, the IDR Fees proposed rules proposed the amount of the administrative fee and the certified IDR entity fee ranges for disputes initiated on or after the later of the effective date of these rules or January 1, 2024.

The Departments received 44 comments on many different aspects of the IDR Fees proposed rules. In

No Surprises Act: Change in Administrative Fee. https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/amended-cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.

[56] Specifically, the District Court vacated the requirement under 26 CFR 54.9816–8T(c)(3)(i)(C), 29 CFR 2590.716–8(c)(3)(i)(C), and 45 CFR 149.510(c)(3)(i)(C) that for a qualified IDR item and service to be considered the same or similar item and service, it must be billed under the same service code or a comparable code under a different procedural code system, such as the Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable.

[57] U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury (August 2023). *Federal Independent Dispute Resolution (IDR) Process Administrative Fee FAQs. https://www.cms.gov/files/document/idr-admin-fees-faqs-081123-508.pdf-0.*

[58] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of Treasury, Office of Personnel Management (October 6, 2023), *FAQs about Consolidated Appropriations Act, 2021 Implementation Part 62,* available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-62.pdf and https://www.cms.gov/files/document/faqs-part-62.pdf.*

[59] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of Treasury, Office of Personnel Management (November 28, 2023), *FAQs about Consolidated Appropriations Act, 2021 Implementation Part 63,* available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-62.pdf* and *https://www.cms.gov/files/document/faqs-part-63.pdf.*

[60] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of Treasury, Office of Personnel Management (November 28, 2023), *Federal Independent Dispute Resolution (IDR) Process Batching and Air Ambulance FAQs,* available at *https://www.cms.gov/files/document/faqs-batching-air-ambulance.pdf.*

[61] 88 FR 75744.

[62] 88 FR 65888.

particular, the Departments received many comments stating that the administrative fee amount and the certified IDR entity fee ranges create a barrier to accessing the Federal IDR process for many parties, particularly small, rural, or independent providers, and these comments supported retaining the current $50 per party per dispute administrative fee amount. The Departments also received many comments on the proposed certified IDR entity fee ranges, particularly the proposed additional tiered batched fee range for disputes with more than 25 line items. While some commenters supported the increased flexibility for certified IDR entity fee ranges, many commenters were concerned about the proposed further increases in the certified IDR entity fee ranges. The Departments respond to these comments in section II of this preamble.

Many comments concerned matters that were outside of the scope of the proposed rules and therefore are not addressed in these final rules. For example, the Departments received comments stating that the current Federal IDR process lacks the efficiency needed to resolve disputes quickly. The Departments also received many comments related to the eligibility determination process, including on difficulties determining eligibility in States with a specified State law and the lack of information provided by plans and issuers. Comments on the efficiency of the Federal IDR process and eligibility determinations relate to operations that are outside of the scope of these final rules' limited focus on the administrative fee and certified IDR entity fee ranges and the processes for setting such amounts. The Departments encourage interested parties to submit comments regarding the proposals included in the IDR Operations proposed rules, including the proposal to establish a Departmental eligibility review process, in accordance with the instructions set forth in those proposed rules.[63]

Some other out-of-scope comments addressed the impacts of the Federal IDR portal closure, which occurred in response to litigation previously described in this preamble. For example, the Departments received comments requesting that, as a result of *TMA IV,* the Departments should refund $300 to each party that paid a $350 administrative fee between January 1, 2023 and August 3, 2023, and the Departments should offer an extension to parties that would have initiated a dispute if the administrative fee during that time was $50, rather than $350, to now initiate that dispute. The Departments note that this relief was requested by the plaintiffs in *TMA IV* and was denied by the court.[64] Comments also addressed the impact of *TMA III* on the calculation of the QPA, specifically asking the Departments to address underpayments to providers due to purported artificially suppressed QPAs. Additionally, the Departments received comments related to the batching requirements for submission of disputes. Some of these comments addressed specific difficulties in batching emergency medicine, radiology, and anesthesiology services and expressed a desire to broaden the batching criteria. While the IDR Operations proposed rules included proposals related to the batching requirements, these comments were outside the scope of this rulemaking because the IDR Fees proposed rules did not propose any changes to the batching requirements or calculation of the QPA.

Finally, the Departments received many comments suggesting different administrative fee structures. For example, the Departments received comments suggesting that the administrative fee amount be split between the parties, be refundable to the prevailing party, be funded 75 percent by plans and issuers and 25 percent by providers or be payable at the end of the Federal IDR process. The Departments also received comments recommending a variable administrative fee amount tied to the amount in dispute or the QPA, either for all disputes or just for batched disputes. Further comments suggested capping the administrative fee amount or imposing a base administrative fee amount and an additional tiered fee amount based on the amount in dispute.

As a result of the *TMA IV* opinion and order having set aside the Departments' guidance establishing administrative fees, the Departments set a goal of establishing in rulemaking administrative fee amounts that would be effective as close to January 1, 2024 as possible, because the current $50 administrative fee amount is insufficient to satisfy the statutory requirement that the total amount of fees paid for the year be estimated to be equal to the amount of expenditures estimated to be made for the year in carrying out the Federal IDR process. If the Departments were to continue to impose a $50 per party per dispute administrative fee amount throughout 2024, the Departments estimate that they would collect approximately $24.6 million in administrative fees for the year (492,000 administrative fees paid × $50 per party per dispute), as discussed further in section IV.D.2.a of this preamble. As discussed further in section II.A of this preamble, the Departments estimate that their expenditures to carry out the Federal IDR process in 2024 will be approximately $56.6 million. Therefore, if the administrative fee amount remains at $50 per party per dispute in 2024, the Departments would significantly under-collect administrative fees required to carry out the Federal IDR process. Accordingly, to be able to implement an increase to the administrative fee amount as soon as possible, consistent with the statutory requirement, the IDR Fees proposed rules proposed the amount of the administrative fee and the preamble to the proposed rules described the methodology for calculating it.

The Departments did not propose any changes to the structure of the administrative fee as this would take longer to develop and implement and would be more efficiently operationalized with the changes proposed in the IDR Operations proposed rules, which are intended to be more comprehensive. While the Departments considered alternative fee structures in this rulemaking, the Departments were of the view that addressing the structure of the administrative fee in the IDR Operations proposed rules would give interested parties more time to comment, consider, and prepare for any fee structure change, because the effective date of the IDR Operations proposed rules, if finalized, will be later than the effective date of these final rules.

Additionally, the policies proposed in the IDR Operations proposed rules would require more time for the Departments to develop and implement due to the substantial changes to the Federal IDR portal required by those proposals, if finalized, including adopting new processes to collect the administrative fees directly from the parties and collecting differing amounts of administrative fees from different parties in certain circumstances, as described further in the IDR Operations proposed rules. Therefore, the Departments deferred those proposed changes to the Federal IDR process and administrative fee structure and collection procedures to the IDR Operations proposed rules and prioritized completing this rulemaking.

The Departments encourage interested parties to submit relevant comments

[63] *See* 88 FR 75744.

[64] *See* Memorandum Opinion and Order, *Tex. Med. Ass'n., et al.* v. *U.S. Dep't of Health and Human Servs., et al.,* No. 6:23–cv–00059–JDK (E.D. Tex. August 3, 2023).

regarding batching and the administrative fee structure, the new inputs to the administrative fee methodology, and the amount of the fee proposed in the IDR Operations proposed rules, in response to those proposed rules.[65]

The Departments also sought to establish in rulemaking certified IDR entity fee ranges that would be effective as close to January 1, 2024 as possible, because this effective date would provide predictability for certified IDR entities, who must plan for and finalize their 2024 certified IDR entity fixed fee amounts, and parties, who must budget for their participation in the Federal IDR process taking into account both the administrative and certified IDR entity fees. Establishing the certified IDR entity fee ranges in rulemaking with an effective date close to January 1, 2024 would also allow for greater transparency than the current method of establishing the fee ranges in guidance.

F. Scope and Purpose of Rulemaking

These final rules amend 26 CFR 54.9816–8(d)(2)(ii) and (e)(2)(vii), 29 CFR 2590.716–8(d)(2)(ii) and (e)(2)(vii), and 45 CFR 149.510(d)(2)(ii) and (e)(2)(vii) to provide that the administrative fee amount and the ranges for certified IDR entity fees for single and batched disputes will be set by the Departments through notice and comment rulemaking, rather than in guidance published annually. The preamble to this rulemaking also sets forth the methodology used to calculate the administrative fee amount and the considerations used to develop the certified IDR entity fee ranges. These rules also finalize the administrative fee amount and certified IDR entity fee ranges for disputes initiated on or after the effective date of these rules. The finalized administrative fee amount and certified IDR entity fee ranges in these rules will remain in effect until changed by notice and comment rulemaking.

The IDR Fees proposed rules proposed that the administrative fee amount and certified IDR entity fee ranges finalized in these final rules would be effective for disputes initiated on or after the later of the effective date of these rules or January 1, 2024. As these final rules will not be effective by January 1, 2024, the Departments are finalizing the proposal that the administrative fee amount and certified IDR entity fee ranges in these rules will be effective for disputes initiated on or after the effective date of these rules, which is 30 calendar days from publication in the **Federal Register**.

[65] *See* 88 FR 75744.

II. Overview of the Final Rules—Departments of the Treasury, Labor, and HHS

A. Administrative Fee Amount and Methodology

1. Summary of Proposed and Finalized Policies

Under section 9816(c)(8)(A) of the Code,[66] section 716(c)(8)(A) of ERISA,[67] section 2799A–1(c)(8)(A) of the PHS Act,[68] and the October 2021 interim final rules,[69] each party to a determination for which a certified IDR entity is selected must pay an administrative fee for participating in the Federal IDR process. Under section 9816(c)(8)(B) of the Code,[70] section 716(c)(8)(B) of ERISA,[71] section 2799A–1(c)(8)(B) of the PHS Act,[72] and the October 2021 interim final rules,[73] the administrative fee is established in a manner such that the total amount of administrative fees paid for a year are estimated to be equal to the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process for that year.

The Departments proposed to establish the amount of the administrative fee through notice and comment rulemaking by amending 26 CFR 54.9816–8(d)(2)(ii), 29 CFR 2590.716–8(d)(2)(ii), and 45 CFR 149.510(d)(2)(ii). The Departments also proposed at 26 CFR 54.9816–8(d)(2)(ii), 29 CFR 2590.716–8(d)(2)(ii), and 45 CFR 149.510(d)(2)(ii) that, for disputes initiated on or after the later of the effective date of these rules or January 1, 2024, the administrative fee amount would be $150 per party per dispute, which would remain in effect until changed by notice and comment rulemaking.[74] Under the proposed rules, the Departments would have retained the flexibility to update the administrative fee more or less frequently than annually if the total estimated amount of administrative fees paid or amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process changed such that a new administrative fee amount would be required to satisfy the requirement that the total amount of administrative fees paid is estimated to be equal to the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process.

The Departments proposed to set the administrative fee amount by estimating the amount of expenditures made by the Departments in carrying out the Federal IDR process and dividing this amount by the estimated total number of administrative fees paid by the parties. As explained in the preamble to the IDR Fees proposed rules, the Departments estimated the total number of administrative fees paid based on the total volume of closed disputes.

For the purpose of calculating the administrative fee amount in the IDR Fees proposed rules, the Departments projected that approximately 225,000 disputes would be closed annually, resulting in 450,000 administrative fees paid. Additionally, the Departments estimated that the expenditures made by the Departments for carrying out the Federal IDR process in 2024 would be approximately $70 million.[75] Using this methodology, proposed in paragraphs 26 CFR 54.9816–8(d)(2)(ii), 29 CFR 2590.716–8(d)(2)(ii), and 45 CFR 149.510(d)(2)(ii), the Departments calculated the proposed administrative fee for disputes initiated on or after the effective date of these rules, and continuing until changed by notice and comment rulemaking, by dividing the annual expenditures of approximately $70 million estimated to be made by the Departments in carrying out the Federal IDR process by 450,000, the estimated annual number of administrative fees to be paid by the disputing parties. This resulted in a proposed administrative fee amount of $150 per party per dispute.[76]

After considering comments received on the proposals, as discussed further in this preamble section, the Departments are finalizing the policy to set the administrative fee amount in notice and comment rulemaking no more frequently than once per calendar year. The Departments may set the administrative fee less frequently than annually if the Departments estimate

[66] 26 U.S.C. 9816(c)(8)(A).

[67] 29 U.S.C. 1185e(c)(8)(A).

[68] 42 U.S.C. 300gg–111(c)(8)(A).

[69] 26 CFR 54.9816–8T(d)(2)(i), 29 CFR 2590.716–8(d)(2)(i), and 45 CFR 149.510(d)(2)(i).

[70] 26 U.S.C. 9816(c)(8)(B).

[71] 29 U.S.C. 1185e(c)(8)(B).

[72] 42 U.S.C. 300gg–111(c)(8)(B).

[73] 26 CFR 54.9816–8T(d)(2)(ii), 29 CFR 2590.716–8(d)(2)(ii), and 45 CFR 149.510(d)(2)(ii).

[74] As previously mentioned, in the event the effective date of these final rules is after January 1, 2024, the $50 per party per dispute administrative fee amount in effect for 2023, as provided in the October 2022 guidance, will continue to apply to disputes initiated between January 1, 2024 and the effective date of these rules.

[75] The list of expenditures associated with the estimated $70 million was provided in the IDR Fees proposed rules at 88 FR 65893.

[76] As described in the IDR Fees proposed rules, the Departments estimated that the proposed administrative fee amount of $150 per party per dispute would result in an estimated annual collection approximately equal to the estimated annual expenditures of approximately $70 million. *See* 88 FR 65888 at 65899.

that the total amount of administrative fees paid under the current administrative fee amount would continue to be equal to the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process for the upcoming calendar year.

Additionally, in response to comments received on the proposals, the Departments are modifying the administrative fee methodology used to estimate the number of administrative fees paid. The Departments will use the estimated number of administrative fees paid to certified IDR entities, rather than the estimated number of closed disputes, to estimate the total number of administrative fees paid. In addition, the Departments will not assume, as set forth in the IDR Fees proposed rules, a 25 percent reduction in the volume of disputes as the result of the District Court vacating certain batching requirements in *TMA IV.* The Departments are also revising the expenditures estimated to be made by the Departments in carrying out the Federal IDR process from approximately $70 million to approximately $56.6 million to reflect a reduction in the Departments' anticipated assistance with eligibility determinations, as discussed later in this preamble. Collectively, these modifications to the methodology result in a finalized administrative fee amount of $115 per party per dispute for disputes initiated on or after the effective date of these rules. As the administrative fee methodology in the IDR Operations proposed rules included some of the same elements as the administrative fee methodology in the IDR Fees proposed rules, the Departments will consider whether any modifications made to the administrative fee methodology in these final rules should also be adopted when finalizing the administrative fee amount using the methodology proposed in the IDR Operations proposed rules.

2. Summary of Comments Received and Responses to Comments

a. Establishing the Administrative Fee in Notice and Comment Rulemaking

Many commenters supported the proposal to establish the administrative fee in notice and comment rulemaking. Commenters stated that this transparent process would allow the public to evaluate the administrative fee amount and provide feedback on the feasibility of providers using the Federal IDR process. However, several commenters opposed the proposal to establish the administrative fee amount more or less frequently than annually and stated that adopting this proposal would introduce uncertainty in the Federal IDR process and would make budgeting more challenging. These commenters requested that the Departments update the administrative fee annually, to balance stability, transparency, and responsiveness, which they stated would mitigate the impact of changes to the administrative fee. One commenter supported the proposal to establish the administrative fee amount more or less frequently than annually, but only if a mid-year change led to a decrease to the administrative fee amount. Commenters also stated that any increases to the administrative fee amount should be on an annual basis with advance notice to interested parties. One of these commenters stated that the administrative fee amount should be set predictably and with at least 90 days' advance notice. Some commenters requested further clarification on the process for proposing and finalizing administrative fee amounts in notice and comment rulemaking.

The Departments agree that one of the goals of establishing the administrative fee amount in notice and comment rulemaking is to foster transparency and allow interested parties to provide feedback on the methodology and process for setting the proposed fee amount. The Departments recognize commenters' concerns about establishing the administrative fee amount more or less frequently than annually, and the Departments are finalizing a policy under which they would establish the administrative fee amount no more frequently than once per calendar year. In addition, the Departments are finalizing as proposed the proposal to change the administrative fee amount less frequently than annually if the expenditures estimated to be made by the Departments in carrying out the Federal IDR process and the estimated total amount of administrative fees paid in the upcoming year are estimated to be equal. If the Departments determine that the estimated total amount of administrative fees paid in a future year at the current administrative fee amount would be less than the expenditures estimated to be made by the Departments in carrying out the Federal IDR process for that year, the Departments would propose to raise the administrative fee amount in notice and comment rulemaking. Alternatively, if the Departments determine that the estimated total amount of administrative fees paid in a future year at the current administrative fee amount would be more than the expenditures estimated to be made in carrying out the Federal IDR process for that year, the Departments would propose to lower the administrative fee amount in notice and comment rulemaking. Consistent with the statute, the Departments will set the administrative fee such that the estimated total amount of administrative fees paid is equal to the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process.[77]

The Departments also reiterate that using the notice and comment rulemaking process to establish the administrative fee amount will provide interested parties with substantial advance notice of fee changes, so additional advance notice is not needed. As described in the IDR Fees proposed rules, the Departments will provide details on the methodology used to determine the proposed administrative fee amount, and the proposed administrative fee amount, if finalized, would be effective prospectively. Interested parties will be provided with a period to submit public comments on the proposals, and the Departments will consider all comments submitted within the comment period in developing the final rules.

In addition, other commenters raised concerns regarding the amount of the administrative fee changing between any proposed and final rules. One commenter did not support making changes to the administrative fee amount between the proposed and final rules, while another commenter stated that any such changes should be by no more than 10 percent.

The Departments acknowledge these commenters' suggestions but note that the Departments may have more recent data available to estimate the total amount of administrative fees paid or the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process while developing the final rules than they had while developing the IDR Fees proposed rules, and it is reasonable for the Departments to rely on the more recent data in developing the final rules, provided that they use the methodology described in the preamble to the IDR Fees proposed rules or a methodology modified from the preamble to the IDR Fees proposed rules in response to comments. As in these final rules, these circumstances may result in the Departments finalizing a different administrative fee amount than the amount proposed. The finalized

[77] Section 9816(c)(8)(B) of the Code, section 716(c)(8)(B) of ERISA, and section 2799A–1(c)(8)(B) of the PHS Act.

administrative fee amount will differ from the amount proposed, if necessary, to comply with the statutory requirement that the total administrative fees paid are estimated to be equal to the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process.[78]

One commenter was concerned about the ability to comment on the administrative fee amount rather than just the methodology used to calculate the amount and stated that only seeking comment on the methodology could inhibit commenters' ability to accurately express the impact of the proposed fee amount on a disputing party's access to the Federal IDR process.

As previously explained, the Departments are finalizing a policy to establish the administrative fee amount in notice and comment rulemaking no more frequently than once per calendar year and will provide opportunity for comment on any new proposed administrative fee amount, as well as any changes to the methodology used to calculate the administrative fee amount.

b. Administrative Fee Methodology—Estimated Total Number of Administrative Fees Paid

Many commenters opposed the Departments' proposed administrative fee methodology for estimating the total number of administrative fees to be paid. Many commenters suggested that estimating the total number of administrative fees paid based on the projected total number of disputes closed would not capture all disputes in which administrative fees are paid. Some commenters were concerned that this methodology could result in an overpayment of administrative fees to the Departments. One of these commenters was concerned that the data from the six-month period in 2023 used to estimate the number of disputes closed would be radically different from 2024 data. Several commenters suggested using other metrics to calculate the estimated total number of administrative fees paid, including the number of disputes initiated, the number of disputes for which a certified IDR entity fee was paid, and the number of disputes for which parties submitted offers. Moreover, some commenters asserted that using disputes closed contradicts the Departments' regulations requiring each party to pay the administrative fee at the time the certified IDR entity is selected and the Departments' guidance permitting certified IDR entities to collect the administrative fee from parties up to the time of offer submission.[79]

The Departments proposed to use the projected total number of disputes closed to calculate the administrative fee amount because that metric reflected collections under current collections processes,[80] and the Departments were of the view that it was a reliable metric upon which to base the estimated total number of administrative fees to be paid. However, after considering the comments, the Departments agree with the commenters who stated that estimating the total number of administrative fees paid using the projected number of disputes closed would not capture all disputes in which administrative fees are paid because administrative fees may be paid for disputes that have not yet been closed. To capture all disputes in which parties pay administrative fees, the Departments are finalizing the administrative fee amount based on a methodology that estimates the total number of administrative fees paid by projecting Federal IDR portal data on the number of administrative fees paid to certified IDR entities, as explained in the subsequent paragraphs. The number of administrative fees paid to certified IDR entities is currently the best available metric in the Federal IDR portal data to capture all administrative fees parties pay for disputes in any stage of the Federal IDR process.

In the preamble to the IDR Fees proposed rules, the Departments set the administrative fee amount based on the projection that 225,000 disputes would be closed annually. Because both initiating and non-initiating parties to a dispute are required to pay the administrative fee, the Departments estimated in the preamble to the IDR Fees proposed rules that 450,000 administrative fees would be paid annually, or 37,500 per month. As explained above, in setting the administrative fee in these final rules, the Departments are using the total number of administrative fees paid to certified IDR entities for disputes in any stage of the Federal IDR process after certified IDR entity selection. Using the methodology being adopted in these final rules, the Departments estimate that 492,000 administrative fees will be paid annually, or 41,000 administrative fees will be paid per month, by the parties. The Departments estimate the total number of administrative fees paid annually based on the monthly average number of administrative fees paid to certified IDR entities between February 2023 and July 2023. This monthly average was approximately 41,000, and the Departments projected this figure forward by 12 months to estimate that 492,000 administrative fees will be paid annually.

The Departments are using data from the same time period that was used in the IDR Fees proposed rules (February 2023 to July 2023), without updating to newer data. Data from this time period remains the best available data to project future trends due to portal closures and other Federal IDR process changes that began in August 2023 due to the *TMA III* and *TMA IV* opinions and orders. While the Departments considered using data from the most recent six-month period prior to the finalization of this rule (June 2023 to November 2023), they concluded this would inaccurately reflect the monthly average number of administrative fees paid, as various aspects of the Federal IDR process were temporarily suspended from August 4, 2023 to October 6, 2023 for all disputes.[81]

The Departments considered comments providing alternatives for estimating the total number of administrative fees paid in calculating the administrative fee amount. Some commenters wanted the Departments to estimate the total number of administrative fees paid based on the number of disputes initiated. This metric is inaccurate for purposes of calculating the administrative fee amount because the administrative fee may not be collected for all disputes initiated. The obligation for parties to pay the administrative fee attaches at the time of certified IDR entity selection (with guidance permitting certified IDR entities to collect the administrative fee from parties until the time of offer submission). Therefore, if a dispute is withdrawn before selection of the certified IDR entity, there is no obligation for the parties to pay

[78] *Id.*

[79] *See* 26 CFR 54.9816–8(d)(2)(i), 29 CFR 2590.716–8(d)(2)(i), and 45 CFR 149.510(d)(2)(i); *see also* section 4.8 of the *Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities.* October 2022. *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/federal-independent-dispute-resolution-process-guidance-for-certified-idr-entities.pdf.*

[80] Under current guidance, the administrative fee may be collected by certified IDR entities up until the time the parties submit their offers, and therefore the administrative fee is not collected for all disputes initiated. *See,* for example, Centers for Medicare & Medicaid Services (March 2023). *Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities. https://www.cms.gov/files/document/federal-idr-guidance-idr-entities-march-2023.pdf.*

[81] Of note, batched disputes and single disputes involving air ambulance services also remained suspended after October 6, 2023 and would not be reflected in the most recent data.

administrative fees for that dispute. For this reason, using the total number of disputes initiated to estimate the number of administrative fees to be paid in the administrative fee methodology risks the Departments underfunding the Federal IDR process.[82]

Other commenters requested the Departments to estimate the total number of administrative fees paid based on the number of disputes for which a certified IDR entity fee was paid. Because parties are not required to pay their certified IDR entity fees and administrative fees at the same time, the number of certified IDR entity fees paid would not necessarily reflect the number of administrative fees paid. Therefore, this metric would also be inaccurate for purposes of calculating the administrative fee amount.

Finally, the Departments also considered estimating the total number of administrative fees paid based on the number of disputes for which parties submitted offers. However, the Departments did not believe this metric would accurately reflect the estimated number of administrative fees that would be paid, since parties may pay administrative fees without submitting offers. Thus, the metric could understate the total number of administrative fees paid.

In summary, the Departments are of the view that it is most accurate to use the total number of administrative fees paid to certified IDR entities in the administrative fee methodology rather than the other metrics suggested by commenters in the prior paragraphs, as this metric reflects actual administrative fees that have been paid for disputes in any stage of the Federal IDR process after certified IDR entity selection.[83] Therefore, in recognition of commenters' concerns about a methodology that could underestimate the total number of administrative fees paid in 2024, resulting in an overestimate of the amount of the administrative fee needed for 2024, the Departments are establishing the administrative fee methodology using the total number of administrative fees paid to certified IDR entities, rather than the total number of closed disputes, to estimate the total number of administrative fees paid in 2024.

The Departments also received comments regarding the Departments' projections of the total number of closed disputes used to estimate the total number of administrative fees paid. Several commenters suggested that the Departments' estimate of 225,000 closed disputes is too low. A few commenters suggested that the Departments are underestimating utilization of the Federal IDR process and recommended that the Departments analyze the available data from States implementing similar policies before the No Surprises Act.

In the IDR Fees proposed rules, the Departments estimated that 225,000 disputes would be closed annually, and because both the initiating and non-initiating parties to a dispute are required to pay the administrative fee, 450,000 administrative fees would be paid annually. The Departments now estimate that 492,000 administrative fees will be paid to certified IDR entities in the year, as described earlier in this preamble section. The Departments continue to be of the view that Federal IDR process data is the best available data to project trends in the Federal IDR process, especially because regulations and volume differ in State IDR processes. As mentioned in the IDR Fees proposed rules, the Departments initially anticipated 17,333 disputes involving non-air ambulance services would be initiated during the first year of implementation of the Federal IDR process. The Departments developed this estimate based on the experience of New York State. However, the use of State data resulted in the Departments underestimating utilization of the Federal IDR process, as nearly 335,000 disputes were initiated in the Federal IDR process between April 2022 and March 2023.[84] As demonstrated by this result, past data from State processes has limited applicability in predicting future use of the Federal IDR process. For this reason, the Departments are of the view that it is better to use Federal IDR process data rather than State data to estimate the total number of administrative fees paid.

In addition, several commenters disagreed with the Departments' assumption of a 25 percent reduction in the volume of disputes in estimating the total number of administrative fees paid to account for the impact of *TMA IV*'s vacatur of batching regulations and guidance, or asked for more detail on how the projected 25 percent reduction factor was determined, including the details on how the batching of claims will be treated in the future. One commenter noted that the vacatur of the $350 administrative fee amount and batching regulations as a result of *TMA IV* allows many additional claims to become economically viable, so the Departments should expect dispute volume to increase. Another commenter stated that the Departments cannot know with certainty that the *TMA IV* opinion and order will decrease the number of disputes. This commenter also asserted that *TMA IV* did not affect the batching criteria that serve as the largest obstacle for emergency medicine, and therefore there will not be large batches in emergency medicine, which the commenter noted comprised over 70 percent of disputes reflected in the Partial Report on the Independent Dispute Resolution (IDR) Process October 1–December 31, 2022.[85] Moreover, a few commenters suggested that the *TMA III* opinion and order will increase dispute volume as providers will continue to see low QPAs from plans and issuers and will rely on the Federal IDR process for appropriate payment. One commenter agreed with the Departments' assumption that the *TMA IV* opinion and order will decrease the volume of disputes but disagreed with the Departments' rationale that the increased number of line items will take more time to close. This commenter expected that providers batching claims rather than submitting claims individually would increase efficiencies in the Federal IDR process.

After reviewing the comments, the Departments have reconsidered the assumption that the number of disputes will decrease by 25 percent as a result of *TMA IV*'s vacatur of batching regulations and guidance. Therefore, the Departments are not finalizing the projected 25 percent reduction in the estimated total number of administrative fees paid.

The Departments recognize that certain batching criteria remain in place,

[82] In the IDR Operations proposed rules, the Departments proposed to use the total volume of disputes projected to be initiated because the proposed operational changes in those rules, if finalized, would result in the Departments' collection of administrative fees closer to a dispute's date of initiation, and therefore, it may be appropriate to estimate the total volume of administrative fees paid using the total volume of disputes initiated. 88 FR 75793.

[83] As explained in these final rules, under current processes, the total volume of administrative fees paid to certified IDR entities is the best metric to use in the administrative fee methodology to align with statute requiring the Departments to estimate the total number of administrative fees paid. As operations of the Federal IDR process improve over time, the Departments will consider changes to the methodology to best estimate the total number of administrative fees paid.

[84] Centers for Medicare & Medicaid Services (April 27, 2023). *Federal Independent Dispute Resolution Process—Status Update. https://www.cms.gov/files/document/federal-idr-processstatus-update-april-2023.pdf.*

[85] U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury. *Partial Report on the Independent Dispute Resolution (IDR) Process October 1–December 31, 2022. https://www.cms.gov/files/document/partial-report-idr-process-octoberdecember-2022.pdf.*

such as criteria that impact the batching of emergency medicine claims, and items and services included in such claims will have to be submitted as separate disputes if they do not comply with the applicable batching criteria.[86] Moreover, because the Departments are finalizing the administrative fee amount based on a methodology that estimates the total number of administrative fees paid based on the total number of administrative fees paid to certified IDR entities, rather than the total number of closed disputes, the methodology no longer requires the Departments to make an assumption on whether batched disputes will take more time to close after the vacatur of the batching regulations as a result of *TMA IV.* In addition, the Departments do not have data available to support commenters' assertion that *TMA III* will lead more providers to rely on the Federal IDR process for appropriate claims payment. Plans and issuers are required to calculate QPAs using a good faith, reasonable interpretation of the applicable statutes and regulations that remain in effect after the *TMA III* opinion and order.[87] Furthermore, in their experience operating the Federal IDR process, the Departments have not seen a clear or quantifiable relationship between changes in policy and changes in the number of disputes initiated. The Departments are of the view that the historical data from February 2023 to July 2023 is the best available data at this time to project utilization of the Federal IDR process in 2024, and the Departments are therefore finalizing the administrative fee amount based on a methodology that does not include a 25 percent reduction in the volume of disputes.

c. Administrative Fee Methodology—Estimated Expenditures

The Departments also received comments related to their estimated expenditures for purposes of calculating the administrative fee amount. Several commenters suggested that the Departments should disclose more data supporting the estimated costs to carry out the Federal IDR process in the administrative fee methodology to provide the public with an opportunity to comment. Some of these commenters asserted that the IDR Fees proposed rules did not provide enough detail on the estimated expenditures to allow interested parties to provide meaningful comment on the proposed administrative fee amount. One commenter urged the Departments to establish a regular process for detailing the Departments' data on the administrative fee, including an annual disclosure statement with a balance sheet, to promote transparency and predictability. A few commenters disputed the Departments' reference that Freedom of Information Act (FOIA) regulations prevent the Departments from providing detail on certain estimated expenditure amounts. These commenters stated that without this transparency, interested parties were not afforded an opportunity to meaningfully comment on the proposals related to the administrative fee amount and methodology inputs.

The Departments are finalizing the administrative fee amount based on a methodology that divides the ''estimated,'' rather than ''projected,'' expenditures to carry out the Federal IDR process by the estimated total number of administrative fees to be paid in the year. The use of ''estimated'' rather than ''projected'' expenditures is to ensure the terminology used to describe the methodology is consistent with that of the statutory text.[88] To calculate the estimated expenditures to carry out the Federal IDR process, the Departments included the Federal resources needed to carry out the Federal IDR process, such as future personnel and contract costs. The preamble to the IDR Fees proposed rules provided an overview of the future contract costs and Federal resources included in the estimated expenditures and explained that the estimated expenditures to carry out the Federal IDR process in 2024 were approximately $70 million. The Departments disagree with commenters that the Departments did not provide sufficient information to allow meaningful comment. In particular, in the preamble to the IDR Fees proposed rules, the Departments provided details on the types of costs that are included in the estimated expenditures.[89]

While the Departments described the contract costs and Federal resources associated with estimated expenditures to carry out the Federal IDR process in the preamble to the IDR Fees proposed rules, in response to comments requesting additional specifics on the estimated expenditures and in an effort to promote transparency, the Departments are providing further detail on costs included in the total estimated expenditures in these final rules within the bounds of the Departments' ability to disclose these amounts. To avoid releasing sensitive contract information, the Departments are breaking down the costs, which include the future contract and Federal personnel costs, by category of expenditure, and providing approximate cost estimates for carrying out the following categories of Federal IDR process activities: [90]

- Maintaining, operating, and improving the Federal IDR portal, certifying IDR entities, and collecting data from certified IDR entities (approximately $26,360,000);
- Conducting program integrity activities, such as certain QPA audits (as further described subsequently in this preamble) and IDR decision audits, and receiving and investigating Federal IDR process-related complaints (approximately $13,060,000, of which QPA audits resulting from complaints filed by providers, facilities, or providers of air ambulance services comprise approximately $5,000,000);
- Providing outreach to parties and technical assistance to certified IDR entities, including assisting with eligibility determinations when the volume of disputes submitted exceeds the capacity of certified IDR entities to perform those determinations (approximately $11,630,000, of which assisting with eligibility determinations comprises approximately $10,000,000); [91] and
- Collecting administrative fees (approximately $5,530,000), which includes costs to invoice certified IDR entities for administrative fees collected, provide the system infrastructure for certified IDR entities to record and remit administrative fees collected, track data on fees collected and make continuous improvements to the collections process and invoicing systems.

[86] U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of Treasury, Office of Personnel Management (October 6, 2023). *FAQs about Consolidated Appropriations Act, 2021 Implementation Part 62. https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-62.pdf* and *https://www.cms.gov/files/document/faqs-part-62.pdf.*

[87] *Id.*

[88] Section 9816(c)(8)(B) of the Code, section 716(c)(8)(B) of ERISA, and section 2799A–1(c)(8)(B) of the PHS Act.

[89] 88 FR 65893.

[90] As discussed further later in this preamble section, the Departments have reconsidered costs associated with total estimated expenditures of carrying out the Federal IDR process and are revising the total estimated expenditures for 2024 from approximately $70 million to approximately $56.6 million. Additionally, certain expenses apply across multiple categories that were included in the IDR Fees proposed rules. This revised combination of categories better provides a meaningful cost estimate of these activities.

[91] Centers for Medicare & Medicaid Services (November 21, 2022). *Notice of the Federal Independent Dispute Resolution (IDR) Team Technical Assistance to Certified Independent Dispute Resolution Entities (IDREs) in the Dispute Eligibility Determination Process. https://www.cms.gov/files/document/idre-eligibility-support-guidance-11212022-final-updated.pdf.*

The Departments are publishing summary-level estimated budget information and have provided meaningful data for public input for the purposes of calculating the administrative fee amount. The Departments intend to continue to provide data on the Federal IDR process to promote transparency and predictability in the administrative fee amount, including publishing quarterly public reports with the Departments' expenditures and administrative fee collections.[92]

In response to commenters' concerns regarding the Departments' reference to the applicability of FOIA exemptions to information shared during the rulemaking process, the Departments clarify that they will disclose information in response to any requests in accordance with the FOIA and accompanying regulations. However, the Departments are not publishing specific future contract estimates in this rule in response to commenters' requests for more detail on estimated expenditures of Federal IDR process activities and the data underlying those estimates because publishing those contract estimates could undermine future contract procurements. For example, if the Departments were to publish the projected future cost of the contracts used to maintain the Federal IDR portal, the Federal Government would be meaningfully disadvantaged in future contract negotiations related to the Federal IDR portal, as bidders would know how much the Departments anticipate such a future contract being worth. Although current contract awards are published and publicly available,[93] these award amounts do not necessarily reflect the future value of the contract, as there may be future changes in policy and operations and the scope of work.

The Departments are of the view that interested parties had sufficient information to meaningfully comment on the IDR Fees proposed rules. For example, commenters provided valuable information in their comments regarding how the Departments should estimate the total number of administrative fees paid. Based on these comments, the Departments modified the methodology accordingly. Similarly, the Departments provided detailed information in the IDR Fees proposed rules on their calculation of the estimated expenditures to carry out the Federal IDR process. Specifically, the Departments detailed the types of activities included in estimating the annual expenditures of approximately $70 million and received comments on these activities. After considering comments received on these details of the administrative fee methodology, the Departments have revised this estimate of annual expenditures down to approximately $56.6 million, as explained in later paragraphs.

In addition, many commenters raised concerns about the inclusion of certain types of expenses in the administrative fee methodology. Several commenters recommended excluding all or some of the QPA audit costs given that the QPA also serves a purpose outside of the Federal IDR process in calculating patient cost sharing. Some commenters asked the Departments to disclose their total expenditures on QPA audits and the portion proposed to be funded by administrative fees compared to other sources.

As previously mentioned, the Departments are required to include estimated expenditures to carry out the Federal IDR process, which include contract costs and Federal resources, in calculating the administrative fee amount. Accordingly, the Departments disagree with commenters who suggested that QPA audit costs should not be included in the calculation of the administrative fee amount and are adopting an administrative fee methodology that includes certain QPA audit costs in the estimated expenditures. For any dispute in the Federal IDR process, a plan or issuer would have been required to disclose the QPA to the provider along with the initial payment or notice of denial of payment for items and services, and disputing parties must include the QPA for items and services when initiating a dispute. Certified IDR entities are required to consider the QPA when selecting between the offers submitted by disputing parties when determining the total out-of-network payment rate for items and services subject to the Federal IDR process.[94]

Furthermore, it is the responsibility of the Departments (or the applicable State authorities), rather than the provider, facility, provider of air ambulance services, or the certified IDR entity, to monitor plan and issuer compliance with the QPA requirements.[95] To date, the Departments have only conducted audits as part of investigations of complaints, and anticipate continuing to conduct these risk-based audits in the future, though the No Surprises Act permits the Departments to conduct random and risk-based audits.[96] Given the role of the QPA in the Federal IDR process and the direct impact on providers, performing audits on plans and issuers in response to allegations that the plan's or issuer's QPAs are inaccurate is necessary to carry out the Federal IDR process and promotes the integrity of and confidence in the Federal IDR process.

Moreover, addressing concerns about inaccurately calculated QPAs helps to ensure plans and issuers provide correctly calculated QPAs when they participate in the Federal IDR process. For example, in the absence of QPA audits to investigate complaints from providers, facilities, and providers of air ambulance services that one or more of a plan's or issuer's QPAs are inaccurate, plan and issuer compliance with QPA requirements would go unchecked.[97] Certified IDR entities must consider the relevant QPA in making each payment determination under the No Surprises Act,[98] and unchecked QPAs would significantly threaten the integrity of QPAs and the payment determinations made by certified IDR entities. These audits help to increase transparency into the QPA calculation methodology and encourage compliance among plans and issuers. Accordingly, QPA audits are an integral part of the Federal IDR process, the costs of which are reasonably included in the calculation of the administrative fee amount.

[92] *See, e.g.,* U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury. *Initial Report on the Independent Dispute Resolution (IDR) Process April 15–September 30, 2022. https://www.cms.gov/files/document/initial-report-idr-april-15-september-30-2022.pdf.* U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury. *Partial Report on the Independent Dispute Resolution (IDR) Process October 1–December 31, 2022. https://www.cms.gov/files/document/partial-report-idr-process-octoberdecember-2022.pdf.*

[93] *Available at www.sam.gov.*

[94] Section 9816(c)(5)(C)(i)(I) of the Code, section 716(c)(5)(C)(i)(I) of ERISA, and section 2799A–1(c)(5)(C)(i)(I) of the PHS Act.

[95] Section 9816(a)(2)(A)(i) of the Code, section 716(a)(2)(A) of ERISA, and section 2799A–1(a)(2)(A)(i) of the PHS Act. *See also* 86 FR 36899. However, a provider or facility may always assert to the certified IDR entity that additional information points in favor of the selection of its offer as the out-of-network payment amount, even where that offer is for a payment amount that is different from the QPA. 87 FR 52627.

[96] Section 9816(a)(2)(A)(ii) of the Code, and section 2799A–1(a)(2)(A)(ii) of the PHS Act. The July 2021 interim final rules describe the enforcement responsibilities for each Department and OPM. 86 FR 36899 (July 13, 2021). *https://www.federalregister.gov/documents/2021/07/13/2021-14382/requirements-related-to-surprise-billing-part-i.*

[97] The accuracy of a plan's or issuer's QPA (or QPA methodology) may not be reviewed within a payment determination under the Federal IDR process. *See* 86 FR 55996.

[98] Section 9816(c)(5)(C)(i)(I) of the Code, section 716(c)(5)(C)(i)(I) of ERISA, and section 2799A–1(c)(5)(C)(i)(I) of the PHS Act.

In estimating the expenditures to carry out the Federal IDR process, the Departments are including estimated costs only for certain QPA audits that the Departments anticipate incurring to investigate complaints regarding inaccurate QPAs made by providers, facilities, and providers of air ambulance services under the Federal IDR process. The Departments are not including the costs of QPA audits conducted: (1) in connection with Department of Labor, OPM, or Department of the Treasury investigations; (2) randomly; or (3) in response to complaints from consumers, as not all of these audits are necessarily related to the Federal IDR process. The Departments are of the view that only the costs related to QPA audits conducted in response to complaints from entities that are potential parties to a payment determination are sufficiently related to the Federal IDR process to justify their inclusion in the administrative fee calculation. For example, consumers who complain that a plan or issuer inaccurately calculated their cost sharing based on an erroneously calculated QPA will not be involved in the Federal IDR process, and therefore the costs of such audits are appropriately excluded from those costs supported by administrative fees paid by parties to the Federal IDR process. Because HHS is primarily responsible for the implementation of the Federal IDR process, the Departments view similarly random QPA audits that may be conducted by the Departments, as well as any QPA audits in connection with Department of Labor, OPM, and Department of the Treasury investigations.

The costs of HHS conducting QPA audits for complaints that a plan's or issuer's QPAs are inaccurate are estimated to be approximately $5,000,000 in 2024. As plans and issuers improve their compliance in calculating QPAs correctly, the Departments anticipate that the costs of conducting these audits will decrease, which would be reflected in the estimated expenditures used to determine future administrative fee amounts.

Several commenters also disagreed with including costs associated with assisting with eligibility reviews in the estimated expenditures to carry out the Federal IDR process. A few of these commenters noted that certified IDR entities are responsible for conducting eligibility reviews and therefore certified IDR entity fees should cover this cost. Some commenters asserted that such costs should be recovered through the non-prevailing party's certified IDR entity fee, as the eligibility determination is part of the payment determination. One of these commenters expressed concern that including this expense would incentivize certified IDR entities to understaff as HHS would intervene to address a staffing shortage.

The Departments disagree that the costs of assisting with eligibility determinations should be excluded from estimated expenditures. Certified IDR entities voluntarily participate in the Federal IDR process and set their certified IDR entity fees within ranges established by the Departments to ensure they remain financially viable and that such fees can cover their operating expenses to participate in the Federal IDR process, which include the costs incurred in determining the eligibility of items and services for the Federal IDR process. While certified IDR entities are responsible for making eligibility determinations, and therefore incur costs associated with this activity, the Departments have also incurred costs since November 2022 to assist certified IDR entities in making these determinations by performing research and outreach on disputes pending eligibility determinations, including identifying and obtaining information necessary for certified IDR entities to make eligibility determinations, and will continue to incur such costs in 2024.[99] The Departments disagree with the commenter that stated that the Departments' assistance would incentivize certified IDR entities to understaff. Certified IDR entities could not have reasonably predicted the amount of personnel they would need to make eligibility determinations within the required timeframe given the extremely high volume of disputes. Moreover, it has been difficult for certified IDR entities to make staffing adjustments in response to utilization of the Federal IDR process due to the repeated temporary pauses in the Federal IDR portal resulting from litigation matters and changes in operations.

When the Departments first developed the Federal IDR process and the rules and guidance establishing how certified IDR entities were to calculate their fees for the scope of work they were expected to perform, the Departments and the certified IDR entities did not anticipate the significant difficulty and costs involved in determining eligibility for the Federal IDR process. After six months of operating the Federal IDR process and receiving feedback from disputing parties and certified IDR entities, the Departments determined that it was necessary to assist certified IDR entities with determining eligibility through performing research and outreach on disputes pending eligibility determinations, including identifying and obtaining information necessary to make an eligibility determination.[100] The Departments determined that this course of action was necessary when it became clear that eligibility determinations were taking significantly longer than the Departments had anticipated.

In the IDR Operations proposed rules, the Departments proposed several policies aimed at improving communication between the parties that would make eligibility determinations less burdensome for certified IDR entities and speed up the Federal IDR process, as well as allow the Departments to make eligibility determinations under extenuating circumstances.[101] However, these policies, if finalized, will take time to implement. In the interim, the Departments are working to balance feedback from interested parties asking the Departments to increase the efficiency of the Federal IDR process and decrease the backlog of disputes with other feedback asking the Departments to minimize expenditures and avoid increases to the administrative fee. The Departments have also received comments urging them to shorten the time it takes for payment determinations to be reached. The Departments continue to believe that some level of assistance is necessary to address the high volume of disputes submitted and the backlog of disputes, due in part to the closing and reopening of the Federal IDR process to make necessary systems updates in light of the *TMA III* and *TMA IV* opinion and orders.

However, after reviewing comments, the Departments have reconsidered the amount of estimated costs associated with pre-eligibility reviews that should be included in the estimated expenditures to carry out the Federal IDR process in calendar year 2024. In estimating the expenditures of approximately $70 million in the IDR

[99] Centers for Medicare & Medicaid Services (November 21, 2022). *Notice of the Federal Independent Dispute Resolution (IDR) Team Technical Assistance to Certified Independent Dispute Resolution Entities (IDREs) in the Dispute Eligibility Determination Process. https://www.cms.gov/files/document/idre-eligibility-support-guidance-11212022-final-updated.pdf.*

[100] The Departments are providing technical assistance regarding eligibility but are not making eligibility determinations, as, under current regulations, only certified IDR entities may make eligibility determinations. *Id.*

[101] 88 FR 75744.

Fees proposed rules, the Departments included an increase in costs to reflect the Departments taking on a greater role in assisting with eligibility determinations to improve the efficiency of the Federal IDR process.[102] Based on comments received urging the Departments to avoid increasing the administrative fee, the Departments will not take on a greater role in broadly assisting certified IDR entities with eligibility determinations at this time. Instead, the Departments will limit their assistance with eligibility determinations to more complex disputes, such as disputes where there is missing information to determine Federal versus State jurisdictions in a State with a specified State law. This approach will ensure efficient use of the Departments' resources by leveraging the Departments' assistance and expertise in handling pre-eligibility reviews for disputes that certified IDR entities may need to spend more time on, such as disputes for which information was limited due to the systems in place when those disputes were initiated, and will allow certified IDR entities to focus on moving disputes through the Federal IDR process. Furthermore, this will allow the Departments to keep the costs of assisting with eligibility determinations lower in 2024 such that the expenditures estimated to be made by the Departments to carry out the Federal IDR process are now estimated to be approximately $56.6 million in 2024. The total estimated expenditures in the IDR Fees proposed rules included approximately $20 million for the Departments to assist with eligibility determinations via conducting research and outreach. The estimated cost of assisting with eligibility determinations in 2024, as used to calculate the administrative fee as finalized, is approximately $10 million.

Furthermore, the Departments do not anticipate that the decision to focus their assistance with pre-eligibility reviews on more complex disputes and the revised administrative fee amount finalized in these rules will impact the fees certified IDR entities choose to charge. Given the backlog of disputes, utilization of the Federal IDR process strains the current capacity of certified IDR entities to make timely determinations. While the Departments' assistance with eligibility determinations is currently helping to alleviate the backlog of disputes, certified IDR entities' operating expenses are not expected to decrease as a result. If the Departments are able to decrease their assistance with eligibility determinations, the costs of pre-eligibility reviews would decrease, which would be reflected in the estimated expenditures used to determine future administrative fee amounts.

In addition, some commenters disagreed with including the costs of investigating complaints of non-compliance in the administrative fee methodology. Commenters asked for clarity in the ''investigating relevant complaints'' expense and asserted that ''relevant'' complaints beyond the Federal IDR process would be inappropriate to include in the calculation of the administrative fee amount. A few of these commenters suggested that the party found to be non-compliant should bear the costs of the investigation and asked the Departments to publicly report summary data on these investigations and the costs covered by non-compliant parties compared to those covered by administrative fees. One commenter suggested that the investigation of complaints related to violations of the No Surprises Act should be funded by a congressional appropriation as these are largely unrelated to the Federal IDR process.

The Departments clarify that the complaints costs included in the estimated expenditures in the administrative fee methodology only include costs associated with receiving and investigating Federal IDR process-related complaints. For example, such costs include investigating complaints within the Departments' jurisdiction regarding the failure of a non-prevailing party to pay the payment determination amount to the prevailing party within 30 days of the certified IDR entity's payment determination as required by the No Surprises Act.[103] Complaints costs do not include costs for complaints that are not related to the Federal IDR process, such as those related to the QPA for patient cost sharing. Therefore, the Departments are of the view that those costs are appropriate to include in the administrative fee methodology and are necessary to ensure compliance with the Federal IDR process.[104]

Many commenters suggested that the Departments consider other funding sources besides the administrative fee to fund expenditures. Several commenters suggested that implementing penalties could help fund expenditures, including penalties for submitting ineligible disputes, failing to comply with disclosure obligations, or delaying the Federal IDR process. Some commenters suggested the CAA's $500 million appropriation to implement the No Surprises Act should cover at least a portion of the Departments' estimated expenditures. One commenter asked for confirmation that the implementation appropriation has been exhausted fully and suggested requesting additional funds from Congress in upcoming budget requests to support the funding of the Departments' ongoing implementation. Another commenter asserted that the administrative fee methodology set forth in the IDR Fees proposed rules did not take into account any appropriations funding.

As required by the No Surprises Act,[105] both parties to a dispute must pay an administrative fee for participating in the Federal IDR process. By statute, the administrative fee amount must be calculated such that the total amount of fees paid for a year is estimated to be equal to the amount of expenditures estimated to be made by the Departments for such year in carrying out the Federal IDR process. While the CAA appropriated $500 million to remain available until expended through 2024 for preparing regulations, guidance, and reports, collecting data, conducting audits and enforcement activities,[106] and

[102] While there is an implementation appropriation, the initial appropriation of $500 million in the CAA is finite and only remains available until expended through 2024. Moreover, the Departments note that additional mandatory funding for the Federal IDR process has not been appropriated beyond the initial $500 million made available in the CAA. However, the Departments cannot rely on budget requests or on appropriations enacted by Congress when calculating this fee. The statute requires the fee to be set at an amount such that the total amount of fees paid is estimated to be equal to the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process.

[103] Section 9816(c)(6) of the Code, section 716(c)(6) of ERISA, and section 2799A–1(c)(6) of the PHS Act.

[104] While there is an implementation appropriation, the initial appropriation of $500 million in the CAA is finite and only remains available until expended through 2024. Moreover, the Departments note that additional mandatory funding for the Federal IDR process has not been appropriated beyond the initial $500 million made available in the CAA. The Departments are unable to appropriate this funding themselves, although they have made numerous requests to Congress for additional funding, and therefore this is not a reliable source of Federal IDR process funding.

[105] Section 9816(c)(8)(A) of the Code, section 716(c)(8)(A) of ERISA, and section 2799A–1(c)(8)(A) of the PHS Act.

[106] As previously explained in the preamble to these final rules, the Departments may conduct random or risk-based QPA audits. The Departments consider it appropriate to include some of the costs of conducting risk-based QPA audits resulting from complaints filed by providers, facilities, or providers of air ambulance services alleging that the QPA was inaccurate as expenditures made in carrying out the Federal IDR process, and therefore include the costs of conducting these audits in

establishing and initially implementing the No Surprises Act and Title II Transparency provisions through calendar year 2024, this finite appropriation is not solely for the Federal IDR process. Additionally, while the Fiscal Year 2024 President's budget included another $500 million appropriation request for the continued implementation of the No Surprises Act and Title II Transparency provisions, the administrative fee amount finalized in these rules must still be consistent with the statutory requirement to set the administrative fee amount such that the total amount of administrative fees paid is estimated to be equal to the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process. As a result, when calculating this fee, the Departments cannot rely on budget requests or on appropriations enacted by Congress.

In addition, commenters urged the Departments to consider strategies to decrease utilization of the Federal IDR process, decrease administrative burden, increase the efficiency of the Federal IDR process, and ultimately reduce the cost of administering the Federal IDR process. Examples of commenters' suggestions include enforcing disclosure requirements, requiring plans and issuers to include remittance advance remark codes (RARCs) at the time of initial claim determination, easing batching requirements, disincentivizing bad faith conduct, making improvements to the Federal IDR portal, and implementing a required initial payment amount for out-of-network emergency services. Several commenters suggested that the volume of ineligible disputes and the cost of conducting eligibility reviews would be reduced or eliminated if the Departments enforced disclosure requirements or required plans and issuers to provide adequate information for providers to determine whether a claim is eligible for the Federal IDR process. One commenter suggested that plans and issuers should cover the cost of eligibility reviews when they fail to inform the provider of eligibility for the Federal IDR process. Another commenter suggested that the cost of eligibility reviews should be assessed to the party that challenges eligibility as this cost would be avoidable if the plan or issuer provided sufficient information. One commenter suggested that the Departments could reduce the administrative burden of the Federal IDR process by contracting with an established claims processing clearinghouse that currently possesses the capabilities to perform real-time eligibility determinations to create an in-portal eligibility validation process.

The Departments continue to consider improvements to the Federal IDR process and recently published the IDR Operations proposed rules,[107] which include policies aimed at reducing the volume of ineligible disputes, establishing additional disclosure requirements (such as requiring plans and issuers to use approved claim adjustment reason codes (CARCs) and RARCs), incentivizing good faith conduct with respect to open negotiation and exchange of information, and otherwise improving the Federal IDR process. Overall, these policies would, if finalized, support efficiency in Federal IDR process operations and reduce the cost of administering the Federal IDR process in the future.

Recognizing that the cost of certifying IDR entities is included in the administrative fee methodology, one commenter sought clarity on how the methodology considers efficiencies gained from certifying more IDR entities to make payment determinations and therefore reduce the backlog.

The Departments note that the benefits of certifying new IDR entities will be achieved over time, as new certified IDR entities acclimate to the process and increase the speed at which they move disputes through the Federal IDR process. As efficiencies in the Federal IDR process are adopted over time, the expenditures required to carry out the Federal IDR process could decrease, exerting downwards pressure on the administrative fee amount. If any of these situations results in changes to the data used to calculate the administrative fee amount, the Departments intend to take these changes into consideration when establishing the administrative fee amount in the future.

d. Administrative Fee Methodology—Other Comments

The Departments sought comments on whether, when calculating the administrative fee amount in future years, they should apply an inflationary adjustment, such as the consumer price index for all urban consumers (CPI–U), to the amount of estimated expenditures to be made by the Departments in carrying out the Federal IDR process. A few commenters supported using an inflationary adjustment, such as the CPI–U, to adjust the administrative fee amount in future years. Other commenters opposed this approach, stating that it would not necessarily correlate with the Departments' expenditures to operate the Federal IDR process and may not align with the established methodology of dividing the Departments' estimated expenditures by the estimated total number of administrative fees to be paid. Another commenter stated that this proposal would be unnecessary if the Departments finalize the proposal to establish the administrative fee amount more or less frequently than annually. Finally, another commenter asked the Departments to revisit this proposal when data are more predictable after implementing planned improvements to the Federal IDR process.

Upon consideration of the comments, the Departments are not finalizing the use of an inflationary adjustment, such as the CPI–U, to adjust the administrative fee amount in future years. The Departments agree with commenters that the CPI–U may not correlate with projected increases in the Departments' estimated expenditures to carry out the Federal IDR process and therefore using it could be inconsistent with the statute.

Several commenters urged the Departments to improve the Federal IDR process before increasing the administrative fee amount by decreasing the backlog, enforcing timely payment, and holding all parties accountable to the regulatory requirements. Some commenters recommended maintaining the current administrative fee amount until there is stability in the Federal IDR process and more data are available to accurately forecast long-term costs. A few commenters suggested that the Departments modify the administrative fee amount in future years to make up for any shortfall or surplus created by the finalized administrative fee amount.

As previously mentioned, the Departments continue to consider improvements to the Federal IDR process; however, implementing these improvements would increase the costs of carrying out the Federal IDR process in the short term and would take time to operationalize. As previously mentioned, the Departments proposed policies in the IDR Operations proposed rules aimed to improve the overall efficiency and operations of the Federal

estimating the expenditures made by the Departments in carrying out the Federal IDR process. Other audit costs, such as the QPA audits conducted in connection with Department of Labor, OPM, or Department of Treasury investigations; audits conducted randomly; or audits conducted in response to complaints from consumers regarding QPAs may be funded using other appropriations, as applicable.

[107] 88 FR 75744.

IDR process.[108] The Departments were unable to propose those policies in the IDR Fees proposed rules because they are much more comprehensive than the fee-related policies proposed in the IDR Fees proposed rules and would require more time to develop and implement, if finalized. There is an urgency to publish these final rules due to the need to sufficiently fund the Federal IDR process in 2024, because, as explained above, the current $50 administrative fee amount is insufficient to provide total administrative fees that are estimated to be equal to the expenditures estimated to be made by the Departments in carrying out the Federal IDR process, as required by the No Surprises Act.[109]

e. Administrative Fee Amount and Impact

Many commenters opposed the proposed $150 per party per dispute administrative fee amount and stated that it would make the Federal IDR process cost-prohibitive to pursue for many providers, especially small providers, rural providers, independent practices, and certain medical specialties, such as psychiatry, emergency medicine, radiology, and anesthesiology. Some commenters requested that the Departments analyze how the proposed administrative fee amount would be cost-prohibitive for providers and would deter and limit dispute resolution for small providers. A few commenters asserted that the administrative fee amount would unfairly favor plans and issuers over providers in the Federal IDR process. One commenter recommended against using a methodology to calculate the administrative fee amount that did not consider the increased financial burdens on providers compared to plans and issuers. Another commenter stated that the proposed administrative fee amount prioritizes the interest of certified IDR entities and the Departments in covering their costs at the expense of parties' access to the Federal IDR process.

Similarly, some commenters stressed that it is important to keep the administrative fee amount low to prevent the administrative fee from serving as a *de facto* barrier to the Federal IDR process. These commenters asserted that such a *de facto* barrier would not align with congressional intent, as Congress decided against adding a dollar-value threshold to the No Surprises Act despite considering this while developing the legislation. Several commenters raised concerns that reducing access to the Federal IDR process would reduce providers' reimbursements for out-of-network services, as it would not be cost-effective to dispute certain payment amounts in the Federal IDR process. Some commenters asserted that a cost-prohibitive administrative fee amount would reduce incentives for plans and issuers to negotiate fair in-network contracts or, in some cases, renew contracts, forcing providers out of networks.

A few commenters suggested that patients would also be impacted by the increased administrative fee amount, either through plans and issuers narrowing provider networks or increasing premiums and cost-sharing amounts, or providers passing on costs to patients or going out of business. However, several commenters noted that the proposed fee amount was an improvement from the previous $350 amount.

For reasons described throughout this preamble, the Departments are finalizing the administrative fee amount for disputes initiated on or after the effective date of these rules as $115 per party per dispute. This change in the administrative fee amount between the proposed and final rules reflects modifications to the estimated expenditures and to the administrative fee methodology described elsewhere in this preamble.

While the Departments are statutorily required to set the administrative fee amount such that the total amount of administrative fees paid is estimated to be equal to the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process, the Departments acknowledge the concerns of commenters related to accessibility and affordability of the Federal IDR process and the impact of the proposed administrative fee amount on the parties and patients. In the Departments' effort to balance their statutory obligations with the priority of ensuring equitable access for parties to engage in the Federal IDR process, the Departments proposed in the IDR Operations proposed rules to reduce the administrative fee amount in certain circumstances. In the IDR Operations proposed rules, the Departments proposed to reduce the administrative fee amount to $75 (50 percent of the full administrative fee amount proposed in those proposed rules) for both parties when the highest offer by either party in open negotiation was less than the full administrative fee amount ($150 as proposed in those proposed rules)[110] and to $30 (20 percent of the full administrative fee amount proposed in those proposed rules) for non-initiating parties in ineligible disputes.[111] The Departments also proposed in the IDR Operations proposed rules to revise the requirements for batching qualified IDR items and services together into a single Federal IDR process dispute.[112] The Departments anticipate that these proposals would make the Federal IDR process more accessible for all parties, but especially the parties for whom commenters expressed concerns, such as small and rural providers and certain medical specialties.

The administrative fee amount being finalized in these final rules is applied equally to both parties to a dispute. The Departments are of the view that it would be inequitable to charge a smaller party a lower administrative fee, because a dispute initiated by a smaller party costs the Departments the same amount to process as a dispute initiated by a larger party. Furthermore, the value of a dispute, rather than the size of the party, determines whether it will be cost-effective for the party to pursue the dispute. For example, a smaller party could initiate a high dollar value dispute, while a larger party could initiate a small dollar value dispute. The Departments proposed in the IDR Operations proposed rules to charge both parties a reduced administrative fee when the highest offer made during open negotiation is less than the full administrative fee amount,[113] which is intended to improve the accessibility of the Federal IDR process for parties to low-dollar disputes. The Departments anticipate that such parties may be smaller providers and facilities or independent practices. However, larger parties to low-dollar disputes would not be precluded from paying the reduced administrative fee as long as the dispute meets the aforementioned requirement.

The Departments considered the impact of the proposed $150 administrative fee amount on the parties compared to the current $50 administrative fee amount and the previous $350 administrative fee amount. While the Departments understand that it may be economically infeasible to initiate some claims in the Federal IDR process due to the administrative and certified IDR entity fees associated with accessing the process, as discussed previously, the Departments are statutorily obligated to

[108] 88 FR 75744.

[109] Section 9816(c)(8)(B) of the Code, section 716(c)(8)(B) of ERISA, and section 2799A–1(c)(8)(B) of the PHS Act.

[110] 88 FR 75799.

[111] 88 FR 75800.

[112] 88 FR 75783 through 75791.

[113] 88 FR 75799.

charge an administrative fee amount such that the administrative fees paid are estimated to be equal to the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process.[114] The methodology used by the Departments is derived from this statutory language.

Congress did not include a dollar-value threshold for Federal IDR process disputes in the No Surprises Act. Rather, Congress opted to include a requirement in the No Surprises Act for each party to a dispute for which a certified IDR entity is selected to pay to the Departments, at such time and in such manner as specified by the Departments, a fee for participating in the Federal IDR process.[115] Therefore, regardless of the administrative fee amount, disputing parties must always evaluate whether it would be economically efficient to initiate a dispute in the Federal IDR process. Congress also provided in the No Surprises Act that the administrative fee amount is established by the Departments in a manner such that the total amount of fees paid for such year is estimated to be equal to the amount of expenditures estimated to be made by the Departments for such year in carrying out the Federal IDR process.[116]

In regard to comments stating that the administrative fee could result in narrowing networks, many factors may impact whether a provider, facility, or provider of air ambulance services and a plan or issuer will enter a network agreement with one another, including the market power of each party, Federal and State network adequacy laws, and other factors. The Departments acknowledge that the amount paid for out-of-network services is one of the factors that impacts market participants' decisions whether to enter network agreements. The No Surprises Act represents a substantial change to the way the parties come to agreement on payment for out-of-network services by prohibiting, in many circumstances, the practice of sending surprise medical bills to patients and establishing a Federal IDR process for determining the appropriate out-of-network rate. Many providers report that initial payments made by plans and issuers for out-of-network services are now substantially lower than such payments were before enactment of the No Surprises Act. Some providers report that plans' and issuers' abilities to make lower payments for out-of-network services has impacted their willingness to offer acceptable in-network payment rates in network agreement negotiations. To the extent that the Federal IDR process and the prohibition on surprise medical billing change this equilibrium among parties, they could impact the number of providers and plans and issuers that are able to agree on terms for entering a network agreement and consequently network breadth.

In the IDR Operations proposed rules, the Departments are proposing a number of steps to accelerate throughput in the Federal IDR process,[117] which would make it easier for the parties to use the process to determine the appropriate payment amount for out-of-network services. That said, the appropriate payment rate for out-of-network services is only one factor among many that influences network breadth. It is also important for the parties to meaningfully engage in open negotiation to determine an appropriate out-of-network payment rate, since agreeing to rates in open negotiation allow the parties to avoid the costs of using the Federal IDR process. Even as the Federal IDR process becomes faster and more parties avail themselves of the opportunity to agree to out-of-network payment rates during the open negotiation period, the price paid for out-of-network services will remain one among many factors in a dynamic market. Furthermore, the Departments anticipate that a Federal IDR process with consistent payment determination outcomes will lead to fewer dispute initiations, because parties will have a better understanding of what a determination will likely be and more disputes would likely be settled in open negotiation or even earlier, resulting in the parties avoiding the costs associated with the Federal IDR process.

The Departments also do not anticipate that the policies finalized in these rules would cause plans and issuers to increase premiums, as further discussed in section IV.G of this preamble, or patient cost sharing, because administrative fees paid would likely represent a very small percentage of the costs considered by plans and issuers in calculating annual premiums or cost sharing.

Many commenters emphasized the importance of considering the proposed administrative fee amount alongside batching requirements to determine whether the administrative fee amount would be cost-prohibitive. Some commenters suggested that batching policies could mitigate the financial challenges providers and facilities face, especially when pursuing low-dollar claims. A few commenters suggested it was premature to update the administrative fee amount or provide feedback on a proposed amount until batching guidance is updated. One commenter viewed an administrative fee of $150 per party as reasonable so long as a claim is defined as an episode of care or a single medical encounter in the batching policy.

The Departments are continuing to assess batching flexibilities and the impact of batching on various parts of the Federal IDR process. To further improve batching requirements, the Departments proposed provisions in the IDR Operations proposed rules [118] that would allow for more clarity, certainty, and flexibility in batching multiple items or services in a single dispute.[119] These batching proposals are designed so that the expenses of engaging in the Federal IDR process, including the administrative fee, do not unreasonably impede parties' access to the Federal IDR process. As previously mentioned, the IDR Operations proposed rules [120] also proposed a reduced administrative fee for low-dollar disputes, identified as disputes for which the highest offer by either party in open negotiation was less than the administrative fee amount, which, if finalized, would mitigate financial burden on providers and facilities when pursuing payment on low-dollar claims. The Departments encourage interested parties to submit comments on the IDR Operations proposed rules prior to the comment deadline.[121]

[114] Section 9816(c)(8)(B) of the Code, section 716(c)(8)(B) of ERISA, and section 2799A–1(c)(8)(B) of the PHS Act.

[115] Section 9816(c)(8)(A) of the Code, section 716(c)(8)(A) of ERISA, and section 2799A–1(c)(8)(A) of the PHS Act.

[116] Section 9816(c)(8)(B) of the Code, section 716(c)(8)(B) of ERISA, and section 2799A–1(c)(8)(B) of the PHS Act.

[117] 88 FR 75744.

[118] 88 FR 75744.

[119] On November 28, 2023, the Departments released FAQs pertaining to batching that will be effective until the IDR Operations proposed rules are finalized and take effect. These FAQs discuss how, in light of the *TMA IV* and *TMA III* opinions and orders, the batching requirements of the No Surprises Act apply to qualified IDR items and services for disputes eligible for initiation of the Federal IDR process on or after August 3, 2023, until the Departments engage in future notice and comment rulemaking. *See* U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of Treasury, Office of Personnel Management (November 28, 2023), *FAQs about Consolidated Appropriations Act, 2021 Implementation Part 63,* available at *https://www.cms.gov/files/document/faqs-part-63.pdf.*

[120] *Id.*

[121] As discussed earlier in this preamble section, the Departments were unable to propose these operational policies in the IDR Fees proposed rules because they are more comprehensive than the fee-related policies proposed in the IDR Fees proposed rules and require more time to develop and

Continued

While the Departments continue to consider improvements to the Federal IDR process, including policies surrounding batching and low-dollar claims, the No Surprises Act requires that the administrative fee be estimated to cover the expenditures estimated to be made by the Departments in carrying out the Federal IDR process in the year, and the Departments estimate that $115 per party per dispute is the appropriate administrative fee amount to meet this requirement for disputes initiated on or after the effective date of these rules.

B. Certified IDR Entity Fee Ranges

Under current regulations at 26 CFR 54.9816–8T(e)(2)(vii), 29 CFR 2590.716–8(e)(2)(vii), and 45 CFR 149.510(e)(2)(vii), the certified IDR entity fees for single and batched determinations are set by the certified IDR entities within the upper and lower limits of ranges for each as set forth in guidance issued annually by the Departments.

In the IDR Fees proposed rules, the Departments proposed to amend the provisions of the regulations establishing the ranges for certified IDR entity fees for single and batched disputes to establish the ranges in notice and comment rulemaking, rather than in guidance, at 26 CFR 54.9816–8(e)(2)(vii), 29 CFR 2590.716–8(e)(2)(vii), and 45 CFR 149.510(e)(2)(vii). Further, the IDR Fees proposed rules provided that, consistent with current rules, certified IDR entities must annually provide a fixed fee for single determinations and separate fixed fees for batched determinations within the upper and lower limits for each as set in notice and comment rulemaking. Additionally, the IDR Fees proposed rules provided that the certified IDR entity fee ranges established by the Departments in rulemaking would remain in effect until new certified IDR entity fee ranges are established by notice and comment rulemaking,[122] allowing the Departments to update the certified IDR entity fee ranges more or less frequently than annually. Finally, the Departments proposed that the certified IDR entity or IDR entity seeking certification may seek advance written approval from the Departments to update its fees more often than once annually.

The Departments proposed that for disputes initiated on or after the later of the effective date of these rules or January 1, 2024, certified IDR entities would be permitted to charge a fixed certified IDR entity fee for single determinations within the range of $200 to $840, unless a fee not within that range is approved by the Departments pursuant to paragraphs 26 CFR 54.9816–8(e)(2)(vii)(A) and (B), 29 CFR 2590.716–8(e)(2)(vii)(A) and (B), and 45 CFR 149.510(e)(2)(vii)(A) and (B). The Departments also proposed that for disputes initiated on or after the later of the effective date of these rules or January 1, 2024, certified IDR entities would be permitted to charge a fixed certified IDR entity fee for batched determinations within the range of $268 to $1,173, unless a fee outside this range is approved by the Departments pursuant to paragraphs 26 CFR 54.9816–8(e)(2)(vii)(A) and (B), 29 CFR 2590.716–8(e)(2)(vii)(A) and (B), and 45 CFR 149.510(e)(2)(vii)(A) and (B). The Departments proposed to continue to use a tiered fee structure based on the number of line items within the batch.[123] Under the IDR Fees proposed rules, certified IDR entities would be permitted to charge a fixed tiered fee within the range of $75 to $250 for every additional 25 line items within a batched dispute beginning with the 26th line item.[124] The IDR Fees proposed rules explained the Departments' considerations for proposing the certified IDR entity fee ranges, which included the anticipated time and resources needed for certified IDR entities to make payment determinations meeting the requirements of the statute, rules, and guidance; the anticipated time and resources needed for data reporting; the anticipated time and resources needed to comply with audit requirements; the anticipated volume of Federal IDR initiations and payment determination quality assessments; the anticipated volume of Federal IDR initiations ineligible for the Federal IDR process; and the level of complexity in determining the eligibility of items and services for the Federal IDR process.[125] These fee ranges would apply until another set of fee ranges is proposed and finalized through notice and comment rulemaking.

If a certified IDR entity wishes to charge a fee outside either of these fee ranges, it would continue to follow the existing process for requesting written approval from the Departments outlined in 26 CFR 54.9816–8(e)(2)(vii)(A) and (B), 29 CFR 2590.716–8(e)(2)(vii)(A) and (B), and 45 CFR 149.510(e)(2)(vii)(A) and (B).

Since the publication of the IDR Fees proposed rules, the Departments have analyzed updated data and assumptions as applied to the factors considered in the IDR Fees proposed rules' preamble to set the fee ranges, and the Departments found that the results of the analysis remain the same. The Departments received comments on these proposals.

The Departments are finalizing as proposed the policy to establish the certified IDR entity fee ranges through notice and comment rulemaking, rather than guidance. The Departments are also finalizing the certified IDR entity fee ranges for single and batched disputes as proposed. Finally, the Departments are finalizing the fixed tier fee structure for batched disputes, as well as the range for this structure, as proposed.

However, after considering the public comments, the Departments are not finalizing the proposal which would have allowed the Departments to set the certified IDR entity fee ranges more frequently than annually but are instead finalizing the proposal with modifications to reflect that the certified IDR entity fee ranges may be established by the Departments no more frequently than annually through notice and comment rulemaking. Further, the Departments are finalizing the proposal that the certified IDR entity or IDR entity seeking certification may seek advance written approval from the Departments to update its fees more often than once annually, with modifications to reflect that in addition to setting their initial fee for the calendar year, certified IDR entities may only request approval from the Departments to update their fees one additional time per year, and with additional non-substantive modifications for readability. Finalizing this policy would result in a process where the certified IDR entity or IDR entity seeking certification sets their fixed fees for single and batched determinations for the year, and then is allowed one opportunity at any point during the calendar year to update their fixed fees, provided that their request is approved by the Departments.

implement if finalized. There is an urgency to publish these final rules due to the need to sufficiently fund the Federal IDR process in 2024.

[122] 88 FR 65888.

[123] A tiered fee structure was first proposed in the Calendar Year 2023 Fee Guidance *for the* Federal Independent Dispute Resolution Process *under* the No Surprises Act and implemented for all disputes initiated as of January 1, 2023. *See* Centers for Medicare & Medicaid Services (October 31, 2022). *Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.*

[124] 88 FR 65888.

[125] 88 FR 65888 at 65895 through 65896.

Many commenters supported the proposal to establish the certified IDR entity fee ranges through notice and comment rulemaking. Several commenters noted that establishing the certified IDR entity fee ranges through notice and comment rulemaking would increase transparency and allow interested parties to provide feedback that would help the Departments appropriately adjust the fee ranges. Many commenters expressed opposition to the Departments' proposal to establish the certified IDR entity fee ranges more or less frequently than annually. The majority of these commenters encouraged the Departments to update the certified IDR entity fee ranges only once annually to create a more predictable and stable Federal IDR process. Several commenters expressed concern that changing the certified IDR entity fee ranges more frequently than once annually would prevent providers from effectively budgeting for participation in the Federal IDR process, which would create a barrier to access. A few commenters noted that unpredictable changes to the certified IDR entity fee ranges could impact plans' and issuers' abilities to budget for the Federal IDR process and could lead plans and issuers to budget more conservatively and pass on the cost increase to consumers.

A few commenters generally supported the flexibility to update the certified IDR entity fee ranges more or less frequently than annually. However, one commenter supported the proposed flexibility only if the Departments adjusted the fee ranges less frequently than annually, while another commenter supported the proposed flexibility if the Departments provided adequate notice, such as 90 days, before implementing the changed fee ranges. Further, several commenters opposed the proposal to allow certified IDR entities or IDR entities seeking certification to seek advance written approval from the Departments to set their certified IDR entity fees more often than annually. Similar to the proposal to establish the certified IDR entity fees through notice and comment rulemaking more or less frequently than annually, some commenters expressed concerns that the proposed policy would cause unpredictability for the parties, which would impact their ability to effectively budget for the Federal IDR process. One commenter misinterpreted the proposed policy as proposing to require certified IDR entities to adjust their fees whenever operational or technological efficiencies could justify a decrease in cost, and expressed concern that the proposed policy may discourage certified IDR entities from participating in the Federal IDR process. One commenter opposed multiple fee adjustments within a given year but supported allowing certified IDR entities a limit of one additional fee adjustment per year following a compelling request and formal approval.

The Departments agree with commenters that the proposal to establish the certified IDR entity fee ranges through notice and comment rulemaking will improve transparency and provide opportunity for greater engagement by interested parties in the establishment of the ranges. The Departments recognize commenters' concerns that the proposed flexibility to set the certified IDR entity fee ranges through notice and comment rulemaking more or less frequently than annually would enable multiple changes to the certified IDR entity fee ranges over the course of a year. In general, the Departments recognize that frequent changes to the established certified IDR entity fee ranges could increase unpredictability in the Federal IDR process and potentially burden parties, but note that they did not propose this policy with the intention of pursuing such frequent changes. The Departments contemplated establishing this proposed flexibility so that the certified IDR entity fee ranges could remain effective for multiple years. Further, updating the certified IDR entity fee ranges does not guarantee that certified IDR entities will set new fixed fee amounts. Each certified IDR entity determines their fee amounts independently, and there is no requirement to make a corresponding adjustment each time the certified IDR entity fee ranges established by the Departments change, provided the certified IDR entity's fee stays within the new range.

While it would be unlikely that the Departments would pursue multiple notice and comment rulemakings in a single year to adjust the certified IDR entity fee ranges, the Departments acknowledge the potential for the proposed policy to increase uncertainty within the Federal IDR process. Therefore, to be responsive to commenters' concerns, the Departments are finalizing this proposal with modifications to reflect that the certified IDR entity fee ranges may be established no more frequently than once per calendar year. This allows the certified IDR entity fee ranges to remain effective over multiple years until they are updated in notice and comment rulemaking, while addressing commenters' concerns by preventing multiple adjustments of the certified IDR entity fee ranges in a single year.

The Departments acknowledge that frequent increases to certified IDR entity fees could lead to unpredictability and complicate the ability of the parties to effectively budget for the Federal IDR process. The Departments are of the view that the proposed mechanism for certified IDR entities to request to set their fees more than once annually includes sufficient guardrails to ensure that any changes to the certified IDR entities' fees would not prevent parties from accessing the Federal IDR process. Specifically, the Departments proposed to require certified IDR entities to submit the following information to the Departments in their requests: (1) the fixed fee that the certified IDR entity is seeking to charge; (2) a description that reasonably explains the circumstances that require a change to its fee; and (3) a detailed description that reasonably explains how the change to its fee will be used to mitigate the effects of these circumstances. The Departments would use their discretion to determine if the explanations included in the request demonstrate that the change would ensure the certified IDR entity's financial viability and would not impose on parties an undue barrier to accessing the Federal IDR process.

The Departments seek to strike a balance between predictable fees for parties participating in the Federal IDR process and certified IDR entities' need for flexibility to respond to circumstances that require fee adjustments to maintain program operations. For example, the Departments acknowledge that certified IDR entities consider various factors, including operational costs, in setting fees for the Federal IDR process. However, certified IDR entities have needed to increase staff resources, implement system updates, and adjust operations to respond to unexpectedly frequent changes to guidance or regulations governing the Federal IDR process or the volume of disputes initiated and closed under the Federal IDR process. To ensure that certified IDR entities have sufficient funding to respond to such circumstances, providing certified IDR entities with the ability to request an update to their fees one additional time during a calendar year is appropriate.

To address some of the concerns expressed by commenters, the Departments are finalizing this proposal with modifications to reflect that certified IDR entities may only request approval from the Departments to set their fee one additional time for a

calendar year. In other words, if a certified IDR entity wishes to update its fees an additional time after already setting fees for the calendar year, the certified IDR entity must seek approval from the Departments to do so. A certified IDR entity may set its fees at most two times for a calendar year, once at the initial setting of the fees, and once after receiving approval from the Departments to update the fees, regardless of whether the Departments have established new certified IDR fee ranges in notice and comment rulemaking. If the Departments reject a certified IDR entity's request to update its fees during the calendar year, the certified IDR entity may continue to seek approval by submitting subsequent requests as long as these requests comply with the requirements finalized in this rule.

If a certified IDR entity requests to update its fees after initially setting its fee for the calendar year, and the request is approved by the Departments, the change to its fees will be made public before those fees are effective, in a form and manner specified by the Secretary, to allow the parties time to consider the fee change in their decision making. Updated fees will apply to disputes initiated on or after the effective date of the fee amount. The modified policy will provide an appropriate amount of flexibility to certified IDR entities to make a fee adjustment to account for efficiencies and fluctuations in the conditions of the Federal IDR process in future years, while also capping the number of fee adjustments in a given calendar year and limiting cost volatility for parties participating in the Federal IDR process.

The Departments solicited comment on whether they should apply an inflationary adjustment, such as the CPI–U, to the considerations used to develop the certified IDR entity fee ranges in future years. One commenter supported the use of an inflationary adjustment and suggested updating the certified IDR entity fee ranges annually based on inflation rather than through notice and comment rulemaking. A few commenters opposed updating the certified IDR entity fee ranges using an inflationary adjustment such as the CPI–U. Specifically, one commenter posited that since the CPI–U is updated on a monthly basis, the Departments might pursue monthly adjustments to the certified IDR entity fee ranges, which would severely complicate the Federal IDR process. Another commenter expressed concern that applying an inflationary adjustment would only drive costs up over time, prompting plans and issuers to pass any additional costs on to consumers. One commenter neither explicitly supported nor opposed the general use of an inflationary adjustment to set the certified IDR entity fee ranges but noted that setting the certified IDR entity fee ranges through notice and comment rulemaking could be an opportunity to adjust based on inflation. This commenter cautioned that if the Departments pursued the use of an inflationary adjustment, such an adjustment should be the only consideration used to update the certified IDR entity ranges.

The Departments appreciate the comments on the use of an inflationary adjustment to update the certified IDR entity fee in future years. The Department share the commenters' desire to maintain predictable and accessible costs for participating in the Federal IDR process and agree that additional adjustments to the fee ranges more frequently than annually would complicate the Federal IDR process for all parties. As stated earlier in this preamble, based on the comments received, the Departments are finalizing the proposal to establish the certified IDR entity fee ranges through notice and comment rulemaking, which will allow for greater transparency and feedback related to the establishment of the ranges. Further, the Departments are of the view that the considerations being finalized in this rulemaking are necessary to develop reasonable certified IDR entity fee ranges, and that the addition of inflationary adjustment to the considerations, or the exclusive use of an inflationary adjustment to develop the ranges, is not practical or necessary at this time. The Departments will continue to carefully consider whether such a policy may be appropriate in future rulemaking.

Several commenters expressed concerns with the proposed certified IDR entity fee ranges' increased upper limits. Some of these commenters stated that the proposed certified IDR entity fee ranges may be cost-prohibitive and limit access to the Federal IDR process, particularly for small providers. A few of the commenters opposed to the proposed increase in the upper limits of the certified IDR entity fee ranges asserted that any increase in the certified IDR entity fee ranges would limit participation in the Federal IDR process. Specifically, one of these commenters asserted that the proposed ranges would result in costs passed on to patients in the form of increased premiums and cost-sharing amounts.

Some commenters, however, supported the proposed certified IDR entity fee ranges. Some of these commenters asserted that the increase to the upper limit of the certified IDR fee ranges is reasonable and will encourage greater plan and issuer participation prior to the Federal IDR process, such as during open negotiation, and will reduce the time needed for certified IDR entities to render payment determinations.

The Departments maintain the view that the proposed certified IDR entity fee ranges will keep costs reasonable such that participating in the Federal IDR process will not be cost-prohibitive, including for smaller providers, while also ensuring that certified IDR entities are able to cover their operating costs and continue participating in the Federal IDR process. The Departments acknowledge that broadening the certified IDR entity fee ranges could have an impact on the cost to parties to engage in the Federal IDR process. However, the current range of fees charged by certified IDR entities reflects that, since the opening of the Federal IDR process, certified IDR entities do not all charge the same fees, nor do they all charge the maximum fee amount in the ranges set by the Departments.[126] To remain competitive, the certified IDR entities have an incentive to charge fees on the lower end of the established range. As a result, the Departments do not believe that an increase to the upper limits of the certified IDR entity fee ranges will result in drastic increases to the fees charged by certified IDR entities. Further, the Departments have not seen any data suggesting that the proposed increases to the certified IDR entity fee ranges will result in a substantial enough increase in costs to plans and issuers that they will impact patients in the form of increased premiums and cost-sharing amounts. However, the Departments will continue to monitor this dynamic.

The Departments agree with commenters asserting that the increases to the certified IDR entity fee ranges will encourage greater plan and issuer participation prior to the Federal IDR process, such as during open negotiation. The Departments believe that the increases to the certified IDR entity fee ranges will encourage parties to actively participate in open negotiation to preclude the need for the Federal IDR process, thereby eliminating the need for parties to pay the certified IDR entity fee.

The Departments emphasize that while they establish ranges for the certified IDR entity fees, certified IDR entities choose the fixed fees they

[126] *See https://www.cms.gov/nosurprises/help-resolve-payment-disputes/certified-idre-list.*

charge for single and batched determinations based on a number of factors. As noted earlier in this preamble, certified IDR entities have needed to make numerous adjustments in response to high volumes of disputes, complex determinations, and litigation resulting in changes to guidance and regulations governing the Federal IDR process. The proposed ranges for the single and batched determination fees, including the proposed range for the tiered fee for batched determinations, allow for appropriate compensation corresponding to the complexity and effort associated with making eligibility and payment determinations. The Departments remain of the view that the proposed ranges would keep costs for participating in the Federal IDR process reasonable and reduce the potential for increased costs to be passed on to patients.

Several commenters opposed the proposed tiered fee structure for batched determinations. Commenters were concerned that the proposed tiered fee structure would be cost-prohibitive, particularly due to the absence of a limitation on the number of line items considered in the price tiers (that is, no line item cap to the application of the tiered fee, as currently exists). Further, some commenters asserted that the proposed tiered fee structure and range would disincentivize the submission of batched disputes.

A few commenters supported an increased fee for larger batched determinations but recommended that the tiering structure reflect intervals of 50 line items rather than 25. Further, one commenter supported a fixed-dollar tiered fee, as opposed to a range, suggesting that a fixed-dollar fee would provide more consistency across the fees charged by different certified IDR entities and avoid potential issues such as certified IDR entities being overwhelmed with disputes and resulting delays in the Federal IDR process.

The proposed tiered fee structure and range reflect the Departments' intent to keep the costs of participating in the Federal IDR process affordable while ensuring that certified IDR entities are compensated for their work in rendering payment determinations on complex batched disputes. Certified IDR entities have indicated to the Departments that making determinations on large batches of dissimilar items and services is particularly complex and burdensome and that they generally do not realize economies of scale as the number of batched line items increases. The Departments considered the impact of the *TMA IV* opinion and order as discussed in section I.C of this preamble on the anticipated complexity and volume of batched disputes while determining the certified IDR entity fee ranges. The Departments acknowledge the efficiencies gained by batching and believe that the proposed tiered fee structure would maintain those efficiencies while allowing certified IDR entities to charge a reasonable fee for the level of work involved in batched determinations.

Several commenters stated that the proposed tiered fee structure might increase the costs to disputing parties submitting batched disputes with many line items because there is no cap to the number of line items within a batched dispute after which the tiered fee would no longer apply.

A tiered fee selected by each certified IDR entity from a dollar range established by the Departments allows for greater flexibility, as opposed to applying a standard fixed dollar amount or applying a percentage of the certified IDR entity's batched determination fee as is currently used.[127] The tiered fee range reflects the costs associated with increasing line items in a batched dispute and provides certified IDR entities the appropriate flexibility to set fees commensurate with their costs. Additionally, the Departments believe that a dollar range based on the number of line items in a batched dispute would provide transparent and consistent pricing for both parties and certified IDR entities. The Departments agree that instances of batched disputes with exceedingly high numbers of line items occur infrequently but remain a possible occurrence. In addition, as mentioned previously, certified IDR entities have indicated that they generally do not realize economies of scale for batched disputes with high numbers of line items. For instance, certified IDR entities often need to verify the acuity of every patient in a batch, even when the service is the same. Given the anticipated infrequency of batched disputes with exceedingly high numbers of line items and in recognition of the need for the certified IDR entity to cover its costs for such batched disputes, the Departments believe the tiered fee structure is a reasonable approach.

The Departments also considered whether certified IDR entities should be permitted to charge only an additional fixed dollar amount (for example, $125, $150, $200, etc.) per every additional 25 line items but determined that the proposed range for a tiered fee would provide the appropriate operational flexibility for certified IDR entities. Providing this flexibility is important to maintain participation of certified IDR entities in the Federal IDR process. The operational costs for the Federal IDR process incurred by each certified IDR entity may vary, requiring certified IDR entities to consider their unique circumstances in determining their fixed fee amounts to maintain financial viability. Therefore, allowing certified IDR entities to select a tiered fee within a dollar range established by the Departments will allow the certified IDR entities the flexibility to tailor their pricing to fit their company's needs, while ensuring reasonable costs for parties participating in the Federal IDR process.

For the purposes of the batched tiered fee range intervals, the Departments considered whether a grouping of 50 line items would be a more appropriate interval than the proposed interval of 25 line items. A few commenters suggested that 50 line items would be a more appropriate interval than the proposed 25-line-item increment. In determining the interval appropriate for the tiered fee range for batched determinations, the Departments considered historical trends in the number of line items submitted in batched disputes in addition to the anticipated changes in batching behaviors due to the *TMA IV* vacatur of certain batching provisions. The Departments remain of the view that a 25-line-item increment is the most reasonable increment to balance the affordability to parties and the amount of resources expended by the certified IDR entities to review those line items. As a result, the Departments are finalizing this policy as proposed.

III. Severability

In the event that any portion of these final rules is declared invalid, the Departments intend that the various aspects of the finalized administrative fee provisions and certified IDR entity fee provisions be severable. The Departments proposed at 26 CFR 54.9816–8(d)(3)(i), 29 CFR 2590.716–8(d)(3)(i), and 45 CFR 149.510(d)(3)(i) that any provision of paragraph (d) or paragraphs (e)(2)(vii) through (e)(2)(ix) held to be invalid or unenforceable as applied to any person or circumstance would be construed so as to continue to give the maximum effect to the provision permitted by law, including as applied to persons not similarly

[127] *See* Centers for Medicare & Medicaid Services (December 23, 2022). *Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act: Change in Administrative Fee. https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/amended-cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.*

situated or to dissimilar circumstances, unless such holding is that the provision of these paragraphs is invalid and unenforceable in all circumstances, in which event the provision would be severable from the remainder of these paragraphs and would not affect the remainder thereof. The Departments further proposed at new 26 CFR 54.9816–8(d)(3)(ii), 29 CFR 2590.716–8(d)(3)(ii), and 45 CFR 149.510(d)(3)(ii) that the provisions in paragraphs (d) and (e)(2)(vii) through (ix) are intended to be severable from each other. Additionally, the Departments further proposed that if a court were to find unlawful the administrative fee policies, the certified IDR entity fee policies should stand. In the alternative, if a court were to find unlawful the certified IDR entity fee policies, the administrative fee policies should stand.

A few commenters supported the proposed severability provisions. These commenters stated that the provisions would help mitigate uncertainty that may result from future court decisions if a lawsuit occurs.

The Departments agree that the severability clause will help mitigate uncertainty. After considering the comments, the Departments are finalizing these policies as proposed, with a technical modification that the provisions in 26 CFR 54.9816–8(d) and (e)(2)(vii) and (viii), 29 CFR 2590.716–8(d) and (e)(2)(vii) and (viii), and 45 CFR 149.510(d) and (e)(2)(vii) and (viii) are intended to be severable, rather than 26 CFR 54.9816–8(d) and (e)(2)(vii) through (ix), 29 CFR 2590.716–8(d) and (e)(2)(vii) through (ix), and 45 CFR 149.510(d) and (e)(2)(vii) through (ix). This technical modification is due to the restructuring of the regulatory text in these final rules pertaining to certified IDR entity fees at 26 CFR 54.9816–8(e)(2)(vii) and (viii), 29 CFR 2590.716–8(e)(2)(vii) and (viii), and 45 CFR 149.510(e)(2)(vii) and (viii) compared to what was proposed, as discussed further in section II.B of this preamble.

The Departments further clarify their intent that the methodology being adopted here to set the administrative fee amount and the considerations the Departments used in developing the certified IDR entity fee ranges are also intended to be severable. Should any aspect of the methodology or considerations be determined to be unlawful, the Departments intend for the administrative fee amount or certified IDR entity fee ranges to be adjusted by applying the methodology in accordance with the remaining elements of the methodology or considerations. For instance, if it is determined that certain expenditures should not have been included in calculating the administrative fee amount, then the Departments would implement these rules by eliminating those expenditures from the total expenditures estimated to be made by the Departments in carrying out the Federal IDR process, and dividing the new expenditures amount by the same estimated number of administrative fees paid to calculate the new administrative fee amount. The resulting administrative fee amount would be immediately effective, without requiring additional notice and comment rulemaking.

IV. Economic Impact and Paperwork Burden

A. Summary—Departments of Health and Human Services and Labor

These final rules establish the administrative fee amount and the certified IDR entity fee ranges in notice and comment rulemaking, and the preamble sets forth the methodology for setting the administrative fee amount and the considerations used to develop the certified IDR entity fee. The Departments have examined the effects of these final rules as required by Executive Order 13563 (76 FR 3821, January 21, 2011, Improving Regulation and Regulatory Review); Executive Order 12866 (58 FR 51735, October 4, 1993, Regulatory Planning and Review); Executive Order 14094 (88 FR 21879, April 11, 2023, Modernizing Regulatory Review); the Regulatory Flexibility Act (Pub. L. 96–354, September 19, 1980); section 1102(b) of the Social Security Act (42 U.S.C. 1102(b)); section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995); and Executive Order 13132 (64 FR 43255, August 10, 1999, Federalism).

B. Executive Orders 12866, 13563, and 14094—Departments of Health and Human Services and Labor

Executive Orders 12866, 13563, and 14094 direct Federal 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). Under Executive Order 12866, ''significant'' regulatory actions are subject to review by the Office of Management and Budget (OMB). Executive Order 14094, entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.), amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended 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 $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OMB's Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (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 legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for rules deemed significant. OMB's OIRA has deemed this rule significant. The Departments have prepared an RIA that to the best of their ability presents the costs and benefits of these rules. OMB has reviewed these final regulations, and the Departments have provided the following assessment of their impact.

C. Need for Regulatory Action—Departments of Health and Human Services and Labor

The Departments are amending the certified IDR entity and administrative fee provisions of the rules for the Federal IDR process to set the administrative fee amount and the certified IDR entity fee ranges in notice and comment rulemaking, and set forth the methodology for setting the administrative fee amount and the considerations for developing the certified IDR entity fee ranges. These policies will ensure that all interested parties are sufficiently notified and provided an opportunity to comment on the fees associated with the Federal IDR process.

D. Summary of Impacts and Accounting Table—Departments of Health and Human Services and Labor

The expected benefits and costs of these final rules are summarized in Table 1 and discussed in this section of the preamble. In accordance with OMB Circular A–4, Table 1 depicts an

accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action. The Departments are unable to quantify all benefits and costs of these final rules but have sought, where possible, to describe these non-quantified impacts. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of these final rules.

TABLE 1: Accounting Table

Accounting Statement				
Benefits:				
Non-Quantified: ● Increased interested party transparency as a result of the policies to establish the administrative fee amount and certified IDR entity fee ranges in notice and comment rulemaking, as well as setting forth the methodology for calculating the administrative fee amount and the considerations for developing the certified IDR entity fee ranges.				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/Year)	$0.14 million	2023	7 percent	2023-2027
	$0.13 million	2023	3 percent	2023-2027
Quantified: ● Costs to interested parties of $638,631 to review and interpret these rules in 2023.				
Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$31.65 million	2023	7 percent	2023-2027
	$32.31 million	2023	3 percent	2023-2027
Quantified: ● Transfers from the parties to the Federal Government of approximately $32 million annually beginning in 2024 as a result of the policy to set the administrative fee amount at $115 per party per dispute for disputes initiated on or after the effective date of these rules. ● Transfers from the parties to certified IDR entities of approximately $9 million annually beginning in 2024 as a result of the policy to set the certified IDR entity fee ranges at $200-$840 for single determinations, $268-$1,173 for batched determinations, and an additional $75-$250 for every 25 line items in excess of the first 25 line items.				

1. Benefits

The primary benefit of these final rules is to allow the Federal IDR process to function through establishing the administrative fee amount and certified IDR entity fee ranges in rulemaking and establishing the amounts of these fees for disputes initiated on or after the effective date of these rules. In response to the opinion and order in *TMA IV,* these final rules are necessary in order to set the administrative fee amount as close to January 1, 2024 as possible, because the current $50 administrative fee amount is insufficient to satisfy the statutory requirement that the total amount of fees paid for the year be estimated to be equal to the amount of expenditures estimated to be made by the Departments in carrying out the Federal IDR process. The primary non-quantifiable benefit of these final rules is the continuation of a functioning Federal IDR process, which helps to protect consumers from certain surprise medical bills and helps providers to receive compensation for certain out-of-network services. Additional benefits specific to each Federal IDR process fee type appear in the following sections.

a. Administrative Fee Amount and Methodology

The Departments are finalizing the proposal to establish the administrative fee amount in notice and comment rulemaking for disputes initiated on or after the effective date of these rules, and the Departments are setting forth the methodology for determining the administrative fee amount. Utilizing notice and comment rulemaking will increase transparency of the administrative fee-setting process and allow interested parties to provide feedback to the Departments prior to the Departments setting the administrative fee amount.

The Departments sought comment on these benefits. The Departments received comments on these benefits and respond to these comments in section II.A of this preamble. The Departments are finalizing these benefits as proposed.

b. Certified IDR Entity Fee Ranges

The Departments proposed to establish the certified IDR entity fee ranges for single and batched determinations, which include a tiered fee range for batched determinations that exceed 25 line items, in notice and comment rulemaking for disputes initiated on or after the effective date of these rules. Utilizing notice and comment rulemaking to set the appropriate ranges for certified IDR entity fees will increase transparency for parties interested in the certified IDR entity fee ranges and allow these parties to identify in advance the impacts of changing the certified IDR entity fee ranges.

The Departments sought comment on these benefits. The Departments received comments on these benefits and respond to these comments in section II.B of this preamble. The Departments are finalizing these benefits as proposed.

2. Costs

a. Administrative Fee Amount and Methodology

The Departments are finalizing the proposal to establish the administrative fee amount in notice and comment rulemaking for disputes initiated on or after the effective date of these rules, and set forth the methodology for setting the administrative fee amount with modifications described in section II.A of this preamble to ensure that disputing and other parties are sufficiently notified and provided an opportunity to comment on the administrative fee amount. The Departments are also finalizing the administrative fee amount for disputes initiated on or after the effective date of these rules at $115 per party per dispute.

The current administrative fee is $50 per party per dispute.[128] In the IDR Fees proposed rules, the Departments estimated that approximately 225,000 disputes are closed per year.[129] Therefore, if the current administrative fee were to remain applicable, the Departments estimated in the IDR Fees proposed rules that the parties would pay approximately $22.5 million in administrative fees annually (225,000 disputes × 2 parties per dispute × $50 per party). In the IDR Fees proposed rules, the Departments also estimated that if they were to finalize an administrative fee amount of $150 per party per dispute for disputes initiated on or after the effective date of these rules, the parties would pay approximately $67.5 million in administrative fees annually beginning in 2024 (225,000 disputes × 2 parties per dispute × $150 per party), assuming the number of disputes remains stable year over year and the administrative fee amount is not subsequently changed through notice and comment rulemaking. Therefore, in the IDR Fees proposed rules, the Departments estimated that the costs associated with this proposal, if finalized, would be approximately $45 million ($67.5 million if this proposal is finalized minus $22.5 million if the status quo were to continue).

The Departments sought comment on these costs and assumptions. The Departments received comments on these assumptions.

Several commenters suggested that the Departments' estimate of 225,000 closed disputes is too low. A few commenters suggested that the Departments are underestimating utilization of the Federal IDR process and recommended that the Departments analyze the available data from States implementing similar policies before the No Surprises Act. Several commenters disagreed with the assumption used to calculate the 225,000 closed disputes, which assumed that *TMA IV*'s vacatur of batching regulations and guidance would reduce the volume of disputes by 25 percent.

As discussed in section II.A of this preamble, after consideration of comments, the Departments are finalizing the administrative fee using the estimated total number of administrative fees paid to certified IDR entities, rather than the projected total number of closed disputes, to estimate the number of administrative fees to be paid under the administrative fee methodology. Federal IDR process data show that the monthly average number of administrative fees paid to certified IDR entities between February 2023 and July 2023 was 41,000. The Departments project this monthly average forward by 12 months to estimate 492,000 administrative fees paid in a year.

After consideration of public comments, the Departments are modifying the proposed assumptions and cost estimates as follows. If the current administrative fee were to remain applicable, the parties would pay approximately $24.6 million in administrative fees annually (492,000 administrative fees paid × $50 per party per dispute). As stated in section II.A of this preamble, the estimated $24.6 million in administrative fee collections if the Departments were to retain the current $50 administrative fee would be inadequate for the Departments to carry out the Federal IDR process in 2024, as they estimate the expenditures to be made in 2024 to be approximately $56.6 million. As the Departments are now finalizing an administrative fee amount of $115 per party per dispute for disputes initiated on or after the effective date of these rules, the Departments estimate that the parties will pay approximately $56.6 million in administrative fees annually beginning in 2024 (492,000 administrative fees paid × $115 per party per dispute), which is sufficient to cover the estimated annual expenditures of approximately $56.6 million, assuming the number of administrative fees paid remains stable year over year and the administrative fee amount is not subsequently changed through notice and comment rulemaking. Therefore, the costs associated with this policy are approximately $32.0 million ($56.6 million minus $24.6 million if the status quo were to continue).

b. Certified IDR Entity Fee Ranges

The Departments are finalizing the proposal to set the certified IDR entity fee ranges for single and batched determinations, with a tiered fee range for batched determinations that exceed 25 line items, in notice and comment rulemaking for disputes initiated on or after the effective date of these rules in response to the opinion and order in *TMA IV* to ensure that interested parties are sufficiently notified and provided an opportunity to comment on the certified IDR entity fee ranges. The certified IDR entity fee range for single determinations for disputes initiated on or after the effective date of these rules is $200 to $840. The certified IDR entity fee range for batched disputes initiated on or after the effective date of these rules is $268 to $1,173. Further, the tiered fee range for batched determination for disputes initiated on or after the effective date of these rules is $75 to $250.

While the certified IDR entities are responsible for setting their fees for single and batched determinations, the Departments acknowledge that the changes to the certified IDR entity fee ranges may impact the cost to the parties to participate in the Federal IDR process. The Departments anticipate that the vacatur of batching standards by the District Court's opinion and order in *TMA IV* could result in initiating parties submitting single and batched disputes in proportions similar to those prior to the issuance of the August 2022 guidance, which interpreted the now-vacated standards for batching qualified IDR items or services. Based on internal data relating to disputes initiated prior to the establishment of the now vacated batching criteria that were released in August 2022, approximately 70 percent of disputes at the time were single disputes and approximately 30 percent were batched disputes.[130] The

[128] As a result of the opinion and order in *TMA IV,* which vacated the portion of the December 2022 guidance that increased the administrative fee amount to $350 per party per dispute for disputes initiated during calendar year 2023, the administrative fee amount reverted to the amount established in the October 2022 guidance. *See* Centers for Medicare & Medicaid Services (August 11, 2023). Federal Independent Dispute Resolution (IDR) Process Administrative Fee FAQs. *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/no-surprises-act-independent-dispute-resolution-administrative-fee-frequently-asked-questions.pdf. Also see* Centers for Medicare & Medicaid Services (October 31, 2022). Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process *under* the No Surprises Act. *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.*

[129] The details of the calculation of the number of disputes are provided at 88 FR 65893.

[130] The Departments estimate that currently approximately 80 percent of disputes are single

Departments anticipate that, as a result of *TMA IV,* initiating parties will return to the batching practices they engaged in prior to issuance of the August 2022 guidance, such as initiating a higher proportion of batched disputes and including more items or services within those batched disputes.

Based on internal Federal IDR process data, the Departments estimate that certified IDR entities collect a certified IDR entity fee for approximately 135,000 disputes annually.[131] Therefore, for the purposes of this analysis, the Departments estimate that certified IDR entities will collect certified IDR entity fees for approximately 94,500 single disputes and 40,500 batched disputes annually (135,000 × 0.70 and 135,000 × 0.30, respectively). The Departments acknowledge that each party must pay a certified IDR entity fee to the certified IDR entity no later than the time that party submits its offer. However, because the non-prevailing party is ultimately responsible for the full certified IDR entity fee, which is retained by the certified IDR entity for the IDR services it performed, it is the Departments' position that providing a per-dispute calculation reasonably captures the overall cost of the dispute with respect to the certified IDR entity fee without implicating false precision on the amount of certified IDR entity fee costs that initiating and non-initiating parties ultimately may incur.

To develop a reasonable estimate for the certified IDR entity fee amount for both single and batched disputes, the Departments assume that the certified IDR entities will set single determination fixed fees that approximate the median value of the finalized fee range and will set batched determination fixed fees that approximate the 3rd quartile of the finalized fee range.[132] Therefore, for the purposes of this analysis, the Departments estimate that the typical single determination fixed fee (range $200–$840) will be approximately $520, and that the typical batched determination fixed fee (range $268–$1,173) will be approximately $947. At an estimated cost of $520 per single determination for approximately 94,500 single determinations annually, the Departments estimate that single determinations will cost disputing parties approximately $49,140,000 annually ($520 × 94,500). At an estimated cost of $947 per batched determination for approximately 40,500 batched determinations annually, the Departments estimate that batched determinations will cost disputing parties approximately $38,353,500 annually ($947 × 40,500).

Further, the Departments estimate that using the finalized tiered fee range for batched determinations, certified IDR entities will set and apply a fixed fee that approximates the average of the proposed range ($75–$250) for batched determinations based on the number of line items. The Departments estimate that certified IDR entities will typically set their tiered fee at approximately $163. The Departments acknowledge the uncertainty surrounding the number of line items that may be submitted in batched disputes due to the *TMA IV* opinion and order. However, to produce an estimate, and for the purposes of this analysis, the Departments estimate that of the total estimated 40,500 batched disputes, approximately 4,455 batched determinations will potentially be subject to at least 2 applications of the tiered fee ($163 × 2 = $326).[133] The Departments therefore estimate that this subset of approximately 4,455 batched determinations exceeding 25 line items will cost disputing parties approximately $1,452,330 annually ($326 × 4,455). In total, assuming the number of disputes remains stable year over year, the Departments estimate the parties will pay approximately $89 million in certified IDR entity fees annually in accordance with the finalized policies ($49,140,000 for single determinations + $38,353,500 for batched determinations + $1,452,330 for the subset of batched determinations subject to the tiered fee).

The calendar year 2023 certified IDR entity fee ranges for single determinations and batched determinations are $200–$700 and $268–$938, respectively. Certified IDR entities currently charge a median fixed fee of $549 for single determinations and $770 for batched determinations in 2023. Therefore, for approximately 108,000 single determinations and 24,840 batched determinations (not subject to the batched percentage fee amount) annually,[134] if current certified IDR entity fixed fees remained applicable, the Departments estimate that the parties would pay approximately $59,292,000 for single determinations ($549 × 108,000) and $19,126,800 for batched determinations ($770 × 24,840). Current guidance permits certified IDR entities to charge a batching percentage on batched determinations based on the number of line items.[135] For the purposes of this analysis, the Departments assume that a subset of approximately 8 percent of batched determinations, or 2,160 determinations, potentially subject to the batched percentages would receive at least a 120 percent increase from the median batched determination fixed fee ($770 × 1.20 = $924). As such, the Departments estimate that the parties would pay approximately $1,995,840 for this subset of batched determinations potentially subject to a batching percentage (2,160 × $924), resulting in a total cost of approximately $80 million under the current calendar year 2023 certified IDR entity fee structure ($59,292,000 for single determinations + $19,126,800 for batched determinations + $1,995,840 for the subset of batched determinations subject to the tiered fee). Therefore, taking into account the current costs to the parties associated with the current certified IDR entity fee structure, the total cost to the parties

disputes and 20 percent of disputes are batched disputes, and the Departments anticipate that this ratio will return to 70 percent of disputes being single disputes and 30 percent of disputes being batched disputes beginning in calendar year 2024.

[131] While the administrative fee must be paid by the disputing party for any dispute for which a certified IDR entity is selected, the certified IDR entity fee is only assessed for disputes that are determined eligible for the Federal IDR process.

[132] The Departments anticipate that, due to the uncertainty around batching practices as a result of the *TMA IV* opinion and order, certified IDR entities will likely choose to increase their batched determination fee. Therefore, using the 75th percentile of the proposed fee range to calculate the cost of batched determinations provides a reasonable approximation of the expected increase.

[133] Based on internal data the Departments estimate that approximately 11 percent of batched disputes submitted prior to the establishment of the batching criteria released in August 2022 exceeded 25 line items. For this reason, we project that a similar number of batched disputes with number of line items exceeding 25 line items will be submitted due to *TMA IV.*

[134] The Departments estimate that 80 percent of disputes are single disputes and 20 percent are batched disputes (135,000 × 0.80 and 135,000 × 0.20, respectively). For the purposes of this analysis, the Departments estimate that a subset of approximately 8 percent, or 2,160 batched disputes would be subject to a batching percentage (27,000 × 0.08).

[135] Without the need to seek further approval, to account for the differential in the workload of batched determinations, a certified IDR entity may charge the following percentages of its approved certified IDR entity batched determination fee (''batching percentage'') for batched determinations, which are based on the number of line items initially submitted in the batch:

- 2–20 line items: 100 percent of the approved batched determination fee;
- 21–50 line items: 110 percent of the approved batched determination fee;
- 51–80 line items: 120 percent of the approved batched determination fee; and
- 81 line items or more: 130 percent of the approved batched determination fee.

See Centers for Medicare & Medicaid Services (October 31, 2022). *Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.*

associated with this policy is approximately $9 million ($89 million as finalized minus $80 million if the status quo fee ranges were to continue).

The Departments sought comment on these costs and assumptions. The Departments did not receive comments on these costs or assumptions and are finalizing them as proposed.

3. Uncertainties

It is unclear whether the Federal IDR process will experience the same operating conditions when these rules are effective compared to the current state, such as the number of disputes initiated, future policy changes finalized after future notice and comment rulemaking, or increased or decreased costs by the Departments to carry out the Federal IDR process. Due to the need to take point-in-time estimates of volume and expenditures for the purposes of developing the analyses in the preamble to these rules, there is inherent uncertainty in the estimates in these analyses as the data are constantly changing. It is difficult to project the impact on the administrative fee amount charged to the parties if the Federal IDR process landscape changes. Although the Departments have analyzed the Federal IDR process data available to inform their projections, it is uncertain whether the trends in these data will remain applicable in the future. At the same time, the Departments do not know what impact the changes to the Federal IDR process as a result of the District Court's opinions and orders in *TMA IV* and *TMA III* will have on the number of disputes initiated and the time it will take certified IDR entities to close those disputes. The Departments continue to monitor trends in the Federal IDR process and will make any necessary changes through future notice and comment rulemaking.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on entities, such as the time needed to read and interpret rules, regulatory agencies should estimate the total cost associated with regulatory review. Based on comments received for the July 2021 interim final rules and October 2021 interim final rules, the Departments estimate that more than 2,100 entities will review these final rules, including 1,500 issuers, 205 third party administrators (TPAs), and at least 395 other interested parties (for example, State insurance departments, State legislatures, industry associations, advocacy organizations, and providers and provider organizations). The Departments acknowledge that this assumption may understate or overstate the number of entities that will review these final rules.

Using the median hourly wage rate from the Bureau of Labor Statistics for a Lawyer (Code 23–1011) to account for average labor costs (including a 100 percent increase for the cost of fringe benefits and other indirect costs), the Departments estimate that the cost of reviewing these final rules will be $130.52 per hour.[136] The Departments estimate, based on an estimated rule length of approximately 35,000 words and an average reading speed of 200 to 250 words per minute, that it will take each reviewing entity approximately 2.33 hours to review these final rules, with an associated cost of approximately $304.11 (2.33 hours × $130.52 per hour). Therefore, the Departments estimate that the total burden to review these final rules will be approximately 4,893 hours (2,100 reviewers × 2.33 hours per reviewer), with an associated cost of approximately $638,631 (2,100 reviewers × $304.11 per reviewer).

The Departments sought comments in the IDR Fees proposed rules on this approach to estimating the total burden and cost for interested parties to read and interpret the IDR Fees proposed rules, which is the same approach used to estimate the total burden and cost for interested parties to read and interpret these final rules. The Departments did not receive comments on this approach and cost. The Departments are finalizing these estimates as proposed.

E. Regulatory Alternatives—Departments of Health and Human Services and Labor

In developing these final rules, the Departments considered various alternative approaches.

1. Administrative Fee Amount and Methodology (26 CFR 54.9816–8(d)(2), 29 CFR 2590.716–8(d)(2), and 45 CFR 149.510(d)(2))

In its *TMA IV* opinion and order, the District Court indicated that notice and comment rulemaking is necessary to set the administrative fee, and the Departments are of the view that alternative approaches would lead to unnecessary uncertainty. In addition, providing a description of the methodology used to calculate the fee amount and proposing the administrative fee amount in the IDR Fees proposed rules would increase transparency for the parties and provide interested parties the opportunity to be included in the fee setting process. The Departments considered that guidance has historically been used to set the administrative fee amount based on concerns that the requirement to collect fees sufficient to fund the Federal IDR process. The lead time required to set the fee amount in notice and comment rulemaking could constrain the Departments' responsiveness to program needs and artificially inflate the administrative fee amount due to the need to ensure adequate funding of the process. However, in light of *TMA IV,* the increased transparency and opportunity for interested parties to provide feedback on the administrative fee methodology and amount outweighed the potential concern that the administrative fee might be artificially inflated by the need to make conservative estimates to set the administrative fee amount further in advance through notice and comment rulemaking.

The Departments considered proposing other administrative fee policies in the IDR Fees proposed rules, such as those proposed in the IDR Operations proposed rules.[137] However, as discussed in section II.A of this preamble, the Departments were unable to propose those policies in the IDR Fees proposed rules because they are much more comprehensive than the fee-related policies proposed in the IDR Fees proposed rules and would require more time to develop and implement if finalized. There is an urgency to publish these final rules to be effective as close to January 1, 2024 as possible due to the need to sufficiently fund the Federal IDR process in 2024. As discussed in sections I.E and II.A of these final rules, the current $50 administrative amount is insufficient to satisfy the statutory requirement that the total amount of fees paid for a year be estimated to be equal to the amount of expenditures estimated to be made by the Departments for the year in carrying out the Federal IDR process. Therefore, the Departments deferred those substantial changes to the Federal IDR process and administrative fee structure and collection procedures to the IDR Operations proposed rules, which are aimed at improving Federal IDR process operations and making the process more accessible.

2. Certified IDR Entity Fee Ranges (26 CFR 54.9816–8(e)(2), 29 CFR 2590.716–8(e)(2), and 45 CFR 149.510(e)(2))

The Departments considered maintaining the current policy that the allowable ranges for certified IDR entity

[136] U.S. Bureau of Labor Statistics (May 1, 2022). *May 2022 National Occupational Employment and Wage Estimates. https://www.bls.gov/oes/current/oes_nat.htm.*

[137] 88 FR 75744.

fees would be set in guidance yearly instead of through notice and comment rulemaking. The Departments considered whether continuing to set the certified IDR entity fee ranges in guidance would preserve necessary flexibility for the certified IDR entities to choose their fixed fees within the allowable ranges and submit those fees for approval to the Departments, and would allow the Departments time to review and approve each certified IDR entity's fees and publish them in advance of the year to which the fees apply. The Departments concluded that publishing the fee ranges in guidance could be a more expedient process compared to rulemaking because of the lack of required comment period; however, establishing the fee ranges through notice and comment rulemaking would not prevent the Departments from reviewing and approving each certified IDR entity's fixed fee amounts in a timely manner. The Departments are of the view that there would be no impact to the ability of the certified IDR entities to select their fees from the established ranges if those ranges were published through notice and comment rulemaking. Further, setting the certified IDR entity fee ranges through guidance does not allow interested parties to engage through the submission of public comments, while the notice and comment rulemaking process increases transparency and will afford an opportunity for the Departments to consider feedback from interested parties on the appropriateness of proposed fee ranges.

F. Paperwork Reduction Act

These final rules are not subject to the requirements of the Paperwork Reduction Act of 1995,[138] because the Departments anticipate that fewer than 10 certified IDR entities will submit requests to update their certified IDR entity fees an additional time during the calendar year based on current experience operating the Federal IDR process, and they do not contain any other collection of information as defined in 44 U.S.C. 3502(3). Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq.*) requires agencies to analyze options for regulatory relief of small entities and to prepare a final regulatory flexibility analysis to describe the impact of these final rules on small entities, unless the head of the agency can certify that the rule would 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.'' The Departments use a change in revenues of more than 3 to 5 percent as their measure of significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The Secretaries of Labor, the Treasury, and Health and Human Services certify that these final rules will not have a significant economic impact on a substantial number of small entities, as presented in the analysis in the following subsections of this preamble.

1. Small Entities Regulated

The provisions in these final rules will affect plans (or their TPAs),[139] health insurance issuers offering group or individual health insurance coverage, and providers, facilities, and providers of air ambulance services.

For purposes of analysis under the RFA,[140] the Departments consider an employee benefit plan with fewer than 100 participants to be a small entity.[141] The basis of this definition is found in section 104(a)(2) of ERISA,[142] which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under section 104(a)(3),[143] the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Under the authority of section 104(a)(3),[144] the Department of Labor has previously issued simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans, which cover fewer than 100 participants and satisfy certain requirements.[145] While some large employers have small plans, small plans are generally maintained by small employers. Thus, the Departments are of the view that assessing the impact of these final rules on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of a small entity considered appropriate for this purpose differs, however, from a definition of a small business based on size standards issued by the SBA [146] in accordance with the Small Business Act.[147]

In 2021, there were 1,500 issuers in the U.S. health insurance market [148] and 205 TPAs.[149] Health insurance issuers are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,[150] entities with average annual receipts of $47 million or less are considered small entities for this NAICS code. The Departments expect that few, if any, insurance companies underwriting health insurance policies fall below these size thresholds. Based on data from Medical Loss Ratio (MLR) annual report submissions for the 2021 MLR reporting year, approximately 87 out of 483 issuers of health insurance coverage nationwide had total premium revenue of $47 million or less.[151] However, it should be noted that also based on MLR data, over 77 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies, are likely to have non-health lines of business that would result in their revenues exceeding $47 million. The Departments are of the view that the same assumptions also apply to TPAs that would be affected by these proposed rules.[152] To produce a conservative estimate, for the purposes of this analysis, the Departments assume 4.1 percent, or 62 issuers and 8 TPAs, of the total of 1,500 health insurance

[138] 44 U.S.C. 3501 *et seq.*

[139] The Departments expect that most self-insured group health plans will work with a TPA to meet the requirements.

[140] 5 U.S.C. 601, *et seq.*

[141] The Department of Labor consulted with the Small Business Administration Office of Advocacy in making this determination, as required by 5 U.S.C. 603(c) and 13 CFR 121.903(c) in a memo dated June 4, 2020.

[142] 29 U.S.C. 1024(a)(2).

[143] 29 U.S.C. 1024(a)(3).

[144] *Id.*

[145] 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46, and 2520.104b-10.

[146] 13 CFR 121.201 (2011).

[147] 15 U.S.C. 631 *et seq.* (2011).

[148] Centers for Medicare & Medicaid Services (2022). *Medical Loss Ratio Data and System Resources. https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[149] Non-issuer TPAs based on data derived from the 2016 benefit year reinsurance program contributions.

[150] United States Small Business Administration (March 17, 2023). *Table of Size Standards. https://www.sba.gov/document/support--table-size-standards.*

[151] Centers for Medicare & Medicaid Services (2022). *Medical Loss Ratio Data and System Resources. https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[152] The Departments are of the view that most TPAs are also issuers.

issuers and 205 TPAs across the country, are considered small entities.[153]

These final rules also affect health care providers and facilities due to the proposed requirements related to the certified IDR entity and administrative fees. The Departments estimate that 140,270 physicians, on average, bill on an out-of-network basis annually.[154] The number of small physician providers is estimated based on the SBA's size standards. The size standard applied for providers is NAICS 62111 (Offices of Physicians), for which a business with less than $16 million in receipts is considered to be small. By this standard, the Departments estimate that 47.2 percent or 66,207 physicians are considered small under the SBA's size standards.[155] The size standard for facilities is NAICS 62211 (General Medical and Surgical Hospitals), for which a business with less than $47 million in receipts is considered to be small. By this standard, the Departments estimate that 43.5 percent or 1,113 facilities are considered small under the SBA's size standards.[156] These final rules are also expected to affect non-physician providers who bill on an out-of-network basis. The Departments lack data on the number of non-physician providers who will be impacted by these final rules.

The Departments do not have the same level of data for the air ambulance subsector. In 2020, the total revenue of providers of air ambulance services was estimated to be $4.2 billion, with 1,114 air ambulance bases.[157] This results in an industry average of $3.8 million per air ambulance base. Based on a 2020 U.S.C.-Brookings Schaeffer report on air ambulance services,[158] by 2017, large private equity firms controlled roughly two-thirds of the air ambulance market.

Although based on the Departments' experience operating the Federal IDR process, significantly fewer than 67,320 small providers and facilities have accessed the process to date,[159] the Departments lack adequate data to better inform the number of small providers impacted by these final rules. Therefore, although the estimate of 67,320 small providers and facilities is likely a significant overestimate of the number of small providers and facilities impacted by these final rules, the Departments use this number of small providers and facilities in this analysis to be conservative.[160]

Additionally, as discussed in the *Partial Report on the Federal Independent Dispute Resolution (IDR) Process, October 1–December 31, 2022,* the top 10 initiating parties (or entities acting on behalf of initiating parties) are large companies that initiate approximately 85 percent of disputes, and the top 10 non-initiating parties are large companies that are initiated against in approximately 95 percent of disputes.[161] Therefore, for purposes of this analysis, the Departments assume that only 15 percent of all disputes involve small providers. The 5 percent of all disputes that do not involve the top 10 non-initiating parties could involve any of the 1,695 issuers and TPAs that are not the top 10 non-initiating parties (1,500 issuers and 205 TPAs total −10 top non-initiating parties = 1,695 remaining issuers and TPAs). The Departments assume that the proportion of small issuers and TPAs to non-top 10 issuers and TPAs is the same as the proportion of disputes involving small issuers and TPAs to disputes involving non-top 10 issuers and TPAs, as the volume of disputes issuers and TPAs are involved in should be proportional to the size of their enrollment. Taking into consideration these estimates of the small entities, the policies in these rules that result in an increased burden to small entities are described below.

2. Compliance Costs

The Departments are finalizing the policy to establish the administrative fee amount in notice and comment rulemaking and are finalizing that the administrative fee amount for disputes initiated on or after the effective date of these rules is $115 per party per dispute. The annual burden per small provider or facility associated with this policy is $115,[162] and the annual burden per small issuer/TPA is $805.[163] For more details, please refer to the Regulatory Impact Analysis in these final rules.

[153] These numbers are calculated as follows: 77 percent of small companies belong to larger holding groups, so 23 percent do not and would be small entities. 87 issuers × 0.23 = 20. 20/483 = 4.1 percent. Applying the 4.1 percent to 1,500 issuers and 205 TPAs total = 62 small issuers and 8 small TPAs.

[154] *See* 86 FR 56051 for more information on this estimate.

[155] Based on data from the NAICS Association for NAICS code 62111, the Departments estimate the percent of businesses within the industry of Offices of Physicians with less than $16 million in annual sales. United States Census Bureau (May 2021). *2017 SUSB Annual Data Tables by Establishment Industry. https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*

[156] Based on data from the NAICS Association for NAICS code 62211, the Departments estimate the percent of businesses within the industry of General Medical and Surgical Hospitals with less than $47 million in annual sales. United States Census Bureau (May 2021). *2017 SUSB Annual Data Tables by Establishment Industry. https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*

[157] ASPE Office of Health Policy (September 10, 2021). *Air Ambulance Use and Surprise Billing. https://aspe.hhs.gov/sites/default/files/2021-09/aspe-air-ambulance-ib-09-10-2021.pdf.*

[158] Adler, L., Hannick, K., and Lee, S. ''High Air Ambulance Charges Concentrated in Private Equity-Owned Carriers.'' U.S.C.-Brookings Schaffer Initiative for Health Policy. October 13, 2020. *https://www.brookings.edu/articles/high-air-ambulance-charges-concentrated-in-private-equity-owned-carriers/.*

[159] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury, *Partial Report on the Federal Independent Dispute Resolution (IDR) Process, October 1–December 31, 2022.* (n.d.). *https://www.cms.gov/files/document/partial-report-idr-process-octoberdecember-2022.pdf.*

[160] Based on the Departments' experience operating the Federal IDR process, the estimate of 67,320 small providers and facilities is likely a significant overestimate, and therefore the Departments assume that this estimate accounts for any non-physician providers who may be impacted by these rules for whom the Departments lack data to estimate.

[161] Top initiating parties represent hundreds of individual providers across multiple states. Top non-initiating parties operate across multiple states and market segments. *See* U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury, *Partial Report on the Federal Independent Dispute Resolution (IDR) Process, October 1–December 31, 2022.* (n.d.). *https://www.cms.gov/files/document/partial-report-idr-process-octoberdecember-2022.pdf.*

[162] 492,000 administrative fees paid/2 types of parties = 246,000 administrative fees paid by providers. 246,000 administrative fees paid by providers −85 percent (209,100) administrative fees paid for disputes initiated by the top 10 initiating parties = 36,900 administrative fees paid for disputes initiated by other initiating parties. 36,900 disputes/67,320 small providers and facilities = approximately 0.5 disputes initiated per small provider or facility annually. For simplicity and to be conservative, the Departments assume 1 dispute per provider or facility. 1 dispute × $115 per dispute = $115 per small provider or facility.

[163] 492,000 administrative fees paid/2 types of parties = 246,000 administrative fees paid by issuers/TPAs. 246,000 administrative fees paid by issuers/TPAs −95 percent (233,700) administrative fees paid for disputes initiated against the top 10 non-initiating parties = 12,300 administrative fees paid for disputes initiated against other non-initiating parties. 12,300 disputes/1,695 issuers/TPAs = approximately 7 disputes per small issuer/TPA annually. 7 disputes × $115 per dispute = $805.

The Departments are finalizing the policy to establish the certified IDR entity fee ranges in notice and comment rulemaking and are finalizing that the ranges are $200–$840 for single determinations and $268–$1,173 for batched determinations, with a $75–$250 tiered fee range for disputes that contain more than 25 line items. The annual burden per small provider or facility associated with this policy is $657,[164] and the annual burden per small issuer/TPA is $1,971.[165] For more details, please refer to the Regulatory Impact Analysis in these final rules.

Thus, the per-entity annual cost for small providers and facilities is $772, and the per-entity annual cost for small issuers and TPAs is $2,776. The total estimated annual cost for small providers and facilities is $51,971,040, and the total estimated annual cost for small issuers and TPA is $194,320. See Tables 2 and 3.

TABLE 2: Detailed Annual Costs for Small Entities

Description of Cost	Annual Cost per Small Provider or Facility	Annual Cost per Small Issuer/TPA
Administrative Fee	$115	$805
Certified IDR Entity Fee	$657	$1,971
Total	$772	$2,776

TABLE 3: Aggregate Annual Costs for Small Entities

Affected Entity	Affected Small Entities	Annual Cost per Entity	Aggregate Annual Cost for Small Entities
Provider or Facility	67,320	$772	$51,971,040
Issuer/TPA	70	$2,776	$194,320

3. Analysis and Certification Statement

The annual cost per small provider or facility of $772 is approximately 0.07 percent of the average annual receipts per small provider and approximately 0.04 percent of the average annual receipts per small facility. The Departments anticipate that small providers and facilities would be unlikely to initiate disputes and thereby incur these costs unless they anticipate prevailing in the dispute and receiving payment from plans or issuers that exceed the costs incurred to initiate the dispute. Additionally, data from the public reports on the Federal IDR process released to date by the Departments show that providers and facilities prevail in approximately 70 percent of disputes.[166] Therefore, small providers and facilities are likely to experience an increase in receipts commensurate or larger than the increase in costs.

The annual cost per small issuer/TPA of $2,776 is approximately 0.15 percent of the average annual receipts per small issuer/TPA. While small issuers/TPAs could pass on these increased costs to consumers in the form of higher premiums (or for TPAs, higher administration fees), resulting in an increase in receipts commensurate with the increase in costs, the actual increase in costs and subsequent impact on revenue would be *de minimis* as the annual cost per small issuer/TPA is so small. Additionally, the Departments anticipate that by batching qualified IDR items and services, there may be a reduction in the per-service cost of the Federal IDR process to providers of certain services and specialties, and potentially the aggregate administrative costs, because the Federal IDR process is likely to exhibit at least some economies of scale.[167]

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5

[164] Data from the first full year of Federal IDR process operations show that initiating parties prevail in approximately 70 percent of disputes. *See* Centers for Medicare & Medicaid Services (April 27, 2023). *Federal Independent Dispute Resolution Process—Status Update.* Therefore, as the prevailing party's certified IDR entity fee is refunded per 26 CFR 54.9816–8T(d)(1)(ii), 29 CFR 2590.716–8(d)(1)(ii), and 45 CFR 149.510(d)(1)(ii), initiating parties only pay the certified IDR entity fee for 30 percent of disputes, while non-initiating parties pay for the other 70 percent.*https://www.cms.gov/files/document/federal-idr-processstatus-update-april-2023.pdf.* The Departments estimate based on internal data that certified IDR entity fees are paid for approximately 135,000 disputes annually. Of those 135,000 disputes, the Departments estimate that 30 percent (or 40,500) have their certified IDR entity fees paid by providers/facilities, and 70 percent (or 94,500) have their certified IDR entity fees paid by issuers/TPAs. Of the 40,500 disputes for which the certified IDR entity fee is paid by providers or facilities, 85 percent (or 34,425) are paid by the top 10 initiating parties. The remaining 15 percent (or 6,075) are paid by other initiating parties. 6,075 disputes/67,320 small providers and facilities = less than 1 certified IDR entity fee paid per small provider or facility. For simplicity and to be conservative, the Departments assume 1 certified IDR entity fee paid per small provider or facility. The average certified IDR entity fee across both single and batched disputes, including the tiered batched fee, in 2024 is $657 as calculated in accordance with these final rules.

[165] Of the 94,500 disputes that have their certified IDR entity fees paid by issuers, 95 percent (or 89,775) are paid by the top 10 non-initiating parties. The remaining 5 percent (or 4,725) are paid by other non-initiating parties. 4,725 disputes/1,695 issuers/TPAs = approximately 3 certified IDR entity fees paid per small issuer/TPA. The average certified IDR entity fee across both single and batched disputes, including the tiered batched fee, in 2024 is $657 as calculated in accordance with these final rules. 3 disputes × $657 per dispute = $1,971 per small issuer/TPA.

[166] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury, *Partial Report on the Federal Independent Dispute Resolution (IDR) Process, October 1–December 31, 2022.* (n.d.). *https://www.cms.gov/files/document/partial-report-idr-process-octoberdecember-2022.pdf.*

[167] Fielder, M., Adler, L., Ippolito, B. (March 16, 2021). *Recommendations for Implementing the No Surprises Act.* U.S.C.-Brookings Schaeffer on Health Policy. *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/03/16/recommendations-for-implementing-the-no-surprises-act/.*

percent. The Departments are of the view that this threshold will not be reached by the requirements in these final rules, given that the annual per-entity cost of $2,776 per small issuer/TPA represents 0.15 percent of the average annual receipts for a small issuer/TPA and the annual per-entity cost of $772 per small provider/facility represents 0.07 percent and 0.04 percent of the average annual receipts for a small provider or facility, respectively.[168] Therefore, the Secretaries of Labor, the Treasury, and Health and Human Services hereby certify that these final rules will not have a significant economic impact on a substantial number of small entities.

The Departments sought comment on this analysis and sought information on the number of small plans (or TPAs), issuers, providers, and facilities that may be affected by the provisions in the IDR Fees proposed rules. The Departments did not receive comments on this analysis. The Departments received comments on the impact of the provisions in the IDR Fees proposed rules on small providers and respond to those comments in section II of this preamble.

In addition, section 1102(b) of the Social Security Act requires the Departments to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA.[169] For purposes of section 1102(b) of the Act, the Departments define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. These final rules are not subject to section 1102 of the Act because the IDR Fees proposed rules were not proposed under title XVIII, title XIX, or part B of title XI of the Act, and therefore section 1102(b) of the Act does not apply.

H. Special Analyses—Department of the Treasury

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required. Pursuant to section 7805(f) of the Code,[170] these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

I. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA)[171] requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule or any final rule for which a general notice of proposed rulemaking was published that includes any Federal mandate that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. That threshold is approximately $177 million in 2023. As discussed earlier in the RIA, plans, issuers, TPAs, and providers, facilities, and providers of air ambulance services will incur costs to comply with the provisions of these final rules. The Departments estimate the combined impact on State, local, or tribal governments and the private sector will not be above the threshold.

J. Federalism

Executive Order 13132 outlines the fundamental principles of federalism. It requires adherence to specific criteria by Federal agencies in formulating and implementing policies that have ''substantial direct effects'' on the States, the relationship between the National Government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies issuing regulations that have these federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the IDR Fees proposed rules.

The Departments do not anticipate that these final rules will have federalism implications or limit the policy-making discretion of the States in compliance with the requirement of Executive Order 13132.

State and local government health plans may be subject to the Federal IDR process where a specified State law or All-Payer Model Agreement does not apply. The No Surprises Act authorizes States to enforce the new requirements, including those related to balance billing, for issuers, providers, facilities, and providers of air ambulance services, with HHS enforcing only in cases where the State has notified HHS that the State does not have the authority to enforce or is otherwise not enforcing, or HHS has made a determination that a State has failed to substantially enforce the requirements. However, in the Departments' view, the federalism implications of these final rules are substantially mitigated because some States have their own process for determining the total amount payable under a plan or coverage for out-of-network emergency services and to out-of-network providers for patient visits to in-network facilities for non-emergency services. Where a State has a specified State law, the State law, rather than the Federal IDR process, will apply.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners and consulting with State insurance officials on an individual basis.

While developing these rules, the Departments attempted to balance the States' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, the Departments complied with the requirements of Executive Order 13132.

In accordance with Federal law, a summary of these rules may be found at *https://www.regulations.gov/.*

List of Subjects

26 CFR Part 54

Excise taxes, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

[168] United States Census Bureau (March 2020). *2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size. https://www.census.gov/data/tables/2020/econ/susb/2020-susb-annual.html.*

[169] 5 U.S.C. 603.

[170] 26 U.S.C. 7805(f).

[171] 2 U.S.C. 1511.

45 CFR Part 149

Balance billing, Health care, Health insurance, Reporting, and recordkeeping requirements, Surprise billing.

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Lily L. Batchelder,

Assistant Secretary of the Treasury (Tax Policy), Department of the Treasury.

Lisa M. Gomez

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Xavier Becerra,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

For the reasons stated in the preamble, the Department of the Treasury and the IRS amend 26 CFR part 54 as set forth below:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 is amended by adding an entry for § 54.9816–8 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 54.9816–8 also issued under 26 U.S.C. 9816.

* * * * *

■ 2. Section 54.9816–8 is amended by revising paragraphs (a), (b), (c) introductory text, (d), and (e) and adding headings for paragraphs (f) and (g) to read as follows:

§ 54.9816–8 Independent dispute resolution process.

(a) *Scope and definitions.* For further guidance, see § 54.9816–8T(a).

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process.* For further guidance, see § 54.9816–8T(b).

(c) *Federal IDR process following initiation.* For further guidance, see § 54.9816–8T(c) introductory text through (c)(3).

* * * * *

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* For further guidance, see § 54.9816–8T(d)(1).

(2) *Administrative fee.* (i) For further guidance, see § 54.9816–8T(d)(2)(i).

(ii) The administrative fee amount will be established through notice and comment rulemaking no more frequently than once per calendar year in a manner such that the total administrative fees paid for a year are estimated to be equal to the amount of expenditures estimated to be made by the Secretaries of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process. The administrative fee amount will remain in effect until changed by notice and comment rulemaking. For disputes initiated on or after January 22, 2024, the administrative fee amount is $115 per party per dispute.

(3) *Severability.* (i) Any provision of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) of this section held to be invalid or unenforceable as applied to any person or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, including as applied to persons not similarly situated or to dissimilar circumstances, unless such holding is that the provision of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) and shall not affect the remainder thereof.

(ii) The provisions in this paragraph (d) and paragraphs (e)(2)(vii) and (viii) of this section are intended to be severable from each other.

(e) *Certification of IDR entity*—(1) *In general.* For further guidance see § 54.9816–8T(e)(1).

(2) *Requirement*s. (i) For further guidance, see § 54.8616–8T(e)(2)(i) through (vi).

(ii) through (vi) [Reserved]

(vii) Provide, no more frequently than once per calendar year, a fixed fee for single determinations and a separate fixed fee for batched determinations, as well as additional fixed tiered fees for batched determinations, if applicable, within the upper and lower limits for each, as established by the Secretary in notice and comment rulemaking. The certified IDR entity fee ranges established by the Secretary in rulemaking will remain in effect until changed by notice and comment rulemaking. The certified IDR entity may not charge a fee outside the limits set forth in rulemaking unless the certified IDR entity or IDR entity seeking certification receives advance written approval from the Secretary to charge a fixed fee beyond the upper or lower limits by following the process described in paragraph (e)(2)(vii)(A) of this section. A certified IDR entity may also seek advance written approval from the Secretary to update its fees one additional time per calendar year by meeting the requirements described in paragraph (e)(2)(vii)(A). The Secretary will approve a request to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking or to update the fixed fee during the calendar year if, in their discretion, they determine the information submitted by a certified IDR entity or IDR entity seeking certification demonstrates that the proposed change to the certified IDR entity fee would ensure the financial viability of the certified IDR entity or IDR entity seeking certification and would not impose on parties an undue barrier to accessing the Federal IDR process.

(A) In order for the certified IDR entity or IDR entity seeking certification to receive the Secretary's written approval to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking or to update the fixed fee during the calendar year, the certified IDR entity or IDR entity seeking certification must submit to the Secretary, in the form and manner specified by the Secretary:

(*1*) The fixed fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(*2*) A description of the circumstances that require the alternative fixed fee, or that require a change to the fixed fee during the calendar year, as applicable; and

(*3*) A detailed description that reasonably explains how the alternative fixed fee or the change to the fixed fee during the calendar year, as applicable, will be used to mitigate the effects of those circumstances.

(B) [Reserved]

(viii) For disputes initiated on or after January 22, 2024, certified IDR entities are permitted to charge a fixed certified IDR entity fee for single determinations within the range of $200 to $840, and a fixed certified IDR entity fee for batched determinations within the range of $268 to $1,173, unless a fee outside such ranges is approved by the Secretary, pursuant to paragraph (e)(2)(vii)(A) of this section. As part of the batched determination fee, certified IDR entities are permitted to charge an additional fixed tiered fee within the range of $75 to $250 for every additional 25 line items within a batched dispute, beginning with the 26th line item. The ranges for the certified IDR entity fees for single and batched determinations will remain in effect until changed by notice and comment rulemaking.

(ix) For further guidance, see § 54.9816–8T(e)(2)(ix) through (xii).

(x) through (xii) [Reserved]

(f) *Reporting of information relating to the Federal IDR process.* * * *

* * * * *

(g) *Extension of time periods for extenuating circumstances.* * * *

* * * * *

■ 3. Section 54.9816–8T is amended by:
■ a. Revising paragraph (d)(2)(ii);
■ b. Adding paragraph (d)(3);
■ c. Removing the semicolon at the end of paragraphs (e)(2)(iii) and (vi) and adding a period in its place;
■ d. Revising paragraph (e)(2)(vii);
■ e. Redesignating paragraphs (e)(2)(viii) through (xi) as paragraphs (e)(2)(ix) through (xii);
■ f. Adding new paragraph (e)(2)(viii);
■ g. Removing the semicolon at the end of newly redesignated paragraphs (e)(2)(ix) and (x) and adding a period in its place; and
■ h. Removing ''; and'' at the end of newly redesignated paragraph (e)(2)(xii) and adding a period in its place.

The revisions and additions read as follows:

§ 54.9816–8T Independent dispute resolution process (temporary).

* * * * *

(d) * * *

(2) * * *

(ii) For further guidance, see § 54.9816–8(d)(2)(ii).

(3) *Severability.* For further guidance, see § 54.9816–8(d)(3).

(e) * * *

(2) * * *

(vii) For further guidance, see § 54.9816–8(e)(2)(vii).

(viii) For further guidance, see § 54.9816–8(e)(2)(viii).

* * * * *

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons stated in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 4. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Pub. L. 116–260, 134 Stat. 1182; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 5. Section 2590.716–8 is amended by:
■ a. Revising paragraph (d)(2)(ii);
■ b. Adding paragraph (d)(3);
■ c. Removing the semicolon at the end of paragraphs (e)(2)(iii) and (vi) and adding a period in its place;
■ d. Revising paragraph (e)(2)(vii);
■ e. Redesignating paragraphs (e)(2)(viii) through (xi) as paragraphs (e)(2)(ix) through (xii);
■ f. Adding new paragraph (e)(2)(viii);
■ g. Removing the semicolon at the end of newly redesignated paragraphs (e)(2)(ix) and (x) and adding a period in its place; and
■ h. Removing ''; and'' at the end of newly redesignated paragraph (e)(2)(xii) and adding a period in its place.

The revisions and additions read as follows:

§ 2590.716–8 Independent dispute resolution process.

* * * * *

(d) * * *

(2) * * *

(ii) The administrative fee amount will be established through notice and comment rulemaking no more frequently than once per calendar year in a manner such that the total administrative fees paid for a year are estimated to be equal to the amount of expenditures estimated to be made by the Secretaries of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process. The administrative fee amount will remain in effect until changed by notice and comment rulemaking. For disputes initiated on or after January 22, 2024, the administrative fee amount is $115 per party per dispute.

(3) *Severability.* (i) Any provision of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) of this section held to be invalid or unenforceable as applied to any person or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, including as applied to persons not similarly situated or to dissimilar circumstances, unless such holding is that the provision of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) and shall not affect the remainder thereof.

(ii) The provisions in this paragraph (d) and paragraphs (e)(2)(vii) and (viii) of this section are intended to be severable from each other.

(e) * * *

(2) * * *

(vii) Provide, no more frequently than once per calendar year, a fixed fee for single determinations and a separate fixed fee for batched determinations, as well as an additional fixed tiered fee for batched determinations, if applicable, within the upper and lower limits for each, as established by the Secretary in notice and comment rulemaking. The certified IDR entity fee ranges established by the Secretary in rulemaking will remain in effect until changed by notice and comment rulemaking. The certified IDR entity may not charge a fee outside the limits set forth in rulemaking unless the certified IDR entity or IDR entity seeking certification receives advance written approval from the Secretary to charge a fixed fee beyond the upper or lower limits by following the process described in paragraph (e)(2)(vii)(A) of this section. A certified IDR entity may also seek advance written approval from the Secretary to update its fees one additional time per calendar year by meeting the requirements described in paragraph (e)(2)(vii)(A). The Secretary will approve a request to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking, or to update the fixed fee during the calendar year if, in their discretion, they determine the information submitted by a certified IDR entity or IDR entity seeking certification demonstrates that the proposed change to the certified IDR entity fee would ensure the financial viability of the certified IDR entity or IDR entity seeking certification and would not impose on parties an undue barrier to accessing the Federal IDR process.

(A) In order for the certified IDR entity or IDR entity seeking certification to receive the Secretary's written approval to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking or to update the fixed fee during the calendar year, the certified IDR entity or IDR entity seeking certification must submit to the Secretary, in the form and manner specified by the Secretary:

(*1*) The fixed fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(*2*) A description of the circumstances that require the alternative fixed fee, or that require a change to the fixed fee during the calendar year, as applicable; and

(*3*) A detailed description that reasonably explains how the alternative fixed fee or the change to the fixed fee

during the calendar year, as applicable, will be used to mitigate the effects of those circumstances.

(B) [Reserved]

(viii) For disputes initiated on or after January 22, 2024, certified IDR entities are permitted to charge a fixed certified IDR entity fee for single determinations within the range of $200 to $840, and a fixed certified IDR entity fee for batched determinations within the range of $268 to $1,173, unless a fee outside such ranges is approved by the Secretary pursuant to paragraph (e)(2)(vii)(A) of this section. As part of the batched determination fee, certified IDR entities are permitted to charge an additional fixed tiered fee within the range of $75 to $250 for every additional 25 line items within a batched dispute, beginning with the 26th line item. The ranges for the certified IDR entity fees for single and batched determinations will remain in effect until changed by notice and comment rulemaking.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

49 CFR Subtitle A

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 149 as set forth below:

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

■ 6. The authority citation for part 149 continues to read as follows:

Authority: 42 U.S.C. 300gg–92 and 300gg–111 through 300gg–139, as amended.

■ 7. Section 149.510 is amended by:
■ a. Revising paragraph (d)(2)(ii);
■ b. Adding paragraph (d)(3);
■ c. Removing the semicolon at the end of paragraphs (e)(2)(iii) and (vi) and adding a period in its place;
■ d. Revising paragraph (e)(2)(vii);
■ e. Redesignating paragraphs (e)(2)(viii) through (xi) as paragraphs (e)(2)(ix) through (xii);
■ f. Adding new paragraph (e)(2)(viii);
■ g. Removing the semicolon at the end of newly redesignated paragraphs (e)(2)(ix) and (x) and adding a period in its place; and
■ h. Removing ''; and'' at the end of newly redesignated paragraph (e)(2)(xii) and adding a period in its place.

The revisions and additions read as follows:

§ 149.510 Independent dispute resolution process.

* * * * *

(d) * * *

(2) * * *

(ii) The administrative fee amount will be established through notice and comment rulemaking no more frequently than once per calendar year in a manner such that the total administrative fees paid for a year are estimated to be equal to the amount of expenditures estimated to be made by the Secretaries of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process. The administrative fee amount will remain in effect until changed by notice and comment rulemaking. For disputes initiated on or after January 22, 2024, the administrative fee amount is $115 per party per dispute.

(3) *Severability.* (i) Any provision of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) of this section held to be invalid or unenforceable as applied to any person or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, including as applied to persons not similarly situated or to dissimilar circumstances, unless such holding is that the provision of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) and shall not affect the remainder thereof.

(ii) The provisions in this paragraph (d) and paragraphs (e)(2)(vii) and (viii) of this section are intended to be severable from each other.

(e) * * *

(2) * * *

(vii) Provide, no more frequently than once per calendar year, a fixed fee for single determinations and a separate fixed fee for batched determinations, as well as an additional fixed tiered fee for batched determinations, if applicable, within the upper and lower limits for each, as established by the Secretary in notice and comment rulemaking. The certified IDR entity fee ranges established by the Secretary in rulemaking will remain in effect until changed by notice and comment rulemaking. The certified IDR entity may not charge a fee outside the limits set forth in rulemaking unless the certified IDR entity or IDR entity seeking certification receives advance written approval from the Secretary to charge a fixed fee beyond the upper or lower limits by following the process described in paragraph (e)(2)(vii)(A) of this section. A certified IDR entity may also seek advance written approval from the Secretary to update its fees one additional time per calendar year by meeting the requirements described in paragraph (e)(2)(vii)(A). The Secretary will approve a request to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking or to update the fixed fee during the calendar year if, in their discretion, they determine the information submitted by a certified IDR entity or IDR entity seeking certification demonstrates that the proposed change to the certified IDR entity fee would ensure the financial viability of the certified IDR entity or IDR entity seeking certification and would not impose on parties an undue barrier to accessing the Federal IDR process.

(A) In order for the certified IDR entity or IDR entity seeking certification to receive the Secretary's written approval to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking or to update the fixed fee during the calendar year, the certified IDR entity or IDR entity seeking certification must submit to the Secretary, in the form and manner specified by the Secretary:

(*1*) The fixed fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(*2*) A description of the circumstances that require the alternative fixed fee, or that require a change to the fixed fee during the calendar year, as applicable; and

(*3*) A detailed description that reasonably explains how the alternative fixed fee or the change to the fixed fee during the calendar year, as applicable, will be used to mitigate the effects of those circumstances.

(B) [Reserved]

(viii) For disputes initiated on or after January 22, 2024, certified IDR entities are permitted to charge a fixed certified IDR entity fee for single determinations within the range of $200 to $840, and a fixed certified IDR entity fee for batched determinations within the range of $268 to $1,173, unless a fee outside such ranges is approved by the Secretary, pursuant to paragraph (e)(2)(vii)(A) of this section. As part of the batched determination fee, certified IDR entities are permitted to charge an additional fixed tiered fee within the range of $75 to $250 for every additional 25 line items within a batched dispute, beginning with the 26th line item. The ranges for the certified IDR entity fees for single and batched determinations will remain in effect until changed by notice and comment rulemaking.

* * * * *

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