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U.S. GOVERNMENT
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FEDERAL REGISTER

Vol. 85 Thursday,
No. 251 December 31, 2020

Pages 86793–87352

OFFICE OF THE FEDERAL REGISTER

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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

OFFICE OF MANAGEMENT AND BUDGET

2 CFR Part 200

Uniform Administrative Requirements, Cost Principles, and Audit Requirements

AGENCY: Office of Management and Budget.

ACTION: Guidance.

SUMMARY: This document announces the availability of the 2020 Compliance Supplement Addendum (2020 Addendum) for the Office of Management and Budget's uniform administrative requirements, cost principles, and audit requirements regulations. This document also offers interested parties an opportunity to comment on the 2020 Addendum.

DATES: The 2020 Addendum serves as a complement to the 2020 Compliance Supplement published on August 18, 2020 (FR Doc. 2020–17987) and applies to fiscal year audits beginning after June 30, 2019.

ADDRESSES: All comments to the 2020 Supplement must be in writing and received by January 30, 2021. Late comments will be considered to the extent practicable. Comments will be reviewed and addressed, when appropriate, in the 2021 Compliance Supplement. Electronic mail comments may be submitted to: *http://www.regulations.gov.* Please include ''2 CFR part 200 Subpart F—Audit Requirements, Appendix XI—Compliance Supplement Addendum—2020'' in the subject line and the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and email address in the text of the message. Comments may also be sent to: *GrantsTeam@omb.eop.gov.*

Please note that all public comments received are subject to the Freedom of Information Act and will be posted in their entirety, including any personal and/or business confidential information provided. Do not include any information you would not like to be made publically available.

The 2020 Addendum is available online on the OMB home page at *https://www.whitehouse.gov/omb/offices/offm.*

FOR FURTHER INFORMATION CONTACT: Recipients and auditors should contact their cognizant or oversight agency for audit, or Federal awarding agency, as appropriate under the circumstances. The Federal agency contacts are listed in appendix III of the Supplement. Subrecipients should contact their pass-through entity. Federal agencies should contact Gil Tran at *Hai_M._Tran@omb.eop.gov* or (202) 395–3052 or the OMB Grants team at *GrantsTeam@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: The 2020 Addendum (2 CFR part 200, subpart F, appendix XI) adds 5 new COVID–19 programs and updates 9 current programs for COVID–19 related compliance requirements. Consistent with the President's Management Agenda, Cross Agency Priority (CAP) goal number 8, ''Results-Oriented Accountability for Grants,'' Federal awarding agencies are encouraged to begin a paradigm shift in grants management from one heavy on compliance to a balanced approach that includes establishing measurable program and project goals and analyzing data to improve results. To that end, the 2020 Addendum continues the reduction of the compliance areas for auditor review in part 2, Matrix from a maximum of twelve to six, which was first implemented in the 2019 Supplement, and requires a review for performance reporting, where applicable.

The 2020 Addendum also includes an increased emphasis on transparency related requirements, including a requirement for auditor's to review the Federal Funding Accountability and Transparency Act (FFATA) subaward reporting requirements for the COVID–19 programs included in this Addendum, where applicable. In addition, these requirements apply to all programs for audits with fiscal year-ending after September 30, 2020.

John C. Pasquantino,

Acting Deputy Controller.

[FR Doc. 2020–28429 Filed 12–30–20; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 110

[NRC–2018–0294]

RIN 3150–AK26

Updates and Clarifications on the Export of Nuclear Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its export and import regulations to maintain the regulatory status quo for nuclear exports to the United Kingdom (U.K.), upon the entry into force of a new civil nuclear cooperation agreement between the United States (U.S.) and the U.K. (the U.S.-U.K. 123 Agreement). The amendment will add the U.K. to the list of countries eligible to receive certain small quantities of special nuclear material under a general license, and to the list of countries whose export license applications do not require Executive Branch or Commission level reviews for certain exports of source material or low-enriched uranium. This amendment is necessary to bring the NRC's regulations into conformity with U.S. Government foreign policy and preserve existing provisions for nuclear exports to the U.K.

DATES: This final rule is effective on December 31, 2020.

ADDRESSES: Please refer to Docket ID NRC–2018–0294 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–2018–0294. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.*

• *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.*

• *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lauren Mayros, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–287–9088; email: *Lauren.Mayros@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

The purpose of this final rule is to revise the NRC's export and import regulations in part 110 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Export and Import of Nuclear Equipment and Material,'' to include the United Kingdom (U.K.) as a country eligible to receive certain small quantities of special nuclear material under a general license, and to add the U.K. to the list of countries whose export license applications do not require Executive Branch or Commission level reviews for certain exports of source material or low-enriched uranium. In light of the impending U.K. departure from the European Union and European Atomic Energy Agency (EURATOM), this final rule is necessary to conform the NRC's regulations with U.S. Government foreign policy and preserve existing provisions for nuclear exports to the U.K., upon the entry into force of the new civil nuclear cooperation agreement between the U.S. and the U.K.

The U.S. Department of State has requested that the NRC update its regulations in 10 CFR part 110 to meet the commitment made by the U.S. Government to the U.K. Government to prepare for entry into force of the new U.S.-U.K. 123 Agreement. The two Governments plan to bring the U.S.-U.K. 123 Agreement into force when the U.K. is no longer covered by the U.S. civil nuclear cooperation agreement with the European Atomic Energy Community (EURATOM). During the negotiations of the U.S.-U.K. 123 Agreement, the U.S. Government committed to take the necessary steps to ensure a seamless continuation of close nuclear cooperation with the U.K. Fulfilling this commitment will require current nuclear export regulatory and policy understandings to remain in place for U.S. companies exporting nuclear material to the U.K. after entry into force of the U.S.-U.K. 123 Agreement. As a result, the U.S. Department of State requested that the NRC amend §§ 110.21(b)(3), 110.40(b)(3), and 110.41(a)(6) to meet a U.S. Government foreign policy objective and to provide confidence that the regulatory status quo between the U.K. and the U.S. will be maintained.

The NRC has determined that revising §§ 110.21(b)(3), 110.40(b)(3), and 110.41(a)(6) to include the U.K. after EURATOM in the requirements for these sections, is consistent with current U.S. law and policy, and will pose no unreasonable risk to the public health and safety or to the common defense and security of the U.S. Further, the revisions are essential to preserve the current provisions for export to the U.K. once the U.S.-U.K. 123 Agreement enters into force.

II. Summary of Changes

10 CFR Part 110

This final rule revises §§ 110.21(b)(3), 110.40(b)(3), and 110.41(a)(6) to include the U.K. after EURATOM in the requirements for these sections.

III. Rulemaking Procedure

Because this rule involves a foreign affairs function of the U.S., the notice and comment provisions of the Administrative Procedures Act do not apply (5 U.S.C. 553(a)(1)), and good cause exists to make this rule immediately effective upon publication. The effective date for those entities who receive actual notice of this rule is the date of receipt of this rule.

IV. Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in 10 CFR 51.22(c)(1), which categorically excludes from environmental review any amendments to 10 CFR part 110. Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this rule.

V. Paperwork Reduction Act

This final rule does not contain new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget (OMB) under approval number 3150–0036.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

VI. Regulatory Analysis

This final rule revises §§ 110.21(b)(3), 110.40(b)(3), and 110.41(a)(6) to include the U.K. after EURATOM, and is necessary to maintain the existing regulatory status quo for nuclear exports to the U.K. upon the entry into force of a new U.S.-U.K. 123 Agreement. The addition of the U.K. in § 110.21(b)(3) will continue to allow for the return of uranium-235, in the form of uranium hexafluoride heels in cylinders, to suppliers in the U.K. under an NRC general license. Adding the U.K. in § 110.40(b)(3) preserves the current regulation that excludes Commission review for exports of source material or low-enriched uranium to EURATOM or Japan for enrichment up to 5 percent in the isotope uranium-235. Lastly, adding the U.K. in § 110.41(a)(6) preserves the current regulation that excludes Executive Branch review for exports of source material or low-enriched uranium to EURATOM or Japan for enrichment up to 5 percent in the isotope uranium–35. There is no alternative to amending the regulations for the export and import of nuclear equipment and material. This final rule is expected to have no changes in the information collection burden or cost to the public.

VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883).

VIII. Backfitting and Issue Finality

The NRC has determined that a backfit analysis is not required for this rule, because these amendments do not include any provisions that would impose backfits as defined in 10 CFR chapter I.

IX. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a ''major rule'' as defined by that act.

List of Subjects in 10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalties, Exports, Imports, Intergovernmental relations, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Scientific equipment.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 110:

PART 110—EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL

■ 1. The authority citation for part 110 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 51, 53, 54, 57, 62, 63, 64, 65, 81, 82, 103, 104, 109, 111, 121, 122, 123, 124, 126, 127, 128, 129, 133, 134, 161, 170h, 181, 182, 183, 184, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2071, 2073, 2074, 2077, 2092, 2093, 2094, 2095, 2111, 2112, 2133, 2134, 2139, 2141, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2160c, 2160d, 2201, 2210h, 2231, 2232, 2233, 2234, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); Administrative Procedure Act (5 U.S.C. 552, 553); 42 U.S.C. 2139a, 2155a; 44 U.S.C. 3504 note.

Section 110.1(b) also issued under 22 U.S.C. 2403; 22 U.S.C. 2778a; 50 App. U.S.C. 2401 *et seq.*

■ 2. In § 110.21, revise paragraph (b)(3) to read as follows:

§ 110.21 General license for the export of special nuclear material.

* * * * *

(b) * * *

(3) Uranium, enriched to less than 20 percent in uranium–235, in the form of uranium hexafluoride (UF6) heels in cylinders being returned to suppliers in EURATOM or the United Kingdom.

* * * * *

■ 3. In § 110.40, revise paragraph (b)(3) to read as follows:

§ 110.40 Commission review.

* * * * *

(b) * * *

(3) An export involving assistance to end uses related to isotope separation, chemical reprocessing, heavy water production, advanced reactors, or the fabrication of nuclear fuel containing plutonium, except for exports of source material or low-enriched uranium to EURATOM, the United Kingdom, or Japan for enrichment up to 5 percent in the isotope uranium–235, and those categories of exports which the Commission has approved in advance as constituting permitted incidental assistance.

* * * * *

■ 4. In § 110.41, revise paragraph (a)(6) to read as follows:

§ 110.41 Executive Branch review.

(a) * * *

(6) An export involving assistance to end uses related to isotope separation, chemical reprocessing, heavy water production, advanced reactors, or the fabrication of nuclear fuel containing plutonium, except for exports of source material or low-enriched uranium to EURATOM, the United Kingdom, or Japan for enrichment up to 5 percent in the isotope uranium–235, and those categories of exports approved in advance by the Executive Branch as constituting permitted incidental assistance.

* * * * *

Dated: December 14, 2020.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2020–27816 Filed 12–30–20; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 19 and 109

Notification of Inflation Adjustments for Civil Money Penalties

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notification of monetary penalties 2021.

SUMMARY: The Office of the Comptroller of the Currency (OCC) is providing notice of its maximum civil money penalties as adjusted for inflation. The inflation adjustments are required to implement the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: The adjusted maximum amount of civil money penalties in this document are applicable to penalties assessed on or after January 1, 2021, for conduct occurring on or after November 2, 2015.

FOR FURTHER INFORMATION CONTACT: Lee Walzer, Counsel, Chief Counsel's Office, (202) 649–5490, Office of the Comptroller of the Currency.

SUPPLEMENTARY INFORMATION: This document announces changes to the maximum amount of each civil money penalty (CMP) within the OCC's jurisdiction to administer to account for inflation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (the 1990 Adjustment Act),[1] as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Adjustment Act).[2] Under the 1990 Adjustment Act, as amended, Federal agencies must make annual adjustments to the maximum amount of each CMP they administer. The Office of Management and Budget (OMB) is required to issue guidance to Federal agencies no later than December 15 of each year providing an inflation adjustment multiplier (*i.e.,* the inflation adjustment factor agencies must use) applicable to CMPs assessed in the following year. The agencies are required to publish their CMPs, adjusted pursuant to the multiplier provided by OMB, by January 15 of the applicable year.

To the extent an agency has codified a CMP amount in its regulations, the agency would need to update that amount by regulation. However, if an agency has codified the formula for making the CMP adjustments, then subsequent adjustments can be made solely by notice.[3] In 2018, the OCC published a final regulation to remove the CMP amounts from its regulations, while updating those amounts for inflation through the notification process.[4]

On December 23, 2020, the OMB issued guidance to affected agencies on implementing the required annual adjustment, which included the relevant inflation multiplier.[5] The OCC has

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

[2] Public Law 114–74, Title VII, section 701(b), Nov. 2, 2015, 129 Stat. 599, *codified at* 28 U.S.C. 2461 note.

[3] See OMB Memorandum M–18–03, ''Implementation of the 2018 Annual Adjustment Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,'' at 4, which permits agencies that have codified the formula to adjust CMPs for inflation to update the penalties through a notification rather than a regulation.

[4] 83 FR 1517 (Jan. 12, 2018) (final rule); 83 FR 1657 (Jan. 12, 2018) (2018 CMP Notice).

[5] The inflation adjustment multiplier for 2021 is 1.01182 . *See* OMB Memorandum M–21–10,

Continued

applied that multiplier to the maximum CMPs allowable in 2020 for national banks and Federal savings associations as listed in the 2020 CMP notification [6] to calculate the maximum amount of CMPs that may be assessed by the OCC in 2021.[7] There were no new statutory CMPs administered by the OCC during 2020.

The following charts provide the inflation-adjusted CMPs for use beginning on January 1, 2021, pursuant to 12 CFR 19.240(b) and 109.103(c)(2) for conduct occurring on or after November 2, 2015:

PENALTIES APPLICABLE TO NATIONAL BANKS

U.S. Code citation	Description and tier (if applicable)	Maximum penalty amount (in dollars) [1]
12 U.S.C. 93(b)	Violation of Various Provisions of the National Bank Act:	
	Tier 1	10,366
	Tier 2	51,827
	Tier 3	[2] 2,073,133
12 U.S.C. 164	Violation of Reporting Requirements:	
	Tier 1	4,146
	Tier 2	41,463
	Tier 3	[2] 2,073,133
12 U.S.C. 481	Refusal of Affiliate to Cooperate in Examination	10,366
12 U.S.C. 504	Violation of Various Provisions of the Federal Reserve Act:	
	Tier 1	10,366
	Tier 2	51,827
	Tier 3	[2] 2,073,133
12 U.S.C. 1817(j)(16)	Violation of Change in Bank Control Act:	
	Tier 1	10,366
	Tier 2	51,827
	Tier 3	[2] 2,073,133
12 U.S.C. 1818(i)(2) [3]	Violation of Law, Unsafe or Unsound Practice, or Breach of Fiduciary Duty:	
	Tier 1	10,366
	Tier 2	51,827
	Tier 3	[2] 2,073,133
12 U.S.C. 1820(k)(6)(A)(ii)	Violation of Post-Employment Restrictions:	
	Per violation	341,000
12 U.S.C. 1832(c)	Violation of Withdrawals by Negotiable or Transferable Instrument for Transfers to Third Parties:	
	Per violation	3,011
12 U.S.C. 1884	Violation of the Bank Protection Act	301
12 U.S.C. 1972(2)(F)	Violation of Anti-Tying Provisions regarding Correspondent Accounts, Unsafe or Unsound Practices, or Breach of Fiduciary Duty:	
	Tier 1	10,366
	Tier 2	51,827
	Tier 3	[2] 2,073,133
12 U.S.C. 3110(a)	Violation of Various Provisions of the International Banking Act (Federal Branches and Agencies):	47,378
12 U.S.C. 3110(c)	Violation of Reporting Requirements of the International Banking Act (Federal Branches and Agencies):	
	Tier 1	3,791
	Tier 2	37,901
	Tier 3	[2] 1,895,095
12 U.S.C. 3909(d)(1)	Violation of International Lending Supervision Act	2,579
15 U.S.C. 78u–2(b)	Violation of Various Provisions of the Securities Act, the Securities Exchange Act, the Investment Company Act, or the Investment Advisers Act:	
	Tier 1 (natural person)—Per violation	9,753
	Tier 1 (other person)—Per violation	97,523
	Tier 2 (natural person)—Per violation	97,523
	Tier 2 (other person)—Per violation	487,616
	Tier 3 (natural person)—Per violation	195,047
	Tier 3 (other person)—Per violation	975,230
15 U.S.C. 1639e(k)	Violation of Appraisal Independence Requirements:	
	First violation	11,906
	Subsequent violations	23,811
42 U.S.C. 4012a(f)(5)	Flood Insurance:	
	Per violation	2,252

[1] The maximum penalty amount is per day, unless otherwise indicated.
[2] The maximum penalty amount for a national bank is the lesser of this amount or 1 percent of total assets.
[3] These amounts also apply to CMPs in statutes that cross-reference 12 U.S.C. 1818, such as 12 U.S.C. 2804, 3108, 3349, 4309, and 4717 and 15 U.S.C. 1607, 1693o, 1681s, 1691c, and 1692*l*.

PENALTIES APPLICABLE TO FEDERAL SAVINGS ASSOCIATIONS

U.S. Code citation	CMP description	Maximum penalty amount (in dollars) [1]
12 U.S.C. 1464(v)	Reports of Condition:	

Implementation of Penalty Inflation Adjustments for 2021, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Dec. 23, 2020).

[6] *See* 84 FR 71735 (Dec. 30, 2019).

[7] Penalties assessed for violations occurring prior to November 2, 2015, will be subject to the maximum amounts set forth in the OCC's regulations in effect prior to the enactment of the 2015 Adjustment Act.

PENALTIES APPLICABLE TO FEDERAL SAVINGS ASSOCIATIONS—Continued

U.S. Code citation	CMP description	Maximum penalty amount (in dollars) [1]
	1st Tier	4,146
	2nd Tier	41,463
	3rd Tier	[2] 2,073,133
12 U.S.C. 1467(d)	Refusal of Affiliate to Cooperate in Examination	10,366
12 U.S.C. 1467a(r)	Late/Inaccurate Reports:	
	1st Tier	4,146
	2nd Tier	41,463
	3rd Tier	[2] 2,073,133
12 U.S.C. 1817(j)(16)	Violation of Change in Bank Control Act:	
	Tier 1	10,366
	Tier 2	51,827
	Tier 3	[2] 2,073,133
12 U.S.C. 1818(i)(2) [3]	Violation of Law, Unsafe or Unsound Practice, or Breach of Fiduciary Duty:	
	Tier 1	10,366
	Tier 2	51,827
	Tier 3	[2] 2,073,133
12 U.S.C. 1820(k)(6)(A)(ii)	Violation of Post-Employment Restrictions:	
	Per violation	341,000
12 U.S.C. 1832(c)	Violation of Withdrawals by Negotiable or Transferable Instruments for Transfers to Third Parties:	
	Per violation	2,737
12 U.S.C. 1884	Violation of the Bank Protection Act	301
12 U.S.C. 1972(2)(F)	Violation of Provisions regarding Correspondent Accounts, Unsafe or Unsound Practices, or Breach of Fiduciary Duty:	
	Tier 1	10,366
	Tier 2	51,827
	Tier 3	[2] 2,073,133
15 U.S.C. 78u–2(b)	Violations of Various Provisions of the Securities Act, the Securities Exchange Act, the Investment Company Act, or the Investment Advisers Act:	
	Tier 1 (natural person)—Per violation	9,753
	Tier 1 (other person)—Per violation	97,523
	Tier 2 (natural person)—Per violation	97,523
	Tier 2 (other person)—Per violation	487,616
	Tier 3 (natural person)—Per violation	195,047
	Tier 3 (other person)—Per violation	975,230
15 U.S.C. 1639e(k)	Violation of Appraisal Independence Requirements:	
	First violation	11,906
	Subsequent violations	23,811
42 U.S.C. 4012a(f)(5)	Flood Insurance:	
	Per violation	2,252

[1] The maximum penalty amount is per day, unless otherwise indicated.
[2] The maximum penalty amount for a federal savings association is the lesser of this amount or 1 percent of total assets.
[3] These amounts also apply to statutes that cross-reference 12 U.S.C. 1818, such as 12 U.S.C. 2804, 3108, 3349, 4309, and 4717 and 15 U.S.C. 1607, 1681s, 1691c, and 1692*l*.

Jonathan V. Gould,

Senior Deputy Comptroller and Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2020–28942 Filed 12–30–20; 8:45 am]

BILLING CODE 4810–33–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

RIN 3133–AF24

Fees Paid by Federal Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The NCUA Board (Board) is amending its regulation governing assessment of an annual operating fee to Federal credit unions (FCUs). First, for purposes of calculating the annual operating fee, the final rule amends the current rule to exclude from total assets any loan an FCU reports under the Small Business Administration's Paycheck Protection Program (PPP) or similar future programs approved for exclusion by the NCUA Board. Second, the final rule deletes from the current regulation references to the Credit Union System Investment Program and the Credit Union Homeowners Affordability Relief Program, both of which no longer exist. Third, the final rule amends the period used for the calculation of an FCU's total assets. Currently, total assets are calculated using the FCU's December 31st Call Report of the preceding year. Under the final rule, total assets will be calculated as the average total assets reported on the FCU's previous four Call Reports available at the time the NCUA Board approves the agency's budget for the upcoming year, adjusted for any excludable programs as determined by the Board. Finally, the final rule makes some minor technical changes.

DATES: This final rule is effective on February 1, 2021.

FOR FURTHER INFORMATION CONTACT: James Holm, Supervisory Budget Analyst, Office of the Chief Financial Officer, at (703) 518–6570; Kevin Tuininga, Associate General Counsel, or John H. Brolin, Senior Staff Attorney, Office of General Counsel, at (703) 518–6540; or by mail at 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Introduction
II. Legal Authority
III. Summary of the Proposal and Public Comments
IV. Summary of the Final Rule
V. Regulatory Procedures

I. Introduction

At its July 2020 meeting, the Board issued a proposed rule [1] to amend the NCUA's regulation governing assessment of an annual operating fee to Federal credit unions (FCUs), 12 CFR 701.6. For purposes of calculating the annual operating fee, the proposed amendments would have: (1) Excluded from total assets any loan an FCU reports under the Small Business Administration's (SBA) Paycheck Protection Program (PPP), or similar future programs approved for exclusion by the NCUA Board; (2) deleted from the current regulation references to the Credit Union System Investment Program and the Credit Union Homeowners Affordability Relief Program, both of which no longer exist; and (3) revised the period used for the calculation of an FCU's total assets. Currently, total assets are calculated using the FCU's December 31st Call Report of the preceding year. Under the proposal, total assets would be calculated as the average total assets reported on the FCU's previous four Call Reports available at the time the NCUA Board approves the agency's budget for the upcoming year, adjusted for any excludable programs as determined by the Board. Finally, the proposal would have made some minor technical conforming changes.

A. Background on the NCUA Annual Budget and Fees Paid by FCUs

The NCUA charters, regulates, and insures deposits in FCUs and insures deposits in state-chartered credit unions that have their shares insured through the National Credit Union Share Insurance Fund (Share Insurance Fund). To cover expenses related to the NCUA's tasks, the Board adopts an annual budget in the fall of each year. The Federal Credit Union Act (FCU Act) provides two primary sources to fund the budget: (1) Requisitions from the Share Insurance Fund; [2] and (2) operating fees charged against FCUs.[3] The Board uses an allocation formula, the Overhead Transfer Rate (OTR), to determine the amount of the budget that it will requisition from the Share Insurance Fund.[4] Remaining amounts needed to fund the annual budget are charged to FCUs in the form of operating fees, based on each FCU's total assets.[5]

The FCU Act requires each FCU to, ''in accordance with rules prescribed by the Board [. . .] pay to the [NCUA] an annual operating fee which may be composed of one or more charges identified as to the function or functions for which assessed.'' [6] The fee must ''be determined according to a schedule, or schedules, or other method determined by the Board to be appropriate, which gives due consideration to the expenses of the [NCUA] in carrying out its responsibilities under the [FCU Act] and to the ability of [FCUs] to pay the fee.'' [7] The statute requires the Board to, among other things, ''determine the periods for which the fee shall be assessed and the date or dates for the payment of the fee or increments thereof.'' [8]

Section 701.6 of the NCUA's regulations governs operating fee processes.[9] The regulation establishes the following: (1) The basis for charging operating fees (*i.e.,* total assets of the FCU, with certain exclusions, as of December 31st of the preceding year); (2) the notice the NCUA must provide to FCUs regarding the fees; (3) coverage provisions providing certain exceptions for new FCU charters, conversions, mergers, and liquidations; and (4) the assessment of administrative fees and interest for late payment, among other principles and processes.[10] Certain aspects of and adjustments to the operating fee process, such as the multipliers used to determine fees applicable to designated asset tiers, are not included in the NCUA's regulations. Instead, the Board generally adopts an operating fee schedule at an open meeting each year and publishes the schedule in the agency's annual budget and on its website.[11]

Section 701.6(a) sets out the basis on which the NCUA assesses the operating fee. Paragraph (a) provides that FCUs must pay the NCUA an annual operating fee based on the credit union's total assets.[12] The NCUA calculates an FCU's operating fee by multiplying the dollar amount of its total assets by a percentage set by the Board based on asset tiers after considering the expenses of the NCUA and the ability of FCUs to pay the fee. The term ''total assets'' for purposes of the operating fee presently includes all assets, with certain exclusions, reported on an FCU's Call Report as of December 31st of the previous fiscal year.

Operating fee payments are due from FCUs in April each year, and the NCUA prepares invoices using reported assets from the prior year's December Call Report.[13] In order to provide clarity to FCUs about their operating fee charges for the upcoming year, the Board typically approves the budget and sets the associated operating fee rates in November or December of the year before the operating fee is billed. Because the budget and operating fee rates are approved before December Call Report data is available, the Chief Financial Officer uses projected FCU asset growth to set the operating fee rates. Therefore, if actual total assets reported in December Call Reports are below the projected asset growth used for setting the operating fee rates, the NCUA will collect less in operating fee revenue than it requires to fund the budget. Conversely, if total assets reported in December Call Reports are greater than projected growth, the NCUA may collect more than is required.

B. Background on the CARES Act and the SBA's Paycheck Protection Program

On March 27, 2020, President Trump signed the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, into law.[14] The law is designed to provide aid to the U.S. economy in the midst of the COVID–19 pandemic. The CARES Act authorized the SBA to create a loan guarantee program, the PPP, to help certain businesses affected by the COVID–19 pandemic meet payroll needs (including employee salaries, sick leave, other paid leave, and health insurance expenses), as well as mortgage, rent, and utilities expenses. Provided credit union lenders comply with the applicable lender obligations set forth in the SBA's interim final rule, the SBA will fully guarantee loans

[1] 85 FR 53708 (Aug 31, 2020).

[2] *See, e.g.,* 12 U.S.C. 1783(a) (making the Share Insurance Fund available ''for such administrative and other expenses incurred in carrying out the purpose of [Subchapter II of the FCU Act] as [the Board] may determine to be proper.'').

[3] 12 U.S.C. 1755(a) (''In accordance with rules prescribed by the Board, each Federal credit union shall pay to the Administration an annual operating fee which may be composed of one or more charges identified as to the function or functions for which assessed.'').

[4] *See, e.g.,* Request for Comment Regarding Revised Overhead Transfer Rate Methodology, 82 FR 29935 (June 30, 2017).

[5] 12 CFR 701.6(a).

[6] 12 U.S.C. 1755(a).

[7] 12 U.S.C. 1755(b).

[8] *Id.*

[9] 12 CFR 701.6.

[10] *Id.*

[11] In November 2015, the Board delegated authority to the Chief Financial Officer to administer the Board-approved methodology and to set the operating fees as calculated per the approved methodology each annual budget cycle beginning with 2016. *See* Board Action Memorandum on 2016 Operating Fee (Nov. 19, 2015), *https://www.ncua.gov/About/Documents/Agenda%20Items/AG20151119Item6a.pdf.* Since that time, the operating fee schedule has been published in the NCUA's annual budget. *See* 2020–2021 Budget Justification (December 12, 2019), *https://www.ncua.gov/files/agenda-items/AG20191212Item1b.pdf.*

[12] 12 CFR 701.6(a).

[13] *Id.*

[14] Public Law 116–136 (Mar. 27, 2020).

issued under the PPP, backed by the full faith and credit of the United States. Most federally insured credit unions were eligible to make PPP loans to members.[15] Under the CARES Act, PPP loans must receive a zero percent risk weighting for purposes of the NCUA's risk-based capital requirements.[16]

Following enactment of the CARES Act, the Board issued an interim final rule to make several amendments to the NCUA's regulations relating to PPP loans.[17] The April 27, 2020 interim final rule provided that if a covered PPP loan made by a federally insured credit union is pledged as collateral for a non-recourse loan that is provided as part of the Board of Governors of the Federal Reserve System's (FRB) PPP Liquidity Facility,[18] the covered loan can be excluded from a credit union's calculation of total assets for the purposes of calculating its net worth ratio.[19] The exclusion of PPP loans pledged to the FRB's Liquidity Facility was comparable to an interim final rule issued by the other banking agencies with respect to their capital regulations,[20] which is consistent with the statutory requirement for the Board to prescribe a system of prompt corrective action that is, among other things, comparable to the section of the Federal Deposit Insurance Act that established prompt corrective action requirements for banks.

That change applied to only the calculation of the net worth ratio and not to other requirements or calculations in the NCUA's regulations that depend on a credit union's total assets. At present, an FCU must report the value of all of its PPP loans in its Call Reports, whether the FCU originated the loans, purchased them in the secondary market, or has pledged them to the FRB Liquidity Facility.[21] The value of PPP loans reported in Call Reports could therefore increase the total asset amounts the NCUA uses to compute the annual operating fees due. Without a change to the NCUA's current operating fee regulation,[22] an FCU's PPP loans could subject the FCU to a higher operating fee, and this could impose a burden for participation in the program, or a disincentive to participate now that the program has been extended. As the PPP serves an important public purpose, the Board believes PPP loans warrant exclusion from total assets when determining operating fees to avoid these harms.

Under the FCU Act, the Board considers, among other things, FCUs' ability to pay assessments.[23] The Board finds that an increase in an FCU's assets based on PPP loans—regardless of whether they are pledged to the PPP Liquidity Facility—poses no undue risk to the credit union's capital strength. Additionally, given the short-term and low-fee nature of PPP loans, FCUs that report increased total assets as a result of them are unlikely to have a corresponding increase in their ability to pay a higher assessment. Furthermore, excluding PPP loans from operating fee assessments makes the program more affordable to the participants and avoids imposing a burden based on participation in a program designed to provide an important public benefit. These benefits closely align with the mission of credit unions to support their member communities through trusted and affordable financial services. Accordingly, based on this statutory analysis and application, the NCUA's proposal had a broader scope of exclusion than the Board's April 27, 2020, interim final rule on PPP loans.[24]

In a separate **Federal Register** document,[25] the Board requested comment on the methodologies it uses to set the rate schedule for operating fees and how it determines the OTR. Members of the public were encouraged to comment about these methodologies by responding to that **Federal Register** notice.

II. Legal Authority

The Board is issuing this final rule pursuant to its authority under the FCU Act.[26] The FCU Act grants the Board a broad mandate to issue regulations governing both FCUs and, more generally, all federally insured credit unions. For example, section 120 of the FCU Act is a general grant of regulatory authority and authorizes the Board to prescribe rules and regulations for the administration of the FCU Act.[27] Section 105 of the FCU Act requires FCUs to pay an annual operating fee to the NCUA.[28] In particular, section 105(b) provides that the fee assessed under this section 105 shall be determined according to a schedule, or schedules, or other method determined by the Board to be appropriate, which gives due consideration to the expenses of the Administration in carrying out its responsibilities under this chapter and to the ability of Federal credit unions to pay the fee.[29] Section 105(b) provides further that the Board shall, among other things, determine the periods for which the fee shall be assessed and the date or dates for the payment of the fee or increments thereof. [30]

Accordingly, the FCU Act provides the Board with broad discretion to decide how the amount of the operating fee is determined.

III. Summary of the Proposed Rule and Public Comments

At its July 30, 2020 meeting, the NCUA Board (Board) proposed amending the agency's regulation governing assessment of an annual operating fee to Federal credit unions (FCUs). The proposal provided for a 60-day comment period, which ended on October 30, 2020. The NCUA received nine comment letters in response to the proposed rule. In general, all of the letters received from commenters—two from credit union trade associations and seven from state credit union leagues—expressed broad support for the proposal. A few of the commenters, however, did raise issues for the NCUA's consideration, which are discussed in more detail below.

The proposed rule would have amended § 701.6(a) by excluding PPP loans from FCUs' total assets for purposes of calculating its operating fee. In particular, the proposal would have amended current § 701.6(a) to provide, among other things, that the operating fee shall be based on the total assets of each FCU, less loans made under the PPP.[31] Under the proposed rule, participating FCUs would have continued to report their assets in the quarterly Call Report. For purposes of determining the operating fee, the

[15] Credit unions that are currently permitted to make loans under the SBA's 7(a) program are automatically approved to make PPP loans. Federally insured credit unions that are not current SBA 7(a) lenders can receive approval by submitting an application to the SBA, unless they are currently designated as being in troubled condition or are subject to a formal enforcement action that addresses unsafe and unsound lending practices. Non-depository financing providers, such as credit union service organizations, may qualify as a PPP lender subject to the requirements listed in the interim final rule.

[16] Public Law 116–135, section 1102(a)(2).

[17] 85 FR 23212 (Apr. 27, 2020).

[18] The program was named as both the PPP Lending Facility and the PPP Liquidity Facility when the Board approved the interim final rule. It is now named the PPP Liquidity Facility in FRB documentation on the program.

[19] 85 FR 23212.

[20] 85 FR 20387 (Apr. 13, 2020).

[21] *See* SBA Procedural Notice, Guidance on Whole Loan Sales of Paycheck Protection Program Loans (May 1, 2020), *available at https://www.sba.gov/sites/default/files/2020-05/5000-20024.pdf.*

[22] 12 CFR 701.6(a).

[23] 12 U.S.C. 1755.

[24] 85 FR 23212 (Apr. 27, 2020).

[25] 85 FR 53854 (Aug. 31 2020).

[26] 12 U.S.C. 1751 *et seq.*

[27] 12 U.S.C. 1766(a).

[28] 12 U.S.C. 1755(a).

[29] 12 U.S.C. 1755(b).

[30] *Id.*

[31] 15 U.S.C. 636(a)(36).

NCUA would have excluded reported PPP loans in the calculation of total assets. The NCUA believed the change would ensure that FCUs interested in making PPP loans did not bear greater financial burdens for doing so. The Board proposed excluding PPP loans from the calculation of total assets even if the PPP loans were not pledged to the FRB PPP Liquidity Facility because PPP loans pose no undue risk to the FCU's capital strength and, due to their unique structure, do not increase an FCU's ability to pay a higher operating fee. Excluding all reported PPP loans when determining total assets would also ensure that FCUs that do not pledge their PPP loans to the FRB are treated consistently with those FCUs that do. Absent such consistent treatment, FCUs that do not pledge their PPP loans to the FRB's Liquidity Facility would bear a larger relative cost burden of the operating fee compared to those FCUs that do pledge their PPP loans.

Comments Received: None of the commenters objected to this change. All nine of the commenters stated that they supported excluding from total assets any loan an FCU reports under the PPP and agreed with the NCUA's rationale supporting this change. Four of the commenters specifically stated further that they supported excluding PPP loans from the calculation of total assets even if the PPP loans are not pledged to the Federal Reserve Board's (FRB) PPP Liquidity Facility.

Proposing to exclude PPP loans from the calculation of total assets was similar to the amendment the Board made to the calculation of total assets in a 2009 final rule to encourage FCU participation in the Credit Union System Investment Program (CU SIP) or the Credit Union Homeowners Affordability Relief Program (CU HARP).[32] Investments in those programs were excluded from the computation of total assets because the instruments were guaranteed by the Share Insurance Fund, posed no credit risk to the participating credit unions, and the exclusion was intended to encourage a greater participation rate in programs with a clear public benefit. The CU SIP ended in 2010. Similarly, CU HARP investments were issued by the U.S. Central Federal Credit Union and all of those investments matured prior to that credit union's liquidation in 2012. Because these programs no longer exist and have no remaining investments, the Board proposed to amend current § 701.6(a) to delete references to them.

Comments Received: None of the commenters objected to this change. Two commenters expressly stated that they supported deleting references to the programs and agreed with the NCUA's rationale supporting this change.

Given the potential for additional programs similar to the PPP to arise in the near future or as a result of future economic crises, the Board proposed adding regulatory language that would allow for the exclusion of assets in the future under similar programs without requiring a reference to the specific program in the regulation. Under the proposed new language, the Board anticipated making exclusions of similar future programs by issuing an order, which could be published in a letter to FCUs or a similar notice.

Comments Received: None of commenters objected to the language, and eight of the commenters stated that they supported including the general language allowing the exclusion of such programs to be approved by the Board. One of the commenters, however, suggested that the NCUA also include provisions to exclude assets related to programs that provide relief during nationwide and regional crises; for example, disaster declarations and associated SBA disaster lending authorized as a result of hurricanes or other national disasters.

NCUA Response: In response to the comment suggesting the NCUA also exclude assets related to programs that provide relief during nationwide and regional crises, the agency has decided not to make that change in the final rule. Such a change is beyond the scope of the proposal. The NCUA, however, does plan to evaluate the feasibility and impact of such exclusions in its next cyclical review of the operating fee rule. In particular, the NCUA plans to evaluate whether SBA disaster lending presents the same general low level of risk to credit unions' balance sheets, and whether excluding SBA disaster lending from total assets would have a material impact on the regional distribution of operating fees.

In addition, the Board proposed amending current § 701.6(a) to use the average of FCUs' four most-recently reported quarterly assets to calculate operating fees and to make conforming amendments to the regulatory text to ensure this same approach was applied to merged and recently converted FCUs. The Board proposed to use an average of total assets because it believed that doing so would reduce the effect of seasonal fluctuation in the total assets of FCUs, and would provide more certainty to FCUs about their operating fee charges for the forthcoming year. The change to a four-quarter average of reported assets would also reduce the risk that the Board would collect less in operating fee revenue than it requires if actual assets reported in FCUs' December Call Reports were below the asset growth assumption used to set the operating fee rates in the budget.

In particular, the proposed rule would have amended current § 701.6(a) to provide, among other things, that the operating fee shall be based on the average of total assets of each FCU based on data reported in the preceding four Call Reports (as reported on NCUA Form 5300 for natural person FCUs and Form 5310 for corporate FCUs), or as otherwise determined pursuant to paragraph (b) of § 701.6. When determining the operating fee rate and the invoice amounts due under the proposal, the NCUA Board would have used the average of FCUs' four most-recent Call Reports available at the time the Board approved the budget for the forthcoming year.

The Board anticipated that the proposed change would have no impact on current billing practices for newly chartered FCUs because such credit unions do not receive an operating fee invoice until the second year after they are chartered. The Board proposed continuing its current practice of treating merged FCUs and conversions of non-FCUs into FCUs as a single entity for purposes of calculating the average total assets that are the basis for determining the amount of operating fees due. For purposes of calculating the average total assets of an FCU that converts from or merges with a federally insured, state-chartered credit union (FISCU), the Board proposed computing comparable quarterly total assets using the Call Report data in the agency's possession. For conversions to an FCU charter from entities not insured by the NCUA, the Board proposed to average assets based only on Call Reports filed by the time the Board finalized its budget because the NCUA cannot validate the accuracy or consistency of other data sources that may be similar to NCUA Call Reports.

Under the proposed rule, in circumstances in which a conversion to an FCU charter from an entity not insured by the NCUA occurs in the fourth quarter of the year before the operating fee is due, no Call Report data would have been available at the time the Board finalized its budget, and the converted entity would therefore pay no operating fee in the year following conversion. While this approach would have produced a different result based only on insured status prior to conversion for entities that are otherwise of the same FCU status after

[32] 74 FR 29934 (June 24, 2009).

the conversion, the Board believed its lack of access to verified Call Report data for non-NCUA insured entities supported the distinction. In addition, the Board expected such circumstances to be rare occurrences, with relatively small impacts, as the maximum amount of forgone revenue is one quarter of reported assets for which a converted entity could be exempt from paying an operating fee.

While this discrepancy could be avoided if the Board continued its current practice of estimating December Call Report data as the sole point of reference for determining total assets for the operating fee, the Board believed the four-quarter average was more equitable on the whole because it could account for seasonal share account fluctuations that some FCUs experience based on the characteristics and transaction patterns engaged in by their fields of membership. As discussed above, the proposed four-quarter average approach also would have eliminated the risk that the Board could over- or under-collect operating fees based on differences between its estimation of and actual December Call Report data.[33]

With respect to mergers in which an entity not insured by the NCUA merges into a continuing FCU, the same issue existed under the proposed rule with regard to the Board's access to data comparable to the Call Report for periods prior to the merger date. Here again, the proposed rule would have combined assets looking back four quarters for mergers involving two FCUs or where a FISCU merges into a continuing FCU. On the other hand, for mergers into FCUs of entities that are not insured by the NCUA, the proposed rule would not have required the combination of assets prior to the merger date, because the NCUA does not collect asset data for entities it does not insure. Instead, the continuing FCU would have paid a fee based only on assets reported on its own Call Reports filed prior to the effective date of the merger. Depending on the specific timing of when the merger occurred, this could have resulted in multiple quarters where the assets acquired from the non-NCUA insured entity were not included in the calculated average assets used to bill the continuing FCU. For the same reasons expressed above with respect to conversions, the Board believed the benefits of the four-quarter average outweighed the different treatment for mergers with FISCUs compared to mergers with entities not insured by the NCUA.

With respect to purchase and assumption transactions, the regulation presently designates that such transactions will be treated as mergers in circumstances in which an FCU purchases all or essentially all of the assets of another credit union. Under the proposal, the Board retained that language, but requested comments on alternative approaches the Board may wish to consider. The Board acknowledged that, in some circumstances, determining whether a purchase and assumption included all or essentially all assets could be a difficult determination.

Comments Received: All nine commenters stated that they supported these change and generally agreed with the NCUA's rationale supporting this change. While all of the commenters supported this change, four of the commenters did ask that the NCUA also regularly review this change and its impact to ensure it does not cause any unintended consequences.

Although beyond the scope of this proposal, one commenter did suggested that the NCUA further amend § 701.6 to treat mergers into and conversions with federally insured, state-chartered credit unions (FISCUs) differently. The commenter stated that, while the current rule bars the payment of a fee refund when a conversion to or merger into a FISCU occurs, the NCUA should reconsider this issue since the resulting credit union's NCUSIF deposit will reflect the merger, unlike a combination with an entity that is not NCUSIF-insured, and the resulting entity is not an FCU. The commenter suggested that the NCUA provide pro rata fee refunds if an FCU converts to or merges into a FISCU.

NCUA Response: In response to the comment suggesting that the NCUA regularly review these changes and their impact, the NCUA reviews all of its existing regulations every three years. The NCUA's Office of General Counsel maintains a rolling review schedule that identifies one-third of the NCUA's existing regulations for review each year and provides notice to the public of those regulations under review so the public may have an opportunity to comment. The changes made by this final rule will be regularly reviewed as part of that process and the credit union industry and public will be given a regular opportunity to raise any concerns they may have.

In response to the comment suggesting that the NCUA issue a pro rata fee refund to an FCU that converts to or merges into a FISCU, the agency has made no changes in the final rule. Such a change would be outside the scope of the proposal. Moreover, the operating fees charged to FCUs are based on a detailed workload projection of the agency's examination program, which is used to inform the agency's annual budget formulation and calculation of operating fee collections. The agency generally does not have insight into the future merger or charter conversion plans of a given FCU, and therefore must base its workload estimates on the population of FCUs that exist in the year before the budget is set and the fee is calculated. If the NCUA were to issue pro rata refunds to FCUs that subsequently merge with or convert to a FISCU, it would face continuing, unfunded liabilities for staff salaries and associated expenses that could not be recouped from other sources since the operating fee is billed only once annually. Similarly, the OTR share of the annual operating budget is determined in part based on the relative distribution of projected workload between FCUs and FISCUs in the year before the OTR is applied to actual operating expenses. Although the NCUA's actual workload may be marginally reduced if an FCU converts to or merges with a FISCU, such a change cannot be retroactively applied to the OTR used in a given year.

The Board also proposed some technical changes to existing rule language. First, the proposed rule clarified that the NCUA would not issue refunds of operating fees to FCUs that convert to any other type of charter, not just a state charter. The proposed rule was intended to ensure the same treatment for a conversion to a mutual savings bank or any other charter type. The Board also proposed removing the language ''in the year in which the conversion takes place'' from the provision, as a refund is never provided to any converting FCU, regardless of timing. The Board proposed the same changes to the rule text on refunds in the context of mergers.

Comments Received: The NCUA received no objections to this change.

In addition, the Board proposed to expand the situations expressly covered in the regulation to include conversions and mergers involving entities not insured by the NCUA. Such transactions could involve privately insured, state-chartered credit unions or banking institutions. To support this expansion, the proposed regulatory language introduced the phrase ''entity not

[33] While the proposed regulatory language introducing § 701.6(b)(2)(i)(B) could be read to require an entity not insured by the NCUA that converts to a FCU charter in the fourth quarter to pay a fee in the year following conversion, the lack of available Call Report data prior to the date the Board adopts the budget would preclude a fee in that scenario.

insured by the NCUA.'' In the language specifying that certain purchase and assumption transactions would be treated as mergers, the Board proposed changing the term ''credit union'' to ''depository institution'' to clarify that a purchase and assumption involving a bank, for example, would be treated in the same manner. Finally, the proposed rule would have divided paragraph (b) of the regulation into additional subparagraphs to improve readability.

Comments Received: The NCUA received no objections to this change.

III. Summary of the Final Rule

For the reasons discussed above, the Board is issuing this final rule without change from the proposed rule. Revised § 701.6(a) provides that each calendar year, or as otherwise directed by the Board, each Federal credit union shall pay an operating fee to the NCUA for the current fiscal year (January 1 to December 31) in accordance with a schedule fixed by the Board from time to time. New § 701.6(a)(1) provides that the operating fee shall be based on the average of total assets of each Federal credit union based on data reported in NCUA Forms 5300 and 5310 from the four quarters immediately preceding the time the Board approves the agency's budget or as otherwise determined pursuant to paragraph (b) of this section. New § 701.6(a)(2) provides that for purposes of calculating the operating fee, total assets shall not include any loans on the books of a natural person Federal credit union made under the Small Business Administration's Paycheck Protection Program, 15 U.S.C. 636(a)(36), or any similar program approved for exclusion by the Board.

Revised § 701.6(b), Coverage, provides that the operating fee shall be paid by each Federal credit union engaged in operations as of January 1 of each calendar year in accordance with paragraph (a), except as otherwise provided by this paragraph. Section 701.6(b)(1), New Charters, continues to provide that a newly chartered FCU will not pay an operating fee until the year following the first full calendar year after the date chartered. Revised § 701.6(b)(2), Coverage, continues to address coverage issues, but now includes several new subsections. New § 701.6(b)(2)(i)(A) provides that in the first calendar year following conversion: A FISCU that converts to an FCU charter must pay an operating fee based on the average assets reported in the year of conversion on NCUA Forms 5300 or 5310 from the four quarters immediately preceding the time the Board approves the agency's budget in the year of conversion. New § 701.6(b)(2)(i)(B) provides that in the first calendar year following conversion: An entity not insured by the NCUA that converts to an FCU charter must pay an operating fee based on the assets, or average thereof, reported on NCUA Forms 5300 or 5310 for any one or more quarters immediately preceding the time the Board approves the agency's budget in the year of conversion. New § 701.6(b)(2)(ii) provides that an FCU converting to a different charter will not receive a refund of any operating fees paid to the NCUA.

Revised § 701.6(b)(3), Mergers, continues to address merger issues, but now includes several new subsections. New § 701.6(b)(3)(i)(A) provides that in the first calendar year following merger: A continuing FCU that has merged with one or more federally insured credit unions must pay an operating fee based on the average combined total assets of the FCU and any merged federally insured credit unions as reported on NCUA Forms 5300 or 5310 in the four quarters immediately preceding the time the Board approves the agency's budget in the merger year. New § 701.6(b)(3)(i)(B) provides that for purposes of paragraph (b)(3), a purchase and assumption transaction in which the continuing FCU purchases all or essentially all of the assets of another depository institution shall be deemed a merger. New § 701.6(b)(3)(ii) provides that an FCU that merges with a Federal or state-chartered credit union, or an entity not insured by the NCUA, will not receive a refund of any operating fee paid to the NCUA.

Finally, § 701.6(b)(4), Liquidations, continues to provide that an FCU placed in liquidation will not pay any operating fee after the date of liquidation.

IV. Regulatory Procedures

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a final rule, an agency prepare and make available for public comment an final regulatory flexibility analysis that describes the impact of a proposed rule on small entities. A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined for purposes of the RFA to include federally insured credit unions with assets less than $100 million) and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule. This final rule will make a technical change to the period for measuring total assets for calculating the Operating Fee. However, the Board does not believe the impact will disproportionally impact small credit unions such that a regulatory flexibility analysis is required. First, small credit unions are still required to report assets on a quarterly basis, and the regulation only increases the number of quarters the NCUA will consider in adjusting the operating fee. Nor does the exclusion of PPP loans from assets increase reporting requirements, as the NCUA already has the information necessary to make that exclusion. Finally, although exclusion of PPP loans will decrease fee amounts for some small credit unions, the Board does not believe the change will amount to a significant impact on a substantial number of small entities. Accordingly, the NCUA certifies that this final rule will not have a significant economic impact on a substantial number of small credit unions.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency creates a new or amends existing information collection requirements.[34] For the purpose of the PRA, an information collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement. This final rule does not contain information collection requirements that require approval by OMB under the PRA.[35]

C. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) (SBREFA) generally provides for congressional review of agency rules.[36] A reporting requirement is triggered in instances where the NCUA issues a final rule as defined by Section 551 of the APA.[37] An agency rule, in addition to being subject to congressional oversight, may also be subject to a delayed effective date if the rule is a ''major rule.''[38] The NCUA does not believe this rule is a ''major rule'' within the meaning of the relevant sections of SBREFA. As required by SBREFA, the NCUA will submit this final rule to OMB for it to determine if the final rule is a ''major rule'' for purposes of SBREFA. The NCUA also will file appropriate reports with Congress and the Government

[34] 44 U.S.C. 3507(d); 5 CFR part 1320.

[35] 44 U.S.C. Chap. 35.

[36] 5 U.S.C. 801–804.

[37] 5 U.S.C. 552.

[38] 5 U.S.C. 804(2).

Accountability Office so this rule may be reviewed.

D. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, the NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the Executive order. This final rule will not have a substantial direct effect on the states, on the connection between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. The NCUA has determined that this final rule does not constitute a policy that has federalism implications for purposes of the Executive order.

D. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this final rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.[39]

List of Subjects in 12 CFR Part 701

Credit unions, Low income, Nonmember deposits, Secondary capital, Shares.

By the National Credit Union Administration Board on December 17, 2020.

Melane Conyers-Ausbrooks,

Secretary of the Board.

For the reasons discussed above, the Board amends 12 CFR part 701 as follows:

PART 701—Organization and Operations of Federal Credit Unions

■ 1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1758, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1785, 1786, 1787, 1788, 1789. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 *et seq.;* 42 U.S.C. 1981 and 3601–3610. Section 701.35 is also authorized by 42 U.S.C. 4311–4312.

■ 2. In § 701.6, revise paragraphs (a) and (b) to read as follows:

§ 701.6 Fees paid by Federal credit unions.

(a) *Basis for assessment.* Each calendar year, or as otherwise directed by the NCUA Board, each Federal credit union shall pay an operating fee to the NCUA for the current fiscal year (January 1 to December 31) in accordance with a schedule fixed by the Board from time to time.

(1) *General.* The operating fee shall be based on the average of total assets of each Federal credit union based on data reported in NCUA Forms 5300 and 5310 from the four quarters immediately preceding the time the Board approves the agency's budget or as otherwise determined pursuant to paragraph (b) of this section.

(2) *Exclusions from total assets.* For purposes of calculating the operating fee, total assets shall not include any loans on the books of a natural person Federal credit union made under the Small Business Administration's Paycheck Protection Program, 15 U.S.C. 636(a)(36), or any similar program approved for exclusion by the NCUA Board.

(b) *Coverage.* The operating fee shall be paid by each Federal credit union engaged in operations as of January 1 of each calendar year in accordance with paragraph (a) of this section, except as otherwise provided by this paragraph (b).

(1) *New charters.* A newly chartered Federal credit union will not pay an operating fee until the year following the first full calendar year after the date chartered.

(2) *Conversions.* (i) In the first calendar year following conversion:

(A) A federally insured state-chartered credit union that converts to a Federal credit union charter must pay an operating fee based on the average assets reported in the year of conversion on NCUA Forms 5300 or 5310 from the four quarters immediately preceding the time the Board approves the agency's budget in the year of conversion.

(B) An entity not insured by the NCUA that converts to a Federal credit union charter must pay an operating fee based on the assets, or average thereof, reported on NCUA Forms 5300 or 5310 for any one or more quarters immediately preceding the time the Board approves the agency's budget in the year of conversion.

(ii) A Federal credit union converting to a different charter will not receive a refund of any operating fees paid to the NCUA.

(3) *Mergers.* (i) In the first calendar year following merger:

(A) A continuing Federal credit union that has merged with one or more federally insured credit unions must pay an operating fee based on the average combined total assets of the Federal credit union and any merged federally insured credit unions as reported on NCUA Forms 5300 or 5310 in the four quarters immediately preceding the time the Board approves the agency's budget in the merger year.

(B) For purposes of this paragraph (b)(3), a purchase and assumption transaction where the continuing Federal credit union purchases all or essentially all of the assets of another depository institution shall be deemed a merger.

(ii) A Federal credit union that merges with a Federal or state-chartered credit union, or an entity not insured by the NCUA, will not receive a refund of any operating fee paid to the NCUA.

(4) *Liquidations.* A Federal credit union placed in liquidation will not pay any operating fee after the date of liquidation.

* * * * *

[FR Doc. 2020–28490 Filed 12–30–20; 8:45 am]

BILLING CODE 7535–01–P

[39] Public Law 105–277, 112 Stat. 2681 (1998).

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 210

[Docket No. 2020–8]

The Public Musical Works Database and Transparency of the Mechanical Licensing Collective

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Interim rule.

SUMMARY: The U.S. Copyright Office is issuing an interim rule regarding the Musical Works Modernization Act, title I of the Orrin G. Hatch-Bob Goodlatte Music Modernization Act. The law establishes a new blanket compulsory license that will be administered by a mechanical licensing collective, which will make available a public musical works database as part of its statutory duties. Having solicited public comments through previous notifications of inquiry and a notice of proposed rulemaking, the Office is issuing interim regulations prescribing categories of information to be included in the public musical works database, as well as rules related to the usability, interoperability, and usage restrictions of the database. The Office is also issuing interim regulations related to ensuring appropriate transparency of the mechanical licensing collective itself.

DATES: Effective February 16, 2021.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, by email at *regans@copyright.gov* or Anna B. Chauvet, Associate General Counsel,

by email at *achau@copyright.gov.* Each can be contacted by telephone by calling (202) 707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

On October 11, 2018, the president signed into law the Orrin G. Hatch-Bob Goodlatte Music Modernization Act, H.R. 1551 (''MMA'').[1] Title I of the MMA, the Musical Works Modernization Act, substantially modifies the compulsory ''mechanical'' license for making and distributing phonorecords of nondramatic musical works under 17 U.S.C. 115.[2] It does so by switching from a song-by-song licensing system to a blanket licensing regime that becomes available on January 1, 2021 (the ''license availability date''), and is administered by a mechanical licensing collective (''MLC'') designated by the Copyright Office (''Office'').[3] Among other things, the MLC is responsible for ''[c]ollect[ing] and distribut[ing] royalties'' for covered activities, ''[e]ngag[ing] in efforts to identify musical works (and shares of such works) embodied in particular sound recordings and to identify and locate the copyright owners of such musical works (and shares of such works),'' and ''[a]dminister[ing] a process by which copyright owners can claim ownership of musical works (and shares of such works).''[4] It also must ''maintain the musical works database and other information relevant to the administration of licensing activities under [section 115].''[5]

A. Regulatory Authority Granted to the Office

The MMA enumerates several regulations that the Office is specifically directed to promulgate to govern the new blanket licensing regime, and Congress invested the Office with ''broad regulatory authority''[6] to ''conduct such proceedings and adopt such regulations as may be necessary or appropriate.''[7] The MMA specifically directs the Office to promulgate regulations related to the MLC's creation of a database to publicly disclose musical work ownership information and identify the sound recordings in which the musical works are embodied.[8] As discussed more below, the statute requires the public database to include various types of information, depending upon whether a musical work has been matched to a copyright owner.[9] For both matched and unmatched works, the database must also include ''such other information'' ''as the Register of Copyrights may prescribe by regulation.''[10] The database must ''be made available to members of the public in a searchable, online format, free of charge,''[11] and its contents must also be made available ''in a bulk, machine-readable format, through a widely available software application,'' to certain parties, including blanket licensees and the Office, free of charge, and to ''[a]ny other person or entity for a fee not to exceed the marginal cost to the mechanical licensing collective of providing the database to such person or entity.''[12]

In addition, the legislative history contemplates that the Office will ''thoroughly review[ ]''[13] policies and procedures established by the MLC and its three committees, which the MLC is statutorily bound to ensure are ''transparent and accountable,''[14] and promulgate regulations that ''balance[ ] the need to protect the public's interest with the need to let the new collective operate without over-regulation.''[15] Congress acknowledged that ''[a]lthough the legislation provides specific criteria for the collective to operate, it is to be expected that situations will arise that were not contemplated by the legislation,'' and that ''[t]he Office is expected to use its best judgement in determining the appropriate steps in those situations.''[16] Legislative history further states that ''[t]he Copyright Office has the knowledge and expertise regarding music licensing through its past rulemakings and recent assistance to the Committee[s] during the drafting of this legislation.''[17] Accordingly, in designating the MLC as the entity to administer the blanket license, the Office stated that it ''expects ongoing regulatory and other implementation efforts to . . . extenuate the risk of self-interest,'' and that ''the Register intends to exercise her oversight role as it pertains to matters of governance.''[18] Finally, as detailed in the Office's prior notifications and notice of proposed rulemaking, while the MMA envisions the Office reasonably and prudently exercising regulatory authority to facilitate appropriate transparency of the collective and the public musical works database, the statutory language as well as the collective's structure separately include elements to promote disclosure absent additional regulation.[19]

B. Rulemaking Background

Against that backdrop, on September 24, 2019, the Office issued a notification of inquiry (''September NOI'') seeking public input on a variety of aspects related to implementation of title I of the MMA, including issues regarding information to be included in the public musical works database (*e.g.,* what additional categories of information might be appropriate to include by regulation), as well as the usability, interoperability, and usage restrictions of the database (*e.g.,* technical or other specific language that might be helpful to consider in promulgating regulations, discussion of the pros and cons of applicable standards, and whether historical snapshots of the database should be maintained to track ownership changes over time).[20] In addition, the September NOI sought public comment on any issues that

[1] Public Law 115–264, 132 Stat. 3676 (2018).

[2] *See* S. Rep. No. 115–339, at 1–2 (2018); Report and Section-by-Section Analysis of H.R. 1551 by the Chairmen and Ranking Members of Senate and House Judiciary Committees, at 1 (2018), *https://www.copyright.gov/legislation/mma_conference_report.pdf* (''Conf. Rep.'').

[3] As permitted under the MMA, the Office designated a digital licensee coordinator (''DLC'') to represent licensees in proceedings before the Copyright Royalty Judges (''CRJs'') and the Copyright Office, to serve as a non-voting member of the MLC, and to carry out other functions. 17 U.S.C. 115(d)(5)(B); 84 FR 32274 (July 8, 2019); *see also* 17 U.S.C. 115(d)(3)(D)(i)(IV), (d)(5)(C).

[4] 17 U.S.C. 115(d)(3)(C)(i).

[5] *Id.* at 115(d)(3)(C)(i)(IV).

[6] H.R. Rep. No. 115–651, at 5–6; S. Rep. No. 115–339, at 5; Conf. Rep. at 4.

[7] 17 U.S.C. 115(d)(12)(A).

[8] *See id.* at 115(d)(3)(E), (e)(20).

[9] *Id.* at 115(d)(3)(E)(ii), (iii).

[10] *Id.* at 115(d)(3)(E)(ii)(V), (iii)(II).

[11] *Id.* at 115(d)(3)(E)(v).

[12] *Id.*

[13] H.R. Rep. No. 115–651, at 5–6, 14; S. Rep. No. 115–339, at 5, 15; Conf. Rep. at 4, 12. The Conference Report further recognizes that the Office's review will be important because the MLC must operate in a manner that can gain the trust of the entire music community, but can only be held liable under a standard of gross negligence when carrying out certain of the policies and procedures adopted by its board. Conf. Rep. at 4.

[14] 17 U.S.C. 115(d)(3)(D)(ix)(I)(aa).

[15] H.R. Rep. No. 115–651, at 5–6, 14; S. Rep. No. 115–339, at 5, 15; Conf. Rep. at 4, 12.

[16] H.R. Rep. No. 115–651, at 14; S. Rep. No. 115–339, at 15; Conf. Rep. at 12.

[17] H.R. Rep. No. 115–651, at 14; S. Rep. No. 115–339, at 15; Conf. Rep. at 12.

[18] 84 FR at 32280.

[19] *See* 85 FR 22568, 22570–71 (Apr. 22, 2020) (detailing various ways the statute promotes transparency of the mechanical licensing collective, such as by requiring the collective to publish an annual report, make its bylaws publicly available and its policies and practices ''transparent and accountable,'' identify a point of contact for publisher inquiries and complaints with timely redress, establish an anti-commingling policy for funds collected and those not collected under section 115, and submit to a public audit every five years; the statute also permits copyright owners to audit the collective to verify the accuracy of royalty payments, and establishes a five-year designation process for the Office to periodically review the collective's performance).

[20] 84 FR 49966, 49972 (Sept. 24, 2019).

should be considered relating to the general oversight of the MLC.[21]

In response, many commenters emphasized the importance of transparency of the public database and the MLC's operations, and urged the Office to exercise expansive and robust oversight.[22] Given these comments, on April 22, 2020, the Office issued a second notification of inquiry,[23] and on September 17, 2020, the Office issued a notice of proposed rulemaking (''NPRM''),[24] both soliciting further comment on these issues. In response to the NPRM, the comments overall were positive about the proposed rule, expressing appreciation for the Office's responsiveness to stakeholder comments.[25]

Having reviewed and considered all relevant comments received in response to both notifications of inquiry and the NPRM, and having engaged in transparent *ex parte* communications with commenters, the Office is issuing an interim rule regarding the categories of information to be included in the public musical works database, as well as the usability, interoperability, and usage restrictions of the database. The Office is also issuing interim regulations related to ensuring appropriate transparency of the mechanical licensing collective itself. Except as otherwise discussed below, the proposed rule is being adopted for the reasons discussed in the NPRM. The Office has determined that it is prudent to promulgate this rule on an interim basis so that it retains some flexibility for responding to unforeseen complications once the MLC launches the musical works database.[26] In doing so, the Office emphasizes that adoption on an interim basis is not an open-ended invitation to revisit settled provisions or rehash arguments, but rather is intended to allow necessary modifications to be made in response to new evidence or unforeseen issues, or where something is otherwise not functioning as intended.

The interim rule is intended to grant the MLC flexibility in various ways instead of adopting requirements that may prove overly prescriptive as the MLC administers the public database. For example, and as discussed below, the interim rule grants the MLC flexibility in the following ways:

- To label fields in the public database, as long as the labeling takes into account industry practice and reduces the likelihood of user confusion.
- To include non-confidential information in the public database that is not specifically identified by the statute but the MLC finds useful, including information regarding terminations, performing rights organization (''PRO'') affiliation, and DDEX Party Identifier (DPID).[27]
- To allow songwriters, or their representatives, to have songwriter information listed anonymously or pseudonymously.
- To select the most appropriate method for archiving and maintaining historical data to track ownership and other information changes in the public database.
- To select the method for displaying data provenance information in the public database.
- To determine the precise disclaimer language for alerting users that the database is not an authoritative source for sound recording information.
- To develop reasonable terms of use for the public database, including restrictions on use.
- To block third parties from bulk access to the public database based on their attempts to bypass marginal cost recovery or other unlawful activity with respect to the database.
- To determine the initial format in which the MLC provides bulk access to the public database, with a six-month extension to implement bulk access through application programming interfaces (''APIs'').
- To determine how to represent processing and distribution times for royalties disclosed in the MLC's annual report.

II. Interim Rule

A. Ownership of Data in the Public Musical Works Database

The MLC must establish and maintain a free-of-charge public database of musical work ownership information that also identifies the sound recordings in which the musical works are embodied,[28] a function expected to provide transparency across the music industry.[29] The Office appreciates that the MLC ''is working on launching the public search window on the website that will allow members of the public to search the musical works database in January [2021],'' and that the MLC ''anticipates launching the bulk data program to members of the public in January'' [30] (discussed more below).

As noted in the NPRM, the statute and legislative history emphasize that the database is meant to benefit the music industry overall and is not ''owned'' by

[21] *Id.* at 49973. All rulemaking activity, including public comments, as well as educational material regarding the Music Modernization Act, can currently be accessed via navigation from *https://www.copyright.gov/music-modernization/.* Specifically, comments received in response to the September 2019 notification of inquiry are available at *https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=COLC-2019-0002&refD=COLC-2019-0002-0001,* and comments received in response to the April 2020 notification of inquiry and the notice of proposed rulemaking are available at *https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=COLC-2020-0006.* Guidelines for *ex parte* communications, along with records of such communications, are available at *https://www.copyright.gov/rulemaking/mma-implementation/ex-parte-communications.html.* As stated in the guidelines, *ex parte* meetings with the Office are intended to provide an opportunity for participants to clarify evidence and/or arguments made in prior written submissions, and to respond to questions from the Office on those matters. References to these comments are by party name (abbreviated where appropriate), followed by ''Initial September NOI Comment,'' ''Reply September NOI Comment,'' ''April NOI Comment,'' ''NPRM Comment,'' ''Letter,'' or ''*Ex Parte* Letter,'' as appropriate.

[22] *See* 85 FR at 22571 (citing multiple commenters).

[23] 85 FR at 22568.

[24] 85 FR 58170 (Sept. 17, 2020).

[25] *See* DLC NPRM Comment at 1 (''The DLC supports the Office's proposed rule . . .''); Music Artists Coalition (''MAC'') NPRM Comment at 4 (''MAC would like to again thank the Office for their leadership and responsiveness to public comments during the implementation of the MMA.''); Recording Academy NPRM Comment at 1 (''The Academy is gratified that the Office's NPRM reflects many of the concerns and priorities expressed in the Academy's previous comments . . .''); Songwriters of North America (''SONA'') NPRM Comment at 3 (''SONA is grateful to the Copyright Office for its diligence and oversight in working to develop a strong regulatory framework to implement the MMA as the License Availability Date (''LAD'') quickly approaches.''); SoundExchange NPRM Comment at 3 (''SoundExchange applauds the Office for going to great lengths to ensure that appropriate categories of information are included in the MLC Database. SoundExchange particularly appreciates the Office's consideration of the public comments as it fashioned the regulations . . .'').

[26] *See* 85 FR at 22571 (advising that the Office may issue an interim rule to allow a flexible regulatory structure); DLC NPRM Comment at 1 (''The DLC would support the establishment of an interim rule, for similar reasons to those given by the Office in its recent usage and reporting rulemaking.'').

[27] DPID ''is an alphanumeric identifier that identifies the party delivering the DDEX message,'' and ''is also generally the party to whom the [digital music provider (''DMP'')] sends royalties for the relevant sound recording.'' A2IM & RIAA Reply September NOI Comment at 8.

[28] 17 U.S.C. 115(d)(3)(E), (e)(20).

[29] *See* The MLC, Transparency, *https://themlc.com/faqs/categories/transparency* (last visited Sept. 1, 2020) (web page no longer available) (noting that the MLC will ''promote transparency'' by ''[p]roviding unprecedented access to musical works ownership information through a public database'').

[30] MLC *Ex Parte* Letter Dec. 3, 2020 (''MLC *Ex Parte* Letter #11'') at 3. According to the MLC, it ''began providing members with access to the MLC Portal at the end of September,'' and ''[s]everal thousand members have completed the onboarding process and thousands more have received invitations via email to complete the onboarding process.'' *Id.*

the collective itself.[31] The MLC acknowledges this, stating that ''the data in the public MLC musical works database is not owned by the MLC or its vendor,'' and that ''data in this database will be accessible to the public at no cost, and bulk machine-readable copies of the data in the database will be available to the public, either for free or at marginal cost, pursuant to the MMA.'' [32] The Alliance for Recorded Music (''ARM''), Recording Academy, and Songwriters Guild of America (''SGA'') & Society of Composers & Lyricists (''SCL'') praised the Office for addressing the issue of data ownership, with ARM ''encourag[ing] the Office to make this point explicit in the regulations.'' [33] In light of these comments, and the statute and legislative history, the interim rule confirms that data in the public musical works database is not owned by the mechanical licensing collective or any of its employees, agents, consultants, vendors, or independent contractors.

B. Categories of Information in the Public Musical Works Database

The statute requires the MLC to include various types of information in the public musical works database. For musical works that have been matched (*i.e.,* the copyright owner of such work (or share thereof) has been identified and located), the statute requires the public database to include:

1. The title of the musical work;
2. The copyright owner of the musical work (or share thereof), and the ownership percentage of that owner;
3. Contact information for such copyright owner; and
4. To the extent reasonably available to the MLC, (a) the ISWC for the work, and (b) identifying information for sound recordings in which the musical work is embodied, including the name of the sound recording, featured artist,[34] sound recording copyright owner, producer, ISRC, and other information commonly used to assist in associating sound recordings with musical works.[35]

For unmatched musical works, the statute requires the database to include, to the extent reasonably available to the MLC:

1. The title of the musical work;
2. The ownership percentage for which an owner has not been identified;
3. If a copyright owner has been identified but not located, the identity of such owner and the ownership percentage of that owner;
4. Identifying information for sound recordings in which the work is embodied, including sound recording name, featured artist, sound recording copyright owner, producer, ISRC, and other information commonly used to assist in associating sound recordings with musical works; and
5. Any additional information reported to the MLC that may assist in identifying the work.[36]

In other words, the statute requires the database to include varying degrees of information regarding the musical work copyright owner (depending on whether the work is matched), but for both matched and unmatched works, identifying information for sound recordings in which the work is embodied (*i.e.,* sound recording name, featured artist, sound recording copyright owner, producer, ISRC, and other information commonly used to assist in associating sound recordings with musical works). For both matched and unmatched works, the Register of Copyrights may prescribe inclusion of additional fields by regulation.'' [37] The ''Register shall use its judgement to determine what is an appropriate expansion of the required fields, but shall not adopt new fields that have not become reasonably accessible and used within the industry unless there is widespread support for the inclusion of such fields.'' [38]

In considering whether to prescribe the inclusion of additional fields beyond those statutorily required, the Office focused on fields that the record indicates would advance the goal of the public database: Reducing the number of unmatched musical works by accurately identifying musical work copyright owners so they can be paid what they are owed under the section 115 statutory license.[39] At the same time, the Office is mindful of the MLC's corresponding duties to keep confidential business and personal information secure and inaccessible; for example, data related to computation of market share is contemplated by the statue as sensitive and confidential.[40] Recognizing that a robust musical works database may contain many fields of information, the interim rule establishes a floor of required information that users can reliably expect to access in the public database, while providing the MLC with flexibility to include additional data fields that it finds helpful.[41] Stakeholder comments regarding the types of information to include (or exclude) are discussed by category below.

[31] 85 FR at 58172. Under the statute, if the Copyright Office designates a new entity to be the mechanical licensing collective, the Office must ''adopt regulations to govern the transfer of licenses, funds, records, *data,* and administrative responsibilities from the existing mechanical licensing collective *to the new entity.*'' 17 U.S.C. 115(d)(3)(B)(ii)(II) (emphasis added). The legislative history distinguishes the MLC's public database from past attempts to control and/or own industry data. *See* 164 Cong. Rec. S6292, 6293 (daily ed. Sept. 25, 2018) (statement of Sen. Hatch) (''I need to thank Chairman Grassley, who shepherded this bill through the committee and made important contributions to the bill's oversight and transparency provisions.''); 164 Cong. Rec. S501, 504 (daily ed. Jan. 24, 2018) (statement of Sen. Coons) (''This important piece of legislation will bring much-needed transparency and efficiency to the music marketplace.''); 164 Cong. Rec. H3522, 3541 (daily ed. Apr. 25, 2018) (statement of Rep. Steve Chabot); 164 Cong. Rec. H3522 at 3542 (daily ed. Apr. 25, 2018) (statement of Rep. Norma Torres); Conf. Rep. at 6 (''Music metadata has more often been seen as a competitive advantage for the party that controls the database, rather than as a resource for building an industry on.''); *id.* (noting that the Global Repertoire Database project, an EU-initiated attempt to create a comprehensive and authoritative database for ownership and administration of musical works, ''ended without success due to cost and data ownership issues'').

[32] MLC *Ex Parte* Letter Aug. 21, 2020 (''MLC *Ex Parte* Letter #7'') at 2.

[33] ARM NPRM Comment 1–2; *see* Recording Academy NPRM Comment at 2 (''The Office states unambiguously that 'the statute and legislative history emphasize that the database . . . is not ''owned'' by the collective itself.' This principle is affirmed by the MLC . . . The Academy appreciates that this issue is addressed in a clear, straightforward manner and included in the record to assuage any concerns to the contrary.''); SGA & SCL NPRM Comment at 5 (''SGA and SCL were gratified by the USCO's clear statement'' that MLC and vendor does not own data).

[34] ARM asked that ''the MLC be required to label [the featured artist field] . . . using the phrase 'primary artist,' '' because '' 'primary artist' is the preferred term as 'featured artist' is easily confused with the term 'featured' on another artist's recording, as in Artist X feat. Artist Y.'' ARM April NOI Comment at 6. Because this is a statutory term and the Office wishes to afford the MLC some flexibility in labeling the public database, it tentatively declined this request. The proposed rule did, however, require the MLC to consider industry practices when labeling fields in the public database to reduce the likelihood of user confusion. The interim rule adopts this aspect of the proposed rule. ARM encourages the MLC to consider its previous labeling suggestions, but does not object ''to the Office's decision to grant the MLC flexibility regarding how to label fields in the public database, as long as the MLC's labelling decisions consider industry practices and the MLC picks field labels that reduce the likelihood of user confusion regarding the contents of each data field.'' ARM NPRM Comment at 2.

[35] 17 U.S.C. 115(d)(3)(E)(ii).

[36] *Id.* at 115(d)(3)(E)(iii).

[37] *Id.* at 115(d)(3)(E)(ii)(V), (iii)(II).

[38] Conf. Rep. at 7.

[39] 85 FR at 22573; 85 FR at 58172–73. *See* Conf. Rep. at 7 (noting that the ''highest responsibility'' of the MLC includes ''efforts to identify the musical works embodied in particular sound recordings,'' ''identify[ing] and locat[ing] the copyright owners of such works so that [the MLC] can update the database as appropriate,'' and ''efficient and accurate collection and distribution of royalties'').

[40] 17 U.S.C. 115(d)(3)(J)(i)(II)(bb). *See* MLC Initial September NOI Comment at 24 (contending that not all information contained in its database ''would be appropriate for public disclosure,'' and that it ''should be permitted to exercise reasonable judgment in determining what information beyond what is statutorily required should be made available to the public'').

[41] *See* 37 CFR 210.29(c) (proposing a floor of categories of information to be required in periodic reporting to copyright owners).

1. Songwriter or Composer

Commenters—including the MLC[42]—overwhelmingly agreed that the database should include songwriter and composer information,[43] and so the interim rule requires including such information in the public database, to the extent reasonably available to the collective.[44] SGA & SCL suggest that the phrase ''to the extent reasonably available to the collective'' ''serves to diminish the requisite and explicit value of songwriter/composer identifying information.''[45] The phrase ''to the extent reasonably available to the mechanical licensing collective'' for songwriter or composer information is employed to mirror the statutory qualification with respect to inclusion of other types of information.[46] For consistency with the statute (and the other fields discussed below), the interim rule adopts this aspect of the proposed rule without modification.

Commenters also supported the ability of songwriters, or their representatives, to mask songwriters' identity to avoid being associated with certain musical works by having their information listed anonymously or pseudonymously in the public musical works database.[47] While the proposed rule granted the MLC discretion to allow songwriters this option,[48] SGA & SCL suggest that ''that such a regulation be extended into a mandatory direction to the MLC to accept such direction from a music creator.''[49] By contrast, while acknowledging ''that writers often use pennames and that there are also current trends to hide an artist's identity, in which case the writer may want to remain anonymous,'' SONA expresses concern that ''not having a songwriter's name associated with a musical work is often one of the biggest challenges in ensuring a songwriter receives proper payment,'' and that ''while at the time of creation that may be the express wish of the songwriter, it is critical that the creator and the musical work do not become dissociated over the term of the work's copyright.''[50] SONA suggests that a songwriter should have the option of staying anonymous or using a pseudonym in the public database only if ''the MLC has sufficient contact information with the songwriter's representation,'' and that the rule should ''ensure adequate information to contact the songwriter or their representatives is easily accessible for users of that writer's musical works.''[51]

For its part, the MLC contends that ''[i]f the copyright owner or administrator requests that the writer be identified as 'anonymous' or by a pseudonym, it can do so when it submits the musical work information to the MLC,'' and that the MLC will ''consider subsequent requests by an owner or administrator to change the name to 'anonymous' or to a pseudonym.''[52] The MLC contends that the regulations should not ''make it mandatory for the MLC to change songwriter names in the musical works database at the request of any particular party, because such may not always be appropriate,'' and that the MLC ''is also responsible for maintaining an accurate musical works database, and must be afforded the ability to fulfill that function.''[53]

Having carefully considered this issue, the Office has included in the interim rule adjusted language ensuring that the MLC develops and makes publicly available a policy on how it will consider requests by copyright owners or administrators to change songwriter names to be listed anonymously or pseudonymously. The Office encourages the MLC to grant any subsequent requests by a copyright owner or administrator to change a songwriter name to ''anonymous'' or to a pseudonym.

2. Studio Producer

As the statute requires the public database to include ''producer'' to the extent reasonably available to the MLC,[54] so does the interim rule. Initially, there appeared to be stakeholder disagreement about the meaning of the term ''producer,'' which has since been resolved to clarify that it refers to the studio producer.[55] Because the term ''producer'' relates not only to the public database, but also to information provided by digital music providers in reports of usage, the Office defined ''producer'' in its interim rule concerning reports of usage, notices of license, and data collection efforts, among other things, to define ''producer'' to mean studio producer throughout its section 115 regulations.[56]

3. Unique Identifiers

The statute requires the MLC to include ISRC and ISWC codes, when reasonably available.[57] According to the legislative history, ''[u]sing standardized metadata such as ISRC and ISWC codes, is a major step forward in reducing the number of unmatched works.''[58] The proposed rule required the public database to include the Interested Parties Information (''IPI'')[59] and/or

[42] MLC April NOI Comment at 9 (agreeing with inclusion of songwriter information for musical works); MLC Reply September NOI Comment at 32 (same).

[43] *See* SGA Initial September NOI Comment at 2; The International Confederation of Societies of Authors and Composers (''CISAC'') & the International Organisation representing Mechanical Rights Societies (''BIEM'') April NOI Comment at 2; SONA April NOI Comment at 2; *see also* Barker Initial September NOI Comment at 2; Future of Music Coalition (''FMC'') Reply September NOI Comment at 2; DLC Reply September NOI Comment at 26; Recording Academy NPRM Comment at 2; SONA NPRM Comment at 2, 4.

[44] Because the statute's definition of ''songwriter'' includes composers, the interim rule uses the term ''songwriter'' to include both songwriters and composers. 17 U.S.C. 115(e)(32). To reduce the likelihood of confusion, the MLC may want to consider labeling this field ''Songwriter or Composer'' in the public database.

[45] SGA & SCL NPRM Comment at 2–3.

[46] *See* 17 U.S.C. 115(d)(3)(E)(ii)(IV), (iii)(I); *see also* 37 CFR 210.29(c)(2)(i), (ii), and (v) and (c)(3)(ii) (requiring the MLC to report certain types of information to copyright owners ''known to the MLC'').

[47] *See* Kernen NPRM Comment at 1, U.S. Copyright Office Dkt. No. 2020–7, available at *https://beta.regulations.gov/document/COLC-2020-0004-0001;* Recording Academy NPRM Comment at 2 (''[T]he Academy agrees that it is appropriate to give the MLC discretion to give songwriters the option to remain anonymous or use a pseudonym in the database.''); SGA & SCL NPRM Comment at 3 (''[W]e desire to make clear that SGA and SCL also continue to support the rights of those music creators who may wish *not* to be publicly associated with certain musical works. That is and must continue to be right of any songwriter or composer.'').

[48] 85 FR at 58173.

[49] SGA & SCL NPRM Comment at 3.

[50] SONA NPRM Comment at 4.

[51] *Id.* at 4–5.

[52] MLC *Ex Parte* Letter #11 at 4.

[53] *Id.*

[54] 17 U.S.C. 115(d)(3)(E)(ii)(IV), (iii)(I)(dd). The statute also requires digital music providers to report the ''producer'' to the mechanical licensing collective. *Id.* at 115(d)(3)(E)(ii)(IV), (iii)(I)(dd). *See also* 37 CFR 210.27(e)(1)(i)(E)(*2*).

[55] *See* MLC Initial September NOI Comment at 13 n.6 (originally believing that ''producer'' referred to ''the record label or individual or entity that commissioned the sound recording''); Recording Academy Initial September NOI Comment at 3 (urging Office to ''clarify that a producer is someone who was part of the creative process that created a sound recording''); RIAA Initial September NOI Comment at 11 (stating ''producer'' should be defined as ''the primary person(s) contracted by and accountable to the content owner for the task of delivering the recording as a finished product''); MLC Reply September NOI Comment at 34–35 (updating its understanding).

[56] 37 CFR 210.22(i) (defining ''producer'' for purposes of Subpart B of section 210). *See* Recording Academy NPRM Comment at 2 (supporting proposed rule).

[57] 17 U.S.C. 115(d)(3)(E)(ii)–(iii).

[58] Conf. Rep. at 7. The legislative history also notes that ''the Register may at some point wish to consider after an appropriate rulemaking whether standardized identifiers for individuals would be appropriate, or even audio fingerprints.'' *Id.*

[59] IPI is ''[a] unique identifier assigned to rights holders with an interest in an artistic work, including natural persons or legal entities, made known to the IPI Centre. The IPI System is an international registry used by CISAC and BIEM societies.'' U.S. Copyright Office, Unclaimed Royalties Study Acronym Glossary at 3, *https://*

Continued

International Standard Name Identifier (''ISNI'')[60] for each songwriter, publisher, and musical work copyright owner, as well as the Universal Product Code (''UPC''), to the extent reasonably available to the MLC.[61] As proposed, the public database must also include the MLC's standard identifier for the musical work, and to the extent reasonably available to the MLC, unique identifier(s) assigned by the blanket licensee, if reported by the blanket licensee.[62] The Office sought public comment on whether IPIs and/or ISNIs for foreign collective management organizations (''CMOs'') should be required to be listed separately.[63]

In response to the proposed rule, commenters expressed continued support for including IPIs, ISNIs, and UPC,[64] which the MLC has agreed to include.[65] The interim rule thus adopts this aspect of the proposed rule without modification. SGA & SCL ''support the comments of CISAC and BIEM . . . as to the listing of IPIs and ISNIs for foreign collective management organizations.''[66] As discussed more below, the Office declines to require the MLC to separately include IPIs and ISNIs for foreign CMOs in the database at this time, apart from where they may otherwise already be included as a relevant musical work copyright owner.

4. Information Related to Ownership and Control of Musical Works

By statute, the database must include information regarding the ownership of the musical work as well as the underlying sound recording, including ''the copyright owner of the work (or share thereof), and the ownership percentage of that owner,'' or, if unmatched, ''the ownership percentage for which an owner has not been identified.''[67] The statute also requires a field called ''sound recording copyright owner,'' the meaning of which is discussed further below.

Although the MMA does not reference music publishing administrators—that is, entities responsible for managing copyrights on behalf of songwriters, including administering, licensing, and collecting publishing royalties without receiving an ownership interest in such copyrights—a number of commenters have urged inclusion of this information in the public musical works database.[68] As one commenter suggested, because ''a copyright owner's 'ownership' percentage may differ from that same owner's 'control' percentage,'' the public database should include separate fields for ''control'' versus ''ownership'' percentage.[69] The MLC agreed,[70] stating that ''the database should include information identifying the administrators or authorized entities who license the relevant musical work and/or collect royalties for such work on behalf of the copyright owner.''[71] In addition, with respect to specific ownership percentages, which are required by statute to be made publicly available, the MLC expressed its intention to mark overclaims (*i.e.,* shares totaling more than 100%) as such and show the percentages and total of all shares claimed so that overclaims and underclaims (*i.e.,* shares totaling less than 100%) will be transparent.[72]

Relatedly, CISAC & BIEM raised concerns about needing ''to clarify the concept of 'copyright owner,' '' as ''foreign collective management organizations (CMOs) . . . are also considered copyright owners or exclusively mandated organizations of the musical works administered by these entities,'' and thus ''CMOs represented by CISAC and BIEM should be able to register in the MLC database the claim percentages they represent.''[73] The MLC responded that it will ''engage in non-discriminatory treatment towards domestic and foreign copyright owners, CMOs and administrators,''[74] and that it ''intends to operate on a non-discriminatory basis, and all natural and legal persons or entities of any nationality are welcome to register their claims to works with the MLC.''[75]

The NPRM noted that ''[w]hile the MMA does not reference foreign musical works specifically, nothing in the statute indicates that foreign copyright owners should be treated differently from U.S. copyright owners under the blanket licensing regime, or prevents the MLC from seeking or including data from foreign CMOs in building the public database.''[76] The Office also stated that ''[w]here copyright ownership has been assigned or otherwise transferred to a foreign CMO or, conversely, a U.S. sub-publisher, the statute does not specify that it should be treated differently from a similarly-situated U.S. entity that has been assigned or otherwise been transferred copyright ownership.''[77] The Office noted that the MLC appeared to be planning for data collection from foreign CMOs, as evidenced by promotional material in connection with its Data Quality Initiative (DQI).[78]

Based on public comments, the Office concluded that to the extent reasonably available to the MLC, it would be beneficial for the database to include information related to all persons or entities that own or control the right to license and collect royalties related to musical works in the United States, and that music publishing administrator and control information would be valuable additions.[79] Accordingly, the proposed rule required the public database to include administrator(s) or other authorized entity(ies) who license the musical work (or share thereof) and/or collect mechanical royalties for such musical work (or share thereof) in the United States.[80] It would not prevent the MLC from including additional information with respect to foreign CMOs.[81]

In response, CISAC & BIEM again expressed ''the need to have CMOs clearly recognized as 'copyright

www.copyright.gov/policy/unclaimed-royalties/glossary.pdf (last visited Dec. 18, 2020).

[60] ISNI is ''[a] unique identifier for identifying the public identities of contributors to creative works, regardless their legal or natural status, and those active in their distribution. These may include researchers, inventors, writers, artists, visual creators, performers, producers, publishers, aggregators, and more. A different ISNI is assigned for each name used.'' *Id.*

[61] 85 FR at 58188–89.

[62] *Id.*

[63] 85 FR at 58174.

[64] *See* CISAC & BIEM NPRM Comment at 1 (''appreciat[ing] that the Office has included international identifiers such as ISWC and IPI''); SGA & SCL NPRM Comment at 3 (''strongly support[ing]'' the inclusion of IPI, ISNI, and UPC data''); SONA NPRM Comment at 5 (''commend[ing] the Office'' for including IPI, ISNI, and UPC).

[65] *See* MLC April NOI Comment at 9; MLC *Ex Parte* Letter #7 at 5; MLC NPRM Comment at 2–3.

[66] SGA & SCL NPRM Comment at 3.

[67] 17 U.S.C. 115(d)(3)(E)(ii)–(iii).

[68] *See* DLC Reply September NOI Comment Add. at A–16; ARM April NOI Comment at 2; FMC April NOI Comment at 2; SONA April NOI Comment at 5–6; SoundExchange Initial September NOI Comment at 8; Barker Initial September NOI Comment at 2.

[69] Barker Initial September NOI Comment at 3.

[70] MLC Reply September NOI Comment at 32 n.16.

[71] MLC April NOI Comment at 9.

[72] MLC *Ex Parte* Letter #7 at 5.

[73] CISAC & BIEM April NOI Comment at 1. *See also* Japanese Society for Rights of Authors, Composers and Publishers (''JASRAC'') Initial September NOI Comment at 2.

[74] MLC *Ex Parte* Letter #7 at 6.

[75] MLC Reply September NOI Comment at 44.

[76] 85 FR at 58175; *see* 17 U.S.C. 115.

[77] 85 FR at 58175; *see* 17 U.S.C. 101 (defining ''copyright owner'' and ''transfer of copyright ownership''); *id.* at 115.

[78] 85 FR at 58175; The MLC, Play Your Part, *https://themlc.com/play-your-part* (last visited Dec. 18, 2020). According to the MLC, the DQI ''does not act as a mechanism for delivering work registrations/works data,'' but ''[m]usic publishers, administrators and foreign CMOs may use [Common Works Registration] to deliver new and updated work registrations to The MLC.'' The MLC, MLC Data Quality Initiative 2 (2020), *https://themlc.com/sites/default/files/2020-08/2020%20-%20DQI%20One%20Pager%20Updated%208-18-20.pdf* (last visited Dec. 18, 2020).

[79] 85 FR at 58175.

[80] *Id.*

[81] *Id.*

owners,'" explaining that "outside the U.S., the 'copyright ownership' of the work is attributed to the CMOs managing the mechanical rights . . ."[82] CISAC & BIEM also contended that there is no "business need to include the *creator* percentage shares in the musical works" in the public database (as opposed to copyright *owner* share(s), which is required by the statute), "as this information [is] not required to license or distribute musical works, and constitutes particularly sensitive and confidential financial and business information for creators and their representatives."[83] SONA emphasized the importance of the Office's statement that "there is no indication that foreign copyright owners should have different treatment under the blanket licensing regime."[84] For its part, the MLC has "repeatedly maintained that it will engage in non-discriminatory treatment towards domestic and foreign copyright owners, CMOs and administrators," and that "foreign CMOs should be treated no differently in the database from other mechanical rights administrators."[85] The MLC also stated that if a foreign CMO "is an owner or administrator of US copyright rights, it will be treated as such, and in a non-discriminatory manner as compared to other US copyright owners or administrators."[86]

Having considered these comments, the Office reaffirms the general requirement that the database include information related to all persons or entities that own or control the right to license and collect royalties related to musical works in the United States, irrespective of whether those persons or entities are located outside the United States. The interim rule thus adopts this aspect of the proposed rule without modification. To address CISAC & BIEM's concerns about the recognition of copyright ownership by foreign CMOs, the interim rule references the statutory definitions of "copyright owner" and "transfer of copyright ownership," and states that a copyright owner includes entities, including foreign CMOs, to which "copyright ownership has been transferred through an assignment, mortgage, exclusive license, or any other conveyance, alienation, or hypothecation of a copyright or of any of the exclusive rights comprised in a copyright, whether or not it is limited in time or place of effect, but not including a nonexclusive license."[87] Where a foreign CMO is the copyright owner of the musical work under U.S. law, the database should identify the foreign CMO as the copyright owner, along with its percentage share.[88] The database should take a parallel approach with respect to administration rights. Depending upon the specific arrangements in place, this may mean that the database will need to display information related to both the foreign CMO as well as a U.S. sub-publisher or administrator (along with percentage shares).[89] And while the songwriter or composer of the same musical work must, by regulation, be identified in the database as the songwriter or composer (as discussed above), if he or she is not the copyright owner due to assignment of the copyright to a foreign CMO, he or she would not have ownership shares to display in the database. To the extent that sub-publishers own or control foreign musical works in the U.S. and foreign CMOs do *not* (*i.e.,* the foreign CMOs do not have a U.S. right of ownership or administration), the Office concludes that the mechanical licensing collective should not be required to include information about such foreign CMOs in the database. The Office recognizes that including foreign CMO information even when the CMOs are not copyright owners or administrators in the U.S. may be desired by certain commenters, but the Office is reluctant to require the MLC to include such information at this time, given the MLC's indication that it needs to focus on more core tasks. As noted above, in considering whether to prescribe the inclusion of additional fields beyond those statutorily required, the Office focused on fields that the record indicates would advance the goal of the public database: Reducing the number of unmatched musical works by accurately identifying musical work copyright owners so they can be paid what they are owed under the section 115 statutory license. Should confusion arise after the musical works database becomes publicly available, the Office is willing to consider whether adjustment to the interim rule is warranted.

5. Additional Information Related To Identifying Musical Works and Sound Recordings

Given the general consensus of comments, the interim rule largely adopts the proposed rule without modification, which requires the public database to include the following fields, to the extent reasonably available to the MLC: Alternate titles for musical works, opus and catalog numbers of classical compositions, and track duration,[90] version, and release date of sound recordings.[91] It also incorporates the statutory requirements to include, to the extent reasonably available to the mechanical licensing collective, other non-confidential information commonly used to assist in associating sound recordings with musical works (for matched musical works), and for unmatched musical works, other non-confidential information commonly used to assist in associating sound recordings with musical works, and any additional non-confidential information reported to the mechanical licensing collective that may assist in identifying musical works.[92] The MLC notes that "[o]pus and catalog numbers for classical compositions and UPC have now been added to the DDEX format, so the MLC will provide that information

[82] CISAC & BIEM NPRM Comment at 1–2.

[83] *Id.* at 2 (emphasis added).

[84] SONA NPRM Comment at 6 ("When contemplating rules and procedures to implement a database intended to show the public information on the ownership of a musical work, it is important that the development of the database conceive that the data it incorporates and users that rely on that data are not all of U.S. origin.").

[85] MLC NPRM Comment at 3 (citation omitted).

[86] MLC *Ex Parte* Letter #11 at 4.

[87] 17 U.S.C. 101. SGA maintains that "[m]any songwriters (including composers) and their heirs have carefully opted to retain ownership of the copyrights in their musical compositions, and to assign only limited administration or co-administration rights to third party music publishing entities," and that "any songwriter or heir who retains copyright ownership in her or his portion of a work [should be able to] serve notice on the MLC at any time directing that she or he is to be listed as the copyright owner in the database as to that portion." SGA & SCL NPRM Comment at 4. If a songwriter or a songwriter's heir is the copyright owner of a musical work, the public database should identify the songwriter or heir as such, to the extent such information is available to the mechanical licensing collective.

[88] *See* CISAC & BIEM et al. *Ex Parte* Letter Oct. 27, 2020 at 2.

[89] *See* CISAC & BIEM September NOI Initial Comment at 3 (noting foreign musical works "may have a publisher or may be sub-published in the US in a way that the sub-publisher does not necessarily hold 100% of the mechanical rights"); CISAC & BIEM et al. *Ex Parte* Letter Oct. 27, 2020 at 2 (noting "the existence of certain limitations in certain cases, that prevent sub-publishers from collecting 100% of mechanical (*e.g.* 25% limitation in the case of GEMA works)").

[90] The rule uses the term "playing time." *See* 37 CFR 210.27(e)(1)(i)(D).

[91] 85 FR at 58188–89; *see* Recording Academy NPRM Comment at 2; SONA NPRM Comment at 7; ARM April NOI Comment at 3; MLC Reply September NOI Comment at App. E; MLC April NOI Comment at 10; Recording Academy Initial September NOI Comment at 3; Recording Academy April NOI Comment at 3; RIAA Initial September NOI Comment at 6–7; SONA April NOI Comment at 6; SoundExchange Initial September NOI Comment at 7. Because UPC numbers are "product-level" identifiers and sound recordings can thus have multiple UPC numbers (*i.e.,* one for each product on which the sound recording appears), ARM and SoundExchange ask the MLC to be careful about conveying the association between the UPC number displayed in the database and the track at issue to reduce confusion. ARM NPRM Comment at 2; SoundExchange NPRM Comment at 5.

[92] 17 U.S.C. 115(d)(3)(E)(ii)(IV)(bb), (iii)(I)(dd)–(ee).

to the extent it is reasonably available to the MLC.'' [93]

ARM and SoundExchange seek clarity regarding the meaning of ''release date.'' [94] ARM maintains that because ''it is not uncommon for a given sound recording to be released on more than one product, each with its own release date,'' ''the release date included in the database must reflect the actual, not the intended, release date,'' [95] and ''regulations should prohibit the MLC from publicly displaying any data about a sound recording prior to its actual release date.'' [96] The Office agrees that ''release date'' should not be an intended release date; rather, it should reflect the date on which the recording was first released. The Office encourages the MLC to include an explanation of release date in its glossary.[97]

Finally, the MLC contends that the phrase ''other non-confidential information commonly used to assist in associating sound recordings with musical works'' is vague, and suggests changing it to ''other non-confidential information that the MLC reasonably believes would be useful to assist in associating sound recordings with musical works.'' [98] After carefully considering the statute, legislative history, and comments, the Office agrees that the MLC should have some flexibility to include additional information that may be helpful for matching purposes, but is also mindful that the phrase proposed by the NPRM was taken directly from the statute. Accordingly, the Office has adjusted the interim rule to add the phrase ''reasonably believes, based on common usage'' for consistency with the statute (*i.e.,* the MLC is required to include, to the extent reasonably available to it, other non-confidential information that it reasonably believes, based on common usage, would be useful to assist in associating sound recordings with musical works).

6. Performing Rights Organization Affiliation

In response to the September NOI, a few commenters maintained that the public database should include PRO affiliation.[99] By contrast, the MLC and FMC raised concerns about including and maintaining PRO affiliation in the public database.[100] The largest PROs, the American Society of Composers, Authors, and Publishers (''ASCAP'') and Broadcast Music, Inc. (''BMI''), also objected, stating that because ''music performing rights organizations such as BMI and ASCAP all have comprehensive databases on musical works ownership rights, and these databases are publicly available,'' ''administration of data with respect to the licensing of public performing rights does not require government intervention.'' [101]

After evaluating these comments, in the April NOI the Office tentatively concluded against requiring PRO affiliation in the public database, noting that ''[b]ecause the MMA explicitly restricts the MLC from licensing performance rights, it seems unlikely to be prudent or frugal to require the MLC to expend resources to maintain PRO affiliations for rights it is not permitted to license.'' [102] Similarly, the Office declined to require the inclusion of PRO affiliation in the proposed rule.[103]

In response to the NPRM, the DLC asked the Office to reconsider and include PRO affiliation in the public database.[104] The DLC contends that PRO affiliation may aid matching in some instances, giving the example of songwriters affiliated with ASCAP being able to ''target their searches of the MLC's database for works that the MLC has affiliated with ASCAP,'' and ''more readily confirm that the PRO and MLC databases contain consistent information regarding information such as share splits and unique identifiers'' (*i.e.,* ''mak[ing] the MLC database a useful cross-check for PRO data'').[105] The DLC asks that the MLC ''*not throw away valuable musical works metadata,*'' and states it ''would not be opposed to an accommodation such as a six-month transition period for this aspect of the database.'' [106] MAC similarly requests inclusion of PRO affiliation.[107] By contrast, CISAC & BEIM, FMC, Recording Academy, and SGA & SCL agree it should not be included, with Recording Academy stating that ''information related to public performance rights goes beyond the scope of the MMA, which is focused on mechanical rights.'' [108] For its part, the MLC contends that it ''should be afforded the opportunity to focus on its main priority of a robust and fulsome mechanical rights database,'' and not include PRO affiliation, but that ''[i]f, at some time in the future, the MLC has the capacity and resources to also incorporate performance rights information, it may undertake this task . . .'' [109]

Having considered these comments, the statutory text, and legislative history, the Office concludes that the mechanical licensing collective should not be required to include PRO affiliation in the public database at this time. The Office recognizes that PRO affiliation is desired by certain commenters, particularly licensees, for transparency purposes, and that the record contains some limited suggestions that it could be a useful data point in the MLC's core project of matching works under the mechanical license. Without further information, the Office is reluctant to require the MLC to include such information, given the statutory prohibition against administering performance licenses and the MLC's suggestion that it needs to focus on more core tasks. In addition, in a related rulemaking, the Office declined to require that musical work copyright owners provide information related to PRO affiliation in connection with the statutory obligation to undertake commercially reasonably efforts to deliver sound recording

[93] MLC NPRM Comment at 3.

[94] ARM NPRM Comment at 3; SoundExchange NPRM Comment at 5.

[95] ARM NPRM Comment at 3.

[96] *Id.* at 2.

[97] *See id.* at 3.

[98] MLC NPRM Comment at 3. *See* MLC *Ex Parte* Letter #11 at 4 (contending that its proposed language allows it to ''operate under its reasonable judgment as to which fields fit into the category'').

[99] *See* DLC Initial September NOI Comment at 20; Music Innovation Consumers (''MIC'') Coalition Initial September NOI Comment at 2; Barker Initial September NOI Comment at 8–9.

[100] *See* MLC Reply September NOI Comment at 36 (pointing out that its ''primary responsibility is to engage in the administration of mechanical rights and to develop and maintain a mechanical rights database,'' and that ''gather[ing], maintain[ing], updat[ing] and includ[ing] . . . performance rights information—which rights it is not permitted to license—would require significant effort which could imperil [its] ability to meet its statutory obligations with respect to mechanical rights licensing and administration by the [license availability date]''); FMC Reply September NOI Comment at 3.

[101] ASCAP & BMI Reply September NOI Comment at 2.

[102] 85 FR at 22576; *see* 17 U.S.C. 115(d)(3)(C)(iii) (limiting administration of voluntary licenses to ''only [the] reproduction or distribution rights in musical works for covered activities'').

[103] 85 FR at 58176.

[104] DLC NPRM Comment at 3; DLC *Ex Parte* Letter Dec. 11, 2020 (''DLC *Ex Parte* Letter #8'') at 3–4.

[105] DLC *Ex Parte* Letter #8 at 4. The DLC also states that ''BMI has taken the position that it is not barred from licensing mechanical rights in addition to public performance rights, and ASCAP has sought an amendment to its consent decree permitting it to engage in such licensing,'' and that ''[i]f the PROs begin to administer mechanical rights in the United States, then including information about PRO affiliation in the MLC's database will be especially important.'' *Id.*

[106] *Id.*

[107] MAC NPRM Comment at 4.

[108] Recording Academy NPRM Comment at 3; CISAC & BIEM April NOI Comment at 3; FMC April NOI Comment at 2; SGA & SCL NPRM Comment at 3–4; *see also* SONA NPRM Comment at 7 (accepting Office's decision not to compel PRO affiliation).

[109] MLC April NOI Comment at 10.

information to the MLC.[110] Given that the MLC intends to source musical work information from copyright owners or administrators, requiring the MLC to ''pass through'' PRO affiliation from DMPs may potentially be confusing as to the source of such information or result in incorrect or conflicting information. After the MLC has been up and running, the Office is willing to consider whether modifications to the interim rule prove necessary on this subject. In the meantime, as previously noted by the Office, not requiring the MLC to include PRO affiliation does not inhibit the MLC from optionally including such information.[111] Should the MLC decide to include PRO affiliation in the database and source such information from DMPs' reports of usage, the Office encourages the MLC to include an explanation of PRO affiliation and the sourcing of such information in its glossary.

7. Historical Data

In response to the September NOI and April NOI, multiple commenters asserted that the public database should maintain and make historical ownership information available.[112] For its part, the MLC stated its intention to ''maintain information about each and every entity that, at any given point in time, owns a share of the right to receive mechanical royalties for the use of a musical work in covered activities,'' and to ''maintain at regular intervals historical records of the information contained in the database.'' [113] The MLC confirmed that it ''will maintain an archive of data provided to it after the license availability date ('LAD') and that has subsequently been updated or revised (*e.g.,* where there is a post-LAD change in ownership of a share of a musical work), and the MLC will make this historic information available to the public.'' [114] The MLC contends that ''it should be permitted to determine, in consultation with its vendors, the best method for maintaining and archiving historical data to track ownership and other information changes in its database.'' [115]

The proposed rule adopted the MLC's request for flexibility as to the most appropriate method for archiving and maintaining historical data to track ownership and other information changes in the database, stating that the MLC shall maintain at regular intervals historical records of the information contained in the public musical works database, including a record of changes to such database information and changes to the source of information in database fields, in order to allow tracking of changes to the ownership of musical works in the database over time.[116] No commenters objected to this aspect of the proposed rule. The Office continues to believe that granting the MLC discretion in how to display such historical information is appropriate, particularly given the complexity of ownership information for sound recordings (discussed below). Accordingly, the interim rule adopts this aspect of the proposed rule without modification. As previously noted by the Office, the MLC must maintain all material records of the operations of the mechanical licensing collective in a secure and reliable manner, and such information will also be subject to audit.[117] CISAC & BIEM did seek clarity on whether the database will include historical information for both musical works and sound recordings.[118] The Office confirms that the interim rule broadly covers information changes in the database, which covers information relating to both musical works and sound recordings.

8. Terminations

Title 17 allows authors or their heirs, under certain circumstances, to terminate an agreement that previously granted one or more of the author's exclusive rights to a third party.[119] In response to the September NOI, one commenter suggested that to the extent terminations of musical work grants have occurred, the public database should include ''separate iterations of musical works with their respective copyright owners and other related information, as well as the appropriately matched recording uses for each iteration of the musical work, and to make clear to the public and users of the database the appropriate version eligible for future licenses.'' [120] Separately, as addressed in a parallel rulemaking, the MLC asked that the Office require digital music providers to include server fixation dates for sound recordings, contending that this information will be helpful to its determination whether particular usage of musical works is affected by the termination of grants under this statutory provision.[121] The DLC objected to this request.[122]

In the April NOI, the Office sought public input on issues that should be considered relating to whether termination information should be included in the public database.[123] The DLC, SGA & SCL, and SONA support including information concerning the termination of grants of rights by copyright creators in the public database.[124] By contrast, the MLC contended that it ''should not be required to include in the public database information regarding statutory termination of musical works *per se*.'' [125] The Recording Academy asked the Office to ''set aside any issue related to termination rights and the MLC until it conducts a full and thorough examination of the implications . . . for songwriters and other authors, including an opportunity for public comment.'' [126]

The proposed rule did not require the mechanical licensing collective to include termination information in the public database, an approach that is adopted by the interim rule.[127] While in response to the NPRM, SGA & SCL reiterate their viewpoint that this information should be required, at this time, the Office is not convinced this requirement is necessary in light of the statutory obligation to maintain an up-to-date ownership database.[128] Indeed,

[110] 85 FR 58114, 58121 (Sept. 17, 2020).

[111] 17 U.S.C. 115(d)(3)(E)(v); 85 FR at 22576; 85 FR at 58176–77.

[112] *See* DLC Initial September NOI Comment at 20; SoundExchange Initial September NOI Comment at 10; CISAC & BIEM April NOI Comment at 3; FMC April NOI Comment at 2; SoundExchange April NOI Comment at 4–5; SONA April NOI Comment at 9.

[113] MLC April NOI Comment at 12.

[114] MLC *Ex Parte* Letter #7 at 4.

[115] MLC April NOI Comment at 12.

[116] 85 FR at 58189.

[117] 85 FR at 22576; 85 FR at 58177; 17 U.S.C. 115(d)(3)(M)(i); *id.* at 115(d)(3)(D)(ix)(II)(aa).

[118] CISAC & BIEM NPRM Comment at 2–3. SoundExchange asserts that ''the regulations [should] make clear that, in addition to 'archiving and maintaining such historical data,' the MLC shall make such historical data available to the public.'' SoundExchange NPRM Comment at 4. The interim rule, like the proposed rule, identifies the categories of information that must be included in the public musical works database, which includes historical information. *See* 85 FR at 58188 (''This section prescribes the rules under which the mechanical licensing collective will provide information relating to musical works (and shares of such works), and sound recordings in which the musical works are embodied, in the public musical works database prescribed by 17 U.S.C. 115(d)(3)(E). . . .'').

[119] 17 U.S.C. 203, 304(c), 304(d).

[120] Barker Initial September NOI Comment at 4.

[121] MLC Reply September NOI Comment at 19, App. at 10–11; *see also* 85 FR at 22532–33.

[122] DLC *Ex Parte* Letter Feb. 14, 2020 (''DLC *Ex Parte* Letter #1'') at 3; DLC *Ex Parte* Letter #1 Presentation at 15; DLC *Ex Parte* Letter Feb. 24, 2020 at 4; DLC *Ex Parte* Letter Mar. 4, 2020 (''DLC *Ex Parte* Letter #3'') at 5.

[123] 85 FR at 22576.

[124] DLC April NOI Comment at 4 n.19; SGA & SCL April NOI Comment at 8; SONA April NOI Comment at 2–3.

[125] MLC April NOI Comment at 10.

[126] Recording Academy April NOI Comment at 3. *See also* Recording Academy NPRM Comment at 3 (''The decision not to require the inclusion of termination information in the public database is prudent and appropriate.'').

[127] 85 FR at 58178.

[128] SGA & SCL NPRM Comment at 4.

the MLC has noted its intention to include information regarding administrators that license musical works and/or collect royalties for such works,[129] as well as information regarding ''each and every entity that, at any given point in time, owns a share of the right to receive mechanical royalties for the use of a musical work in covered activities,'' [130] which presumably should include updated ownership information that may be relevant for works that are being exploited after exercise of the termination right. The Office's conclusion does not restrict the MLC from optionally including such information.

9. Data Provenance

In response to both notifications of inquiry, commenters overwhelmingly supported having the public musical works database include data provenance information.[131] The DLC and SoundExchange contend that including data provenance information will allow users of the database to make their own judgments as to its reliability.[132] Others noted that for sound recordings, first-hand data is more likely to be accurate.[133] For its part, the MLC maintains that it ''should be given sufficient flexibility to determine the best and most operationally effective way to ensure the accuracy and quality of the data in its database, rather than requiring it to identify the source of each piece of information contained therein.'' [134] The MLC also stated that it ''intends to show the provenance of each row of sound recording data, including both the name of and DPID for the DMP from which the MLC received the sound recording data concerned,'' and that it ''intends to put checks in place to ensure data quality and accuracy.'' [135] For musical works information, the MLC maintains that it ''will be sourced from copyright owners.'' [136]

The proposed rule would require the MLC to include data provenance information for sound recording information in the public database, though it grants the MLC some discretion on *how* to display such information.[137] The proposed rule would not require the MLC to include data provenance information for musical work information, as the MLC intends to source musical works information from copyright owners (which commenters generally supported).[138] Specifically, the Office noted that ''data provenance issues appear to be especially relevant to sound recording information in the public database,'' particularly ''given that the MLC intends to populate sound recording information in the public database from reports of usage, as opposed to using a single authoritative source.'' [139] The Office sought public input on this aspect of the proposed rule.[140]

ARM and SoundExchange both ask for regulations to require the MLC to identify the actual person or entity from which the information came, as opposed to including a categorical description such as ''digital music provider'' or ''usage report,'' though ARM does ''not oppose inclusion of those sorts of descriptors along with the party name.'' [141] In addition, ARM and CISAC & BIEM contend that the database should also include data provenance information regarding musical works information, with ARM stating that data provenance information for musical works ''would be of similar benefit to users of the database, particularly those who are required to pay mechanical royalties outside of the blanket license.'' [142] For its part, the MLC ''confirmed that it will include in the database DMP names and DPID information where it receives it.'' [143] Accordingly, the interim rule states that for sound recording information received from a digital music provider, the MLC shall include the name of the digital music provider. Because the MLC has stated that it will source musical work information from copyright owners and administrators of those works, and because (as noted above) copyright owners and administrators will already be included in the database, the Office concludes at this time that the regulations do not need to require data provenance information for musical works. Should future instances of confusion suggest that modifications to the interim rule are necessary, the Office is willing to reconsider this subject. The interim rule does not dictate the precise format in which such information is made available in the database.[144]

C. Sound Recording Information and Disclaimers or Disclosures in the Public Musical Works Database

1. ''Sound Recording Copyright Owner'' Information

In response to the September NOI, RIAA and individual record labels expressed concern about which information will populate the database and be displayed to satisfy the statutory requirement to include ''sound recording copyright owner'' (SRCO) in the public musical works database.[145] Specifically, RIAA explained that under current industry practice, digital music providers send royalties pursuant to information received from record companies or others releasing recordings to DMPs ''via a specialized DDEX message known as the ERN (or Electronic Release Notification),'' which ''is typically populated with information about the party that is entitled to receive royalties (who may or may not be the actual legal copyright owner), because that is the information that is relevant to the business relationship between record labels and DMPs.'' [146] In short, information ''in the ERN message is not meant to be used to make legal determinations of ownership.'' [147] RIAA noted the

[129] MLC April NOI Comment at 9.

[130] MLC Reply September NOI Comment at 34.

[131] ARM April NOI Comment at 3 (contending that the public database should indicate ''which data was provided to the MLC by the actual copyright owner or its designee, which was provided by a DMP and which was provided by some other third party'') (footnote omitted); DLC Initial September NOI Comment at 20; DLC Reply September NOI Comment at Add. A–15–16; FMC April NOI Comment at 2 (agreeing that public database ''should include provenance information, not just because it helps allow for judgments about how authoritative that data is, but because it can help writers and publishers know where to go to correct any bad data they discover''); CISAC & BIEM April NOI Comment at 3 (''Submitters of information should be identified, and when the information is derived from copyright owners (creators, publishers, CMOs, etc.), it should be labelled, and it should prevail over other sources of information.'').

[132] DLC April NOI Comment at 4; SoundExchange Initial September NOI Comment at 10–11.

[133] A2IM & RIAA Reply September NOI Comment at 2–3 (asserting MLC should be required to obtain its sound recording data from a single authoritative source); Jessop Initial September NOI Comment at 3 (''The MLC should obtain sound recording information from as close to the source as possible. In practice this means from the record label or someone directly or indirectly authorized to manage this information for them.'').

[134] MLC April NOI Comment at 12.

[135] MLC *Ex Parte* Letter #7 at 4.

[136] *Id.* at 2.

[137] 85 FR at 58189.

[138] *Id.* at 58178.

[139] *Id.*

[140] *Id.*

[141] ARM NPRM Comment at 3; SoundExchange NPRM Comment at 3.

[142] ARM NPRM Comment at 3; CISAC & BIEM NPRM Comment at 2.

[143] MLC *Ex Parte* Letter #11 at 5.

[144] *See id.* (noting ''the importance of flexibility in precisely how such information is provided online to ensure coherent displays and a quality user experience'').

[145] 17 U.S.C. 115(d)(3)(E)(ii)(IV)(bb), (iii)(I)(dd).

[146] RIAA Initial September NOI Comment at 2 (footnote omitted). Although the RIAA's initial September NOI comments suggested that the ERN feed included a field labeled sound recording copyright owner (SRCO), upon reply, it clarified that there is no such specific field. *See* A2IM & RIAA Reply September NOI Comment at 8 n.5.

[147] RIAA Initial September NOI Comment at 2.

potential for confusion stemming from a field labelled ''sound recording copyright owner'' in the public database being populated by information taken from the labels' ERN messages—for both the MLC (*i.e.,* the MLC could ''inadvertently misinterpret or misapply the SRCO data''), and users of the free, public database (*i.e.,* they could mistakenly assume that the so-called ''sound recording copyright owner'' information is authoritative with respect to ownership of the sound recording).[148] Relatedly, SoundExchange noted that it ''devotes substantial resources'' to tracking changes in sound recording rights ownership, suggesting that inclusion of a SRCO field ''creates a potential trap for the unwary.''[149] A2IM & RIAA and Sony suggested that three fields—DDEX Party Identifier (DPID), LabelName, and PLine—may provide indicia relevant to determining sound recording copyright ownership.[150]

In the April NOI, the Office sought public comment regarding which data should be displayed to satisfy the statutory requirement, including whether to require inclusion of multiple fields to lessen the perception that a single field contains definitive data regarding sound recording copyright ownership.[151] In response, ARM did not object ''to a regulation that requires the MLC to include [DDEX Party Identifier (DPID), LabelName, and PLine] in the Database, provided the fields are each labeled in a way that minimizes confusion and/or misunderstanding,'' as ''this will lessen the perception that a single field contains definitive data regarding sound recording copyright ownership information.''[152] For DPID, the Office understands that ARM does not object to including the DPID party's name, but does ''object to the numerical identifier being disclosed, as the list of assigned DPID numbers is not public and disclosing individual numbers (and/or the complete list of numbers) could have unintended consequences.''[153] The MLC ''ha[d] no issue with including LabelName and PLine information in the public database to the extent the MLC receives that information from the DMPs,'' but expressed concern about including DPID because it ''does not identify sound recording copyright owner, but rather, the sender and/or recipient of a DDEX-formatted message.''[154] The DLC stated that LabelName and Pline ''are adequate on their own,'' as DPID ''is not a highly valuable data field,'' and contended that the burden of converting DPID numerical codes into parties' names (to address ARM's concern about displaying the numerical identifier) outweighs any benefit of including DPID in the public database.[155] The Recording Academy, although acknowledging that ''DDEX ERN information is an important source of reliable and authoritative data about a sound recording,'' asserted that ''many of the fields serve a distinct purpose in the digital supply chain and do not satisfy the 'sound recording copyright owner' field required in the MLC database.''[156]

The proposed rule tentatively concluded that DPID does not have as strong a connection to the MLC's matching efforts or the mechanical licensing of musical works as the other fields identified as relevant to the statutory requirement to list a sound recording copyright owner. In light of this, and the commenters' concerns, the proposed rule did not require the MLC to include DPID in the public database. In case the MLC later chooses to include DPID in the public database, the proposed rule states that the DPID party's name may be displayed, but not the numerical identifier. In addition, because industry practice has not included a single data field to provide definitive data regarding sound recording copyright ownership, to satisfy the statute's requirement to include information regarding ''sound recording copyright owner,'' the proposed rule requires the MLC to include data for both LabelName and PLine in the public database, to the extent reasonably available.[157] In light of numerous comments expressing similar views, the Office tentatively concluded that inclusion of these two fields would adequately satisfy the statutory requirement by establishing an avenue for the MLC to include relevant data that is transmitted through the existing digital supply chain, and thus reasonably available for inclusion in the public database.[158]

Regarding labeling, the Office tentatively declined to regulate the precise names of these fields,[159] although the proposed rule precluded the MLC from labeling either the PLine or LabelName field ''sound recording copyright owner,'' and required the MLC to consider industry practices

[148] *Id.* at 3. Those concerns were echoed in *ex parte* meetings with individual record labels. *See* Universal Music Group (''UMG'') & RIAA *Ex Parte* Letter Dec. 9, 2019; Sony & RIAA *Ex Parte* Letter Dec. 9, 2019 at 1–2.

[149] SoundExchange Initial September NOI Comment at 11–12.

[150] Sony & RIAA *Ex Parte* Letter Dec. 9, 2019 at 2 (noting that ''DIY artists and aggregators serving that community'' may be most likely to populate the DPID field); A2IM & RIAA Reply September NOI Comment at 8–10. The LabelName represents the ''brand under which a Release is issued and marketed. A Label is a marketing identity (like a MusicPublisher's 'Imprint' in book publishing) and is not the same thing as the record company which controls it, even if it shares the same name. The control of a Label may move from one owner to another.'' Digital Data Exchange (''DDEX''), DDEX Data Dictionary, *http://service.ddex.net/dd/ERN411/dd/ddex_Label.html* (last visited Dec. 17, 2020). ''PLine'' is ''[a] composite element that identifies the year of first release of the Resource or Release followed by the name of the entity that owns the phonographic rights in the Resource or Release. . . . In the case of recordings that are owned by the artist or the artist's heirs but are licensed to one of [their] member companies, the PLine field typically lists those individuals' names, even though they generally are not actively involved in commercializing those recordings.'' A2IM & RIAA Reply September NOI Comment at 9 (citing Music Business Association and quoting DDEX, *DDEX Release Notification Standard Starter Guide for Implementation* 28 (July 2016), *https://kb.ddex.net/download/attachments/327717/MusicMetadata_DDEX_V1.pdf*).

[151] 85 FR at 22577.

[152] ARM April NOI Comment at 4. A2IM & RIAA initially stated that ''[b]ecause the PLine party is, in many cases, an individual who would not want to be listed in a public database and is often not the party who commercializes the recording, the regulations should prohibit that party name from appearing in the public-facing database.'' A2IM & RIAA Reply September NOI Comment at 9. The Office understands that ARM, of which A2IM and RIAA are members, does not object to PLine being displayed in the public musical works database.

[153] ARM NPRM Comment at 10, U.S. Copyright Office Dkt. No. 2020–5, available at *https://beta.regulations.gov/document/COLC-2020-0005-0001.*

[154] MLC April NOI Comment at 13. *See also* Digital Data Exchange (''DDEX'') NPRM Comment at 2, U.S. Copyright Office Dkt. No. 2020–5, available at *https://beta.regulations.gov/document/COLC-2020-0005-0001* (''[T]he DPID, although a unique identifier and in relevant instances an identifier of ''record companies'', does not identify sound recording copyright owners. It only identifies the sender and recipient of a DDEX formatted message and, in certain circumstances, the party that the message is being sent on behalf of.'').

[155] DLC Letter July 13, 2020 at 10 (stating ''it would require at least a substantial effort for some services'' (around one year of development), ''and would be an impracticable burden for some others'').

[156] Recording Academy April NOI Comment at 3. *Compare* ARM April NOI Comment at 5 (stating ''there is no single field in the ERN that can simultaneously tell the public who owns a work, who distributes the work *and* who controls the right to license the work'').

[157] As the MMA also requires ''sound recording copyright owner'' to be reported by DMPs to the mechanical licensing collective in monthly reports of usage, the Office has separately issued an interim rule regarding which information should be included in such reports to satisfy this requirement. Because industry practice has not included a single data field to provide definitive data regarding sound recording copyright ownership, that rule proposes that DMPs can satisfy this obligation by reporting information in the following fields: LabelName and PLine. *See* 37 CFR 210.27(e)(4).

[158] 85 FR at 58180.

[159] *See* ARM April NOI Comment at 5 (suggesting that ''LabelName'' be described as ''U.S. Releasing Party (if available),'' and that ''PLine'' be described as ''Sound Recording Owner of Record (who may not be the party that commercializes the recording; note that this party may change over time)'').

when labeling fields in the public database to reduce the likelihood of user confusion.[160] The Office also expressed appreciation that the MLC intends to ''make available in the database a glossary or key, which would include field descriptors.'' [161] The Office specifically encouraged ''the MLC to consider ARM's labeling suggestions with respect to the PLine and LabelName fields.'' [162] The Office strongly disagreed with the MLC's notion that ''the names or labels assigned to these fields in the public database is not ultimately the MLC's decision,'' and that ''it is ultimately at DDEX's discretion.'' [163] The Office explained that ''[w]hile DDEX 'standardizes the formats in which information is represented in messages and the method by which the messages are exchanged' 'along the digital music value chain' (*e.g.,* between digital music providers and the MLC), DDEX does not control the public database or how information is displayed and/or labeled in the public database.'' [164]

The Office received no comments in opposition to this aspect of the proposed rule. In response, ARM agreed with the Office's decision to include LabelName and PLine in the public database, prohibit the MLC from labeling either field ''sound recording copyright owner,'' and require that the MLC ''consider industry practices when labeling fields in the public database to reduce the likelihood of user confusion.'' [165] ARM also reiterated its labeling suggestions for the PLine and LabelName fields.[166] Similarly, SoundExchange ''welcome[d]'' the Office's approach of prohibiting the MLC from identifying either the PLine or LabelName field as the ''Sound Recording Copyright Owner,'' and directing the MLC to consider industry practices when labeling fields in the public database to reduce the likelihood of user confusion.[167]

Given the overwhelming support expressed in the comments, and for all of the reasons given in the NPRM, the interim rule adopts this aspect of the proposed rule without modification.

2. Disclaimer

Relatedly, the Office received persuasive comments requesting that the MLC be required to include a conspicuous disclaimer regarding sound recording copyright ownership information in its database. ARM, A2IM & RIAA, CISAC & BIEM, Recording Academy, and SoundExchange agreed that the public database should display such a disclaimer.[168] And the MLC itself has agreed to display a disclaimer that its database should not be considered an authoritative source for sound recording ownership information.[169]

The proposed rule would require the MLC to include in the public-facing version of the musical works database a conspicuous disclaimer that states that the database is not an authoritative source for sound recording ownership information, and explains the labeling of information in the database related to sound recording copyright owner, including the ''LabelName'' and ''PLine'' fields. The proposed rule would not require that the disclaimer include a link to SoundExchange's ISRC Search database.

The proposed rule was largely supported, and is now adopted without modification.[170] Because the MLC intends to populate the public musical works database with sound recording information from reports of usage (discussed below), ARM did suggest that the disclaimer ''explain that the sound recording data displayed in the database has been provided by users of the sound recordings, not by the owners or distributors of the sound recordings,'' and that ''MLC require users to click on the disclaimer to acknowledge that they have seen and accepted it.'' [171] SoundExchange agrees, noting that it is ''critically important the MLC's disclaimer concerning sound recording information be clear and prominent, and perhaps linked to a more detailed explanation of the issue, because this design decision carries a significant risk of confusing the public, which needs to understand what the MLC Database is and what it is not.'' [172] For its part, the MLC believes having the disclaimer state that sound recording information has been provided by users of the sound recordings ''may be confusing to the public, as sound recording information reported by DMPs will largely be the data provided by the respective record labels.'' [173]

Given that the proposed rule requires the MLC to include a conspicuous disclaimer that states that the database is not an authoritative source for sound recording ownership information, and explain the labeling of information related to sound recording copyright owner, including the ''LabelName'' and ''PLine'' fields, the Office adopts this aspect of the proposed rule without modification. The Office endorses SoundExchange's suggestion that the MLC consider providing a more detailed explanation of the issue, and also notes that the rule does not prohibit the MLC from linking to SoundExchange's ISRC Search database.

3. Populating and Deduplication of Sound Recording Information in the Public Musical Works Database

The statute requires the MLC to ''establish and maintain a database containing information relating to musical works (and shares of such works) and, to the extent known, . . . the sound recordings in which the musical works are embodied.'' [174] As noted above, for both matched and unmatched musical works, the public database must include, to the extent reasonably available to the MLC, ''identifying information for sound recordings in which the musical work is embodied.'' [175]

As discussed in the NPRM, throughout this and parallel rulemakings, ''commenters have expressed concern about the MLC using non-authoritative sources to populate the sound recording information in the public database.'' [176] Some commenters, including several representing recorded music interests, maintained that sound recording data in the public database should be taken from copyright owners or an authoritative source (*e.g.,* SoundExchange) rather than DMPs.[177]

[160] The same limitation applies if the MLC elects to include DPID information.

[161] 85 FR at 58180 (quoting MLC *Ex Parte* Letter #7 at 4).

[162] *Id.*

[163] *Id.* (quoting MLC *Ex Parte* Letter #7 at 4).

[164] *Id.* (quoting DDEX NPRM Comment at 1, U.S. Copyright Office Dkt. No. 2020–5, available at *https://beta.regulations.gov/document/COLC-2020-0005-0001*).

[165] ARM NPRM Comment at 3–4.

[166] *Id.* at 4.

[167] SoundExchange NPRM Comment at 4.

[168] A2IM & RIAA Reply September NOI Comment at 9; CISAC & BIEM Reply September NOI Comment at 8; SoundExchange Initial September NOI Comment at 12; RIAA Initial September NOI Comment at 10; ARM April NOI Comment at 6–7; Recording Academy April NOI Comment at 3–4.

[169] MLC Reply September NOI Comment at 36–37; MLC April NOI Comment at 13.

[170] *See* ARM NPRM Comment at 4; MLC NPRM Comment at 4; Recording Academy NPRM Comment at 3; SoundExchange NPRM Comment at 5–6.

[171] ARM NPRM Comment at 4.

[172] SoundExchange NPRM Comment at 6.

[173] MLC *Ex Parte* Letter #11 at 5.

[174] 17 U.S.C. 115(d)(3)(E)(i).

[175] *Id.* at 115(d)(3)(E)(ii)(IV)(bb), (iii)(I)(dd).

[176] 85 FR at 58180.

[177] *See id.* at 58180–81; ARM *Ex Parte* Letter July 27, 2020 at 1–2; ARM April NOI Comment at 3; ARM NPRM Comment at 6, U.S. Copyright Office Dkt. No. 2020–5, available at *https://beta.regulations.gov/document/COLC-2020-0005-0001;* Jessop Initial September NOI Comment at 3; SoundExchange Initial September NOI Comment at 12; DLC Reply September NOI Comment at 10; DLC *Ex Parte* Letter #3 at 2. During this proceeding, RIAA designated SoundExchange as the authoritative source of ISRC data in the United States. RIAA, *RIAA Designates SoundExchange as*

Though raised in the context of data collection by DMPs, as opposed to populating the public database, the DLC supported the MLC obtaining sound recording information from a single, authoritative source, such as SoundExchange, because ''[w]ith record labels acting as the primary and authoritative source for their own sound recording metadata, the MLC could then rely on only a single (or limited number of) metadata field(s) from licensees' monthly reports of usage to look up the sound recordings in the MLC database (*e.g.,* an ISRC or digital music provider's unique sound recording identifier that would remain constant across all usage reporting).'' [178] The DLC further maintained that ''the MLC's suggestion to obtain disparate sound recording data from every digital music provider and significant non-blanket licensee is far less efficient than obtaining it from a single source like SoundExchange.'' [179]

By contrast, the MLC stated that while it intends to use SoundExchange as one source of data about sound recordings, it intends to primarily rely on data received from DMPs to populate sound recording information in the database.[180] The MLC added that receiving unaltered sound recording data from DMPs, as it sought to have required in a separate proceeding, would ''both improve the MLC's ability to match musical works to sound recordings'' and ''better allow the MLC to 'roll up' sound recording data under entries that are more likely to reflect more 'definitive' versions of that sound recording data.'' [181]

The NPRM invited the MLC to reassess how it will populate sound recording information in the public database, noting commenters' concerns about using non-authoritative sources, and that adopting a requirement for DMPs to report unaltered sound recording data fields need not drive display considerations with respect to the public database.[182] The Office stated that ''the MMA anticipates a general reliability of the sound recording information appearing in the public database,'' [183] and that ''[w]hile it may be true that reports of usage are the better indicators of which sound recordings were actually streamed, the public database is not necessarily meant to serve that same function.'' [184] The statute requires the public database to contain information relating to ''the sound recordings in which the musical works are embodied,'' which can reasonably be read as information to *identify* the sound recordings in which musical works are embodied, regardless of whether they were streamed pursuant to disparate attendant metadata or not.[185] In the NPRM, the Office also noted the potential that by passing through inaccurate or confusing sound recording information received by DMPs in the database, such inaccuracies or confusion in the public database could translate into inaccuracies in royalty statements to musical work copyright owners.[186] Further, because the statute requires the MLC to grant free bulk-access to digital music providers, such access ''seems less meaningful if [it] were to mean regurgitating the same information from reports of usage back to digital music providers.'' [187] While the proposed regulatory language did not address the manner in which the MLC populates sound recording information in the database or the deduplication of sound recording records (*i.e.,* eliminating duplicate or redundant sound recording records), the Office invited further comment on these issues.[188]

In response, though commenters did not express additional concerns about the MLC's plans to populate sound recording information in the database, SoundExchange did note that ''the MLC's reluctance to include and organize its data around authoritative sound recording information . . . represents a missed opportunity to develop a resource with authoritative linkages between sound recordings and musical works that would be of significantly greater value for participants in the ecosystem.'' [189] The MLC stated that because the database is ''musical works-driven,'' ''it should be populated in such a way to assist owners of musical works in identifying uses of their works by DMPs so they can be paid royalties to which they are entitled.'' [190] The MLC maintains that ''normalizing'' sound recording data ''may be useful to sound recording copyright owners, but that neither serves the primary purpose of the MMA nor necessarily helps musical work copyright owners.'' [191] Rather, the MLC asserts, ''there could be hundreds of different recorded versions of a popular musical work . . . , including cover versions, live versions, and remastered versions,'' and the musical work copyright owner ''wants to see in the database all of those hundreds of different recordings associated with its musical work when it searches for that musical work, and it also wants to see all of the uses by the different DMPs of each of those different recordings because it is to be paid for each such use.'' [192] The MLC added that, given the requirement for DMPs to provide data unaltered from what they receive from labels, ''that means that the data the MLC receives from the DMPs will itself be 'authoritative' because it comes from the labels.'' [193]

The Office appreciates comments from the various parties on these issues. The interim rule adopts the proposed flexible approach for the MLC to determine the best way to populate the database and display sound recording information. The Office notes, however, that achieving the purpose of the database (*i.e.,* reducing the number of unmatched musical works by accurately identifying musical work copyright owners so they can be paid what they are owed by DMPs operating under the section 115 statutory license) requires accurate information to be presented to musical work copyright owners (and the public) in a user-friendly and meaningful manner. Should a copyright owner be confronted with thousands of entries of the identical sound recording in the database (as opposed to numerous, but different, sound recordings embodying the musical work) that are not linked or associated, and each entry represents a single *use* of a sound recording instead of its *identity,* the Office questions the meaningfulness of such information. The Office is thus encouraged that MLC will work to use unaltered data ''after it begins to receive it in September 2021'' ''as 'keys' to 'roll up' into one set of

Authoritative Source of ISRC Data in the United States (July 22, 2020), *https://www.riaa.com/riaa-designates-soundexchange-as-authoritative-source-of-isrc-data-in-the-united-states/.*

[178] DLC Reply September NOI Comment at 10.

[179] DLC *Ex Parte* Letter #3 at 2.

[180] MLC Initial September NOI Comment at 24.

[181] MLC *Ex Parte* Letter #7 at 2.

[182] 85 FR at 58181.

[183] *Id.; see* SoundExchange Initial September NOI Comment at 5 (''[T]he success of the MLC Database . . . will depend on it having sufficiently comprehensive data of sufficiently high quality that it will be respected and used throughout the industry.''); RIAA Initial September NOI Comment at 11 (record labels ''anticipate making frequent use of the MLC database'').

[184] 85 FR at 58181; *see* 17 U.S.C. 115(d)(3)(E)(i), (ii)(IV)(bb), (iii)(I)(dd). As RIAA explains, ''member labels vary the metadata they send the different DMPs in order to meet the services' idiosyncratic display requirements,'' which if passed to the MLC even in unaltered form, would result in the MLC ''still receiv[ing] conflicting data that it will have to spend time and resources reconciling.'' A2IM & RIAA Reply September NOI Comment at 2.

[185] 85 FR at 58181 (citing 17 U.S.C. 115(d)(3)(E)(i), (ii)(IV)(bb), (iii)(I)(dd)).

[186] *Id.* at 58182.

[187] *Id.*

[188] *Id.*

[189] SoundExchange NPRM Comment at 7.

[190] MLC NPRM Comment at 4.

[191] *Id.* at 4–5.

[192] *Id.* at 5.

[193] *Id.*

metadata different sound recording metadata reported by DMPs in usage reports for an identical sound recording.'' [194] If, after the MLC starts receiving unaltered data from DMPs, it proves appropriate to develop more specific regulatory guidance, the Office is amenable to reconsideration. As even the MLC has acknowledged, sound recording information may be helpful for matching purposes,[195] so its inclusion does not serve only sound recording owners.

D. Access to Information in the Public Musical Works Database

As noted above, the statute directs the Office to ''establish requirements by regulations to ensure the usability, interoperability, and usage restrictions of the [public] musical works database.'' [196] The database must ''be made available to members of the public in a searchable, online format, free of charge.'' [197] The mechanical licensing collective must make the data available ''in a bulk, machine-readable format, through a widely available software application,'' to digital music providers operating under valid notices of license, compliant significant nonblanket licensees, authorized vendors of such digital music providers or significant nonblanket licensees, and the Office, free of charge, and to ''[a]ny other person or entity for a fee not to exceed the marginal cost to the mechanical licensing collective of providing the database to such person or entity.'' [198] The legislative history stresses the importance of the database and making it available to ''the public without charge, with the exception of recovery of the marginal cost of providing access in bulk to the public.'' [199] It adds that ''[i]ndividual lookups of works shall be free although the collective may implement reasonable steps to block efforts to bypass the marginal cost recovery for bulk access if it appears that one or more entities are attempting to download the database in bulk through repeated queries.'' [200] And ''there shall be no requirement that a database user must register or otherwise turn over personal information in order to obtain the free access required by the legislation.'' [201]

1. Method of Access

The proposed rule required the MLC to ''make the musical works database available to members of the public in a searchable, real-time, online format, free of charge.'' [202] The Office agreed that the MLC should—especially initially, due to its start-up nature—have some discretion regarding the precise format in which it provides bulk access to the public database.[203] Given, however, ''the overwhelming desire for the MLC to provide bulk access through APIs from a broad swatch of organizations representing various corners of the music ecosystem,'' the Office proposed that the MLC must begin providing bulk access to the public database through APIs starting July 1, 2021.[204]

The proposed rule was applauded by commenters.[205] The MLC stated its intention to provide bulk access through an API as proposed, but raised concerns regarding implementation by July 1, 2021.[206] It noted in particular that it ''will not be able to commence the work to develop the API until after it has begun issuing royalty statements in the Spring of 2021'' and requested that the deadline be extended to December 31, 2021 ''to ensure sufficient development time.'' [207] The MLC asks for the extension ''to allow time to conduct proper consultation with stakeholders throughout the industry regarding their requirements, gather their feedback, and then design, test and implement, so as to provide the most useful API,'' but did indicate that ''it will aim to implement API access sooner in 2021 where that is reasonably practical.'' [208] In the meantime, the MLC will be ''providing access through Secure File Transfer Protocol (SFTP) on a weekly basis,'' which is ''expected to be available by January 2021.'' [209] Because the proposed rule requires the MLC to provide bulk access in a ''real-time'' format, the MLC asks that the rule be adjusted to delete the words ''real-time.'' [210]

After carefully considering this issue, the Office agrees that having time to seek industry feedback while developing an API increases the chances of developing one that meets the needs of industry participants. Accordingly, the interim rule provides the MLC until December 31, 2021 to implement bulk access through an API. The Office declines, however, to remove the words ''real-time'' from the rule. The Office raised the issue of ''real-time'' access in response to the DLC's initial proposal that bulk access be provided through a weekly file, and multiple commenters objected, asserting that real-time access to the public database is necessary to meet the goals of the statute and avoid industry reliance upon stale data.[211] Given the regulation, the Office thus encourages the MLC to consider offering bulk access via SFTP on a more frequent basis until the API is available.

Next, MAC requests that the regulations require the MLC to provide songwriters with ''access to the same level of certain data as . . . publishers, digital music providers, labels, etc., free of charge.'' [212] Specifically, MAC proposed that any songwriter who has authored or co-authored any musical work should have access ''to the following information at the same time it is provided to the publisher or administrator of record'': (1) The amount of revenue each DSP has paid to the MLC for the work, (2) the amount of revenue the MLC has paid to the respective publisher or administrator, and (3) the total stream count of each work per DSP.[213]

When asked about songwriter access, the MLC made some overtures towards ensuring songwriter access for purposes of correcting data. The MLC confirmed that ''the public musical works database will be viewable by the general public

[194] MLC NPRM Comment at 6. The MLC asked that it be able to defer development on this project until at least October 2021, after it has started receiving and can review unaltered data, to provide it with time to complete development of the database's core functionality. *Id.*

[195] *See* MLC Letter July 13, 2020 at 7 (stating ''[a]ll of the metadata fields proposed in § 210.27(e)(1) will be used as part of the MLC's matching efforts''); *see also* 85 FR 22518, 22541 (Apr. 22, 2020) (sound recording information fields proposed in § 210.27(e)(1)).

[196] 17 U.S.C. 115(d)(3)(E)(vi).

[197] *Id.* at 115(d)(3)(E)(v).

[198] *Id.*

[199] H.R. Rep. No. 115–651, at 8; S. Rep. No. 115–339, at 8; Conf. Rep. at 7.

[200] H.R. Rep. No. 115–651, at 8; S. Rep. No. 115–339, at 8; Conf. Rep. at 7.

[201] H.R. Rep. No. 115–651, at 8; S. Rep. No. 115–339, at 8; Conf. Rep. at 7.

[202] 85 FR at 58189; *see* Muzzey NPRM Comment at 1 (''It is crucial that the MLC database be searchable and completely public-facing . . .''). The MLC has advised that ''[i]n the initial version [of the database], the searchable fields are planned to be: (a) Work Title; (b) Work MLC Song Code; (c) ISWC; (d) Writer Name; (e) Writer IPI name number; (f) Publisher Name; (g) Publisher IPI name number; and (h) MLC Publisher Number,'' and that ''additional searchable fields may be added in the future.'' MLC *Ex Parte* Letter #11 at 3.

[203] 85 FR at 58183.

[204] *Id.* at 58184.

[205] Recording Academy NPRM Comment at 3; SONA NPRM Comment at 7–8; SoundExchange NPRM Comment at 5; ARM NPRM Comment at 4.

[206] MLC NPRM Comment at 7.

[207] *Id.*

[208] MLC *Ex Parte* Letter #11 at 2.

[209] *Id.*

[210] *Id.*

[211] 85 FR at 58182–83 (citing A2IM & RIAA Reply September NOI Comment at 7, FMC Reply September NOI Comment at 3, MAC Initial September NOI Comment at 2, Recording Academy Initial September NOI Comment at 4, SoundExchange Reply September NOI Comment at 9).

[212] MAC NPRM Comment at 3.

[213] *Id.* at 4. The Office notes that to the extent such information is provided in royalty statements to musical work copyright owners from the MLC, as noted above, there are no restrictions on the use of those statements by copyright owners.

without any need to register for the MLC Portal,'' as the portal ''is the platform for copyright owners and administrators of musical works used in covered activities, where they can register their works, claim their shares and provide the necessary information so as to receive royalty distributions.'' [214] The MLC also noted that ''everyone, including songwriters, may participate in the DQI.'' [215] Finally, the MLC said that it intends ''to develop user-friendly methods for songwriters to access information about their musical works and to enable songwriters to notify their administrators of a possible issue with a work's data or registration.'' [216]

Providing songwriters with the ability to review and correct information about their works is important, but the Office also believes that transparency militates in favor of affording songwriters (including those who are not self-published) easier access to information about use of their works. The Office appreciates the MLC's commitment to developing user-friendly methods for songwriters, specifically, to access information about their works. The Office further notes that nothing prevents the MLC from working with publishers and administrators to offer non-self-administered songwriters permissions-based access to view stream count and revenue information for their musical works, and encourages the MLC to explore such options.[217]

2. Marginal Cost

The Office proposed to allow the MLC to determine the best pricing information in light of its operations, so long as the fee does not exceed the marginal cost to the mechanical licensing collective of providing the database to such person or entity, which shall not be unreasonable.[218] In rejecting comments suggesting that the cost of gathering data should be factored into these costs, the NPRM stated ''it [was] difficult for the Office to see how Congress intended third parties to offset the larger cost of the collective acquiring the data and aggregating, verifying, deduping and resolving conflicts in the data.'' [219] The Office also noted that the legislative history emphasizes the importance of accessibility to the public database, and that requiring third parties to pay more than the ''marginal cost'' could create commercial disadvantages that the MMA sought to eliminate.[220]

In response, an anonymous commenter stated that the term ''marginal cost'' is vague and should be defined ''by either establishing a monetary limit or a method for the mechanical licensing collective to determine the amount.'' [221] The MLC expressed concern that the phrase ''which shall not be unreasonable'' ''is inconsistent with the requirement that access be provided at 'marginal cost' because, if access is provided at 'marginal cost,' such cost can never be 'unreasonable,'" and that ''the qualifier opens the door to a third party argument that what is, in fact, marginal cost is nevertheless 'unreasonable' cost.'' [222] The MLC does not believe ''marginal cost'' ''authoriz[es] fees to recoup the overhead costs of design and maintenance of the SFTP or API,'' but rather would ''be set at an amount estimated to recoup the actual cost of provision of the bulk data to the particular person or entity requesting it.'' [223] Currently, it estimates the SFTP bulk access to cost approximately $100 ''to cover one-time setup and a single copy of the database, and a monthly standard fee of $25 which offers access to all weekly copies'' (though ''these expected fees may change, as [the MLC] has no precedent for this access and [associated] costs'').[224] The MLC also confirmed that ''it intends to charge the same fee to all members of the public (who are not entitled to free access) for SFTP access,'' though ''it expects API access would be under a different fee structure and amounts than SFTP access, since the marginal costs will be different.'' [225]

After considering the MLC's comments, including its stated plans, the Office agrees that the phrase ''which shall not be unreasonable'' can be deleted from the rule.[226] This aspect of the proposed rule is otherwise adopted without modification.

3. Abuse

The legislative history states that in cases of efforts by third parties to bypass the marginal cost recovery for bulk access (*i.e.,* abuse), the MLC ''may implement reasonable steps to block efforts to bypass the marginal cost recovery for bulk access if it appears that one or more entities are attempting to download the database in bulk through repeated queries.'' [227] The MLC and DLC suggested providing the mechanical licensing collective discretion to block third parties from bulk access to the public database after attempts to bypass marginal cost recovery.[228]

In light of these comments, the NPRM proposed that the MLC shall establish appropriate terms of use or other policies governing use of the database that allows it to suspend access to any individual or entity that appears, in the collective's reasonable determination, to be attempting to bypass the MLC's right to charge a fee to recover its marginal costs for bulk access through repeated queries, or to otherwise be engaging in unlawful activity with respect to the database (including, without limitation, seeking to hack or unlawfully access confidential, non-public information contained in the database), or misappropriating or using information from the database for improper purposes. To ensure transparency regarding which persons or entities have had bulk database access suspended, the Office also proposed to require the mechanical licensing collective to identify such persons and entities in its annual report and explain the reason(s) for suspension.

[214] MLC *Ex Parte* Letter #11 at 5.

[215] *Id.*

[216] *Id.; see* SONA NPRM Comment at 3 (''[I]t is important that songwriters have access to data information available to music publishers and musical work administrators, such as the MLC's Data Quality Initiative ('DQI').'').

[217] The Office has long rejected the suggestion to place a confidentiality requirement on copyright owners receiving statements of account under the section 115 license due to the inclusion of ''competitively sensitive'' information (*e.g.,* licensees' overall revenues, royalty payments to record companies and performance rights organizations, and overall usage). 79 FR 56190, 56206 (Sept. 18, 2014). Rather, ''once the statements of account have been delivered to the copyright owners, there should be no restrictions on the copyright owners' ability to use the statements or disclose their contents.'' *Id.* In a recent parallel rulemaking, the Office again declined to adopt confidentiality restrictions on copyright owners receiving statements of account. 85 FR at 22561.

[218] 85 FR at 58184.

[219] *Id.*

[220] *Id.; see* Conf. Rep. at 7 (''Given the importance of this database, the legislation makes clear that it shall be made available to the Copyright Office and the public without charge, with the exception of recovery of the marginal cost of providing access in bulk to the public.'').

[221] Anonymous NPRM Comment at 1.

[222] MLC NPRM Comment at 8.

[223] MLC *Ex Parte* Letter #11 at 3.

[224] *Id.*

[225] *Id.*

[226] CISAC & BIEM ''strongly encourage the Office to . . . include CMOs as significant copyright owners among the entities which will have access to the Database and UP files in bulk format free of charge, as is currently the proposed rule for 'significant licensees.' '' CISAC & BIEM NPRM Comment at 3. The Office notes that the regulations mirror the statute in granting bulk access free of charge to those entities enumerated in the statute (*i.e.,* digital music providers, significant nonblanket licensees in compliance with their obligations under 17 U.S.C. 115(d)(6), and the Office). *See* 17 U.S.C. 115(d)(3)(E)(v)(I)–(IV).

[227] H.R. Rep. No. 115–651, at 8; S. Rep. No. 115–339, at 8–9; Conf. Rep. at 7.

[228] MLC Initial September NOI Comment at 25; MLC April NOI Comment at 15; DLC Reply September NOI Comment Add. at A–17; DLC April NOI Comment at 5.

In response, while ARM ''wholeheartedly support[s] giving the MLC the authority to suspend database access for individuals or entities that appear to be engaging in unlawful activity,'' it expresses concern about terms of use or restrictions ''inadvertently disadvantag[ing] bona fide users of the database or creat[ing] unintended barriers to legitimate uses of the data,'' and encouraged the Office to consider an appeals process for those whose access the MLC seeks to suspend or restrict, or ''some sort of graduated sanctions regime, whereby repeat offenders are subjected to increasingly stringent penalties while inadvertent, or one-time, offenders are subjected to less stringent penalties.'' [229] On the other hand, the MLC ''strongly opposes any change to the rule that would prevent the MLC from restricting access to users who have violated the terms of use, which could impede the MLC's ability to prevent fraud and abuse.'' [230] The MLC stated ''that it will have terms of use for the website, the Portal, and the bulk access to the musical works database,'' noting that the ''current version of the website Terms of Use is accessible at *https://www.themlc.com/terms-use.*'' [231]

After considering this issue, the Office has largely adopted this aspect of the proposed rule without modification. The Office agrees that the MLC should have flexibility to block third parties where persons have engaged in unlawful activity with respect to the database and that in the cases of fraud the MLC may need to take immediate action. The Office encourages the MLC, however, in developing its terms of use for the database, to create an appeals process for those who have had access suspended to reduce the likelihood of good-faith users being denied access. Should the MLC fail to create an appeals process and the Office learns of individuals or entities being unreasonably denied access to the database, the Office is willing to consider whether further regulatory action on this issue is warranted.

4. Restrictions on Use

The MMA directs the Office to issue regulations regarding ''usage restrictions'' with respect to the database.[232] Comments have been mixed in response to the Office's solicitations on this issue, generally centering around whether the Office should specify conditions the MLC should or should not include in its database terms of use.

The DLC argues that ''licensees should be able use the data they receive from the MLC for any legal purpose,'' [233] and that ''abusive access can be adequately addressed by empowering the MLC to block efforts to bypass marginal cost recovery.'' [234] Music Reports agrees that data in the public database should be available for any legal use.[235] By contrast, CISAC & BIEM seek ''regulations defining strict terms and conditions, including prohibition for DMPs to use data for purposes other than processing uses and managing licenses and collaborating with the MLC in data collection,'' and generally ''prohibiting commercial uses and allowing exclusively lookup functions.'' [236] FMC is ''inclined to want to see some reasonable terms and conditions'' regarding use of the public database, and suggests that ''[i]t's entirely appropriate for the Office to offer a floor.'' [237]

The MLC agrees that ''there should be some reasonable limitation on the use of the information in the MLC database to ensure that it is not misappropriated for improper purposes,'' and intends to ''include such limitation in its terms of use in the database.'' [238] To avoid abuse by bad actors, the MLC ''does not intend to include in the public database the types of information that have traditionally been considered PII, such as Social Security Number (SSN), date of birth (DOB), and home address or personal email (to the extent those are not provided as the contact information required under 17 U.S.C. 115(d)(3)(E)(ii)(III)),'' and ''further intends to protect other types of PII.'' [239] But the MLC also asks that it ''be afforded the flexibility to disclose information not specifically identified by statute that would still be useful for the database but would not have serious privacy or identity theft risks to individuals or entities.'' [240]

As noted, the Office proposed requiring the MLC to establish appropriate terms of use or other policies governing use of the database that allow it to suspend access to any individual or entity that appears, in the MLC's reasonable determination, to be engaging in unlawful activity with respect to the database (including, without limitation, seeking to hack or unlawfully access confidential, non-public information contained in the database) or misappropriating or using information from the database for improper purposes. The MLC must identify any persons and entities in its annual report that have had database access suspended and explain the reason(s) for such suspension. In issuing the proposed rule, the Office also noted that ''database terms of use should not be overly broad or impose unnecessary restrictions upon good faith users.'' [241]

The MLC states ''that it will have terms of use for the website, the Portal, and the bulk access to the musical works database,'' and that the ''current version of the website Terms of Use is accessible at *https://www.themlc.com/terms-use.*'' [242] In reviewing the MLC's terms of use for its website, the Office notes that multiple provisions would not be appropriate to apply to the public musical works database, and so the Office directs the MLC to develop separate terms of use for the database and make them publicly available. For example, the terms of use for the MLC's website states that that a user may ''not download, reproduce, redistribute, retransmit, publish, resell, distribute, publicly display or otherwise use or exploit any portion of the website in any medium without The MLC's prior written authorization,'' and that ''any use . . . of any of The MLC Materials and website other than for [ ] personal use is strictly prohibited.'' [243] In addition, the website's terms of use state that ''[t]he website, including all content . . . are owned and/or licensed by The MLC and are legally protected.'' [244] Use of information from the musical works database for commercial purposes would not be misappropriating or using that information for an improper purpose, and the MLC and its vendors do not own the data in the musical

[229] ARM NPRM Comment at 5.

[230] MLC *Ex Parte* Letter #11 at 5.

[231] *Id.*

[232] 17 U.S.C. 115(d)(3)(E)(vi).

[233] DLC Initial September NOI Comment at 21.

[234] DLC April NOI Comment at 5.

[235] Music Reports April NOI Comment at 7.

[236] CISAC & BIEM NPRM Comment at 4; *see* CISAC & BIEM Initial September NOI Comment at 4; CISAC & BIEM April NOI Comment at 3.

[237] FMC April NOI Comment at 3.

[238] MLC April NOI Comment at 15; *see* MLC Reply September NOI Comment at 37.

[239] MLC April NOI Comment at 16. CISAC & BIEM contend that ''the Regulations [should] include clear language on the MLC's full compliance with data protection laws, and in particular with the European General Data Protection Regulation, as the MLC will process personal data of EU creators.'' CISAC & BIEM NPRM Comment 3. As noted by the Office in the September NOI, the MLC has ''committed to establishing an information security management system that is certified with ISO/IEC 27001 and meets the EU General Data Protection Regulation requirements, and other applicable laws.'' 84 FR at 49972; *see* Proposal of Mechanical Licensing Collective, Inc. at 50, U.S. Copyright Office Dkt. No. 2018–11.

[240] MLC April NOI Comment at 16 n.9.

[241] 85 FR at 58186.

[242] MLC *Ex Parte* Letter #11 at 5.

[243] The MLC, Terms of Use, *https://www.themlc.com/terms-use* (last visited Dec. 18, 2020).

[244] *Id.*

works database. Accordingly, while the Office is adopting its proposed approach of providing the MLC flexibility to develop reasonable terms of use, the interim rule clarifies the Office's expectation that the MLC's terms of use or other policies governing use of the database must comply with the Office's regulations.

E. Transparency of MLC Operations; Annual Reporting

The legislative history and statute envision the MLC ''operat[ing] in a transparent and accountable manner'' [245] and ensuring that its ''policies and practices . . . are transparent and accountable.'' [246] The MLC has expressed its commitment to transparency, both by including transparency as one of its four key principles underpinning its operations on its current website,[247] and in repeated written comments to the Office.[248] The Office has noted that one main avenue for MLC transparency is through its annual report.[249] By statute, the MLC must publish an annual report ''[n]ot later than June 30 of each year commencing after the license availability date,'' setting forth information regarding: (1) Its operational and licensing practices; (2) how royalties are collected and distributed; (3) budgeting and expenditures; (4) the collective total costs for the preceding calendar year; (5) its projected annual budget; (6) aggregated royalty receipts and payments; (7) expenses that are more than ten percent of the annual budget; and (8) its efforts to locate and identify copyright owners of unmatched musical works (and shares of works).[250] The MLC must deliver a copy of the annual report to the Register of Copyrights and make this report publicly available.[251] The MLC itself has previously recognized that its annual report is one way in which it intends to ''promote transparency.'' [252] Although the phrase ''[n]ot later than June 30 of each year commencing after the license availability date'' could be read as requiring the first annual report to cover the first year of operations after the license availability date (*i.e.,* issued in June 2022 for year 2021), as discussed below, a number of reasons compel the Office to adjust the interim rule to require the MLC to issue a written public update in December 2021, albeit shortened, regarding its operations.

In response to overwhelming desire for increased transparency regarding the MLC's activities expressed by commenters, and the ability of the annual report to provide such transparency, the proposed rule required the MLC to disclose certain information in its annual report besides the statutorily-required categories of information.[253] In response to comments suggesting the creation of a ''feedback loop'' to receive complaints,[254] the Office noted that the statute already requires the mechanical licensing collective to ''identify a point of contact for publisher inquiries and complaints with timely redress.'' [255] The proposed rule emphasized this responsibility by codifying the requirement and expanding it to include a point of contact to receive complaints regarding the public musical works database and/or the collective's activities.[256] The name and contact information for the point of contact must be made prominently available on the MLC's website.[257] In addition, the Office noted that it ''always welcomes feedback relevant to its statutory duties or service,'' and that ''[m]embers of the public may communicate with the Office through the webform available *https://www.copyright.gov/help*'' for inquiries or comments with respect to the MLC or MMA.[258]

Commenters overall approved of the proposed rule.[259] The MLC ''generally agree[d] with the proposed rules as they concern annual reporting, and believes that the Office's additions to what is required in the statute . . . will aid in providing the transparency that the MMA envisions and that the MLC is committed to providing.'' [260] The DLC similarly voiced support, adding, ''[i]t will be critical, however, for the Office to enforce not just the bare letter of the regulations, but the spirit of full transparency that animates those regulations.'' [261] Two commenters commended the Office for requiring disclosure of any application of unclaimed royalties on an interim basis to defray current collective total costs, as permitted under the MMA, ''subject to future reimbursement of such royalties from future collections of the assessment.'' [262] MAC and the Recording Academy welcomed requirements to disclose the appointment and selection criteria of new board members,[263] and the Recording Academy also applauded disclosure requirements for average

[245] S. Rep. No. 115–339, at 7.

[246] 17 U.S.C. 115(d)(3)(D)(ix)(I)(aa).

[247] The MLC, Mission and Principles, *https://themlc.com/mission-and-principles* (last visited Dec. 18, 2020) (''The MLC will build trust by operating transparently. The MLC is governed by a board of songwriters and music publishers who will help ensure our work is conducted with integrity.''). *See also* The MLC, The MLC Process, *https://themlc.com/how-it-works* (last visited Dec. 18, 2020) (''The MLC is committed to transparency. The MLC will make data on unclaimed works and unmatched uses available to be searched by registered users of The MLC Portal and the public at large.'').

[248] *See, e.g.,* MLC Reply September NOI Comment at 42–43 (''The MLC is committed to transparency and submits that, while seeking to enact regulations is not an efficient or effective approach, the MLC will implement policies and procedures to ensure transparency.'').

[249] 85 FR at 58186; 85 FR at 22572.

[250] 17 U.S.C. 115(d)(3)(D)(vii)(I)(aa)–(hh); Conf. Rep. at 7.

[251] 17 U.S.C. 115(d)(3)(D)(vii)(I), (II).

[252] The MLC, Transparency, *https://themlc.com/faqs/categories/transparency* (last visited Sept. 1, 2020) (web page no longer available) (noting that the MLC will ''promote transparency'' by ''[p]roviding an annual report to the public and to the Copyright Office detailing the operations of The MLC, its licensing practices, collection and distribution of royalties, budget and cost information, its efforts to resolve unmatched royalties, and total royalties received and paid out'').

[253] 85 FR at 58187. This information included selection of board members, selection of new vendors, any application of unclaimed accrued royalties on an interim basis to defray MLC costs, average processing and distribution times for distributing royalties, and any suspension of access to an individual or entity attempting to bypass the MLC's right to charge a fee for bulk access to the public database. 85 FR at 58187.

[254] Castle April NOI Comment at 16 (contending the Office should create ''a complaint webform with someone to read the complaints as they come in as part of the Office's oversight role''); Lowery Reply September NOI Comment at 11 (stating ''regulations should provide for a feedback loop that songwriters can avail themselves of that the Copyright Office must take into account when determining its re-designation'').

[255] 85 FR at 58187–88 (quoting 17 U.S.C. 115(d)(3)(D)(ix)(I)(bb)).

[256] *Id.* at 58188.

[257] *Id. See* U.S. Copyright Office, Section 512 of title 17 159 (2020), *https://www.copyright.gov/policy/section512/section-512-full-report.pdf* (suggesting that Congress could thus ''modify the language of section 512(c)(2) to provide that the designated agent's information be not just 'on its website in a location accessible to the public,' but also 'prominently displayed' ''); 17 U.S.C. 512(c)(2).

[258] 85 FR at 58188.

[259] *See, e.g.,* MLC NRPM Comment at 8; DLC NRPM Comment at 1; Recording Academy NRPM Comment at 3–4.

[260] MLC NRPM Comment at 8.

[261] DLC NRPM Comment at 1.

[262] *See* Castle NRPM Comment at 17; Recording Academy NRPM Comment at 3–4; 17 U.S.C. 115(d)(7)(C).

[263] MAC NRPM Comment at 2; Recording Academy NRPM Comment at 3–4. MAC also made some suggestions regarding MLC Board membership, including songwriters receiving notifications when Board member vacancies become available, and having the MLC's website identify any vacant seat(s) and describing the application process. MAC NRPM Comment at 2–3. The MLC has advised that ''it posts information about such vacancies on its website and uses its many channels of outreach to push information about such vacancies to the industry.'' MLC *Ex Parte* Letter #11 at 6. The MLC also stated that ''it accepts through its website suggestions for candidates for board and advisory committee seats, to ensure that candidates may be considered for a seat when one becomes available,'' and that the ''suggestion form is available at[ ] *https://themlc.com/get-involved.*'' *Id.*

processing and distribution times for distributing royalties, stating it 'will promote accountability and hopefully give songwriters confidence in the new system.'' [264]

A number of commenters sought broader disclosure requirements regarding the MLC's vendors hired to help administer the statutory license, expressing concern about their potential commercial advantage. For example, FMC stated that ''Congress intended to encourage a healthy competitive marketplace for other kinds of licensing businesses and intermediaries,'' and so ''it's important that MLC's chosen vendors not be able to leverage their status with the MLC to advantage themselves in other business activities not covered under the MMA.'' [265] SoundExchange similarly expressed concern about potential commercial advantage of MLC vendors, noting that Congress ''intended to preserve a vibrant and competitive marketplace for intermediaries [besides the MLC] who provide other license administration services,'' and this intent would be frustrated ''[i]f the MLC's vendors were to receive an unfair advantage in the music licensing marketplace through means such as preferred access to digital music providers or referrals by the MLC for extrastatutory business opportunities in a manner not available to their competitors.'' [266] SoundExchange proposes requiring the MLC to disclose additional vendor information, including ''[a] description of all work performed by the existing vendors for the MLC in the previous year and the current year; [s]teps the MLC has taken and will take to ensure separation between the MLC and its vendors; and [s]teps the MLC has taken to ensure transferability of functions from one vendor to another, and an assessment of any risks to transferability that the MLC foresees.'' [267] The DLC expresses similar concern about MLC vendors ''gain[ing] a special competitive advantage in related marketplaces—such as the administration of voluntary licenses—merely by dint of their association with the collective responsible for licensing all mechanical rights in the United States.'' [268] Finally, MAC recommends that ''information regarding the selection of vendors should be made available prior to vendors being selected'' to provide opportunity for interested parties to weigh in on potential vendors.[269]

While not opposing general disclosure requirements relating to vendors, the MLC balks at disclosing ''any performance reviews'' of the MLC's vendors that are ''performing materially significant technology or operational services related to the [MLC's] matching and royalty accounting activities.'' [270] The MLC contends that ''performance reviews might include sensitive or confidential information, including about individuals who work for any such vendor,'' and requests that the rule instead ''permit the MLC to summarize or extract the key findings of any reviews, and to include such summaries or extracts in the annual report rather than the full performance reviews themselves.'' [271]

The Office appreciates the overwhelming desire from commenters to have the MLC's annual report include information about the performance and selection of its vendors. The Office accepts the MLC's representation that vendor performance reviews may include sensitive or confidential information. The interim rule thus retains the requirement that the MLC disclose the criteria used in deciding to select its vendors to perform materially significant technology or operational services, but adjusts the language so as to require summaries and key findings from any vendor performance reviews rather than the verbatim reviews. To address concerns of MLC vendors gaining an unfair competitive advantage by virtue of being MLC vendors, in a parallel rulemaking, the Office has proposed a rule prohibiting vendors of the MLC (as well as its agents, consultants, and independent contractors) from using confidential information for any purpose other than the ordinary course of their work for the MLC.[272] In addition, the interim rule in this proceeding clarifies that agents, consultants, vendors, and independent contractors of the MLC must pay the marginal cost to acquire bulk access to the information in the musical works database for purposes other than the ordinary course of their work for the MLC. Beyond the requirements codified in this interim rule, the Office encourages the MLC to consider the commenters' requests for additional disclosure, including information about soliciting and choosing vendors in advance of any vendor selection, and engaging in the highest level of transparency consistent with operational realities and protection of confidential information.[273]

Commenters recommended certain additional disclosures. CISAC & BIEM suggest requiring publication of the MLC Dispute Resolution Committee's rules and procedures,[274] as well as disclosure of the amount of unclaimed royalties received by the MLC [275] and any audits and their results of the MLC or blanket licensees.[276] SoundExchange proposes that the annual report ''include a certification by the MLC that it is in compliance with the statute's limitation that the collective may only administer blanket mechanical licenses and other mechanical licenses for digital distribution.'' [277] SGA & SCL express concern that the proposed rule did not reflect its request for the MLC annual report to include ''an independent report by the board's music creator representatives on their activities in support of songwriter and composer interests, the handling of conflict-related problems by the board and its various controlled committees, and the issues of conflict that remain to be addressed and resolved.'' [278] The DLC

[264] Recording Academy NRPM Comment at 4.

[265] FMC NRPM Comment at 2; *see also id.* (''The Office can require the MLC to disclose what it is doing to prevent any vendor from being too operationally enmeshed with the MLC that it either enjoys an unfair advantage through that relationship, or that it would be practically impossible for another vendor to step in.'').

[266] SoundExchange NRPM Comment at 8; *see also id.* (''[I]t is in the public's interest, including the interest of publishers, songwriters, and DMPs, to ensure that the operations of the MLC do not become so inextricably intertwined with its vendors that DMPs believe that they must turn to the MLC's vendors for extrastatutory licensing requirements or that it becomes difficult if not impossible for the MLC to switch vendors in the future.'').

[267] SoundExchange NRPM Comment at 9.

[268] DLC NPRM Comment at 2.

[269] MAC NRPM Comment at 3.

[270] MLC NRPM Comment at 9.

[271] *Id.*

[272] 85 FR at 22565. The definition of ''confidential information'' in the proposed rule would cover financial information disclosed to the mechanical licensing collective by copyright owners, including publishers. *Id.* at 22566–67.

[273] *See* The MLC, Mission and Principles, *https://themlc.com/mission-and-principles* (last visited Dec. 18, 2020) (''The MLC will build trust by operating transparently.'').

[274] CISAC & BIEM NPRM Comment at 4.

[275] *Id.* at 5

[276] Castle NRPM Comment at 21.

[277] SoundExchange NRPM Comment at 9.

[278] SGA & SCL NPRM Comment at 10; *see also* Castle NRPM Comment at 20.

SGA & SCL also suggests the MLC's bylaws ''indicate an enormous bias in favor of near-total control by the music publisher board majority over —among other things— the selection of songwriter members of the board's advisory committees, and the election of songwriter board members themselves.'' SGA & SCL NPRM Comment at 10. Under the MLC's existing bylaws, songwriter members of the MLC's board of directors are recommended for appointment by a vote of the ''Songwriter Directors of the Board'' and recommendations for MLC Board appointments ''shall be sent to the Register of Copyrights'' and are appointed ''[i]f the Register of Copyrights approves and the Librarian of Congress appoints . . .'' The MLC, The MLC Bylaws, *https://themlc.com/sites/default/files/2020-05/Bylaws%20of%20The%20MLC.pdf* (last visited Dec. 18, 2020).

In addition, SGA, SCL & Music Creators North America, Inc. (''MCNA'') ''formally petition and

suggests that the Office ''invit[e] comments on the MLC's annual reports, to get insight from a broad range of stakeholders both about whether the report fulfills the MLC's transparency obligations and whether it raises (or fails to raise) any issues related to the sound functioning of the mechanical licensing system.'' [279]

After carefully considering these comments, the Office concludes that some suggestions are already addressed by the statute, and some may not need to be addressed by regulation. For example, the statute already requires the MLC to submit to periodic audits, which must be made publicly available.[280] Likewise, the MLC's database will provide insight into the amount of unmatched usages reported to the MLC, as well as a mechanism for claiming such works. Similarly, as the statute prohibits the MLC from administering licenses apart from the mechanical license, requiring the MLC to certify that it is in compliance with the law appears unnecessary. The Office agrees it could be beneficial for the rules and procedures for the MLC's Dispute Resolution Committee to be made publicly available, and encourages their publication as soon as practicable given the MLC's obligation to have ''transparent and accountable'' policies and procedures.[281] Though the interim rule, like the proposed rule, does not require an independent report from the board's music creator representatives, the Office reiterates its expectation that ''the MLC . . . give voice to its board's songwriter representatives as well as its statutory committees, whether through its annual reporting or other public announcements.'' [282] Songwriters on the MLC's board of directors are not a separate entity and should participate with other members of the board to represent and collectively address songwriter concerns and interests.

For its part, the MLC seeks modification of the proposed requirement to disclose ''the average processing and distribution times for distributing royalties to copyright owners,'' calling it ''somewhat confusing.'' [283] The MLC argues that ''there are many different types of averages and methods of calculating averages, leaving room for misunderstanding,'' and that ''the rule should accommodate the inclusion in the annual report of the actual [ ] dates on which distributions were made to copyright owners during the preceding calendar year, as such information will inform copyright owners and other interest[ed] parties of the timeliness of payment.'' [284] The MLC ''intends to and will include in the annual report the dates on which distributions were made to copyright owners during the preceding calendar year, which will inform copyright owners and other interest parties of the timeliness of payment'' and requests that the rule be modified to permit that information instead of ''average processing and distribution times.'' [285] The MLC suggests removing the word ''average'' as one possible solution.[286]

The Office believes that the proposed rule would allow the MLC to determine and explain the metrics it relies upon when reporting processing and distribution times. Indeed, the Office itself reports a variety of average processing times for copyright registration, with accompanying explanatory methodology material.[287] The MLC's core function is to collect and distribute royalties for covered activities; simply reporting the months in which the MLC distributes royalties—without disclosing *how long* the process of matching and distribution of royalties takes—provides limited meaningful insight into how the blanket license is functioning under the MLC's administration (including for example, by identifying external dependencies that may be contributing to delays in the MLC's ability to identify musical works embodied in particular sound recordings and identify and locate corresponding musical work copyright owners).[288] Accordingly, this aspect of the interim rule retains the general requirement, but in order to avoid any confusion, clarifies that the MLC has discretion as to the metrics it measures when reporting average times by stating that the MLC must disclose the manner in which it calculates processing and distribution times.

Finally, as noted above, while the phrase ''[n]ot later than June 30 of each year commencing after the license availability date'' could be read as not requiring the first annual report until June 2022 (to cover year 2021), a number of reasons compel the Office to adjust the interim rule to require the MLC to issue a written public update regarding its operations in December 2021, in a potentially abbreviated version. Because the MLC was designated in July 2019,[289] if the first annual report is issued in June 2022, that could mean three years without a formal written update on the MLC's operations. This may frustrate the noted desire from commenters for transparency regarding the MLC's operations.[290] The Office is also mindful of the statutory five-year designation process for periodic review of the mechanical licensing collective's performance.[291] Additional written information from the MLC may help inform both the Office's and the public's understanding with respect to that period of the MLC's performance. Finally, for musical works for which royalties have accrued but the copyright owner is unknown or not located, the

request that the [Office] consider recommending to Congress that the board of the MLC be expanded by six songwriter members, selected for service in a fair and open manner by the music creator community under the oversight of the USCO and the Librarian of Congress, to ensure at least the possibility of equity and fairness in the conduct of MLC activities that only a balanced board can provide.'' SGA & SCL NPRM Comment at 13. For such statutory proposals, the Office encourages SGA, SCL & MCNA to participate in future roundtables for the Office's congressionally-mandated policy study that will recommend best practices that the MLC may implement to effectively identify and locate copyright owners with unclaimed royalties of musical works, encourage copyright owners to claim accrued royalties, and ultimately reduce the incidence of unclaimed royalties. *See* 85 FR 33735 (June 2, 2020).

[279] DLC NRPM Comment at 2.

[280] 17 U.S.C. 115(d)(3)(D)(ix)(II)(aa), (cc). The Office also declines to require publication of audit results of blanket licensees, and notes such a requirement may implicate confidentiality obligations.

[281] *Id.* at 115(d)(3)(D)(ix)(I)(aa).

[282] 85 FR at 58186 n.266.

[283] MLC NRPM Comment at 8.

[284] MLC *Ex Parte* Letter #11 at 6.

[285] MLC NRPM Comment at 8.

[286] MLC *Ex Parte* Letter #11 at 6.

[287] *See, e.g.,* U.S. Copyright Office, Registration Processing Times, *https://www.copyright.gov/registration/docs/processing-times-faqs/april-1-2020-september-30-2020.pd* (last visited Dec. 20, 2020); *see also* ASCAP, My ASCAP Membership, *https://www.ascap.com/help/my-ascap-membership* (last visited Dec. 20, 2020) (''For writers, there is a time lag of approximately seven (7) to eight (8) months between performances and royalty processing. . . . For publishers, there is a time lag of approximately six (6) months between performance and royalty processing.'').

[288] *See* 17 U.S.C. 115(d)(3)(C) (authorities and functions of mechanical licensing collective); 17 U.S.C. 115(d)(3)(B)(ii) (establishing five-year designation process for the Office to periodically review the mechanical licensing collective's performance).

[289] 84 FR at 32274.

[290] *See, e.g.,* DLC September NOI Reply Comment at 28; MAC Initial September NOI Comment at 2; Music Innovation Consumers (''MIC'') Coalition Initial September NOI Comment at 3; Screen Composers Guild of Canada (''SCGC'') Reply Comments at 2, U.S. Copyright Office Dkt. No. 2018–11, available at *https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=COLC-2018-0011&refD=COLC-2018-0011-0001;* Iconic Artists LLC Initial Comments at 2, U.S. Copyright Office Dkt. No. 2018–11, available at *https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=COLC-2018-0011&refD=COLC-2018-0011-0001; see also* The MLC, Mission and Principles, *https://themlc.com/mission-and-principles* (last visited Dec. 18, 2020) (''The MLC will build trust by operating transparently.'').

[291] 17 U.S.C. 115(d)(3)(B)(ii).

MLC must hold such royalties until at least January 1, 2023.[292] If the first written report were received in June 2022, that may provide a short runway for public disclosure and feedback prior to the MLC potentially ''engag[ing] in diligent, good-faith efforts to publicize'' ''any pending distribution of unclaimed accrued royalties and accrued interest, not less than 90 days before the date on which the distribution is made.'' [293] Accordingly, the interim rule requires the MLC to issue by no later than December 31, 2021 and make available online for a period of not less than three years, a one-time report that contains, at a minimum, many of the categories of information required to be disclosed in the MLC's annual report.

The Office recognizes that certain categories of information for the annual report may not be applicable for the first six months after the license availability date, as the MLC would not have engaged in certain activities (*e.g.,* aggregated royalty receipts and payments). Accordingly, the interim rule states that if it is not practicable for the MLC to provide a certain category of information that is required for the MLC's annual report, the MLC may so state but shall explain the reason(s) for such impracticability and, as appropriate, may address such categories in an abbreviated fashion.

List of Subjects in 37 CFR Part 210

Copyright, Phonorecords, Recordings.

Interim Regulations

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR part 210 as follows:

PART 210—COMPULSORY LICENSE FOR MAKING AND DISTRIBUTING PHYSICAL AND DIGITAL PHONORECORDS OF NONDRAMATIC MUSICAL WORKS

■ 1. The authority citation for part 210 continues to read as follows:

Authority: 17 U.S.C. 115, 702.

■ 2. Add §§ 210.31 through 201.33 to read as follows:

§ 210.31 Musical works database information.

(a) *General.* This section prescribes the rules under which the mechanical licensing collective will provide information relating to musical works (and shares of such works), and sound recordings in which the musical works are embodied, in the public musical works database prescribed by 17 U.S.C. 115(d)(3)(E), and to increase usability of the database.

(b) *Matched musical works.* With respect to musical works (or shares thereof) where the copyright owners have been identified and located, the musical works database shall contain, at a minimum, the following:

(1) Information regarding the musical work:

(i) Musical work title(s);

(ii) The copyright owner of the musical work (or share thereof), and the ownership percentage of that owner. The copyright owner of the musical work owns any one of the exclusive rights comprised in the copyright for that work. A copyright owner includes entities, including foreign collective management organizations (CMOs), to which copyright ownership has been transferred through an assignment, mortgage, exclusive license, or any other conveyance, alienation, or hypothecation of a copyright or of any of the exclusive rights comprised in a copyright, whether or not it is limited in time or place of effect, but not including a nonexclusive license;

(iii) Contact information for the copyright owner of the musical work (or share thereof), which can be a post office box or similar designation, or a ''care of'' address (*e.g.,* publisher);

(iv) The mechanical licensing collective's standard identifier for the musical work; and

(v) To the extent reasonably available to the mechanical licensing collective:

(A) Any alternative or parenthetical titles for the musical work;

(B) ISWC;

(C) Songwriter(s), with the mechanical licensing collective having the discretion to allow songwriters, or their authorized representatives, to have songwriter information listed anonymously or pseudonymously. The mechanical licensing collective shall develop and make publicly available a policy on how the collective will consider requests by copyright owners or administrators to change songwriter names to be listed anonymously or pseudonymously for matched musical works;

(D) Administrator(s) or other authorized entity(ies) who license the musical work (or share thereof) and/or collect mechanical royalties for use of such musical work (or share thereof) in the United States;

(E) ISNI(s) and/or IPI(s) for each musical work copyright owner, and, if different, songwriter, and administrator;

(F) Unique identifier(s) assigned by the blanket licensee, if reported by the blanket licensee; and

(G) For classical compositions, opus and catalog numbers.

(2) Information regarding the sound recording(s) in which the musical work is embodied, to the extent reasonably available to the mechanical licensing collective:

(i) ISRC;

(ii) Sound recording name(s), including all known alternative and parenthetical titles for the sound recording;

(iii) Information related to the sound recording copyright owner, including LabelName and PLine. Should the mechanical licensing collective decide to include DDEX Party Identifier (DPID) in the public database, the DPID party's name may be included, but not the numerical identifier;

(iv) Featured artist(s);

(v) Playing time;

(vi) Version;

(vii) Release date(s);

(viii) Producer;

(ix) UPC; and

(x) Other non-confidential information that the MLC reasonably believes, based on common usage, would be useful to assist in associating sound recordings with musical works.

(c) *Unmatched musical works.* With respect to musical works (or shares thereof) where the copyright owners have not been identified or located, the musical works database shall include, to the extent reasonably available to the mechanical licensing collective:

(1) Information regarding the musical work:

(i) Musical work title(s), including any alternative or parenthetical titles for the musical work;

(ii) The ownership percentage of the musical work for which an owner has not been identified;

(iii) If a musical work copyright owner has been identified but not located, the identity of such owner and the ownership percentage of that owner. The copyright owner of the musical work owns any one of the exclusive rights comprised in the copyright for that work. A copyright owner includes entities, including foreign collective management organizations (CMOs), to which copyright ownership has been transferred through an assignment, mortgage, exclusive license, or any other conveyance, alienation, or hypothecation of a copyright or of any of the exclusive rights comprised in a copyright, whether or not it is limited in time or place of effect, but not including a nonexclusive license;

(iv) The mechanical licensing collective's standard identifier for the musical work;

(v) ISWC;

[292] 85 FR at 33738; 17 U.S.C. 115(d)(3)(H)(i), (J)(i)(I).

[293] 17 U.S.C. 115(d)(3)(J)(iii)(II)(dd).

(vi) Songwriter(s), with the mechanical licensing collective having the discretion to allow songwriters, or their authorized representatives, to have songwriter information listed anonymously or pseudonymously. The mechanical licensing collective shall develop and make publicly available a policy on how the collective will consider requests by copyright owners or administrators to change songwriter names to be listed anonymously or pseudonymously for unmatched musical works;

(vii) Administrator(s) or other authorized entity(ies) who license the musical work (or share thereof) and/or collect mechanical royalties for use of such musical work (or share thereof) in the United States;

(viii) ISNI(s) and/or IPI(s) for each musical work copyright owner, and, if different, songwriter and administrator;

(ix) Unique identifier(s) assigned by the blanket licensee, if reported by the blanket licensee; and

(x) For classical compositions, opus and catalog numbers.

(2) Information regarding the sound recording(s) in which the musical work is embodied:

(i) ISRC;

(ii) Sound recording name(s), including all known alternative and parenthetical titles for the sound recording;

(iii) Information related to the sound recording copyright owner, including LabelName and PLine. Should the mechanical licensing collective decide to include DDEX Party Identifier (DPID) in the public database, the DPID party's name may be included, but not the numerical identifier;

(iv) Featured artist(s);

(v) Playing time;

(vi) Version;

(vii) Release date(s);

(viii) Producer;

(ix) UPC; and

(x) Other non-confidential information that the MLC reasonably believes, based on common usage, would be useful to assist in associating sound recordings with musical works, and any additional non-confidential information reported to the mechanical licensing collective that may assist in identifying musical works.

(d) *Field labeling.* The mechanical licensing collective shall consider industry practices when labeling fields in the public database to reduce the likelihood of user confusion, particularly regarding information relating to sound recording copyright owner. Fields displaying PLine, LabelName, or, if applicable, DPID, information may not on their own be labeled ''sound recording copyright owner.''

(e) *Data provenance.* For information relating to sound recordings, the mechanical licensing collective shall identify the source of such information in the public musical works database. For sound recording information received from a digital music provider, the MLC shall include the name of the digital music provider.

(f) *Historical data.* The mechanical licensing collective shall maintain at regular intervals historical records of the information contained in the public musical works database, including a record of changes to such database information and changes to the source of information in database fields, in order to allow tracking of changes to the ownership of musical works in the database over time. The mechanical licensing collective shall determine, in its reasonable discretion, the most appropriate method for archiving and maintaining such historical data to track ownership and other information changes in the database.

(g) *Personally identifiable information.* The mechanical licensing collective shall not include in the public musical works database any individual's Social Security Number (SSN), taxpayer identification number, financial account number(s), date of birth (DOB), or home address or personal email to the extent it is not musical work copyright owner contact information required under 17 U.S.C. 115(d)(3)(E)(ii)(III). The mechanical licensing collective shall also engage in reasonable, good-faith efforts to ensure that other personally identifying information (*i.e.,* information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to such specific individual), is not available in the public musical works database, other than to the extent it is required by law.

(h) *Disclaimer.* The mechanical licensing collective shall include in the public-facing version of the musical works database a conspicuous disclaimer that states that the database is not an authoritative source for sound recording information, and explains the labeling of information related to sound recording copyright owner, including the ''LabelName'' and ''PLine'' fields.

(i) *Ownership.* The data in the public musical works database prescribed by 17 U.S.C. 115(d)(3)(E) is public data not owned by the mechanical licensing collective or any of the collective's employees, agents, consultants, vendors, or independent contractors.

§ 210.32 Musical works database usability, interoperability, and usage restrictions.

This section prescribes rules under which the mechanical licensing collective shall ensure the usability, interoperability, and proper usage of the public musical works database created pursuant to 17 U.S.C. 115(d)(3)(E).

(a) *Database access.* (1)(i) The mechanical licensing collective shall make the musical works database available to members of the public in a searchable, real-time, online format, free of charge. In addition, the mechanical licensing collective shall make the musical works database available in a bulk, real-time, machine-readable format through a process for bulk data management widely adopted among music rights administrators to:

(A) Digital music providers operating under the authority of valid notices of license, and their authorized vendors, free of charge;

(B) Significant nonblanket licensees in compliance with their obligations under 17 U.S.C. 115(d)(6), and their authorized vendors, free of charge;

(C) The Register of Copyrights, free of charge; and

(D) Any other person or entity, including agents, consultants, vendors, and independent contractors of the mechanical licensing collective for any purpose other than the ordinary course of their work for the mechanical licensing collective, for a fee not to exceed the marginal cost to the mechanical licensing collective of providing the database to such person or entity.

(ii) Starting December 31, 2021, the mechanical licensing collective shall make the musical works database available at least in a bulk, real-time, machine-readable format under this paragraph (a)(1) through application programming interfaces (APIs).

(2) Notwithstanding paragraph (a)(1) of this section, the mechanical licensing collective shall establish appropriate terms of use or other policies governing use of the database that allows the mechanical licensing collective to suspend access to any individual or entity that appears, in the mechanical licensing collective's reasonable determination, to be attempting to bypass the mechanical licensing collective's right to charge a fee to recover its marginal costs for bulk access outlined in 17 U.S.C. 115(d)(3)(E)(v)(V) through repeated queries, or to otherwise be engaging in unlawful activity with respect to the database (including, without limitation, seeking to hack or unlawfully access confidential, non-public information contained in the database) or

misappropriating or using information from the database for improper purposes. The mechanical licensing collective's terms of use or other policies governing use of the database shall comply with this section.

(b) *Point of contact for inquiries and complaints.* In accordance with its obligations under 17 U.S.C. 115(d)(3)(D)(ix)(I)(bb), the mechanical licensing collective shall designate a point of contact for inquiries and complaints with timely redress, including complaints regarding the public musical works database and/or the mechanical licensing collective's activities. The mechanical licensing collective must make publicly available, including prominently on its website, the following information:

(1) The name of the designated point of contact for inquiries and complaints. The designated point of contact may be an individual (*e.g.,* ''Jane Doe'') or a specific position or title held by an individual at the mechanical licensing collective (*e.g.,* ''Customer Relations Manager''). Only a single point of contact may be designated.

(2) The physical mail address (street address or post office box), telephone number, and email address of the designated point of contact.

§ 210.33 Annual reporting by the mechanical licensing collective.

(a) *General.* This section prescribes the rules under which the mechanical licensing collective will provide certain information in its annual report pursuant to 17 U.S.C. 115(d)(3)(D)(vii), and a one-time written update regarding the collective's operations in 2021.

(b) *Contents.* Each of the mechanical licensing collective's annual reports shall contain, at a minimum, the following information:

(1) The operational and licensing practices of the mechanical licensing collective;

(2) How the mechanical licensing collective collects and distributes royalties, including the average processing and distribution times for distributing royalties for the preceding calendar year. The mechanical licensing collective shall disclose how it calculated processing and distribution times for distributing royalties for the preceding calendar year;

(3) Budgeting and expenditures for the mechanical licensing collective;

(4) The mechanical licensing collective's total costs for the preceding calendar year;

(5) The projected annual mechanical licensing collective budget;

(6) Aggregated royalty receipts and payments;

(7) Expenses that are more than 10 percent of the annual mechanical licensing collective budget;

(8) The efforts of the mechanical licensing collective to locate and identify copyright owners of unmatched musical works (and shares of works);

(9) The mechanical licensing collective's selection of board members and criteria used in selecting any new board members during the preceding calendar year;

(10) The mechanical licensing collective's selection of new vendors during the preceding calendar year, including the criteria used in deciding to select such vendors, and key findings from any performance reviews of the mechanical licensing collective's current vendors. Such description shall include a general description of any new request for information (RFI) and/or request for proposals (RFP) process, either copies of the relevant RFI and/or RFP or a list of the functional requirements covered in the RFI or RFP, the names of the parties responding to the RFI and/or RFP. In connection with the disclosure described in this paragraph (b)(10), the mechanical licensing collective shall not be required to disclose any confidential or sensitive business information. For the purposes of this paragraph (b)(10), ''vendor'' means any vendor performing materially significant technology or operational services related to the mechanical licensing collective's matching and royalty accounting activities;

(11) Whether during the preceding calendar year the mechanical licensing collective, pursuant to 17 U.S.C. 115(d)(7)(C), applied any unclaimed accrued royalties on an interim basis to defray costs in the event that the administrative assessment is inadequate to cover collective total costs, including the amount of unclaimed accrued royalties applied and plans for future reimbursement of such royalties from future collection of the assessment; and

(12) Whether during the preceding calendar year the mechanical licensing collective suspended access to the public database to any individual or entity attempting to bypass the collective's right to charge a fee to recover its marginal costs for bulk access outlined in 17 U.S.C. 115(d)(3)(E)(v)(V) through repeated queries, or to otherwise be engaging in unlawful activity with respect to the database (including, without limitation, seeking to hack or unlawfully access confidential, non-public information contained in the database) or misappropriating or using information from the database for improper purposes. If the mechanical licensing collective so suspended access to the public database to any individual or entity, the annual report must identify such individual(s) and entity(ies) and provide the reason(s) for suspension.

(c) *December 31, 2021 Update.* No later than December 31, 2021, the mechanical licensing collective shall post, and make available online for a period of not less than three years, a one-time written report that contains, at a minimum, the categories of information required in paragraph (b) of this section, addressing activities following the license availability date. If it is not practicable for the mechanical licensing collective to provide information in this one-time report regarding a certain category of information required under paragraph (b) of this section, the MLC may so state but shall explain the reason(s) for such impracticability and, as appropriate, may address such categories in an abbreviated fashion.

Dated: December 21, 2020.

Shira Perlmutter,

Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2020–28958 Filed 12–30–20; 8:45 am]

BILLING CODE 1410–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–4189–F]

RIN 0938–AT94

Medicare Program; Secure Electronic Prior Authorization For Medicare Part D

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule names a new transaction standard for the Medicare Prescription Drug Benefit program's (Part D) e-prescribing program as required by the ''Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act'' or the ''SUPPORT Act.'' Under the SUPPORT Act, the Secretary is required to adopt standards for the Part D e-prescribing

program to ensure secure electronic prior authorization request and response transmissions. In this final rule, we amend the Part D e-prescribing regulations to require Part D plan sponsors' support of version 2017071 of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for use in certain electronic Prior Authorization (ePA) transactions with prescribers regarding Part D-covered drugs to Part D-eligible individuals.

DATES: These regulations are effective on February 1, 2021. The incorporation by reference of certain publications listed in the rule was approved by the Director of the Federal Register as of July 28, 2017.

FOR FURTHER INFORMATION CONTACT: Joella Roland (410) 786–7638.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this final rule is to adopt a new standard for certain transactions concerning Part D-covered drugs prescribed to Part D-eligible individuals under the Part D e-prescribing program. Under this final rule, Part D plan sponsors will be required to support version 2017071 of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for four electronic Prior Authorization (ePA) transactions, and prescribers will be required to use that standard when performing ePA transactions for Part D-covered drugs they wish to prescribe to Part D-eligible individuals. Part D plans, as defined in 42 CFR 423.4, include Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA–PDs); Part D sponsor, as defined in 42 CFR 423.4, means the entity sponsoring a Part D plan, MA organization offering a MA–PD plan, a Programs of All-Inclusive Care for the Elderly (PACE) organization sponsoring a PACE plan offering qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage. The ePA transaction standard will provide for the electronic transmission of information between the prescribing health care professional and Part D plan sponsor to inform the sponsor's determination as to whether or not a prior authorization (PA) should be granted. The NCPDP SCRIPT standard version 2017071 was adopted as a Part D e-prescribing program standard for certain defined transactions in the April 16, 2018 final rule (83 FR 16440) titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' that became effective June 15, 2018.

A. Legislative Background

1. Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191) was enacted on August 21, 1996. Title II, Subtitle F, of HIPAA requires covered entities—health plans, health care providers that conduct covered transactions, and health care clearinghouses—to use the standards HHS adopts for certain electronic transactions. The standards adopted by HHS for purposes of HIPAA are in regulations at 45 CFR part 162.

2. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. It amended Title XVIII of the Social Security Act (the Act) by redesignating Part D as Part E and inserting a new Part D to establish a voluntary prescription drug benefit program. As part of that program, section 1860D–4(e) of the Act, as added by the MMA, required the adoption of Part D e-prescribing standards for electronic prescriptions and prescription-related transactions between Part D plan sponsors, providers, and pharmacies. The Secretary's selection of standards is informed by the National Committee on Vital and Health Statistics (NCVHS), an advisory committee that gives advice to the Secretary in accordance with the Federal Advisory Committee Act, including regarding implementation of the administrative simplification provisions of HIPAA. Under section 1860D–4(e)(4)(B) of the Act, NCVHS develops recommendations for Part D e-prescribing standards, in consultation with specified groups of organizations and entities. These recommendations are then taken into consideration when developing, adopting, recognizing, or modifying Part D e-prescribing standards. The statute further requires that the selection of standards be designed, to the extent practicable, so as not to impose an undue administrative burden on prescribers or dispensers, but to be compatible with standards established under Part C of title XI of the Act (the HIPAA standards), comport with general health information technology standards, and permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the Library of Medicine.

The standards adopted by CMS for purposes of the Part D e-prescribing program are in regulations at 42 CFR 423.160. Part D plan sponsors are required to support the Part D e-prescribing program transaction standards, and providers and pharmacies that conduct electronic transactions for which a program standard has been adopted must do so using the adopted standard. (For additional information about the MMA program authority, see the February 4, 2005 proposed rule (70 FR 6256).)

3. Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), hereinafter referred to as the ''SUPPORT Act,'' was enacted on October 24, 2018. Section 6062 of the SUPPORT Act amended section 1860D–4(e)(2) of the Act to require the adoption of transaction standards for the Part D e-prescribing program to ensure secure ePA request and response transactions between prescribers and Part D plan sponsors no later than January 1, 2021. Such transactions are to include an ePA request transaction for prescribers seeking an ePA from a Part D plan sponsor for a Part D-covered drug for a Part D-eligible individual, as well as an ePA response transaction for the Part D plan sponsor's response to the prescriber. A facsimile, a proprietary payer portal that does not meet standards specified by the Secretary or an electronic form are not treated as electronic transmissions for the purposes of ePA requests. The ePA standards adopted under this authority are to be adopted in consultation with the NCPDP or other standards development organizations the Secretary finds appropriate, as well as other stakeholders.

Finally, the SUPPORT Act also authorized the adoption of ePA transaction standards for Part D-covered drugs prescribed to Part D-eligible individuals ''notwithstanding'' any other provision of law.

B. Regulatory History

In 2000, the Secretary adopted HIPAA transaction standards for the ''referral certification and authorization transaction''. The term ''referral certification and authorization transaction'' is defined at 45 CFR

162.1301 as the transmission of any of the following: (1) A request from a health care provider to a health plan for the review of health care to obtain an authorization for the health care; (2) a request from a health care provider to a health plan to obtain authorization for referring an individual to another health care provider; and (3) a response from a health plan to a health care provider to a request described in (1) or (2). The first HIPAA standard adopted for this transaction was version 4010 of the X12 278 (65 FR 50371, August 17, 2000). In 2003, the Secretary adopted another standard, the NCPDP version 5.1, for retail pharmacy drug referral certification and authorization transactions, and specified that version 4010 of the X12 278 was to be used only for dental, professional, and institutional referral certification and authorization transactions. (For more detailed information, see the February 20, 2003 **Federal Register** (68 FR 8398).) Still, as of 2003, the Secretary had not adopted a standard for ePA for medications specifically.

In 2004, NCPDP formed a multi-industry, multi-Standards Development Organization (SDO) ePA Task Group to evaluate existing ePA standards and promote standardized ePA, with a focus on the medication context. The Task Group considered the X12 278 standard, but determined that there were certain gaps in the X12 278 standard that made the standard difficult to use for ePA for medications, including that the standard was unable to support attachments for PA determinations, did not incorporate free text in certain fields, and did not at the time allow functionality for real-time messaging. As a result of these findings, the Task Group wrote a letter to the HHS Secretary stating that the X12 278 standard offered limited support for ePA for medications.

On January 16, 2009, the Secretary adopted later versions of the HIPAA transaction standards, requiring NCPDP Telecommunications D.0 instead of NCPDP 5.1, and version 5010 instead of version 4010 of the X12 278 for referral certification and authorization transactions (74 FR 3326). These standards are specified at 45 CFR 162.1302(b)(2).

In the meantime, the industry continued to work to develop and test alternative ePA transaction standards for use in the medication context. Such work led NCPDP to develop what would ultimately become its first standard to support ePA. In a May 15, 2014, letter to the HHS Secretary, NCVHS stated that they had received a letter from the NCPDP recommending its SCRIPT Standard Version 2013101 as a standard for carrying out medication ePA transactions. (For more information see, *https://ncvhs.hhs.gov/wp-content/uploads/2014/05/140515lt2.pdf*.) In support of this recommendation, NCVHS reported that NCPDP investigators tasked with reviewing the X12 278 standards (the 278 v4010 or v5010) for medication ePA transactions found impediments. These impediments were grounded in the standards having been designed for requests for review and corresponding responses for the ePA of health care services (such as for procedures/services and durable medical equipment), resulting in an inability to facilitate medication ePA. NCPDP also noted the lack of widespread use of the X12 278 transaction in the medication ePA context as evidence of its inadequacy for this purpose.

Despite these findings and NCPDP recommendation to NCVHS, we did not pursue proposing the NCPDP SCRIPT Standard Version 2013101 as a Part D eRx program standard for medication ePA transactions because it was contrary to the HIPAA requirements, which continued to require use of the X12 278 standard. Similarly, when NCPDP wrote to CMS on May 24, 2017 to recommend the adoption of its NCPDP SCRIPT Standard Version 2017071, we were unable to consider it for the Part D e-Rx program due to the HIPAA transaction standards in effect at that time.

Of note, the Part D e-Rx program's authorizing statute requires the selection of Part D standards that are compatible with the HIPAA standards. See section 1860D–4(e)(2)(C) of the Act. However, given the new authority under the SUPPORT Act, we believe we now have authority to adopt Part D eRx ePA transaction standards ''notwithstanding'' any other provision of law, if such proposals are framed in consultation with stakeholders and the NCPDP or other standard setting organizations the Secretary finds appropriate. See section 1860D–4(e) of the Act, as amended by section 6062 of the SUPPORT Act. We believe that this provision explicitly authorizes us to require the use of an ePA standard in the Part D context that is different from the HIPAA standard, as long as it is for use in the ePA of Part D-covered drugs prescribed to a Part D-eligible individuals.

As previously described, Part D plan sponsors are required to establish electronic prescription drug programs that comply with the e-prescribing standards adopted under the Part D e-prescribing program's authorizing statute. There is no requirement that prescribers or dispensers implement eRx. However, prescribers and dispensers who electronically transmit and receive prescription and certain other information regarding covered drugs prescribed for Medicare Part D-eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

As of January 1, 2020, prescribers and dispensers are required to use the NCPDP SCRIPT standard, Implementation Guide Version 2017071, for the communication of the same prescription or prescription-related information between prescribers and dispensers for the transactions for which prior versions of the NCPDP SCRIPT standard were adopted, as well as a handful of new transactions named at § 423.160(b)(2)(iv). For more information, see the April 16, 2018 final rule (83 FR 16635) and for a detailed discussion of the regulatory history of the Part D e-prescribing standards see the November 28, 2017 proposed rule (82 FR 56437).

While not currently adopted as part of the Part D eRx standard, the NCPDP SCRIPT standard version 2017071 includes 4 transaction standards that will enable prescribers to initiate, request, and review the 4 response transactions from Part D plan sponsors at the time of the patient's visit. These eight response transactions include: The PA initiation request/response, PA request/response, PA appeal request/response, and PA cancel request/response. As noted previously, historically we were unable to name this ePA transaction standard as a Part D e-prescribing program standard. Prior to the passage of the SUPPORT Act, the Part D program was required to adopt standards that were compatible with the HIPAA standards, and HIPAA covered entities are currently required to use the X12 278 to conduct referral certification and authorization transactions between health plans and health care providers.

II. Adoption of the NCPDP SCRIPT Standard Version 2017071 as the Part D ePA Transaction for the Part D Program

A. PA in the Part D Context

All Part D plans, as defined under § 423.4, including PDPs, MA–PDs, PACE Plans offering qualified prescription drug coverage, or Cost Plans offering qualified prescription drug coverage, may use approved PA processes to ensure appropriate prescribing and coverage of Part D-covered drugs prescribed to Part D-eligible individuals. We review all PA

criteria as part of the formulary review process. In framing our PA policies, we encourage PDP and MA–PD sponsors to consistently utilize PA for drugs prescribed for non-Part D covered uses and to ensure that Part D drugs are only prescribed when medically appropriate. Non-Part D covered uses may be indicated when the drug is frequently covered under Parts A or B as prescribed and dispensed or administered, is otherwise excluded from Part D coverage, or is used for a non-medically accepted indication. (For more information, see the Medicare Prescription Drug Manual, chapter 6, section 30.2.2.3.) Part D sponsors must submit to CMS utilization management requirements applied at point of sale, including PA.

We may also approve PA for prescriptions when the Part D plan desires to manage drug utilization, such as when step therapy is required, when it needs to establish whether the utilization is a continuation of existing treatment that should not be subject to the step therapy requirements, or to ensure that a drug is being used safely or in a cost-effective manner. Formulary management decisions must be based on scientific evidence and may also be based on pharmaco-economic considerations that achieve appropriate, safe, and cost-effective drug therapy.

The PA process has historically been handled via facsimile exchange of information or telephone call, and only recently via payer-specific web portals. However, stakeholders testifying to NCVHS generally agree that there is a need to move to a user-friendly, real-time ePA for use by prescribers. Minutes from NCVHS meetings can be accessed at *https://ncvhs.hhs.gov/meetings-meeting/all-past-meetings/*. Therefore, we believe the adoption of an ePA standard for the Part D eRx program will improve patient access to required medications.

B. PA for Part D E-Prescribing

In order to meet the SUPPORT Act's mandate to adopt an ePA transaction standard for the Part D-covered drugs prescribed to Part D-eligible individuals, CMS identified ePA transaction standards currently available for use by pharmacies and prescribers. These included the X12 278 and NCPDP Telecommunications D.0 standards, the NCPDP SCRIPT standard version 2017071, and earlier versions of the NCPDP SCRIPT standard. We quickly ruled out the use of older NCPDP SCRIPT standards based on the improvements incorporated in the current HIPAA Administrative Simplification transaction standards and our assessment of the enhanced functionality available in the NCPDP SCRIPT standard version 2017071.

Then we considered the needs of the Part D eRx program; the functionalities offered by the remaining two sets of standards; NCVHS recommendations, stakeholder recommendations based on their experience developing, vetting, evaluating, revising, and using the standards constructed by the respective Standards Development Organizations (SDOs) including NCPDP, the burden on stakeholders to use the standards, the security offered by the standards; and the current EHR capabilities of the industry in order to estimate the potential burden each standard will impose if it were to be adopted in the Part D context.

The NCPDP Telecommunications D.0 standard was designed to be a standard for insurance companies to approve claims, and, to our knowledge, is only used in ''pharmacy to plan'' transactions. We found that it does not include all of the content fields that may be relevant to ePA for medications, and had understood that it does not have the ability to support transmission of information in real time. Then we considered the X12 278 standard. The X12 278 is already used as the HIPAA standard for referral certification and PA for dental, professional and institutional transactions, and retail pharmacy drugs transactions, respectively.

Based on review of NCPDP's testimony and the letters received from NCVHS, we had found that the NCPDP and its participant organizations have historically concluded (and presented to NCVHS via testimony at hearings) that the X12 278 standard is not adequate to enable ePA in the medication e-prescribing context because it does not support ''real-time'' medication e-prescribing, meaning a prescriber seeking an ePA determination during the patient encounter. We understood that this was due to the content logic of the standard not having the technical capabilities to allow for next question logic, which allows the prescriber to determine medication alternatives and determine within minutes if the medication will be authorized or if a coverage determination is required. In addition, we found that the fields, transaction messaging, and software functioning were not structured to include information relevant to ePA, and contained mandatory questions that were unnecessary for medication ePA. Unfortunately, we also found that prescribers are unable to customize these fields as may be needed for medication ePA.

These findings were largely based on NCPDP's 2016 written testimony to NCVHS, which is available via this web link: *https://www.ncvhs.hhs.gov/wp-content/uploads/2016/01/Part-2-Attachments-NCPDP-WrittenOnly.pdf.* The NCPDP testimony urged the exemption of medication transactions from the X12 278 standard. The testimony also advocated for NCPDP's May 24, 2017 recommendation to adopt the NCPDP SCRIPT Standard Version 2017071 for ePA transactions in the HIPAA context, with a 24-month implementation time period due to the extensive coding required by health IT developers and Part D plans to implement the change.

Although NCPDP's recommendation was to adopt this standard for all HIPAA transactions, the Department did not elect to make the suggested changes to the HIPAA Administrative Simplification transaction standards. Based on conversations with the industry, our own assessment of the standard, and under the authority provided by Congress to require the use of a standard for Part D ePA notwithstanding any other provision of law, we concluded that the potential benefits of adopting user-friendly ePA for the Part D eRx program outweigh any difficulties that may arise by virtue of Part D using a different standard than the rest of the industry.

More specifically, we concluded that the NCPDP SCRIPT standard version 2017071 would support an electronic version of today's PA process by providing standardized information fields that are relevant for medication use, mandatory questions, transaction messaging, and standardized ePA data elements and vocabulary for exchanging the PA questions and answers between prescribers and payers, while also allowing the payers to customize the wording of the questions using free form fields. Although the X12 278 standard has standard information fields, mandatory questions, transaction messaging, and standardized data element and values, we believed those fields were more relevant to use in dental, professional, and institutional requests for review and response, and would not be conducive to medication ePA. Since the X12 278 standard does not allow payers to customize the wording of questions, we believe it would be difficult for parties to decide how to fill out the fields. In contrast, we found that NCPDP SCRIPT Standard version 2017071 was specifically designed to support medication ePA. The standard supports features that minimize what the prescriber is asked, creating a customized experience based

on earlier answers or data automatically pulled by their EHR system. These features would reduce the amount of time a prescriber or their staff spend reviewing and responding to the ePA questions. We understood that this functionality exists in most EHR systems, and can be customized based on what information is requested by the plans. We found great value in this potential to automate the collection of data required for ePA from data available within most EHR systems.

Furthermore, unlike the X12 278 standard, NCPDP SCRIPT standard version 2017071 supports solicited and unsolicited models. A solicited model occurs when the prescriber notifies the payer that they wish to initiate the PA process to determine if an authorization is needed for the patient and their desired medication. The prescriber requests guidance as to what information will be required for an ePA request for a particular patient and medication. The payer then responds either with a description of the information required, or an indication that a PA is not required for that patient and medication. An unsolicited model can be used when the information generated in this first interchange of the solicited model is not required. In such a case, the prescriber presumes or knows that an authorization will be required based on past experience or other knowledge, anticipates what the payer needs, and submits the needed information.

We also found that while X12 278 uses Electronic Data Interchange (EDI) syntax, the NCPDP SCRIPT standard version 2017071 uses XML syntax. XML helps to ensure the security of transactions through the encryption of personal health information and through use of XML transaction processing. XML is a newer syntax that provides for an easier interaction among different formats and is more easily readable between disparate systems and when system issues arise. By contrast, EDI is an older syntax more commonly used when there are fewer companies that conduct standard interactions among one another.

Based on this evaluation of the candidate standards, coupled with the recommendations from NCPDP, CMS concluded that the NCPDP SCRIPT standard version 2017071 was the most appropriate standard to propose for the Part D eRx program.

We explicitly recognized that this final rule would not change the ePA transaction standards that will be used outside of the Part D context. We did not believe that it would be problematic to use one standard for Part D and another standard outside of Part D, because we believed that the industry was already equipped to use different standards for different health plans and programs.

Finally, we considered whether adopting the NCPDP SCRIPT standard version 2017071 for Part D ePA would create any difficulties if an individual had multiple forms of drug coverage or wished to pay cash for a prescription. The SUPPORT Act specifies that the adopted standard shall be applicable for ePA of Part D-covered drugs prescribed to Part D-eligible individuals, but it stops short of requiring that the prescribed drug be paid for by the Part D plan. Thus, even if a prescriber were to use the NCPDP SCRIPT standard version 2017071 to seek Part D ePA, the beneficiary's right to pay for the drug directly, or to use non-Part D coverage to pay for the drug would be unaffected. However, we noted that the prescriber may not use the NCPDP SCRIPT standard version 2017071 to seek ePA with non-Part D plans. We expected that their EHR's eRx function would be capable of using the appropriate HIPAA standard or that they may use alternative means to seek PA outside of the Part D context. Furthermore, where a patient has both a Part D plan and a supplementary payer, the NCPDP SCRIPT standard version 2017071 could be used to process the Part D ePA transactions in real time, with the subsequent claims processing transactions made in the usual manner if the prescription is filled. Thus, we believed our proposal would not be overly burdensome for regulated parties, even if beneficiaries seek to use their non-Part D coverage or elect to self-pay.

However, in recognition of patient rights, we also noted that while the prescriber can use the NCPDP SCRIPT standard version 2017071 for all Part D-covered drugs prescribed to Part D-eligible individuals, it should refrain from doing so in instances in which the patient specifically requests that the Part D benefits not be accessed.

As a result of these observations and our understanding that most of the industry is able to support NCPDP SCRIPT standard version 2017071 using their current EHRs, we believed that requiring plans to support, and prescribers to use the NCPDP SCRIPT standard version 2017071 ePA transactions when prescribing Part D-covered drugs to Part D-eligible individuals will not impose an undue administrative burden on plans, prescribers or dispensers. Therefore, based on its inherent features designed to accommodate prescriptions, we believed that the NCPDP SCRIPT standard version 2017071, which includes the following ePA transaction capabilities, would be the best available option to support ePA between prescribers and payers for Part D covered drugs prescribed to Part D-eligible individuals:

- PAInitiationRequest and PAInitiationResponse
- PARequest and PAResponse
- PAAppealRequest and PAAppealResponse
- PACancelRequest and PACancelResponse.

We believed finalization of the ePA transaction proposals would enable the electronic presentation of ePA questions and responses using secure transactions.

The SUPPORT Act states that the Secretary must adopt, and a Part D sponsor's electronic prescription program must implement the adopted ePA by January 1, 2021. As of January 1, 2020, plans will already be required to use the NCPDP SCRIPT 2017071 standard for certain Part D-specified transactions, so we believed that giving plans an additional year to add ePA to that list of other NCPDP SCRIPT 2017071 transactions would not be overly burdensome and would ensure that the SUPPORT Act was implemented as required.

In addition, the SUPPORT Act, allows us to finalize the adoption of an ePA standard for Part D-covered drugs to Part D-eligible individuals notwithstanding any other provision of law. Furthermore, we noted our belief that our proposal, if finalized, being later in time, more specific, and authorized by the SUPPORT Act, would prevail in a conflict of law analysis.

Therefore, we proposed adding § 423.160(b)(7) which would require Part D plans' support the noted NCPDP SCRIPT standard version 2017071 ePA transactions beginning on January 1, 2021, and that prescribers use that standard when conducting ePA for Part D-covered drugs prescribed to Part D-eligible individuals by the same date. This applies to the following list of ePA transactions:

- PAInitiationRequest and PAInitiationResponse
- PARequest and PAResponse
- PAAppealRequest and PAAppealResponse
- PACancelRequest and PACancelResponse

We welcomed comments on the proposed adoption of the NCPDP SCRIPT standard version 2017071 for these ePA transactions for Part D covered drugs prescribed to Part D eligible individuals. We also solicited

comments regarding the impact of the proposed transactions and the proposed effective date on industry and other interested stakeholders, including whether the implementation of these NCPDP SCRIPT standard version 2017071 ePA transactions for use by prescribers and plans in the Part D program would impose an additional burden on the industry as a whole. We were also interested in hearing input as to whether implementation of the proposed transactions would constitute a significant change for Part D sponsors, such that a January 1, 2021 implementation date would not be feasible. We also sought comment on strategies to mitigate burden in order to support successful adoption of this policy, should it be finalized. We also sought comment on any additional ways that we can support plans if they were to be required to transition to the ePA standard by the proposed 2021 deadline. Finally, we solicited comments on the alternatives considered for the proposed rule.

In the June 19, 2019 **Federal Register** (84 FR 28450), we published the proposed rule that would, if finalized, establish a new ePA transaction standard for the Part D e-prescribing program as required by SUPPORT Act. We received 53 timely pieces of correspondence in response to the June 2019 proposed rule. Commenters included Part D sponsors, beneficiaries, beneficiary advocacy groups, pharmacy benefit managers (PBMs), pharmaceutical manufacturers, pharmacies, IT vendors, and other interested parties. Of the comments received, most commenters supported the rule. Summaries of the public comments, our responses to those public comments, and our final policies are set forth as follows.

Comment: Many commenters supported the proposed rule, stating that the standard is already used in the industry, and that any encouragement to use it for ePA will help streamline the PA process.

Response: We thank commenters for their support and agree that ePA will likely help streamline the PA process in the Part D eRx program context.

Comment: A few commenters expressed their dissatisfaction with having to perform PAs so often and stated that providers should be paid to perform PA.

Response: While we appreciate commenters' concerns, the use of PA is outside the scope of this rule. This final rule is limited to establishing the means by which ePA will be conducted in the Part D eRx program context, not the frequency of PAs or provider reimbursement. However, we note that as a part of the agency's Patients Over Paperwork initiative,[1] we are working towards improving the prior-authorization process, and solicited comment on ways to do so in the June 11, 2019, Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork (84 FR 27070). We also solicited comment on how to improve prior authorization in Medicare fee-for-service through our Request for Information on the Future of Program Integrity issued in October 2019.

Comment: A number of commenters provided comments relating to the proposed January 1, 2021, implementation date. Some of these commenters stated that the January 1, 2021 deadline was achievable. However, other commenters encouraged a later deadline for implementation or the use of enforcement discretion for the first 2 years. The reasons given for the requested delay include a desire to focus on the requirement for Part D plans to implement a prescriber real time benefit tool (RTBT) by January 1, 2021 (84 FR 23832) and to allow more time for development and testing. One commenter requested that we allow 24 months after the publication of the final rule for implementation: 12 months for development and testing and 12 months for providers to adopt software updates.

Response: We are sympathetic to commenters requesting a longer period in which to implement these requirements, especially in light of the toll that the current public health emergency (PHE) related to the 2019 Novel Coronavirus Disease (COVID–19) is taking on the industry, our prescriber RTBT requirement, and the need to test the technology before use. However, as noted in the proposed rule and previously in this final rule, the SUPPORT Act established the deadline by which we are required to implement this program standard. The SUPPORT Act requires that the Part D eRx program ''provide for the secure electronic transmission of . . . a prior authorization request . . .'' by January 1, 2021. In light of this mandate and the benefits of encouraging ePA, including increased interoperability between parties and a decrease in time spent performing prior authorizations, we are allowing Part D sponsors to use NCPDP SCRIPT 2017071 for prior authorizations beginning January 1, 2021. In an attempt to balance the statutory mandate and the benefits of use of this standard with the concerns of the commenters requesting more time and the burden on Part D plans in light of the current PHE, we are only requiring use of the standard beginning January 1, 2022. We believe that the January 1, 2022 deadline affords sufficient time to ensure compliance with this rule. Although we understand the request for a 24-month implementation timeframe, we believe that the implementation date in this final rule appropriately balances the benefits of adoption of the standard and the time needed to ensure compliance. We also note that this is only a requirement for Part D plans—not providers—so we do not believe that the additional 12 months for providers to adopt updates needs to be accounted for in the implementation timeframe. As a result of our decision to delay requiring use of the standard until January 1, 2022, we do not anticipate using enforcement discretion.

As discussed later in this final rule, we are finalizing proposed § 423.160(b)(7) as § 423.160(b)(8). Additionally, to effectively finalize the implementation date changes, we are restructuring the regulation text at § 423.160(b)(8). As finalized, paragraph (b)(8)(i) allows for use of the NCPDP SCRIPT standard by January 1, 2021, and paragraph (b)(8)(ii) requires use of the standard by January 1, 2022. Accordingly, we have redesignated proposed paragraphs (b)(7)(i) through (iv), which list the covered electronic prior authorization transactions, as paragraphs (b)(8)(i)(A) through (D).

Comment: Some commenters stated that although they applaud implementing the NCPDP SCRIPT standard version 2017071 ePA transactions for Part D, they believe that it should be acceptable for all pharmacy transactions. The reasons commenters gave for this were their belief that the SCRIPT standard is the most appropriate standard for all pharmacy transactions, regardless of payer or inclusion in Part D, and that using two standards for the same workflow will cause an unnecessary burden.

Response: We thank the commenters for their support for implementing this rule, and appreciate their feedback. However, suggestions regarding the use of these standards outside of the Part D eRx program are outside the scope of this rule. This final rule implements section 6062 of the SUPPORT Act, which requires the program to provide for the secure electronic transmission of Part D drugs for a Part D eligible individual enrolled in a Part D plan. As such, electronic transmissions outside of the Part D context go beyond the scope of this rule.

[1] *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html.*

Although we are sympathetic to concerns about having to support two standards within the same workflow, we are unable to remedy this issue within the scope of this final rule, which implements section 6062 of the SUPPORT Act. We believe that having the two standards is consistent with Congress' intent when promulgating this section of the SUPPORT Act, since the statutory mandate only extended to providing for electronic transmissions in Part D.

Comment: A commenter requested that CMS either issue clarifying guidance in the final rule to indicate that HIPAA's Referral Certification and Authorization standards do not apply to ePA transactions for prescription drugs, or name the NCPDP SCRIPT standard version 2017071 as the HIPAA standard for ePA transactions for prescription drugs. The commenter stated that the ASC X12 prior authorization transaction named under HIPAA is for medical benefits and is not effective for the exchange of information related to prior authorizations of products covered under a pharmacy benefit.

Response: We are unable to do as requested. Suggestions regarding the use of these standards outside of the Part D eRx program are outside the scope of this rule. This final rule implements section 6062 of the SUPPORT Act, which requires the program to provide for the secure electronic transmission of Part D drug for a Part D eligible individual enrolled in a Part D plan. As such, electronic transmissions outside of the Part D context go beyond the scope of this rule.

Comment: Several commenters stated that CMS should allow and encourage other ePA standards, such as the Fast Healthcare Interoperability Resources (FHIR) standard promulgated by the standards development organization Health Level 7 (HL7). This standard supports application programming interfaces (APIs), and encouraged us to adopt these standards for other eRx contexts.

Response: Although we appreciate this feedback, these comments are outside the scope of this rule. The proposed rule only covered our proposals to implement the SUPPORT Act's mandate to implement an ePA standard under Part D. At this time, the suggested standard and application programming interfaces are not used to support most pharmacy transactions. We will continue to monitor the development, maturity, and industry adoption of HL7 FHIR standards for future rulemaking.

In addition, to the extent the commenters were suggesting the adoption of more broadly applicable standards outside of the Part D eRx program, section 6062 of the SUPPORT Act, which this rule implements, only allows for the use of an ePA standard that is different from the HIPAA standard if it is for a Part D covered drug prescribed to a Part D eligible individual. Other ePA medication transactions outside of Part D are still governed by HIPAA standards.

Comment: Some commenters requested more guidance surrounding the use of PA generally, including information about PA processing times allowed under Part D and how PAs interact with subregulatory guidance for Medicare health and drug programs.

Response: Although we appreciate commenters' interest in learning more about use of PA in the Medicare programs, these comments are not within the scope of this rule. As previously mentioned, the sole purpose of this rule is to implement the SUPPORT Act's mandate that requires our adoption of a new standard for ePA in the Part D eRx program. However, we would note that PA is a key component of utilization management under a Part D plan, and consistent with § 423.153, we would further remind commenters that each Part D plan is required to review the effectiveness of its utilization management policies and systems. Such review should include ensuring the prevention of over-utilization and under-utilization of prescribed medications. To the extent that automation of the PA function will allow plans to improve their ongoing monitoring of utilization management programs through enhanced reporting, they should use that improved functioning. In addition, as coverage of drugs that undergo a PA constitutes a coverage determination, such determinations are subject to all applicable coverage determination standards, timelines, and requirements.

Comment: A commenter requested clarification about whether the proposed rule, if finalized, would ban prescribers from conducting PA using non-electronic means or whether it would only require prescribers to use the NCPDP SCRIPT standard version 2017071 ePA transactions if they intend to process PA via electronic means. Another commenter believed that naming the NCPDP SCRIPT standard version 2017071 ePA transactions was premature given the challenges inherent in the practice of rural medicine, which can be impacted by limited or inconsistent technological capabilities.

Response: This rule only requires plans support the NCPDP SCRIPT standard version 2017071. Prescribers who elect to conduct PA electronically in the Part D eRx context will be required to do so using the adopted standards. Prescribers remain free to use non-electronic means of conducting PA, and Part D plans are still required to accept prior authorization requests via existing means, such as via facsimile (FAX).

Comment: A commenter requested that CMS adopt the same electronic prescribing standards used for prescribers to communicate with Prescription Drug Management Program (PDMP) databases. The commenter did not identify the standard generally used by PDMPs.

Response: We did not consider the standard the commenter alluded to because without knowing the details of the standard generally used by PDMPs we are unable to assess whether it was or was not a standard considered for Part D eRx ePA. We appreciate the commenter's concerns about interoperability, but we are unable to delay naming of the proposed transactions while we evaluate the degree to which PDMPs may or may not be using the NCPDP SCRIPT standard version 2017071 or some alternative. Due to the statutory deadline to implement ePA in the Part D eRx program, we needed to select a standard that is ready for use in ePA transactions.

Comment: Another commenter urged CMS to allow voluntary use of other standards if mutually agreed upon between trading partners.

Response: We would like to emphasize that this rule proposed the NCPDP SCRIPT standard version 2017071 ePA transactions in part because health plans are already required to support use of that same version of the standard for other transactions beginning January 1, 2020, in accordance with the April 2018 final rule. As the ePA transactions are part of version 2017071 of the NCPDP SCRIPT standard, we do not believe it would be advisable to allow voluntary use of a different version of the NCPDP SCRIPT standard as that would require all trading partners to support different versions of the standard at the same time in order to comply with Part D program requirements, which we believe would impose unnecessary burden. CMS will consider proposing use of future updates to the NCPDP SCRIPT standard in future Part D e-prescribing rules as the need arises.

In order to ensure that ePA permeates across the industry for Part D and that multiple Part D stakeholders can participate in it, we believe that one Part D ePA standard should be used rather

than simply allowing any stakeholder to use his/her preferred standard.

In addition, based on our analysis of available standards that led to our proposing to adopt the NCPDP SCRIPT standard version 2017071 for ePA under Part D, we question how many trading partners would wish to support the added cost and complexity of using ePA transactions drawn from an entirely different standard. Requiring consistent use of the same ePA standards throughout the Part D eRx program also ensures all plans and prescribers serving Part D eligible patients are able to conduct ePA transactions with one another.

Comment: One commenter noted that although they do not disagree with our characterization of the X12 278 transaction as the wrong type of standard for this transaction, they did alert us to the fact that the X12 278 transaction can now be used in real-time transactions, in addition to batched transactions.

Response: We thank the commenter for alerting us to this new development, and have consequently amended the statement in the background section to clarify that the X12 278 standard was not a real-time transaction in 2004.

Comment: A commenter disagreed with our statement that the SCRIPT transaction can determine whether the beneficiary's plan requires a PA for a given transaction, stating that the standard is not designed to determine whether prior authorization is required for a given transaction.

Response: We thank the commenter for this correction. We have not included this statement in the background section of this final rule.

Comment: A commenter expressed concern that this final rule would conflict with the information blocking and certification requirements from the March 4, 2019, Office of the National Coordinator for Information Technology (ONC) notice of proposed rulemaking (NPRM) (84 FR 7424), should it be finalized. Another commenter urged HHS to incorporate the NCPDP ePA transaction standard into future certification editions from ONC.

Response: In ONC's May 1, 2020 final rule titled ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (ONC 21st Century Cures Act final rule), ONC finalized policies which directly align with the standard adopted in this final rule that supports ePA transactions and standards (85 FR 25642). Specifically, the ONC 21st Century Cures Act final rule adopted the NCPDP SCRIPT standard version 20170701 for Health IT Modules seeking certification to the § 170.315(b)(3) electronic prescribing criterion under the ONC Health IT Certification Program. The ONC 21st Century Cures Act final rule also adopted the ePA transactions in the NCPDP SCRIPT standard version 2017071 as optional for the updated § 170.315(b)(3) electronic prescribing criterion (85 FR 25685). As noted in the 21st Century Cures Act final rule, ONC believes the adoption of the ePA transactions included in version 2017071 of the NCPDP SCRIPT standard as optional transactions within this certification criteria supports alignment between the health IT certification program and Part D ePA policy.

We also note that CMS published the Patient Access and Interoperability final rule (85 FR 25510) concurrently with ONC's 21st Century Cures Act final rule on May 1, 2020. The CMS final rule requires certain payers, such as such as MA plans and Medicaid and CHIP programs, to make enrollee electronic health information held by the payer available through application programming interfaces (APIs) conformant to HL7 FHIR and other API standards that ONC adopted in 45 CFR 170.215.

Neither rule finalized a standard for conduct of ePA, nor did they require ePA be conducted through APIs conformant with the FHIR standard. The purpose of the current rule is to encourage the exchange of electronic health information by naming a standard suitable to support ePA by January 1, 2021. We will continue to monitor efforts within the health IT industry to support electronic prescribing transactions through emerging standards such as HL7 FHIR and technologies like APIs and will consider such developments in future rulemaking.

Comment: A commenter expressed concern that this rule would conflict with the CMS Interoperability and Patient Access proposed rule that was issued on March 4, 2019 (84 FR 7610), should it be finalized. In CMS Interoperability and Patient Access proposed rule, we noted that in June 2018, in support of the Da Vinci project (a private-sector initiative led by Health Level 7 (HL7), the CMS Medicare FFS program began: (1) Developing a prototype Documentation Requirement Lookup Service for the Medicare FFS program and (2) populating it with the list of items/services for which prior authorization is required by the Medicare FFS program (84 FR 7613).

Response: This rule can be finalized, as proposed, without conflicting with the CMS Interoperability and Patient Access final rule (85 FR 25510) which did not require payers to develop a prototype Documentation Requirement Lookup Service (DRLS). The DRLS was described in the proposed rule as work CMS was doing related to HL7 FHIR standards. We believe that the listing of items or services for purposes of a DRLS, as encouraged by CMS, is separate and distinct from requiring that a certain standard be used for ePA transactions for prescribers. This rule would require only the latter in the Part D eRx program context. Although CMS has recently proposed a rule requiring payers to use DRLS (85 FR 82586), this requirement does not extend to Part D. As a result, we continue to believe that this is separate and distinct from the requirements of this final rule.

Comment: A few commenters questioned whether pharmacies would be permitted to actively use the NCPDP SCRIPT standard version 2017071 transactions for ePAs performed on behalf of a beneficiary enrolled in Part D. One of these commenters stated that pharmacies that serve beneficiaries in long term care (LTC) settings would benefit from using the ePA transactions. They noted that applicable state laws permit dispensers to fulfill the terms of a prior authorization and suggest that we change the verbiage of the proposed regulation to allow ''dispensers (as applicable)'' to the parties required to use the NCPDP SCRIPT standard version 2017071 ePA transactions adopted in this final rule.

Response: We appreciate the commenters' concerns. However, this rule does not seek to change the current regulation with regard to who may request a PA on behalf of the beneficiary. Under our regulation at § 423.566(c), a pharmacy cannot request a coverage determination on behalf of an enrollee, unless the pharmacy is the enrollee's appointed representative. We believe that changing who may request a PA is outside the scope of the proposed rule. However, we will take the suggestion under advisement.

Comment: A commenter requested that CMS use this regulation as an opportunity to implement other provisions of the SUPPORT Act, such as section 2003 of the SUPPORT Act requiring the use of e-prescribing for opioids.

Response: We understand the importance of ensuring that all provisions of the SUPPORT Act are implemented. However, what is suggested in this comment is outside the scope of this rule, as the proposed rule only sought to implement section 6062 of the SUPPORT Act—not the entirety of the Act.

Comment: A commenter noted that the proposed NCPDP SCRIPT standard does not in itself prepopulate National Drug Codes (NDCs), rather NDCs are prepopulated by eRx and EHR systems if they are capable of doing so and set up to pre-fill such fields with known values.

Response: Upon re-evaluation we now understand that these NDCs are indeed completed by eRx and EHR systems with certain capabilities that are set up to do this work. During our initial research we had seen that the NDCs were widely prepopulated and incorrectly attributed this to the NCPDP SCRIPT standard. We appreciate this correction. In light of this understanding, we believe that the promulgation of a single standard electronic ePA for Part D-covered drugs prescribed to Part D-eligible individuals will encourage any remaining eRx and EHR vendors that do not offer the functionality to prepopulate NDCs to begin to do so, and continue to follow the NCPDP SCRIPT implementation guide.

Comment: A commenter clarified that the NCPDP Telecommunications standard D.0 is, indeed, a real time transaction.

Response: We appreciate the opportunity to further explain our assertions in the proposed rule. As the commenter states, the NCPDP Telecommunications D.0 standard is, indeed, a real time standard. However, because it is designed as a transaction between the pharmacy and the plan, it does not allow a prescriber to transmit information necessary to satisfy a prior authorization in real time. In practical terms when a drug is subject to prior authorization the Telecommunications standard conveys a real-time rejection to the pharmacy but leaves the prescriber unaware of the rejection, and unable to convey information to the plan which would satisfy the terms of the PA. To our knowledge, the NCPDP SCRIPT standard version 2017071 remains the only mechanism by which a prescriber can satisfy the terms of a prior authorization electronically in real time.

Comment: One commenter recommended that we amend our regulation text so that it states that the prescription-related information flows between prescribers and Part D sponsors, rather than prescribers and dispensers, which is what we stated in the proposed rule.

Response: We thank the commenter for the correction and have amended the text accordingly.

Comment: A commenter noted that since the May 2019 final rule amended the regulation text to include § 423.160(b)(7), the proposed rule should have been amended to include a new § 423.160(b)(8).

Response: We appreciate this comment and are finalizing the proposal in § 423.160(b)(8).

Comment: A commenter noted that some of the citations to the HIPAA standards at section 1860D–4(e)(4) of the Act and the new SUPPORT Act mandate at section 1860D–4(e)(2)(E)(ii)(III) of the Act were incorrect.

Response: We have revised the preamble to correct the citations noted by the commenter.

After review and consideration of the comments received, and for the reasons discussed herein and in the proposed rule, we are finalizing our proposed revision, with the following modifications:

- We are finalizing proposed § 423.160(b)(7) as § 423.160(b)(8).
- We are restructuring the final regulation text to permit Part D sponsors to use the standard beginning January 1, 2021 at § 423.160(b)(8)(i), but not require its use until January 1, 2022 at § 423.160(b)(8)(ii).
- We are redesignating proposed § 423.160(b)(7)(i) through (iv) which list the covered electronic prior authorization transactions, as § 423.160(b)(8)(i)(A) through (D) in this final rule.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Our June 19, 2019 (84 FR 28450) proposed rule solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for our proposed information collection requirements, burden, and assumptions. Two comments were received. A summary of the comments is set out in this section of the document in this section of this rule along with our response.

The following changes will be submitted to OMB for approval under control number 0938–TBD (CMS–10755). Please note that our proposed rule indicated that the changes would be submitted under control number 0938–0763 (CMS–R–262). However, based on internal review we have since determined that the changes should be set out under a new collection of information request. Importantly, the new collection of information request (0938–TBD; CMS–10755) has no effect on our proposed and final requirements and burden estimates. Rather, we are simply changing the location of those requirements and burden estimates. Please note that OMB will issue the new control number when ready. In the meantime it is to be determined (or ''TBD''). The new collection of information request's CMS identification number (CMS–10755) is not subject to change.

This rule implements section 6062 of the SUPPORT Act, which requires the adoption of technical standards for the Part D e-prescribing program to help ensure secure ePA requests and response transactions. Specifically, this final rule amends the Prescription Drug Benefit program (Part D) regulations to require under § 423.160(b)(8) that Part D plan sponsors (hereinafter, ''Part D plans'' or ''plans'') have the technical capability to support the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2017071 when performing ePA for Part D-covered drugs prescribed to Part D-eligible individuals. While this final rule will not impact the PA criteria which Part D plans have in place, the electronic process will make the PA process less burdensome for plans and prescribers. Prescribers who are currently capable of using an electronic prescribing software likely already have access to the ePA transaction standards, and would be expected to generally be able to access the transactions without cost. As ePA is implemented, the current system of manual processing (fax and phone calls) will fade in the Part D context since plans will be able to use the adopted standard, and incentivize their prescribers to conduct ePA. We expect that prescribers will be more likely to conduct ePA now that

this less burdensome standard is currently available to them.

We estimate a one-time cost for plans to implement the necessary changes to support the ePA transactions within NCPDP SCRIPT standard version 2017071. After consulting with industry stakeholders, we have concluded that implementing or building the type of logic which will allow systems engineers to produce the interactive logic which the NCPDP SCRIPT standard requires can vary based on how the PA criteria are currently documented, but $6,500 is the approximate average cost as the cost varies based on the size and expertise of the plan. The $6,500 figure includes only the plan's internal costs including labor, initial development and programming, and systems support to transform each of its CMS-approved PA criteria from a free flowing manual process suitable for telephonic or facsimile communication with a clinical professional into a 2017071-compliant step-by-step query process that can be adapted for use by programmers. Based on our internal data, we estimate that this rule will apply to 774 plans. We estimate that only 2 percent (or 15) of the plans (774 plans × 0.02) do not already have the internal ePA process capabilities that will be required to build the logic to support NCPDP SCRIPT standard version 2017071's ePA transactions. In that regard we estimate a one-time implementation cost of approximately $100,000 (15 plans × $6,500/plan) or $33,000 annually when factoring in OMB's 3-year approval period, which is required for all new Paperwork Reduction Act activities ($100,000/3 years). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

Based on our informal conversations with the industry, we believe that the ongoing cost that plans will incur to process ePA transactions range from $1.20 to $2.85 per transaction, which varies based on vendor and volume. Based on internal CMS data, for the 774 plans we estimate that 560,430 PAs are performed every year and that each authorization requires two individual transactions, one for receiving and one for responding. Using $2.03 as the average cost per transaction ([$1.20 + $2.85]/2) we estimate $4.06 per authorization ($2.03/transaction × 2 transactions/authorization). In aggregate we project an ongoing transaction (both receiving and responding) cost of $2,275,346 annually ($4.06/authorization × 560,430 authorizations) for all plans.

With regard to current practice, 98 percent (or 15) of the plans (774 plans × 0.02) already have the capacity to process automated PAs. However, when they perform these processes manually, they spend an average of $10.00/fax PA for 549,221.4 authorizations (560,430 authorizations × 0.98) at a cost of $5,492,214 (549,221 PAs × $10.00/PA). The remaining 15 plans that rely on phone or fax and manual review spend an average of $25.00/manual PA for 11,209 authorizations (560,430 authorizations × 0.02) at a cost of $280,225, (11,209 PAs × $25.00/PA). In this regard the transaction cost for the current practice is approximately $5,729,439 ($5,492,214 + $280,225).

In addition, we believe that there will be added savings due to fewer appeals being processed. We estimate that 900 appeals are processed annually due to mistakes emanating from the use of manual PA, including missing PA information and the PAs not being received by the correct party. We believe that these appeals would be eliminated, since ePA requires input of all necessary information for the transactions to be processed and provides a secure means of delivery to the recipients. We estimate that it costs $101.63 to process each of these appeals based on the 1.25 hours at $69.72/hr that it takes a quality officer at each organization to process the appeal and the cost of sending the appropriate notices, which would lead to a savings to plans of $91,467 (900 appeals × $101.63). When we add this savings to the $3,454,093 already saved, we project a total annual savings of $3,454,560 ($3,454,093 + $91,467). This figure differs slightly from the estimate that was set out in our June 19, 2019 proposed rule. That rule had inadvertently excluded the savings emanating from the revised number of appeals. In addition, the rule had overestimated the amount of plans that would need to make changes to implement the standard and the burden to implement it. We are correcting that oversight in this final rule.

Since this final rule only requires plans, and not prescribers, to implement the standard, we are not estimating costs that assume prescribers will transition to this standard. As a result, we did not include the aforementioned transaction costs and appeals savings in our tabulation of the final costs of implementing this rule. Therefore, we believe that the final cost of this rule will be the $100,000 for plans to implement this standard. As indicated, we received public comments related to the PRA. The following summarizes the comments and provides our response:

Comment: A commenter requested that CMS include the burden to physicians. Another commenter expressed concern about the potential costs to practices to switch to the new standard, and requested that we bar EHR vendors from passing on additional transaction costs to providers or patients. Another commenter stated that they believe our assumption incorrectly assumed that a provider's electronic prescribing software already has support for all NCPDP SCRIPT transactions.

Response: We thank commenters for the information about other factors that we should consider when estimating the implementation costs for providers to implement a new standard. However, we clarify that this rule imposes requirements only on Part D plans—if physicians elect to utilize ePA in the Part D program context, they will be required to do so using the adopted standard, but they are free to conduct PA through other means. We believe our proposed rule incorrectly included prescriber costs in our estimates. We have removed these estimates from the calculations on this final rule. While we understand the potential costs for providers and EHR vendors to pass on transaction costs to providers or plans, we do not have the statutory authority to regulate EHRs. As previously mentioned, this final rule implements section 1860D–4(e)(2)(E) of the Act requiring that the program provide for the secure electronic transmission of prior authorization requests and responses. However, this section of the Act does not expand CMS's authority to allow the agency to regulate EHR vendors or specify who may bear the cost of implementing the transaction. As a result, we are not able to adopt this commenter's suggestion that we bar EHR vendors from passing on transactions costs to providers or patients.

Comment: A commenter requested that CMS revise its estimates to account for ongoing maintenance costs associated with ePA.

Response: We acknowledged in the proposed rule that there would be a cost associated with maintenance of systems to support electronic prior authorizations. These costs are included in our ongoing methodology which, based on our research, we estimated to range from $1.20 to $2.85 per transaction for a total of $2.27 million. Since commenters did not provide specific feedback on the veracity of this estimate, we will finalize the estimates as initially presented.

IV. Regulatory Impact Statement

A. Statement of Need

This rule implements provisions of the SUPPORT Act, which require the adoption of transaction standards for the Part D program that will help ensure secure electronic PA request and response transactions. Specifically, this final rule amends the Prescription Drug Benefit program (Part D) regulations to require that Part D sponsors have the technical capability to support the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2017071 when performing electronic Prior Authorization (ePA) for Part D-covered drugs prescribed to Part D-eligible individuals.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million annually. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA, because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this rule does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. There are currently 774 PD contracts (excluding PACE organizations, since they are not affected by this regulation)). We assume each entity will have one designated staff member who will review the entire rule. Other assumptions are possible and will be reviewed after the calculations, in this section of this rule.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this final rule is $107.38 per hour, including fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 12.5 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is therefore, $1,342 (12.5 hours × $107.38). Therefore, we estimate that the total cost of reviewing this final rule is $1,342,000 ($1,342 × 1,000 reviewers).

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent entity. Using parent organizations instead of contracts will reduce the number of reviewers to approximately 500 (assuming approximately 250 parent organizations), and this will cut the total cost of reviewing in half. The argument for this is that a parent organization might have local reviewers; even if that parent organization has several contracts that might have a reader for each distinct geographic region, to be on the lookout for effects of provisions specific to that region.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this rule does not impose more than a de minimis costs; and thus, is not a regulatory action for purposes of E.O. 13771.

C. Anticipated Effects

As stated previously, section 6062 of the SUPPORT Act requires the adoption of technical standards for the Part D program that will ensure secure ePA request and response transactions no later than January 1, 2022, and allows for Part D sponsors to begin using the standard by January 1, 2021. We are codifying requirements at § 423.160, which require plans to support the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2017071 by January 1, 2022 when performing ePA for Part D-covered drugs prescribed to Part D-eligible individuals. This final rule has the following impacts.

Entities affected by the PA processes include pharmacies receiving ePAs from providers and filling the prescription, prescribers who use ePA, the Medicare Part D Program, Part D plans, EHR vendors who need to modify their products, and the Promoting Interoperability Programs, for any Part D prescribers in these programs. Information about what programs are included in the Medicare Promoting Interoperability Programs is available via this web link: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHRincentiveprograms.* We do not

anticipate any impacts to the Medicare program, beneficiaries, or other stakeholders.

There are three primary aspects of the provision that could affect its cost and the amount saved. The most immediate cost comes from the one-time implementation cost for the few EHR vendors that need to need to change their programming to use two standards; the NCPDP SCRIPT standard version 2017071 for Part D ePA and the HIPAA standard for other contexts. Based on our conversations with EHR vendors, we believe that it will take the EHR vendors approximately 200 developing hours and 800 programming hours to enable the EHRs to utilize two standards.

We also estimated what it will cost plan sponsors to implement this standard. After consulting with industry stakeholders, we have concluded that implementing or building to the SCRIPT standard can vary, but $6,500 is the approximate amount per plan and $100,000 is the approximate amount for the industry. We estimate that only 2 percent of the 774 plans will have to make changes to their ePA process to implement the NCPDP SCRIPT standard version 2017071 ePA transactions, which gives us an approximate one time implementation cost of $100,000 (15 * $6,500).

E. Alternatives Considered

We considered requiring the adoption of the standard by January 1, 2021 to ensure that this important mandate was implemented quickly. However, we want to help ensure that plans have as much time to comply with the statutory mandate as possible.

F. Accounting Statement and Table

The following table summarizes overall costs for this rule. The cost comes from implementing the new standard.

	2022	2023	2024	2025	2026
Total Costs	$100,000				
Net Savings					

List of Subjects in 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Incorporation by reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 423 as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 1. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 2. Section 423.160 is amended by adding paragraph (b)(8) to read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(8) *Electronic prior authorization.* (i) Beginning January 1, 2021, Part D sponsors and prescribers may use the National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(vii) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and Part D sponsors for the following transactions:

(A) PAInitiationRequest and PAInitiationResponse.

(B) PARequest and PAResponse.

(C) PAAppealRequest and PAAppealResponse.

(D) PACancelRequest and PACancelResponse.

(ii) Beginning January 1, 2022, Part D sponsors and prescribers must use the standard specified in paragraph (b)(8)(i) of this section for the transactions listed in paragraphs (b)(8)(i)(A) through (D) of this section.

* * * * *

Dated: February 6, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 13, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Editorial note: This document was received for publication by the Office of the Federal Register on December 23, 2020.

[FR Doc. 2020–28877 Filed 12–29–20; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 328

[Docket ID FEMA–2020–0018]

RIN 1660–AB01

Prioritization and Allocation of Certain Scarce and Critical Health and Medical Resources for Domestic Use

AGENCY: Federal Emergency Management Agency, Department of Homeland Security (DHS).

ACTION: Temporary final rule; extension of effective date with modifications.

SUMMARY: In April, the Federal Emergency Management Agency (FEMA) issued a temporary final rule to allocate certain health and medical resources for domestic use, so that these resources may not be exported from the United States without explicit approval by FEMA. The rule covered five types of personal protective equipment (PPE), outlined below. While this rule remains in effect, and subject to certain exemptions stated below, no shipments of such designated materials may leave the United States without explicit approval by FEMA. In August, FEMA modified the types of PPE covered and extended the duration of the temporary rule. Through this action, FEMA again extends and modifies the temporary final rule designating the list of scarce and critical materials that cannot be exported from the United States without explicit approval by FEMA.

DATES: *Effective date:* This rule is effective from December 31, 2020 until June 30, 2021.

ADDRESSES: You may review the docket by searching for Docket ID FEMA–2020–0018, via the Federal eRulemaking Portal: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel McMasters, Program Analyst, Office of Policy and Program Analysis, 202–709–0661, *FEMA-DPA@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On April 10, 2020, FEMA published a temporary final rule in the **Federal Register** allocating certain health and

medical resources for domestic use, so that these resources may not be exported from the United States without explicit approval by FEMA.[1] The rule aids the response of the United States to the spread of Coronavirus Disease 2019 (COVID–19) by ensuring that certain health and medical resources are appropriately allocated for domestic use. On April 21, 2020, FEMA published a notification of exemptions to the rule.[2] With the continued goal of ensuring that these resources are appropriately allocated for domestic use, FEMA extended the date through which the allocation in the temporary final rule would be in effect, including the exemptions published on April 21, 2020, and modified the list of covered materials under the rule to reflect domestic supply needs as of August 10, 2020.[3] FEMA is now further extending and modifying this rule to reflect current domestic supply needs of health and medical resources to promote the national defense. The temporary final rule, as extended and modified, will remain in effect until June 30, 2021, unless sooner modified or terminated by the Administrator.

A. The Current COVID–19 Pandemic

COVID–19 is a communicable disease caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2), that was first identified as the cause of an outbreak of respiratory illness that began in Wuhan, Hubei Province, People's Republic of China. On January 30, 2020, the Director-General of the World Health Organization (WHO) declared that the outbreak of COVID–19 is a Public Health Emergency of International Concern under the International Health Regulations.[4] The following day, the Secretary of Health and Human Services (HHS) declared COVID–19 a public health emergency under Section 319 of the Public Health Service (PHS) Act.[5] On March 11, 2020, the WHO declared COVID–19 a pandemic. On March 13, 2020, the President issued a Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak under sections 201 and 301 of the National Emergencies Act, 50 U.S.C. 1601 *et seq.,* and consistent with section 1135 of the Social Security Act, 42 U.S.C. 1320b–5.[6] On March 13, 2020, the President declared a nationwide emergency under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, authorizing FEMA to provide assistance for emergency protective measures to respond to the COVID–19 pandemic.[7] FEMA subsequently issued 57 major disaster declarations in response to COVID–19, including for every State, 5 territories, the Seminole Tribe of Florida, and the District of Columbia.[8]

Within the United States, widespread transmission of COVID–19 has occurred. Widespread transmission of COVID–19 has resulted and will continue to result in large numbers of people needing medical care at the same time. Public health and healthcare systems have become overwhelmed in some areas, with elevated rates of hospitalizations and deaths, as well as elevated demand for PPE, including the PPE covered by this rule. Due to a surge in confirmed COVID–19 cases and hospitalizations in October, November, and December 2020,[9] domestic supply of the allocated PPE has not kept pace with demand and is not anticipated to do so. Additionally, given the high rate of influenza vaccination administrations in 2020,[10] along with the recent developments in COVID–19 vaccines and vaccine trials,[11] the projected domestic supply of syringes and hypodermic needles is not expected to meet demand.

B. Legal Authorities

FEMA is extending and modifying this temporary final rule as part of its response to the COVID–19 pandemic. The rule is issued pursuant to the following authorities, among others:

- The Defense Production Act of 1950, as amended (''DPA'' or ''the Act''), and specifically sections 101 and 704 of the Act, 50 U.S.C. 4511, 4554;
- Executive Order 13909, 85 FR 16227 (Mar. 23, 2020);
- Executive Order 13911, 85 FR 18403 (Apr. 1, 2020);
- Department of Homeland Security (DHS) Delegations, including DHS Delegation Number 09052 Rev. 00, ''Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency'' (Jan. 3, 2017) and DHS Delegation Number 09052 Rev. 00.1, ''Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency'' (Apr. 1, 2020); and
- The Presidential Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (Apr. 3, 2020).[12]

Under subsection 101(a) of the Act, 50 U.S.C. 4511(a), the President may (1) require that performance under contracts or orders (other than contracts of employment) which the President deems necessary or appropriate to promote the national defense shall take priority over performance under any other contract or order, and, for the purpose of assuring such priority, require acceptance and performance of such contracts or orders in preference to other contracts or orders by any person he finds to be capable of their performance. The President may also (2) allocate materials, services, and facilities in such manner, upon such conditions, and to such extent as the President shall deem necessary or appropriate to promote the national defense. FEMA refers to these authorities as relating to ''priority ratings'' and ''allocation,'' respectively.

[1] 85 FR 20195 (Apr. 10, 2020). *See also* 85 FR 22622 (Apr. 23, 2020) (correcting the date filed from ''4–8–20'' to'' 4–7–20'').

[2] 85 FR 22021 (Apr. 21, 2020).

[3] 85 FR 48113 (Aug. 10, 2020).

[4] Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019–nCoV) (Jan. 30, 2020), *available at https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)* (accessed December 2, 2020).

[5] HHS, ''Determination that a Public Health Emergency Exists,'' (Jan. 31, 2020) *available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx* (accessed December 2, 2020).

[6] ''Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak,'' Mar. 13, 2020, *available at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/* (accessed December 15, 2020).

[7] COVID–19 Emergency Declaration *available at https://www.fema.gov/news-release/2020/03/13/covid-19-emergency-declaration* (accessed December 15, 2020).

[8] See *https://www.fema.gov/disasters/* (accessed December 15, 2020).

[9] As of December 22, 2020, the United States has over 17.79 million reported cases and over 300,000 deaths attributed to COVID–19. *See https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days* (accessed December 22, 2020). As of December 7, 2020, the number of reported weekly cases and weekly deaths are forecast to increase. *See https://covid.cdc.gov/covid-data-tracker/#forecasting_weeklycases* (accessed December 22, 2020) and *https://covid.cdc.gov/covid-data-tracker/#forecasting_weeklydeaths* (accessed December 22, 2020).

[10] *See https://www.cdc.gov/flu/prevent/vaccine-supply-distribution.htm* (accessed December 15, 2020).

[11] *See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html* (accessed December 22, 2020).

[12] *See* Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use for the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Administrator of the Federal Emergency Management Agency (Apr. 3, 2020), *https://www.whitehouse.gov/presidential-actions/memorandum-allocating-certain-scarce-threatened-health-medical-resources-domestic-use/* (accessed December 15 2020).

Under subsection 101(b) of the Act, 50 U.S.C. 4511(b), the President may not use the aforementioned authorities to control the general distribution of any material in the civilian market unless the President finds (1) that such material is a scarce and critical material essential to the national defense, and (2) that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship.

Under subsection 101(d) of the Act, 50 U.S.C. 4511(d), the head of each Federal agency to which the President delegates authority under section 101 of the Act (1) shall issue, and annually review and update whenever appropriate, final rules, in accordance with 5 U.S.C. 553, that establish standards and procedures by which the priorities and allocations authority under section 101 is used to promote the national defense, under both emergency and nonemergency conditions; and (2) as appropriate and to the extent practicable, consult with the heads of other Federal agencies to develop a consistent and unified Federal priorities and allocations system.

On March 18, 2020, the President signed Executive Order 13909, which (among other things) contained a finding that health and medical resources needed to respond to the spread of COVID–19, including personal protective equipment and ventilators, meet the criteria specified in section 101(b) of the Act (50 U.S.C. 4511(b)).[13]

On March 27, 2020, the President signed Executive Order 13911, which (among other things) delegated to the Secretary of Homeland Security, the President's authority under section 101 of the Act with respect to health and medical resources needed to respond to the spread of COVID–19 within the United States. The Executive Order provides that the Secretary of Homeland Security may use the authority under section 101 of the Act to determine, in consultation with the heads of other executive departments and agencies as appropriate, the proper nationwide priorities and allocation of health and medical resources, including by controlling the distribution of such materials (including applicable services) in the civilian market, for responding to the spread of COVID–19 within the United States.[14] The Secretary of Homeland Security has redelegated the Secretary's DPA authorities to the FEMA Administrator. *See* DHS Delegation Number 09052, Rev. 00 (Jan. 3, 2017) and DHS Delegation Number 09052, Rev. 00.1 (Apr. 1, 2020).

Additionally, on April 3, 2020, the President signed a Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (the Memorandum). The Memorandum reaffirmed the delegations and findings contained in Executive Orders 13909 and 13911, including that health and medical resources needed to respond to the spread of COVID–19, including personal protective equipment (PPE), meet the criteria specified in section 101(b) of the Act, *i.e.,* that (1) such material is a scarce and critical material essential to the national defense, and (2) that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship. The Memorandum identified certain categories of PPE materials that the Secretary of HHS had previously designated as ''scarce or threatened'' for purposes of section 102 of the DPA, and further stated that to ensure that these materials remain in the United States for use in responding to the spread of COVID–19, it is the policy of the United States to prevent domestic brokers, distributors, and other intermediaries from diverting such PPE materials overseas.

In furtherance of such policy, the President directed the Secretary of Homeland Security, through the FEMA Administrator, and in consultation with the Secretary of HHS, to use any and all authority available under section 101 of the Act to allocate to domestic use, as appropriate, the five types of PPE identified in the Memorandum. On April 10, 2020, FEMA executed this direction by issuing the allocation order as a temporary final rule pursuant to the Memorandum, and with the authority delegated to the Secretary of Homeland Security in E.O. 13911 and re-delegated to the FEMA Administrator.[15] The temporary final rule was modified and extended on August 10, 2020, to ensure certain health and medical resources were appropriately allocated for domestic use.[16]

Finally, on May 13, 2020, FEMA published an interim final rule to establish standards and procedures by which the priorities and allocations authority under section 101 is used to promote the national defense, under both emergency and nonemergency conditions.[17]

As the COVID–19 pandemic continues in the United States, the FEMA Administrator, in consultation with other agencies as appropriate, has determined that FEMA must continue to allocate some materials contained in the August 10, 2020, temporary final rule for domestic use, and to incorporate other health and medical resources due to changes in domestic supply and demand, surges in the number of confirmed COVID–19 cases and deaths in the United States, forecasts anticipating the increased number of COVID–19 cases and deaths, the current and projected volume of influenza vaccination doses, and future COVID–19 vaccination predictions. FEMA has determined, consistent with the Memorandum and FEMA's authorities under section 101 of the DPA, that it is appropriate to designate, with modification, the PPE previously designated and to include syringes and hypodermic needles (whether distributed separately or attached together) to ensure domestic supply is

[13] Executive Order 13909 also delegated to the Secretary of Health and Human Services (HHS) authority under the DPA for the prioritization and allocation of health and medical resources to respond to the spread of COVID–19. Further, on March 23, 2020, the President signed Executive Order 13910, in which the President delegated to the Secretary of HHS the authority under section 102 of the Act to prevent hoarding and price gouging with respect to health and medical resources necessary to respond to the spread of COVID–19. On March 25, 2020, the Secretary of Health and Human Services designated under section 102 of the Act 15 categories of health and medical resources as scarce materials or materials the supply of which would be threatened by accumulation in excess of the reasonable demands of business, personal, or home consumption, or for the purpose of resale at prices in excess of prevailing market prices (''anti-hoarding designation''). *See* 85 FR 17592 (Mar. 30, 2020). The Secretary of HHS later modified and extended this designation. *See* 85 FR 45895 (July 30, 2020). The anti-hoarding designation relates to domestic hoarding and price-gouging activity, and is conceptually distinct from, and serves different purposes than, this rulemaking.

[14] The Executive Order also delegated to the Secretary of Homeland Security the authority under section 102 of the Act to prevent hoarding and price gouging with respect to such resources, and requires that before exercising the authority under section 102 of the Act, the Secretary of Homeland Security shall consult with the Secretary of Health and Human Services.

[15] *See* 85 FR 20195 (Apr. 10, 2020).

[16] *See* 85 FR 48113 (Aug. 10, 2020).

[17] *See* 85 FR 28500 (May 13, 2020) (codified at 44 CFR part 333). In that interim final rule, FEMA noted that although FEMA effectuated the April allocation order via a temporary rule that predated the interim final rule, FEMA retains authority to administer and enforce that allocation order according to its terms, and to issue future allocation orders consistent with the procedures announced in the interim final rule. *See* 85 FR at 28505. As noted above, in August, FEMA opted to extend the April allocation, with modifications, consistent with the form of the April order. FEMA does the same here.

able to meet the continuing demand for these materials. In short, FEMA has determined that the original temporary final rule must be extended, and the list of covered materials under such rule must be modified.

Consistent with the authority delegated to the Secretary of Homeland Security in E.O. 13911 and re-delegated to the FEMA Administrator, FEMA now issues this temporary final rule to extend and modify the allocation order.

II. Provisions of the Temporary Final Rule

Following consultation with the appropriate Federal agencies; pursuant to the President's direction; and as an exercise of the Administrator's priority order, allocation, and regulatory authorities under the Act, the Administrator has determined that the April 10, 2020, temporary final rule (''covered materials'') shall be extended temporarily, and that the list of scarce and critical materials identified in such temporary final rule shall be modified to reflect current domestic needs. The materials identified in this rule will continue to be allocated for domestic use and may not be exported from the United States without explicit approval by FEMA. *See* 44 CFR 328.102(a).

The rule is necessary and appropriate to promote the national defense with respect to the covered materials because the domestic need for them exceeds the supply. Under this temporary final rule extension, before any shipments of such covered materials may leave the United States, U.S. Customs and Border Protection (CBP) will continue to detain the shipment temporarily, during which time FEMA will determine whether to return for domestic use, issue a rated order for, or allow the export of part or all of the shipment under section 101(a) of the Act, 50 U.S.C. 4511(a). FEMA will continue to make such a determination within a reasonable time of being notified of an intended shipment and will make all decisions consistent with promoting the national defense. *See* 44 CFR 328.102(b). FEMA will work to review and make determinations quickly and will endeavor to minimize disruptions to the supply chain.

In determining whether it is necessary or appropriate to promote the national defense to purchase covered materials, or allocate materials for domestic use, FEMA may continue to consult other agencies and will consider the totality of the circumstances, including the following factors: (1) The need to ensure that such items are appropriately allocated for domestic use; (2) minimization of disruption to the supply chain, both domestically and abroad; (3) the circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns; (4) the quantity and quality of the materials; (5) humanitarian considerations; and (6) international relations and diplomatic considerations.

This extension to the rule continues the eleven exemptions that the Administrator has determined to be necessary or appropriate to promote the national defense. *See* 44 CFR 328.102(d).

Specifically, the Administrator has determined that FEMA will not purchase covered materials from shipments made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020, so long as at least 80 percent of such manufacturer's domestic production of covered materials, on a per item basis, was distributed in the United States in the preceding 12 months. The Administrator decided that this exemption is necessary or appropriate to promote the national defense because it would limit the impact of this order on pre-existing commercial relationships, in recognition of the importance of these commercial relationships to the international supply chain, and for humanitarian reasons, in consideration of the global nature of the COVID–19 pandemic. If FEMA determines that a shipment of covered materials falls within this exemption, such materials may be transferred out of the United States without further review by FEMA, provided that the Administrator may waive this exemption and fully review shipments of covered materials subject to this exemption for further action by FEMA, if the Administrator determines that doing so is necessary or appropriate to promote the national defense. FEMA may develop additional guidance regarding which exports are covered by this exemption and encourages manufacturers to contact FEMA with specific information regarding their status under this exemption.

On April 21, 2020, FEMA published notification of 10 additional exemptions to the original temporary final rule.[18] These exemptions will remain in effect for the new effective period of this rule, subject to the Administrator's discretion to waive, modify, or terminate such exemptions at any time in the future. The Administrator has determined that it continues to be necessary and appropriate to promote the national defense to exempt these categories of covered materials from the requirements of 44 CFR 328.102(a) and (b). The Administrator may establish, in his discretion, additional exemptions that he determines are necessary or appropriate to promote the national defense and will announce any such exemptions by notice in the **Federal Register**.

FEMA will continue to implement this rule with the cooperation and assistance of other U.S. Government agencies, including CBP, and will work with manufacturers, brokers, distributors, exporters, and shippers to ensure that the applicable requirements are carried out. Any covered materials intended for export may be detained by CBP while FEMA conducts its review of the shipment. FEMA will review the shipment and provide notification as soon as possible regarding the disposition of the covered materials under this order, provided that any goods that have been detained by CBP and are subsequently made subject to a DPA-rated order will be consigned to FEMA pending further distribution or agency direction. FEMA may provide additional guidance regarding the application of any exemptions to this temporary final rule, as appropriate.

FEMA is modifying the original temporary final rule's authority citation to include both DHS Delegation Number 09052, Rev. 00 (Jan. 3, 2017) and DHS Delegation Number 09052, Rev. 00.1 (Apr. 1, 2020), and to update the formatting of other citations previously included. FEMA is making a number of non-substantive revisions throughout part 328 to correct formatting errors and improve clarity and readability. FEMA is also modifying the original temporary final rule at § 328.101 to reflect the appropriate statutory language from section 101 of the Act. FEMA is further modifying § 328.103(a) to update the designation of covered materials under the rule. FEMA is further clarifying the types of PPE surgical masks subject to the allocation order and is adding specific syringes and hypodermic needles (whether distributed separately or attached together). The continued allocation of certain PPE materials reflects current domestic demand, as indicated by the number of open requests for such materials from State, local, Tribal, and territorial (SLTT) jurisdictions. Specifically—

- FEMA is continuing the designation of Surgical N95 Filtering Facepiece Respirators as covered materials. Surgical N95 respirators for medical use are still subject to high demand within the United States, and supply is not expected to catch up with demand at this time given the current forecasts of

[18] 85 FR 22021 (Apr. 21, 2020).

increases in confirmed cases and hospitalizations.

• FEMA is continuing the designation of PPE surgical masks as covered materials due to the continued inability of domestic supply to meet current demands, with modification. In the original temporary final rule, FEMA designated ''PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials.'' This temporary final rule clarifies the existing language regarding the PPE surgical masks subject to this order. As revised, 44 CFR 328.103(a)(2) now specifically designates PPE surgical masks as described by 21 CFR 878.4040, including masks that cover the user's nose and mouth providing a physical barrier to fluids and particulate materials that meet fluid barrier protection standards pursuant to ASTM F 1862 [19] and to Class I or Class II flammability tests under CPSC CS 191–53,[20] NFPA Standard 702–1980,[21] or UL 2154 standards.[22] As of December 9, 2020, FEMA had open requests for over 13 million surgical masks from SLTT jurisdictions.

• FEMA is also continuing the designation of PPE nitrile gloves as covered materials with one minor edit to clarify the specific types of gloves subject to the order. There is still a significant shortage of nitrile gloves. As of December 9, 2020, FEMA had open requests for over 168 million nitrile gloves from SLTT jurisdictions.

• FEMA is continuing the designation of Level 3 and 4 Surgical Gowns and Surgical Isolation Gowns that meet all of the requirements in ANSI/AAMI PB70 [23] and ASTM F2407–06 [24] and are classified by Surgical Gown Barrier Performance based on AAMI PB70. At this time, domestic supply is not meeting demand. As of December 9, 2020, FEMA had open requests for over 1.2 million of these gowns from SLTT jurisdictions.

• FEMA is adding designations for specific syringes and hypodermic needles (whether distributed separately or attached together) to the covered materials list. The designated materials are piston syringes and hypodermic needles that are either: Piston syringes that allow for the controlled and precise flow of liquid as described by 21 CFR 880.5860, that are compliant with ISO 7886–1:2017,[25] and use only Current Good Manufacturing Practice (CGMP) processes; [26] or hypodermic single lumen needles as described by 21 CFR 880.5570 that have engineered sharps injury protections as described in the Needlestick Safety and Prevention Act.[27] Due to the current high rate of influenza vaccine administration, in conjunction with the development of COVID–19 vaccines, the projected domestic supply of these materials is not anticipated to meet demand. As of the week of December 4, 2020, more than 189.4 million influenza vaccine doses had been distributed in the United States for this influenza season [28] compared to the 2019–2020 influenza season, where approximately 174.5 million influenza vaccine doses were distributed for the entire season,[29] representing an increase of over 14.9 million vaccine doses so far in the 2020–2021 influenza season. A record number of influenza vaccine doses is being produced and distributed this influenza season, and production and distribution will occur over a longer period of time as a result,[30] further reducing the domestic supply of syringes. Additionally, as of December 22, 2020, the United States has authorized for emergency use two COVID–19 vaccines, with multiple other vaccines in large clinical trials.[31] As of December 16, 2020, the United Kingdom and Canada have also already approved the use of one vaccine for COVID–19.[32] As vaccination efforts expand, FEMA anticipates that these materials will be in short supply.

Consistent with the DPA and the original temporary final rule, FEMA may continue to conduct such investigations and issue such requests for information as may be necessary for the enforcement of the Act, including this rule. *See* 44 CFR 328.104(a); *see also* section 705 of the Act, 50 U.S.C. 4555; Executive Order 13911, 85 FR 18403 (Apr. 1, 2020). FEMA may seek an injunction or other order whenever, in the Administrator's judgment, a person has engaged or is about to engage in any acts or practices which constitute or will constitute a violation of the Act or any rule or order issued thereunder. *See* 44 CFR 328.104(b); *see also* section 706 of the Act, 50 U.S.C. 4556. In addition to an injunction, failure to comply fully with this rule is a crime punishable by a fine of not more than $10,000 or imprisonment for not more than one year, or both. *See* 44 CFR 328.104(c); *see also* section 103 of the Act, 50 U.S.C. 4513. In addition, pursuant to 18 U.S.C. 554, whoever fraudulently or knowingly exports or sends from the United States, or attempts to export or send from the United States, any merchandise, article, or object contrary to any U.S. law or regulation, or receives, conceals, buys, sells, or in any manner facilitates the transportation, concealment, or sale of such merchandise, article, or object, prior to exportation, knowing the same to be intended for exportation contrary to any U.S. law or regulation, faces up to 10 years' imprisonment, a fine, or both, if convicted.

At any point in time, and to the extent consistent with United States policy, the

[19] The American Society for Testing and Materia (ASTM) F 1862 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) is the test method used to evaluate the resistance of medical face masks to penetration by the impact of a small volume ((~2 mL) of a high-velocity stream of synthetic blood. Medical face mask pass/fail determinations are based on visual detection of synthetic blood penetration.

[20] The Consumer Protection Safety Commission (CPSC) CS 191–53 standard is the flammability standard for clothing textiles pursuant to 16 CFR part 1610.

[21] The National Fire Protection Association (NFPA) Standard 702–1980 is the standard for classification of the flammability of wearing apparel.

[22] UL (previously Underwriters Laboratories) is a global independent safety science company with expertise in innovating safety solutions. The UL 2154 is the standard for safety fire tests of surgical fabrics.

[23] ANSI/AAMI PB70 is the second edition of the standard for liquid barrier performance of protective apparel.

[24] The American Society for Testing and Material (ASTM) F2407 is an umbrella document which describes testing for surgical gowns: Tear resistance, seam strength, lint generation, evaporative resistance, and water vapor transmission.

[25] ISO 7886–1:2017 specifies requirements and test methods for verifying the design of empty sterile single-use hypodermic syringes, with or without needle, made of plastic or other materials and intended for the aspiration and injection of fluids after filling by the end-users.

[26] More information on CGMP processes can be found on the Food and Drug Administration (FDA) website, Facts About the Current Good Manufacturing Practices (CGMPs) (June 25, 2018), *https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps.*

[27] Public Law 106–430, 114 Stat. 1901 (Nov. 6, 2000).

[28] *https://www.cdc.gov/flu/prevent/vaccine-supply-distribution.htm* (accessed December 15, 2020). As of November 27, 2020, 188 million doses of influenza vaccine had been distributed in the United States, the highest number of influenza doses distributed in the United States during a single influenza season. *https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-distribution.html* (accessed December 15, 2020).

[29] *https://www.cdc.gov/flu/prevent/vaccine-supply-historical.htm* (accessed December 15, 2020).

[30] *https://www.cdc.gov/flu/prevent/vaccine-supply-distribution.htm* (accessed December 15, 2020).

[31] *See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html* (accessed December 22, 2020).

[32] *https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine* (accessed December 15, 2020) and *https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines.html* (accessed December 15, 2020).

FEMA Administrator may determine additional materials to be subject to this allocation order. Upon a determination under section 101(b) of the DPA that an additional material is a scarce and critical material essential for national defense, and that being allocated to domestic use under this allocation order is the only way to meet national defense requirements without significant disruption to the domestic markets, the Administrator will include these additional materials in this allocation order, and will provide notification of this decision through publication in the **Federal Register**.

III. Regulatory Procedure and Analyses

A. Temporary Final Rule With Immediate Effective Date

Agency rulemaking is generally governed by the agency rulemaking provisions of the Administrative Procedure Act (APA). *See* 5 U.S.C. 553. Such provisions generally require that, unless the rule falls within one of a number of enumerated exceptions, or unless another statute exempts the rulemaking from the requirements of the APA, FEMA must publish a notice of proposed rulemaking in the **Federal Register** that provides interested persons an opportunity to submit written data, views, or arguments, prior to finalization of regulatory requirements. Section 553(b)(B) authorizes a department or agency to dispense with the prior notice and opportunity for public comment requirement when the agency, for ''good cause,'' finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

This rule is exempt from the APA under section 709(a) of the Act, 50 U.S.C. 4559(a). Instead, this rule is issued subject to the provisions of section 709(b). Pursuant to section 709(b)(2) of the Act, the Administrator has concluded, based on the facts related to the COVID–19 pandemic, that, with respect to this temporary final rule, urgent and compelling circumstances continue to make compliance with the notice and comment requirements of section 709(b)(1) of the Act, 50 U.S.C. 4559(b)(1), impracticable. The COVID–19 pandemic continues to grow worldwide. The World Health Organization reports over 71.5 million cases and over 1.6 million deaths in 220 countries as of December 15, 2020.[33] The severity of the pandemic has increased significantly in the United States in recent months, with surges of up to 244,007 new cases in a single day.[34] The United States now leads the world in the total number of COVID–19 cases and deaths [35] and the Centers for Disease Control and Prevention (CDC) estimates the number of confirmed cases and deaths in the United States will continue to increase.[36] As a result of the surge in U.S. confirmed cases and deaths, demand for PPE used to treat patients with the disease has increased and the domestic supply has been unable to keep pace. As explained above, FEMA continues to have a high volume of open requests for the specific types of PPE listed in this allocation order and anticipates this volume will increase given the COVID–19 forecasts from the CDC. The historic increase in the number of influenza vaccine doses manufactured and distributed this influenza season combined with the authorization for emergency use of vaccines for COVID–19 and the demand for the same by those who wish to be vaccinated against the disease means the projected domestic supply of syringes and hypodermic needles will not meet demand in the upcoming months.[37] If final regulations become necessary, an opportunity for public comment will be provided for not less than 30 days before such regulations become final, pursuant to section 709(b)(2)(C) of the Act, 50 U.S.C. 4559(b)(2)(C).

Furthermore, the same facts that warrant waiver under section 709(b)(2) of the Act would constitute good cause for FEMA to determine, under the APA, that notice and public comment thereon are impractical, unnecessary, or contrary to the public interest, and that the temporary final rule should become effective immediately upon publication in the **Federal Register**. The exigent need for this rule is related to the COVID–19 pandemic.

Although the Federal Government, along with State and local governments, have taken preventative and proactive measures to slow the spread of COVID–19, and to treat those affected, the current surge of confirmed COVID–19 cases and deaths within the Nation's communities is straining the Nation's healthcare systems. It is imperative that health and medical resources needed to respond to the spread of COVID–19, including the PPE and other health and medical resources affected by this rule, continue to be allocated for domestic use as appropriate. Given the evolving nature of this pandemic, the current surge in confirmed COVID–19 cases and deaths, and the frequently changing supply of and demand for the health and medical resources needed to combat it, full public notice and comment proceedings are impracticable. As explained earlier in the preamble, the volume of requests for certain health and medical resources continues to outpace domestic supply. FEMA is continuously monitoring SLTT jurisdictions' demand for these scarce and critical health and medical resources and is taking this immediate action to continue to ensure that such resources are appropriately allocated for domestic use to continue to combat the current surge of confirmed COVID–19 cases and deaths, the forecasted increase in both, and the projected shortages of supplies to ensure the effective distribution of influenza vaccine doses and COVID–19 vaccine doses for those who wish to be vaccinated against these diseases.

In short, given the national and international emergency caused by COVID–19 and the current surge of confirmed cases and deaths, FEMA finds that urgent and compelling circumstances have made it impracticable and contrary to the public health—and, by extension, the public interest—to delay these implementing regulations until a full public notice-and-comment process is completed. Based on current needs, this temporary final rule modification and extension is needed to appropriately allocate scarce and critical materials for domestic use. Specifically, FEMA seeks to continue designation of certain PPE materials with minor modifications based on current demand and to add other health and medical resources based on projected domestic supply not meeting demand.

The measures described in this rule are being issued on a temporary basis. This temporary final rule with

[33] *https://www.who.int/emergencies/diseases/novel-coronavirus-2019* (accessed December 15, 2020).

[34] *https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases* (accessed December 15, 2020).

[35] *https://covid19.who.int/* (accessed December 15, 2020). The United States has over 16 million confirmed cases compared to over 9.9 million confirmed cases in India as of December 15, 2020. The United States has over 296,000 deaths from COVID–19 compared to over 181,000 deaths in Brazil from COVID–19 as of December 15, 2020.

[36] *https://covid.cdc.gov/covid-data-tracker/#forecasting_weeklycases* (accessed December 15, 2020) and *https://covid.cdc.gov/covid-data-tracker/#forecasting_weeklydeaths* (accessed December 15, 2020).

[37] A record number of influenza vaccine doses is being produced and distributed this influenza season, and production and distribution will occur over a longer period as a result. *https://www.cdc.gov/flu/prevent/vaccine-supply-distribution.htm* (accessed December 15, 2020). As of December 22, 2020, the United States has authorized for emergency use two COVID–19 vaccines, with multiple other vaccines in large clinical trials. *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html* (accessed December 22, 2020).

modification remains in effect until June 30, 2021, unless sooner modified or terminated by the Administrator.

B. Executive Orders 12866 and 13563

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 (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a regulation that may (1) have an annual effect on the economy of $100 million or more, or adversely affect in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities (also referred to as ''economically significant''); (2) create a serious inconsistency or otherwise interfere 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) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The Office of Management and Budget has designated this temporary final rule as an economically significant regulatory action. Given that the temporary final rule is a significant regulatory action, FEMA proceeds under the emergency provision of Executive Order 12866, section 6(a)(3)(D) based on the need for immediate action, as described above, to ensure these health and medical resources are appropriately allocated for domestic use.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that when an agency issues a proposed rule, or a final rule that the agency issues under 5 U.S.C. 553 after being required by that section or any other law to publish a general notice of proposed rulemaking, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**. 5 U.S.C. 603, 604.

This is neither a proposed rule, nor a final rule that the agency has issued under 5 U.S.C. 553 after being required by that section or any other law to publish a general notice of proposed rulemaking. This is a temporary final rule issued without a prior proposed rule, under the separate authority of the Defense Production Act of 1950. Accordingly, a regulatory flexibility analysis is not required.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), 2 U.S.C. 1532, requires that covered agencies prepare a budgetary impact statement before promulgating a 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 million in 1995 dollars, updated annually for inflation. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. DHS has determined that this rule is not expected to result in expenditures by State, local, and Tribal governments, or by the private sector, in that amount in any one year. This rule imposes no requirements on State, local, and Tribal governments and, therefore, cannot require them to expend any funds, let alone in excess of the threshold. To the extent that this rule affects the private sector, it only prohibits conduct, namely certain exports. It does not require any private sector expenditures within the meaning of the Unfunded Mandates Act. Further, the rule is excluded from the Unfunded Mandates Act under 2 U.S.C. 1532(a) and 1503(4) and (5).

E. National Environmental Policy Act (NEPA)

Under the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 4321 *et seq.,* an agency must prepare an environmental assessment or environmental impact statement for any rulemaking that significantly affects the quality of the human environment. FEMA has determined that this rulemaking does not significantly affect the quality of the human environment and consequently has not prepared an environmental assessment or environmental impact statement.

Rulemaking is a major Federal action subject to NEPA. Categorical exclusion A3 included in the list of exclusion categories at Department of Homeland Security Instruction Manual 023–01–001–01, Revision 01, Implementation of the National Environmental Policy Act, Appendix A, issued November 6, 2014, covers the promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, and advisory circulars if they meet certain criteria provided in A3(a–f). This temporary final rule meets Categorical Exclusion A3(a), ''Those of a strictly administrative or procedural nature''.

F. Executive Order 13132: Federalism

This rule has been reviewed under Executive Order 13132, Federalism, 64 FR 43255 (August 4, 1999). That Executive order imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. DHS has determined that this temporary final rule will not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Furthermore, there are no provisions in this rule that impose direct compliance costs on State and local governments. Accordingly, DHS is not providing the additional analysis as the rule does not warrant additional analysis under Executive Order 13132.

G. Congressional Review Act

Under the Congressional Review Act (CRA), 5 U.S.C. 801–808, before a rule can take effect, the Federal agency promulgating the rule must: Submit to Congress and to the Government Accountability Office (GAO) a copy of the rule; a concise general statement relating to the rule, including whether it is a major rule; the proposed effective date of the rule; a copy of any cost-benefit analysis; descriptions of the agency's actions under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act; and any other information or statements required by relevant Executive orders.

FEMA has sent this rule to the Congress and to GAO pursuant to the CRA. The Office of Information and Regulatory affairs has determined that this rule is a ''major rule'' within the meaning of the CRA. As this rule contains FEMA's finding for good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, there is not a required delay in the effective date. *See* 5 U.S.C. 808.

List of Subjects in 44 CFR Part 328

Administrative practice and procedure, Business and industry, Government contracts, Health or medical resource, Hoarding, Investigations, Materials, National defense, Scarce materials, Strategic and critical materials, Threatened materials.

■ Accordingly, for the reasons set forth in the preamble, and effective from December 31, 2020 until June 30, 2021, chapter I of title 44 of the Code of Federal Regulations is amended by revising part 328 to read as follows:

PART 328—COVID–19 ALLOCATION ORDERS AND PRIORITY ORDER REVIEW UNDER THE DEFENSE PRODUCTION ACT

Sec.
328.101 Basis and purpose.
328.102 Requirements.
328.103 Designation of covered materials.
328.104 Investigations and injunctions; penalties.

Authority: 50 U.S.C. 4511, *et seq.;* E.O. 13909, 85 FR 16227; E.O. 13911, 85 FR 18403; DHS Delegation Number 09052, Rev. 00 (Jan. 3, 2017); DHS Delegation Number 09052, Rev. 00.1 (Apr. 1, 2020); Presidential Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (Apr. 3, 2020).

§ 328.101 Basis and purpose.

(a) *Basis.* The rules in this part are issued pursuant to section 101 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4511, and complementary authorities, including such authorities as are contained in subchapter III of chapter 55 of title 50, United States Code (50 U.S.C. 4554, 4555, 4556, and 4559), which have been delegated to the Federal Emergency Management Agency (FEMA).

(b) *Purpose.* The purpose of the rules in this part are to aid the response of the United States to the spread of COVID–19 by ensuring that scarce and critical health and medical resources are appropriately allocated for domestic use.

§ 328.102 Requirements.

(a) *Allocation order and requirement for the Administrator's approval.* All shipments of covered materials, as designated in § 328.103, shall be allocated for domestic use, and may not be exported from the United States without explicit approval by FEMA.

(b) *Procedures.* U.S. Customs and Border Protection (CBP), in coordination with such other officials as may be appropriate, will notify FEMA of an intended export of covered materials. CBP must temporarily detain any shipment of such covered materials, pending the Administrator's determination whether to return for domestic use or issue a rated order for part or all of the shipment, pursuant to the Administrator's delegated authorities. The Administrator will make such a determination within a reasonable timeframe after notification of an intended export.

(c) *Administrator's determination.* In making the determination described in paragraph (b) of this section, the Administrator may consult other agencies and will consider the totality of the circumstances, including the following factors:

(1) The need to ensure that scarce or threatened items are appropriately allocated for domestic use;

(2) Minimization of disruption to the supply chain, both domestically and abroad;

(3) The circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns;

(4) The quantity and quality of the materials;

(5) Humanitarian considerations; and

(6) International relations and diplomatic considerations.

(d) *Exemption.* (1) The Administrator has determined in the interest of promoting the national defense to generally allow the export of covered materials from shipments made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020, so long as at least 80 percent of such manufacturer's domestic production of such covered materials, on a per item basis, was distributed in the United States in the preceding 12 months. If FEMA determines that a shipment of covered materials falls within the exemption in this paragraph (d), such materials may be exported without further review by FEMA, provided that the Administrator may waive the exemption in this paragraph (d) and fully review shipments of covered materials under paragraph (b) of this section, if the Administrator determines that doing so is necessary or appropriate to promote the national defense. FEMA will communicate to CBP regarding the application of the exemption in this paragraph (d) to shipments identified by CBP.

(2) The Administrator may establish, in his or her discretion, additional exemptions that he or she determines necessary or appropriate to promote the national defense and will announce any such exemptions by notice in the **Federal Register**.

(e) *Exportations prohibited.* The exportation of covered materials other than in accordance with this section is prohibited.

§ 328.103 Designation of covered materials.

(a) The Administrator has designated the following materials as ''covered materials'' under this part:

(1) Surgical N95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates;

(2) PPE surgical masks as described by 21 CFR 878.4040, including masks that cover the user's nose and mouth providing a physical barrier to fluids and particulate materials, that meet fluid barrier protection standards pursuant to—

(i) ASTM F 1862; and

(ii) Class I or Class II flammability tests under CPSC CS 191–53, NFPA Standard 702–1980, or UL 2154 standards;

(3) PPE nitrile gloves, specifically those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such nitrile gloves intended for the same purposes;

(4) Level 3 and 4 Surgical Gowns and Surgical Isolation Gowns that meet all of the requirements in ANSI/AAMI PB70 and ASTM F2407–06 and are classified by Surgical Gown Barrier Performance based on AAMI PB70; and

(5) Syringes and hypodermic needles (whether distributed separately or attached together) that are either:

(i) Piston syringes that allow for the controlled and precise flow of liquid as described by 21 CFR 880.5860, that are compliant with ISO 7886–1:2017 and use only Current Good Manufacturing Practices (CGMP) processes; or

(ii) Hypodermic single lumen needles that have engineered sharps injury protections as described in the Needlestick Safety and Prevention Act, Pub. L. 106–430, 114 Stat. 1901 (Nov. 6, 2000).

(b) Upon determination that additional items are scarce and necessary for national defense, and that consideration under the allocation order in this part is the only way to meet national defense requirements without significant disruption to the domestic markets, the Administrator may designate additional materials as ''covered materials'' in the list provided in paragraph (a) of this section. The Administrator will publish notice of

these additional ''covered materials'' in the **Federal Register**.

§ 328.104 Investigations and injunctions; penalties.

(a) To administer or enforce this part, the Administrator may exercise the authorities available under section 705 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4555, including the conduct of investigations, requests for information or testimony, and inspections of records or premises. Before such authorities are utilized, the Administrator will determine the scope and purpose of the investigation, inspection, or inquiry, and be assured that no adequate and authoritative data are available from any Federal or other responsible agency.

(b) Whenever, in the judgment of the Administrator, any person has engaged or is about to engage in any acts or practices that constitute or will constitute a violation of any provision of this part, or order issued thereunder, the Administrator may exercise the authorities available under section 706 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4556, including applying for a preliminary, permanent, or temporary injunction, restraining order, or other order to enforce compliance with this part.

(c) Any person who willfully engages in violations of this part is subject to penalties available under section 103 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4513, or other available authority.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–29060 Filed 12–30–20; 8:45 am]

BILLING CODE 9111–19–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 389

[Docket No. FMCSA–2016–0341]

RIN 2126–AB96

Rulemaking Procedures Update

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

ACTION: Final rule.

SUMMARY: FMCSA amends its rulemaking procedures by revising the process for preparing and adopting rules and petitions. Also, the Agency adds new definitions, and makes general administrative corrections throughout its rulemaking procedures. These actions are authorized under the Fixing America's Surface Transportation (FAST) Act and the Administrative Procedure Act (APA).

DATES: This final rule is effective March 1, 2021.

Petitions for Reconsideration of this final rule must be submitted to the FMCSA Administrator no later than February 1, 2021. You may use today's amended procedures below in 49 CFR 389.35.

FOR FURTHER INFORMATION CONTACT: Mr. Steven J. LaFreniere, Regulatory Ombudsman, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–0596, *steven.lafreniere@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: This final rule is organized as follows:

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I. Rulemaking Documents

A. Availability of Rulemaking Documents

For access to docket FMCSA–2016–0341 to read background documents and comments received, go to *http://www.regulations.gov* at any time, or to Dockets Operations at U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, 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.*

II. Legal Basis for the Rulemaking

The FAST Act requires FMCSA to address its rulemaking and petitions procedures. Specifically, section 5202 provides requirements for the Agency to follow regarding the development of proposed rulemakings [49 U.S.C. 31136(f)–(h)]. Section 5204 also directs the Agency to be more transparent to the public regarding how FMCSA prioritizes and defines petitions.

The APA (5 U.S.C. 551–706) established procedures for all Federal agencies to use in developing rules and regulations. It also established the standards that allow the public to participate in a rulemaking as well as the opportunity to petition the Federal government for the issuance, amendment, or repeal of a rule. The APA authorizes changes to 49 CFR part 389, beyond what is required by the FAST Act.

DOT's regulatory procedures, codified at 49 CFR part 5, also describe how persons may petition a departmental Operating Administration, like FMCSA, for a new rulemaking, an exemption from an existing rule, or a retrospective review. These departmental procedures apply unless a statute or an Operating Administration's regulations or procedures provide alternate procedures for processing petitions. FMCSA's procedures are housed in 49 CFR part 389, and are the subject of this rulemaking.

III. Discussion of Proposed Rulemaking

FMCSA published a notice of proposed rulemaking (NPRM) on August 7, 2017 (82 FR 36719) that proposed several changes to the regulatory procedural requirements found in 49 CFR part 389. These changes fell into the three general categories outlined below, and are explained in further detail in the section-by-section analysis.

A. Advance Rulemaking Procedures Required

FMCSA proposed new rulemaking provisions required by the FAST Act where the Agency must consider undertaking a negotiated rulemaking or an ANPRM for all major rules regarding commercial motor vehicle (CMV) safety. However, the FAST Act allows the Administrator to waive this requirement in instances where those tools would be impracticable, unnecessary, or contrary to the public interest. Additionally, the NPRM proposed to adopt the definition of a ''major rule'' from the Congressional Review Act (5 U.S.C. 804). FMCSA would use this definition to determine whether an ANPRM or negotiated rulemaking process is necessary.

B. Definition and Processing of a Petition

Prior to this final rule, FMCSA regulations for submitting petitions (49 CFR part 389) included no regulatory definition of a petition. Section 5204 of the FAST Act defines the term *petition.* It includes requests for: A new regulation; a regulatory interpretation or clarification; or a determination by FMCSA that a regulation should be modified or eliminated for one of several enumerated reasons prescribed in section 5204. FMCSA proposed including this definition in part 389.

Additionally, the NPRM proposed a new process for filing and addressing petitions. These changes were proposed to clarify FMCSA's procedures for rulemaking, and to make editorial changes.

Finally, FMCSA proposed to add a definition for *written or in writing* that would include electronic documentation.

C. Direct Final Rulemaking Procedures

Under FMCSA's direct final rulemaking (DFR) procedures in effect at the time of the NPRM, if the Agency received a notice of intent (NOI) to file an adverse comment, the DFR would be withdrawn, even if the comment that was eventually filed did not meet the definition of an adverse comment found in 49 CFR 389.39(b). The NPRM proposed to change this requirement. Upon receiving an NOI to file an adverse comment, the Agency would extend the comment period rather than withdraw the DFR, allowing the commenter additional time to file the comment. Once FMCSA received the comment, the Agency would determine whether it was adverse. If it was an adverse comment, FMCSA would withdraw the DFR; however, if it did not meet the definition of *adverse comment* in § 389.39(b), the Agency would move forward with the DFR. If the same or another commenter submitted an NOI at the end of the extended comment period, FMCSA would determine, on a case-by-case basis, whether to extend the comment period again, withdraw the DFR, or proceed with the DFR using only the comments already received.

IV. Discussion of Comments and Responses

General

FMCSA received comments from 10 commenters: The National Federation of Independent Business (NFIB); the National Rural Electric Cooperative Association (NRECA); the National Tank Truck Carriers (NTTC); the American Fuel and Petrochemical Manufacturers (AFPM); the Transportation Trades Department of the AFL–CIO; an individual, Mr. Max Miller; the New York University School of Law (NYU); the National School Transportation Association (NSTA); and two anonymous commenters. Generally, all commenters were supportive of the rule, though some suggested additional regulatory changes.

Two commenters were overall supportive of the rule, stating that the proposed changes would make the rulemaking process more efficient and alleviate confusion. In addition, the changes to the DFR procedures provide the Agency greater flexibility.

AFPM supports the definition of a ''major rule'' and the provisions requiring advance or negotiated rulemakings for major rules.

Comments Outside the Scope of This Rulemaking

One anonymous commenter appeared to copy and paste a partial section of Executive Order 13783, Promoting Energy Independence and Economic Growth, which is outside the scope of this rulemaking.

Another anonymous commenter stated that FMCSA should expand on the Digital Accountability and Transparency Act, which was enacted to link Federal agency spending to Federal program activities so that taxpayers and policymakers can more effectively track Federal spending. That comment is outside the scope of this rulemaking.

Comments on the Petition Process

NFIB and NYU both suggested changes to the definition of *petition.* NFIB said the definition should be revised to include FMCSA's constitutional obligation to receive petitions for the redress of grievances. Secondly, FMCSA should receive petitions for any reason when it comes to issuance, amendment, or repeal of FMCSA rules. NYU stated that the definition of *petition* should be revised because it is too narrowly focused on ''burdensome'' rules. NYU also stated that FMCSA should provide additional details on its online petition docket such as including links to the text of the original petitions and timetables for responses to them.

NYU also provided recommendations from the Administrative Conference of the United States (ACUS), Recommendations 2014–6, Petitions for Rulemaking. NYU recommended that the Agency should explain how it will coordinate consideration of petitions with other processes used to determine Agency priorities; explain what type of data and arguments are most useful for petitioners to provide to aid FMCSA's evaluation; expand on its openness to new evidence by facilitating communication between Agency personnel and petitioners; and invite public comment on petitions as appropriate.

FMCSA Response

FMCSA does not limit the scope of stakeholders' petitions for rulemaking. The purpose of the final rule is to implement the FAST Act provisions regarding petitions for rulemaking. The First Amendment right to petition for redress of grievances is available at any time on any issue. FMCSA notes that in addition to petitions for rulemaking, departmental regulations provide that interested persons may file petitions for DOT to issue an exemption from any requirements of a rule or perform a retrospective review of an existing rule.[1] However, this final rule is specific to petitions for rulemaking concerning FMCSA's regulations.

FMCSA does not agree that the proposed definition of *petition,* as defined in the FAST Act, narrowly focuses only on ''burdensome'' rules. The definition provides perspective on what petitions should focus on. The fact that the first part in the definition is a request for ''a new regulation'' without

[1] See 49 CFR 5.13(c).

any constraints around it, means that Congress is not focused on only removing ''burdensome'' rules.

With respect to NYU's comment, FMCSA agrees that the Agency should provide more transparent and timely information on the status of petitions that have been filed. While FMCSA has not made any changes to the regulatory text, the Agency currently provides information concerning the status of petitions via its website, *https://www.fmcsa.dot.gov/petitions.* Interested parties can review information on petitions that have been submitted, the date the Agency acknowledged the petition, and the date of Agency decisions and rulemaking actions initiated in response to the petitions. The Agency is committed to continuing to provide such information in the future.

FMCSA has already implemented many of the ACUS recommendations, such as coordinating within FMCSA offices on the prioritization of petitions, and the Agency already invites public comment on petitions as appropriate.

Comments on Section 389.31

NTTC stated that FMCSA's proposed definition of *written or in writing* includes any method of electronic documentation such as email, but that an email address was not included in proposed § 389.31. FMCSA should specify an email address or submission form for electronic petitions for rulemaking to be consistent with the definition of *written or in writing.*

NTTC also stated that in proposed § 389.31(a), FMCSA should add the words ''interpret or clarify,'' between ''amend,'' and ''withdraw.'' AFPM supported the definition of a *petition,* but noted that including ''a regulatory interpretation or clarification'' in the definition would change the scope of the current regulations, with potentially ''negative impacts on FMCSA's ability to provide needed guidance in a timely manner to stakeholders.'' Additionally, AFPM stated that the NPRM did not include FAST Act requirements from section 5204(a)(1)–(5) for transparency, incorporating process timelines, and petition prioritization.

FMCSA Response

FMCSA currently accepts petitions submitted electronically and agrees that petitioners should be able to submit petitions electronically. FMCSA has provided explicit procedures for stakeholders to use for electronically submitting petitions in § 389.31 and in § 389.35. Petitions should be submitted by mail to the Administrator or electronically by using *www.regulations.gov.*

Despite AFPM's concern about its effect, the term ''a regulatory interpretation or clarification'' is one of the elements of the statutory definition of *petition* in section 5204(c) and cannot be omitted.

FMCSA is aware of the requirements on the processing of petitions imposed by section 5204(a)(1)–(5) of the FAST Act. FMCSA determined that inclusion of these requirements in the regulations would make future changes more difficult if alternate methods prove to be more efficient or transparent. However, the Agency will provide more information in the future, once it determines the best path forward to ensure maximum transparency.

Comments on the Comments Process

NFIB requested that FMCSA revise § 389.21 to allow itself to solicit comments in a language other than English, should the need arise.

NFIB also stated that FMCSA should permit commenters to incorporate by reference laws referred to in the comment, instead of requiring submission of copies of such materials.

FMCSA Response

FMCSA does not see a need to add regulatory text to allow submission of comments in a language other than English. Should the need arise for comments in another language, the **Federal Register** document soliciting those comments can make such an exception.

With regard to incorporation by reference, FMCSA can readily obtain copies of State or Federal statutes or regulations mentioned in comments. However, it would be in the petitioners' best interest to quote or provide copies of any other material essential to their argument.

Comments on the Rulemaking Process

NFIB stated that FMCSA should eliminate confusion about when a rule is a final rule in § 389.29. The commenter said that if a final rule is prepared and submitted to the Administrator for consideration, and then, if appropriate, to the Office of Management and Budget (OMB), it is not a final rule.

NYU stated that FMCSA should consider comments to ANPRMs on benefits as well as costs.

The Transportation Trades Department of the AFL–CIO objected to the FAST Act mandates requiring an ANPRM or negotiated rulemaking for all major rules, but recognized the Agency has limited discretion. However, this commenter believed the Agency could make some changes, and suggested the following:

(1) Additional clarification of the term ''significant adverse effect,'' which the commenter believes is vague;

(2) Additional consideration on how FMCSA plans to ensure that major regulations are promulgated in a timely manner; and

(3) Judicious use of the waiver provisions, for example where review of a major rule by the Office of Information and Regulatory Affairs (OIRA) took more than 100 days.

FMCSA Responses

NFIB should note that the changes proposed in § 389.29 are about the various offices within FMCSA that prepare final rules as opposed to a select few FMCSA offices. The process for preparing final rules and submitting them to the Administrator, and if necessary OMB, was codified in the CFR in 1970 and amended in 1988. Although a final rule is not legally binding until its effective date, FMCSA drafts the document with the intent of making it final. The term final rule is therefore appropriate.

FMCSA agrees with NYU and has added the term ''benefits'' to the regulatory text of § 389.13(b)(1)(iii).

Regarding AFL–CIO's comments:

(1) FMCSA will continue to interpret the terms within the definition of ''major rule'' as it has done when interpreting 5 U.S.C. 804, using guidance provided by OIRA, the Small Business Administration (SBA), and the Department of Transportation;

(2) FMCSA will continue to use its prioritization tools to ensure that delays in rulemaking proceedings do not impose or prolong safety risks; and

(3) FMCSA acknowledges that the example provided by the commenter may present a scenario where use of the waiver provision would be necessary, but the Agency cannot commit to any specific use of the waiver at this time. The Administrator will determine, on a case-by-case basis whether to rely upon the waiver for any particular rulemaking proceeding.

Since the publication of the NPRM, DOT published a final rule on Administrative Rulemaking, Guidance, and Enforcement Procedures,[2] which applies to FMCSA's rulemaking procedures. These DOT procedures also require the publication of ANPRMs for the Department's costliest rulemakings (*i.e.,* those rulemakings considered to be either ''economically significant'' or

[2] See 84 FR 71714 (Dec. 27, 2019).

''high impact'').[3] FMCSA anticipates that if a rule is a ''major rule,'' then it would likely also qualify as an ''economically significant'' or ''high impact'' rulemaking, as defined by the Department's procedures at 49 CFR 5.17(a). FMCSA's publication of an ANPRM for these ''major rules'' would thus satisfy both the requirements of the FAST Act, FMCSA's procedures in part 389, and DOT's procedures in part 5. Unlike FMCSA's part 389 procedures, the ANPRM requirement found in DOT procedures, however, may only be waived by the Secretary of Transportation, the Department's Regulatory Reform Officer, Regulatory Reform Task Force, or unless otherwise required by law.

Comments on the Direct Final Rule Process

AFPM did not object to the change to the Notice of Intent/Direct Final Rule (NOI/DFR) procedures in § 389.39 but questioned the need to make the change. It contended that the proposal was not adequately discussed in the NPRM and did not follow the DFR procedures of other DOT modes.

FMCSA Response

FMCSA is not including any changes to the Direct Final Rule procedures in § 389.39 in today's final rule. Since the publication of the NPRM, the Department's final rule on Administrative Rulemaking, Guidance, and Enforcement Procedures [4] revised all direct final rule procedures to ensure consistency across DOT Operating Administrations, including FMCSA's procedures at 49 CFR part 389. In that final rule, the Department removed language that requires FMCSA to withdraw a direct final rule if a notice of intent to file an adverse comment is received; instead, withdrawal is required only upon the actual receipt of an adverse comment. Individuals who intend to file an adverse comment, but do not have enough time to do so, may instead ask to extend the comment period of a direct final rule so that they may have more time to file an adverse comment.

V. International Impacts

The FMCSRs, and any exceptions to the FMCSRs, apply only within the United States (and, in some cases, United States territories). Motor carriers and drivers are subject to the laws and regulations of the countries they operate in, unless an international agreement states otherwise. Drivers and carriers should be aware of the regulatory differences amongst nations.

VI. Section–By–Section Analysis

Throughout part 389, FMCSA will change the term ''rule making'' to ''rulemaking'' for consistency.

Section 389.3 Definitions

FMCSA adds new definitions of *major rule, petition,* and *written or in writing* to § 389.3.

FMCSA slightly revises the definition of *major rule* to ensure that the term ''geographic area'' is not modified by the terms ''Federal, state, or local government agencies.'' The Agency believes this matches the intent of the statutory definition found in the CRA. This change is not intended to create a new category of rules that might be deemed major under the CRA but not major under the FMCSA regulations, or vice versa. In applying this definition, FMCSA will adhere to the same guidance used to determine whether a rule is major under the CRA.

Section 389.13 Initiation of Rulemaking

In § 389.13, FMCSA redesignates the existing text as paragraph (a) and adds paragraphs (b)(1) through (c).

Paragraph (a) is revised to align the FMCSA regulations with the DOT final rule on Administrative Rulemaking, Guidance, and Enforcement Procedures,[5] which requires that the Office of the Secretary approve all new FMCSA rulemakings.

Paragraph (b) of § 389.13 and its subparagraphs include the advanced public participation requirements from section 5202 of the FAST Act. Additionally, based on comments to the NPRM, the term ''benefits'' has been added to further describe the type of information FMCSA would like to receive if a proposed rule is likely to lead to the promulgation of a major rule. Paragraph (c) includes the waiver provision for bypassing the advanced public participation requirements in certain cases, and a cross reference to the DOT requirements for economically significant and high-impact rules, found in 49 CFR 5.17.

Section 389.15 Contents of Notices of Proposed Rulemaking

The title of § 389.15 and § 389.15(a) are changed by removing the space between ''rule'' and ''making.''

Section 389.21 Submission of Written Comments

FMCSA revises § 389.21 to include directions on how comments should be submitted. The Agency removes the text regarding incorporation by reference because it is not relevant to the topic of comment submission. FMCSA also renames the section heading ''Submission of written comments'' to reflect this change.

Section 389.29 Adoption of Final Rules

In § 389.29, FMCSA makes minor changes to the text to clarify the procedure followed when the Agency finalizes a rule.

Section 389.31 Petitions for Rulemaking

In § 389.31(a), the word ''repeal'' is replaced with ''withdraw'' to more accurately describe the removal of a regulation. In paragraph (b)(1) the word ''duplicate'' is replaced with ''writing'' to make use of and follow the definition of this term in § 389.3. This change reflects that the Agency no longer requires duplicate submissions. As a result of comments to the NPRM, FMCSA adds the terms ''interpret'' and ''clarify'' to § 389.31(a) to more accurately describe when an interested person may petition the Administrator.

In § 389.31(b)(1), FMCSA added a means for persons wishing to submit petitions electronically to do so.

Section 389.35 Petitions for Reconsideration

In § 389.35(a), FMCSA added a means for persons wishing to submit petitions electronically to do so.

VII. Regulatory Analyses

A. Executive Order 12866 (Regulatory Planning and Review, as Supplemented by E.O. 13563 and DOT Regulations)

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563 (76 FR 3821, Jan. 21, 2011). In addition, this rule is not significant within the meaning of DOT regulations (49 CFR 5.13(a)). Accordingly, OMB has not reviewed it under that Order.

This rule is procedural in nature, primarily impacting FMCSA's process for promulgation of regulations. Therefore, there are no costs associated with this final rule.

B. Executive Order 13771 Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' does not apply to this action because it is not a significant regulatory

[3] See 49 CFR 5.17(b).

[4] See 84 FR 71714 (Dec. 27, 2019).

[5] See 84 FR 71714 (Dec. 27, 2019).

action, as defined in section 3(f) of Executive Order 12866.

C. Regulatory Flexibility Act (Small Entities)

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term ''small entities'' comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.[6] Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies strive to lessen any adverse effects on these businesses.

As FMCSA believes there are no costs associated with this rule, the Agency does not expect this final rule to have a significant economic impact on a substantial number of small entities. Consequently, I certify that the action would not have a significant economic impact on a substantial number of small entities.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, FMCSA wants to assist small entities in understanding this final rule so that they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the final rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance; please consult the FMCSA point of contact, Mr. Steven LaFreniere, listed in the **FOR FURTHER INFORMATION CONTACT** section of this final rule.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. Specifically, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $168 million (which is the value equivalent of $100 million in 1995, adjusted for inflation to 2019 levels) or more in any one year. As the final rule is procedural in nature and is not expected to result in any costs at the societal level, it would likewise not impose costs to State, local, or Tribal governments.

F. Paperwork Reduction Act (Collection of Information)

This final rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Any changes to existing collections are de minimis.

G. Executive Order 13132 (Federalism)

A rule has implications for federalism under section 1(a) of Executive Order 13132 if it has ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' FMCSA has determined that this final rule does not have substantial direct costs on or for States, nor does it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Impact Statement.

H. Executive Order 12988 (Civil Justice Reform)

This final rule meets applicable standards in sections 3(a) and 3(b) (2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. Executive Order 13045 (Protection of Children)

Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, Apr. 23, 1997), requires agencies issuing ''economically significant'' rules, if the regulation also concerns an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, to include an evaluation of the regulation's environmental health and safety effects on children. The Agency determined this final rule is not economically significant. Therefore, no analysis of the impacts on children is required. In any event, the Agency does not anticipate that this regulatory action would in any respect present an environmental or safety risk that could disproportionately affect children.

J. Executive Order 12630 (Taking of Private Property)

FMCSA reviewed this final rule in accordance with Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and has determined it does not effect a taking of private property or otherwise have taking implications.

K. Privacy

Section 522 of title I of division H of the Consolidated Appropriations Act, 2005, enacted December 8, 2004 (Pub. L. 108–447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note), requires the Agency to conduct a privacy impact assessment (PIA) of a regulation that will affect the privacy of individuals. This final rule does not require the collection of personally identifiable information.

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency which receives records contained in a system of records from a Federal agency for use in a matching program.

The E-Government Act of 2002, Public Law 107–347, 208, 116 Stat. 2899, 2921 (Dec. 17, 2002), requires Federal agencies to conduct a PIA for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form.

No new or substantially changed technology would collect, maintain, or disseminate information due to this final rule. Therefore, FMCSA did not conduct a PIA.

L. Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this final rule.

M. Executive Order 13211 (Energy Supply, Distribution, or Use)

FMCSA has analyzed this final rule under Executive Order 13211, Actions

[6] Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*). See National Archives at *http://www.archives.gov/federal-register/laws/regulaotry-flexibility/601.html.*

Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Agency has determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211. The Administrator of OIRA has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

N. Executive Order 13175 (Indian Tribal Governments)

This final 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.

O. National Technology Transfer and Advancement Act (Technical Standards)

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) are standards that are developed or adopted by voluntary consensus standards bodies. This final rule does not use technical standards. Therefore, FMCSA did not consider the use of voluntary consensus standards.

P. National Environmental Policy Act of 1969

FMCSA analyzed this rule for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321, *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680, Mar. 1, 2004), Appendix 2, paragraph 6.x. The Categorical Exclusion (CE) in paragraph 6.x. addresses regulations implementing procedures for the issuance, amendment, revision and rescission of Federal motor carrier regulations (*e.g.,* the establishment of procedural rules that would provide general guidance on how the agency manages its notice-and-comment rulemaking proceedings, including the handling of petitions for rulemakings, waivers, exemptions, and reconsiderations, and how it manages delegations of authority to carry out certain rulemaking functions.) The content in this rule is covered by this CE and the final action would not have any effect on the quality of the environment.

Q. Executive Order 13783 (Promoting Energy Independence and Economic Growth)

Executive Order 13783 directs executive departments and agencies to review existing regulations that potentially burden the development or use of domestically produced energy resources, and to appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources. In accordance with Executive Order 13783, DOT prepared and submitted a report to the Director of OMB that provides specific recommendations that, to the extent permitted by law, could alleviate or eliminate aspects of agency action that burden domestic energy production. This final rule was not identified by DOT under Executive Order 13783 as potentially causing or alleviating unnecessary burdens on domestic energy production.

List of Subjects in 49 CFR Part 389

Administrative practice and procedure, Highway safety, Motor carriers, Motor vehicle safety.

In consideration of the foregoing, FMCSA amends 49 CFR chapter III, part 389 to read as follows:

PART 389—RULEMAKING PROCEDURES—FEDERAL MOTOR CARRIER SAFETY REGULATIONS

■ 1. The authority citation for part 389 is revised to read as follows:

Authority: 49 U.S.C. 113, 501 *et seq.,* subchapters I and III of chapter 311, chapter 313, and 31502; sec. 5204 of Pub. L. 114–94, 129 Stat. 1312, 1536; 42 U.S.C. 4917; and 49 CFR 1.87.

■ 2. Amend § 389.3 by adding the definitions for ''*Major rule*'', ''*Petition*'', and ''*Written or in writing*'', in alphabetical order to read as follows:

§ 389.3 Definitions.

* * * * *

Major rule means—

(1) Any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in:

(i) An annual effect on the economy of $100,000,000 or more;

(ii) A major increase in costs or prices for consumers, individual industries, geographic regions, or Federal, State, or local government agencies; or

(iii) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

(2) The term does not include any rule promulgated under the Telecommunications Act of 1996 and the amendments made by that Act.

Petition means a request for:

(1) A new regulation;

(i) A regulatory interpretation or clarification; or

(ii) A determination made by the Administrator that a regulation should be modified or eliminated because it is:

(A) No longer:

(*1*) Consistent and clear;

(*2*) Current with the operational realities of the motor carrier industry; or

(*3*) Uniformly enforced;

(B) Ineffective; or

(C) Overly burdensome.

Written or in writing means printed, handwritten, typewritten either on paper or other tangible medium, or by any method of electronic documentation such as electronic mail.

§ 389.7 [Amended]

■ 3. Amend § 389.7 by replacing the term ''rule making'' with ''rulemaking''.

■ 4. Revise § 389.13 to read as follows:

§ 389.13 Initiation of rulemaking.

(a) Rulemakings are initiated in accordance with the procedures found in 49 CFR 5.11. The Administrator may recommend the initiation of a rulemaking to the Office of the Secretary on his/her own motion. However, in so doing, he/she may, in his/her discretion, consider the recommendations of his/her staff or other agencies of the United States or of other interested persons.

(b) If a proposed rule regarding commercial motor vehicle safety is likely to lead to the promulgation of a major rule, the Administrator, before publishing such proposed rule, shall—

(1) Issue an advance notice of proposed rulemaking that:

(i) Identifies the need for a potential regulatory action;

(ii) Identifies and requests public comment on the best available science

or technical information relevant to analyzing potential regulatory alternatives;

(iii) Requests public comment on the available data, benefits, and costs with respect to regulatory alternatives reasonably likely to be considered as part of the rulemaking; and

(iv) Requests public comment on available alternatives to regulation; or

(2) Proceed with a negotiated rulemaking.

(c) Paragraph (b) of this section does not apply to a proposed rule if the Administrator, for good cause, finds (and incorporates the finding and a brief statement of reasons for such finding in the proposed or final rule) that an advance notice of proposed rulemaking is impracticable, unnecessary, or contrary to the public interest. A proposed rule subject to paragraph (b) of this section should also be evaluated to determine the applicability of 49 CFR 5.17.

§ 389.15 [Amended]

■ 5. The title of § 389.15 and paragraphs (a) and (b)(1) are revised by removing the term ''rule making'' and replacing it with the term ''rulemaking.''

■ 6. Revise § 389.21 to read as follows:

§ 389.21 Submission of written comments.

(a) You may submit comments identified by the docket number provided in the rulemaking document using any of the following methods. To avoid duplication, please use only one of these four methods.

(1) *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.

(2) *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

(3) *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

(4) *Fax:* (202) 493–2251.

(b) All written comments must be submitted in English and include copies of any material that the commenter refers to within the comment.

■ 7. Revise § 389.29 to read as follows:

§ 389.29 Adoption of final rules.

Final rules are prepared by representatives from all relevant offices of FMCSA. The final rule is then submitted to the Administrator for his/her consideration and forwarded, as necessary, to the Office of the Secretary for review and approval. Once approved by the Office of the Secretary, and, if necessary, by the Office of Management and Budget's Office of Information and Regulatory Affairs, the final rule is signed by the Administrator. All final rules must be published in the **Federal Register**, unless all persons subject to the final rule are named and personally served with a copy of it.

■ 8. Revise § 389.31 to read as follows:

§ 389.31 Petitions for rulemaking.

(a) Any interested person may petition the Administrator to establish, amend, interpret, clarify, or withdraw a rule.

(b) Each petition filed under this section must:

(1) Be submitted in writing by mail to the Administrator, Federal Motor Carrier Safety Administration, 1200 New Jersey Ave. SE, Washington, DC 20590–0001 or electronically at *www.regulations.gov,* using the general petitions for rulemaking docket listed on FMCSA's website at *www.FMCSA.gov.*

(2) Set forth the text or substance of the rule or amendment proposed, or specify the rule that the petitioner seeks to have interpreted, clarified or withdrawn, as the case may be;

(3) Explain the interest of the petitioner in the action requested;

(4) Contain any information, data, research studies, and arguments available to the petitioner to support the action sought.

■ 9. Revise § 389.35 paragraph (a) to read as follows:

§ 389.35 Petitions for reconsideration.

(a) Any interested person may petition the Administrator for reconsideration of any rule issued under this part. The petition for reconsideration must be in English and submitted to the Administrator, Federal Motor Carrier Safety Administration, 1200 New Jersey Ave. SE, Washington, DC 20590–0001, or electronically submitted using the docket for the rulemaking at *www.regulations.gov,* and received not later than thirty (30) days after publication of the rule in the **Federal Register**. Petitions for reconsideration filed after that time will be considered as petitions for rulemakings filed under § 389.31 of this part. The petition for reconsideration must contain a brief statement of the complaint and an explanation as to why compliance with the rule is not practicable, is unreasonable, or is not in the public interest.

* * * * *

Issued under authority delegated in 49 CFR 1.87.

James W. Deck,

Deputy Administrator.

[FR Doc. 2020–27854 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 201222–0352]

RIN 0648–BK16

Fisheries of the Northeastern United States; Increase in Sector Carryover of 2019 Annual Catch Entitlements and Carryover of Unused Leased-In Days-at-Sea by Common Pool Vessels

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

ACTION: Temporary rule; emergency action.

SUMMARY: This temporary rule implements emergency measures under the authority of the Magnuson-Stevens Fishery Conservation and Management Act to revise portions of the fishing year 2019 carryover provisions in the Northeast Multispecies Fishery Management Plan into fishing year 2020. This action is necessary to address an emergency presenting conservation and management plans to the fishery. This action is intended to mitigate economic harm to the Northeast multispecies fishery participants by providing the opportunity to use sector Annual Catch Entitlement and unused leased-in Days-at-Sea that would have otherwise may have gone unused.

DATES: This action is effective December 31, 2020, through June 29, 2021. Comments must be received by February 1, 2021.

ADDRESSES: For this action, NMFS developed a Supplemental Impact Report (SIR) for the Environmental Assessment (EA) for Framework Adjustment 59 to the Northeast Multispecies Fishery Management Plan (FMP) that describes the measures in this temporary rule. Copies of the SIR and the Regulatory Impact Review of this rulemaking are available on the internet at *https://www.fisheries.noaa.gov/region/new-england-mid-atlantic.*

You may submit comments on this document, identified by NOAA–NMFS–2020–0162, by the following method:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0162*

2. Click the ''Comment Now!'' icon, complete the required fields, and

3. Enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Spencer Talmage, Fishery Management Specialist, phone: 978–281–9232; email: *Spencer.Talmage@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

At the end of fishing year 2019, the Northeast Multispecies fishery experienced significant unexpected economic harm from the effects of state health and travel restrictions due to COVID–19, in combination with disruptions to fishery markets, which resulted in reduced prices for groundfish and a limitation of fishing opportunity. Because these impacts occurred at the end of the fishing year, this loss of fishing opportunity prevented or limited industry participants from capitalizing on investments in quota and Days-at-Sea (DAS) prior to the start of the new fishing year on May 1, 2020.

On July 2, 2020, the New England Fishery Management Council sent NMFS a letter requesting an emergency action to mitigate these significant adverse economic impacts to the groundfish fishery. The Council recommended that through an emergency action, NMFS should:

• Allow sectors to carry over more than 10 percent of their unused fishing year 2019 Annual Catch Entitlement (ACE) into fishing year 2020 for Gulf of Maine (GOM) haddock, Georges Bank (GB) haddock, American plaice, and witch flounder;

• Allow common pool vessels to carryover unused leased-in DAS from fishing year 2019 to fishing year 2020;

• Allow *de minimis* carryover of fishing year 2019 ACE to be more than one percent of the fishing year 2020 sector sub-ACL for all stocks with carryover; and

• Reopen the post-year sector ACE trading window for fishing year 2019.

After considering the Council's request, NMFS is implementing some, but not all, of the requested emergency action provisions. For the reasons outlined below as justification for an emergency action, this action increases maximum carryover of fishing year 2019 sector ACE for GOM haddock, GB haddock, and American plaice and allows for unused leased-in DAS to be carried over from fishing year 2019 into fishing year 2020 by common pool vessels. This action does not increase maximum carryover of fishing year 2019 sector ACE for witch flounder, increase *de minimis* carryover of fishing year 2019 ACE, or reopen the post-year sector ACE trading window for fishing year 2019.

ACE Carryover

Carryover regulations at 50 CFR 648.87(b)(1)(i)(C) allow each groundfish sector to carry over an amount of unused ACE equal to 10 percent of the sector's original ACE for each stock (except for GB yellowtail flounder) that is unused at the end of the fishing year into the following fishing year. However, the total unused sector ACE being carried over, plus the overall ACL, cannot exceed the ABC for the following year. If this were to occur, sector carryover provisions require us to adjust the maximum ACE carryover down from 10 percent to an amount that prevents total potential catch from exceeding the ABC. The final adjustment to the maximum carryover possible for each sector is based on final fishing year catch for the sectors and each sector's total unused allocation; and is proportional to the cumulative Percent Sector Contributions of permits participating in the sector.

This action revises the ACE carryover regulations to increase the maximum amount of ACE for GOM haddock, GB haddock, and American plaice that may be carried over by groundfish sectors from fishing year 2019 into fishing year 2020. The maximum amount of unused 2019 sector ACE for these stocks carried over into fishing year 2020 will not allow catch to exceed the 2020 ABC for each stock (*i.e.,* the 2020 ABC will be equal to the overall ACL plus the maximum carryover number). The revised carryover cap is a percentage of each sector's original ACE for each stock (Table 1).

TABLE 1—MAXIMUM SECTOR ACE CARRYOVER FROM 2019 TO 2020

Stock	Total carryover available (percent of initial 2019 ACE)
GB haddock	12.6
GOM haddock	13.7
American Plaice	11.3

This action does not make any changes to the sector ACE carryover provisions for witch flounder. Witch flounder is overfished, in a rebuilding plan, and has an unknown overfishing status and Overfishing Limit (OFL). The July 2020 National Standard 1 Technical Guidance for Designing, Evaluating, and Implementing Carry-over and Phase-in Provisions does not recommend applying carryover or phase-in provisions for stocks that have an unspecified OFL. Though carryover of ACE for witch flounder is already permitted by the sector implementing regulations, increasing the maximum amount of carryover for the stock above 10 percent would increase risk of overfishing.

Carryover of Unused Leased-In DAS by Common Pool Vessels

DAS carryover regulations at § 648.82(a)(1) allow limited access vessels that have unused, unleased DAS available at the end of a fishing year to carry over a maximum of 10 DAS into the following fishing year. These measures are intended to promote safety by reducing risk and increasing flexibility while not compromising the conservation impact of the DAS program. The regulations at § 648.82(a)(1) and (k)(4)(iii) do not allow us to adjust the maximum DAS carryover, nor do they authorize us to allow the carryover of unused leased-in DAS.

This action revises the DAS carryover regulations to allow common pool vessels with unused leased-in DAS at the end of fishing year 2019 to carry those DAS into fishing year 2020, even if doing so would result in a vessel carrying over more than 10 DAS into the fishing year. This action does not revise the regulations to allow any additional carryover of unused allocated DAS.

De Minimis Carryover

Regulations at § 648.87(b)(1)(i)(C)(*2*) set *de minimis* carryover at one percent of the overall sector sub-ACL in the fishing year in which carryover would be harvested. If the overall ACL for a particular stock is exceeded, the

allowed carryover, minus the *de minimis* amount, would be counted against the sector's ACE for the purposes of determining an overage subject to a sector accountability measure that requires payback.

This action does not increase *de minimis* carryover for sectors above one percent as requested by the Council because it would not address a recent, unforeseen event or recently discovered circumstance as required by the criteria for an emergency action published in the **Federal Register** on August 21, 1997, 62 FR 44421, as well as subsequent guidance. *De minimis* carryover is only triggered by an overage of the overall ACL for a stock. No such overage has occurred in fishing year 2020 to trigger *de minimis* carryover, and we do not currently anticipate any overages. This action is putting in place measures to address the opposite problem arising from travel and health restrictions, the fishing industry's inability to fully utilize available ACE. Further, there are no immediate benefits from changing the *de minimis* carryover provision at this time that would outweigh the value of advance notice, public comment, and deliberative consideration of the impacts.

Post-Year Sector ACE Trading Window

In the beginning of each fishing year, there is a 2-week period for sectors to address any overages from the prior fishing year by transferring ACE to or from other sectors. This 2-week period generally takes place in early July, once final catch information is available to each sector. Sectors are only allowed to transfer ACE to balance an overage, or transfer out quota to assist another sector in balancing its overage. The Council requested that we consider reopening the post-year sector ACE trading window in order to allow sectors to optimize individual sector carryover amounts for fishing year 2020.

This action does not reopen the post-year sector ACE trading window for fishing year 2019. Reopening the post-year trading window would complicate and delay implementation of this emergency action, without significant benefit to sectors as a whole. It would not result in an increase in the overall amount of carryover that could occur, and any ACE carried over from fishing year 2019 to fishing year 2020 can already be traded without limitation in fishing year 2020, without requiring a reopening of the fishing year 2019 trading window.

Reopening the 2019 post-fishing year trading window could potentially result in increases in individual sector carryover amounts, but this is not guaranteed given that sectors are not obligated to trade. It would not increase the overall amount of carryover available to the sectors because we have already calculated the maximum amount of overall carryover by stock that could be allowed for fishing year 2020 without exceeding a stock's ABC. Further, we have already calculated an increased percentage per sector that may be carried over from fishing year 2019 to fishing year 2020.

Justification for Emergency Action

NMFS' policy guidelines for the use of emergency rules (62 FR 44421; August 21, 1997) specify the following three criteria for emergency actions: (1) The emergency results from recent, unforeseen events or recently discovered circumstances; (2) the emergency presents serious conservation or management problems in the fishery; and (3) the emergency can be addressed through emergency regulations for which the immediate benefits outweigh the value of advance notice, public comment, and deliberative consideration of the impacts on participants to the same extent as would be expected under the normal rulemaking process. NMFS' policy guidelines further provide that emergency action is justified for certain situations where emergency action would prevent significant direct economic loss, or to preserve a significant economic opportunity that otherwise might be foregone. NMFS has determined that extending portions of the carryover provisions in the Northeast Multispecies Fishery Management Plan meets the criteria for emergency action for the reasons outlined below.

The emergency results from recent, unforeseen events or recently discovered circumstances. Towards the end of the 2019 fishing year (March 2020), state health mandates and travel restrictions were implemented in response to the COVID–19 pandemic. These restrictions and mandates contributed to market and supply chain disruptions while also making it difficult for vessels to make fishing trips. This reduced or prevented fishing opportunities. Further, market prices dropped substantially. These impacts were unforeseen during the development of Framework Adjustment 59 that included measures for the 2020 fishing year that began on May 1, 2020.

The emergency presents serious conservation or management problems in the fishery. As described above, unforeseen health mandates and travel restrictions during the last months of fishing year 2019 disrupted vessel business plans, fishing practices and markets. This caused revenues for the groundfish fishery to decline due to abnormally low ex-vessel prices that fell below production costs and lost investment in quota that could not be landed by the end of the 2019 fishing year. Health mandates and travel restrictions additionally prevented or limited common pool vessels from using leased-in DAS, which resulted in lost revenue when the vessels were unable to carry them over into fishing year 2020. Increasing ACE carryover of certain stocks into fishing year 2020 and allowing common pool vessels to carryover unused leased-in DAS will help mitigate negative impacts to the industry, prevent additional economic loss to industry participants, shoreside businesses, and fishing communities, and help offset lost fishing opportunities at the end of fishing year 2019.

The emergency can be addressed through emergency regulations for which the immediate benefits outweigh the value of advanced notice, public comment, and deliberative consideration of the impacts on participants to the same extent as would be expected under the normal rulemaking process. The Council has the authority to develop a management action to increase the maximum of 2019 carryover and allow carryover of unused leased-in DAS. However, an emergency action can be developed and implemented by NMFS more swiftly than a Council action through the public meeting and rulemaking procedures. If the normal Council Framework Adjustment and regulatory process is used to revise the carryover provisions, it would take not be possible for the revised provisions to be implemented prior to the end of the fishing year.

Implementing these measures well in advance of the end of this fishing year will allow vessels more operational flexibility. Timely availability of additional ACE carryover or DAS should provide fishermen with operational flexibility to increase fishing effort within seasonal demands and variations, or to lease out available ACE or DAS to others who may effectively use it. Fully capitalizing on this carryover requires time to plan and adapt to current market and seasonal conditions. Any delay of this action reduces the length of time during which industry could choose to use additional ACE or DAS that have been carried over from fishing year 2019 into fishing year 2020. If the action is not implemented in a timely way well before the end of fishing year 2020, industry participants

would be likely unable or less able to effectively use the increased carryover.

Classification

The Assistant Administrator for Fisheries, NOAA, has determined that this rule is necessary to respond to an emergency situation and is consistent with the national standards and other provisions of the Magnuson-Stevens Act and other applicable laws. The rule may be extended for a period of not more than 186 days as provided under section 305(c)(3)(B) of the Magnuson-Stevens Act.

The Assistant Administrator Fisheries, NOAA, finds that it would be impracticable and contrary to the public interest to provide for prior notice and an opportunity for public comment. This action is intended to mitigate the impact of lost investment in quota and DAS due to health mandates and major disruptions to markets at the end of fishing year 2019. The action increases maximum ACE carryover for some stocks and allows carryover of unused leased-in DAS by the common pool, allowing industry to use the carried over quota and DAS in fishing year 2020 at a time of their choosing. Any delay of this action reduces the length of time during which industry could benefit from increased ACE or DAS that have been carried over. If the action is not implemented in a timely way well before the end of fishing year 2020, industry participants would be unable to use the increased carryover. Given this, a delay in the implementation of this action could result in additional negative impacts to industry participants and fishing communities. As a result, prior notice and the opportunity for public comment, pursuant to authority set forth at U.S.C. 553(b)(B), would be impracticable and contrary to the public interest. Data supporting the additional ACE carryover were available only recently in October. This action could not be implemented prior to the availability of that data, even though the Council request for an emergency action was received in July.

Similarly, the need to implement these measures in a timely manner for the above reasons constitutes good cause under authority contained in 5 U.S.C. 553(d)(3), to make the rule effective immediately upon publication in the **Federal Register**.

This action is being taken pursuant to the emergency provision of MSA and is exempt from OMB review.

This rule is an Executive Order 13771 deregulatory action.

This temporary rule for an emergency action is exempt from the procedures of the Regulatory Flexibility Act because the rule is issued without opportunity for prior notice and opportunity for public comment.

This temporary rule for an emergency action contains no information collection requirements under the Paperwork Reduction Act of 1995.

In the interest of receiving public input on this action, the SIR analyzing this action will be made available to the public and this temporary final rule solicits public comment.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: December 22, 2020.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, 50 CFR part 648 is amended 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. In § 648.82, suspend paragraphs (a)(1) and (2) and (k)(4)(iii) and add paragraphs (a)(3) and (4) and (k)(4)(xii) to read as follows:

§ 648.82 Effort-control program for NE multispecies limited access vessels.

* * * * *

(a) * * *

(3) *End-of-year carryover.* With the exception of vessels that held a Confirmation of Permit History, as described in § 648.4(a)(1)(i)(J), for the entire fishing year preceding the carry-over year, limited access vessels that have unused DAS on the last day of April of any year may carry over a maximum of 10 DAS into the next year. Unused leased DAS may not be carried over, except as specified in paragraph (a)(3)(i) of this section. Vessels that have been sanctioned through enforcement proceedings will be credited with unused DAS based on their DAS allocation minus any total DAS that have been sanctioned through enforcement proceedings. For the 2004 fishing year only, DAS carried over from the 2003 fishing year will be classified as Regular B DAS, as specified under paragraph (d)(2) of this section. Beginning with the 2005 fishing year, for vessels with a balance of both unused Category A DAS and unused Category B DAS at the end of the previous fishing year (*e.g.,* for the 2005 fishing year, carry-over DAS from the 2004 fishing year), Category A DAS will be carried over first, than Regular B DAS, than Reserve B DAS. Category C DAS cannot be carried over.

(i) Leased DAS that remain unused at the end of fishing year 2019 may be carried over to fishing year 2020 by the Lessee vessel, provided that the vessel fished in the common pool in fishing year 2019 and continues to do so in fishing year 2020. Carried over leased DAS from fishing year 2019 do not count towards the maximum number of DAS that can be carried over to fishing year 2020, as described in paragraph (a)(3) of this section.

(ii) [Reserved]

(4) *Vessels carrying passengers for hire.* Notwithstanding any other provision of this part, any vessel issued a NE multispecies limited access permit may not call into the DAS program and fish under a DAS, fish on a sector trip, or fish under the provisions of a limited access Small Vessel Category or Handgear A permits pursuant to paragraphs (b)(5) and (6) of this section, respectively, if such vessel carries passengers for hire for any portion of a fishing trip.

* * * * *

(k) * * *

(4) * * *

(xii) *Carry-over of leased DAS.* Leased DAS that remain unused at the end of the fishing year may not be carried over to the subsequent fishing year by the Lessor or Lessee vessel, except as specified in paragraph (a)(3)(i) of this section.

* * * * *

■ 3. In § 648.87, add paragraph (b)(1)(i)(C)(*1*)(*iii*) to read as follows:

§ 648.87 Sector allocation.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(C) * * *

(*1*) * * *

(*iii*) *Fishing year 2019 carryover.* A sector that has over 10 percent of its original ACE for GB haddock, GOM haddock, or American plaice unused at the end of fishing year 2019 may carry over more than 10 percent of that ACE to fishing year 2020. The total unused fishing year 2019 ACE for a particular stock that is carried over to fishing year 2020, plus the overall ACL for fishing year 2020, may not exceed the ABC for that stock for fishing year 2020. The total maximum carryover of fishing year 2019 ACE for GB haddock, GOM haddock, and American plaice for each sector is specified in Table 1 to this paragraph (b)(1)(i)(C)(*1*)(*iii*).

TABLE 1 TO PARAGRAPH (b)(1)(i)(C)(*1*)(*iii*)—MAXIMUM SECTOR ACE CARRYOVER FROM 2019 TO 2020

Stock	Total maximum carryover (percent of initial 2019 ACE)
GB haddock	12.6
GOM haddock	13.7
American Plaice	11.3

* * * * *

[FR Doc. 2020–28898 Filed 12–30–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 201204–0325]

RIN 0648–BJ74

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; Pacific Coast Groundfish Fishery Management Plan; Amendment 29; 2021–22 Biennial Specifications and Management Measures; Correction

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

ACTION: Final rule; correction.

SUMMARY: NMFS published a final rule on December 11, 2020 to establish the 2021–2022 harvest specifications and management measures for groundfish taken in the U.S. exclusive economic zone off the coasts of Washington, Oregon, and California. That final rule modified the boundaries of the commercial non-trawl rockfish conservation area (RCA) for limited entry fixed-gear and open-access vessels. In implementing these changes, NMFS incorrectly identified the seaward boundary of the commercial non-trawl RCA south of 34°27′ N lat. for limited entry fixed-gear vessels. This correction is necessary so that the implementing regulations are accurate and implement the action as intended by the Pacific Fishery Management Council (Council).

DATES: This correction is effective on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Karen Palmigiano at *karen.palmigiano@noaa.gov* or 206–526–4491.

SUPPLEMENTARY INFORMATION: NMFS published a final rule on December 11, 2020 (853 FR 79880) that established the 2021–2022 harvest specifications and management measures for groundfish taken in the U.S. exclusive economic zone off the coasts of Washington, Oregon, and California. That final rule is effective January 1, 2021.

The December 11, 2020 final rule defined the boundaries of the commercial non-trawl rockfish conservation area (RCA) south of 34°27′ north latitude (N lat.) for limited entry fixed-gear vessels as 100 fathoms (fm) to 125 fm. The same rule defined the boundaries of the commercial non-trawl RCA south 34°27′ N lat. for open-access vessels as 100 fm to 150 fm. The correct boundaries for the commercial non-trawl RCA south of south of 34°27′ N lat. for both limited entry fixed-gear and open-access vessels is 100 fm to 150 fm.

This correction is consistent with the Council recommendation for the 2021–2022 groundfish harvest specifications and is a minor correction to correctly implement the Council intent in their final action taken at the June 2020 Council meeting.

Correction

In FR. Doc. 2020–27142 at 85 FR 79880 in the issue of December 11, 2020, on page 79922, in amendatory instruction 16, Table 2 (South) to part 660, subpart E, is corrected to read as follows:

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Table 2 (South) to Part 660, Subpart E -- Non-Trawl Rockfish Conservation Areas and Trip Limits for Limited Entry Fixed Gear South of 40°10' N.

Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table — 1/1/2021

		JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
	Rockfish Conservation Area (RCA)[1/]:						
1	40°10' N. lat. - 38°57.5' N. lat.	40 fm line[1/] - 125 fm line[1/]					
2	38°57.5' N. lat. -34°27' N. lat.	50 fm line[1/] - 125 fm line[1/]					
3	South of 34°27' N. lat.	100 fm line[1/] - 150 fm line[1/] (also applies around islands)					
	See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and						
	State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.						
3	**Minor Slope rockfish[2/] &**	40,000 lb/ 2 months, of which no more than 6,000 lb may be blackgill rockfish					
4	**Splitnose rockfish**	40,000 lb/ 2 months					
5	**Sablefish**						
6	40°10' N. lat. - 36°00' N. lat.	1,700 lb week, not to exceed 5,100 lbs / 2 months					
7	South of 36°00' N. lat.	2,500 lb/ week					
8	**Longspine thornyhead**	10,000 lb/ 2 months					
9	**Shortspine thornyhead**						
10	40°10' N. lat. - 34°27' N. lat.	2,000 lb/ 2 months			2,500 lb/ 2 months		
11	South of 34°27' N. lat.	3,000 lb/ 2 months					
12 13 14	**Dover sole, arrowtooth flounder, petrale sole, English sole, starry flounder, Other Flatfish[3/]**	10,000 lb/ month					
18	**Whiting**	10,000 lb/ trip					
	Minor Shelf Rockfish[2/]						
	40°10' N. lat. - 34°27' N. lat.	8,000 lbs. / 2 months, of which no more than 500 lbs. may be vermilion					
	South of 34°27' N. lat.	5,000 lbs. / 2 months, of which no more than 3,000lbs. may be vermilion					
	Widow						
	40°10' N. lat. - 34°27' N. lat.	10,000 lbs. / 2 months					
	South of 34°27' N. lat.	8,000 lbs. / 2 months					
21	**Chilipepper**						
	40°10' N. lat. - 34°27' N. lat.	10,000 lbs. / 2 months					
	South of 34°27' N. lat.	8,000 lbs. / 2 months					
	Shortbelly Rockfish						
	South of 40°10' N. lat.	200 lb/ month					
22	**Canary rockfish**	3,500 lbs/ 2 months					
23	**Yelloweye rockfish**	CLOSED					
24	**Cowcod**	CLOSED					
25	**Bronzespotted rockfish**	CLOSED					
26	**Bocaccio**	6,000 lbs/ 2 months					
27	**Minor Nearshore Rockfish**						
	Shallow nearshore[4/]	2,000 lbs/ 2 months					
	Deeper nearshore[5/]	2,000 lbs/ 2 months					
30	**California Scorpionfish**	3,500 lbs/ 2 months					
	Lingcod[6/]	1,600 lbs / 2 months					
32	**Pacific cod**	1,000 lb/ 2 months					
33	**Spiny dogfish**	200,000 lb/ 2 months		150,000 lb/ 2	100,000 lb/ 2 months		
34	**Longnose skate**	Unlimited					
35	**Other Fish[7/] & Cabezon in California**	Unlimited					
36	**Big Skate**	Unlimited					

TABLE 2 (South)

1/ The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N. lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

2/ POP is included in the trip limits for Minor Slope Rockfish. Blackgill rockfish have a species specific trip sub-limit within the Minor Slope Rockfish cumulative limit. Yellowtail rockfish are included in the trip limits for Minor Shelf Rockfish. Bronzespotted rockfish have a species specific trip limit.

3/ "Other Flatfish" are defined at § 660.11 and include butter sole, curlfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.

4/ "Shallow Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(*1*).

5/ "Deeper Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(*2*).

6/ The commercial mimimum size limit for lingcod is 24 inches (61 cm) total length South of 42° N. lat.

7/ "Other Fish" are defined at § 660.11 and include kelp greenling off California and leopard shark.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

Dated: December 28, 2020.

Christopher Wayne Oliver,

Assistant Administrator for Fisheries,
National Marine Fisheries Service.

[FR Doc. 2020–28963 Filed 12–30–20; 8:45 am]

BILLING CODE 3510–22–C

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 201223–0354]

RIN 0648–BK13

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Harvest Specifications for the Central Subpopulation of Northern Anchovy

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

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to revise the annual reference points, including the overfishing limit (OFL), acceptable biological catch (ABC) and annual catch limit (ACL), for the central subpopulation of northern anchovy in the U.S. exclusive economic zone off the west coast under the Coastal Pelagic Species Fishery Management Plan. NMFS prepared this rulemaking in response to a September 2020 court decision (*Oceana, Inc.* v. *Ross et al.*) that vacated the OFL, ABC, and ACL for the central subpopulation of northern anchovy and ordered NMFS to promulgate a new rule in compliance with the Magnuson-Stevens Fishery Conservation and Management Act and Administrative Procedure Act. NMFS is implementing an OFL of 119,153 metric tons (mt), an ABC of 29,788 mt, and an ACL of 25,000 mt. If the ACL for this stock is reached or projected to be reached, then fishing will be closed until it reopens at the start of the next fishing season. This rule is intended to conserve and manage the central subpopulation of northern anchovy off the U.S. West Coast.

DATES: Effective February 1, 2021.

FOR FURTHER INFORMATION CONTACT: Joshua Lindsay, West Coast Region, NMFS, (562) 980–4034.

SUPPLEMENTARY INFORMATION: The coastal pelagic species (CPS) fishery in the U.S. exclusive economic zone (EEZ) off the West Coast is managed under the CPS Fishery Management Plan (FMP). The Pacific Fishery Management Council (Council) developed the FMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.* The six species managed under the CPS FMP are Pacific sardine, Pacific mackerel, jack mackerel, northern anchovy (northern and central subpopulations), market squid, and krill. The CPS FMP is implemented by regulations at 50 CFR part 660, subpart I. As required by the Magnuson-Stevens Act, the CPS FMP and its implementing regulations are consistent with the Act's 10 National Standards. Among other things, the National Standards require that conservation and management measures ''prevent overfishing while achieving, on a continuing basis, the optimum yield (OY) from each fishery'' (National Standard 1) and ''be based upon the best scientific information available'' (National Standard 2).[1]

Background on CPS Management for Monitored Stocks

Management unit stocks in the CPS FMP are classified under three management categories: Active, monitored, and prohibited harvest species. Stocks in the active category (Pacific sardine and Pacific mackerel) are managed under catch limits that are set periodically or annually based on regular stock assessments. Fisheries for these stocks have biologically significant levels of catch, or biological or socioeconomic considerations requiring this type of relatively intense harvest management procedure. In contrast, stocks in the monitored category (jack mackerel, northern anchovy, and market squid[2]) are managed under multi-year catch limits and annual quantitative or qualitative reviews of available abundance data without regular stock assessments or required annual adjustments to target harvest levels. This is in part due to the fact that fisheries for monitored stocks do not have biologically significant catch levels and, therefore, do not require intensive harvest management to ensure overfishing is prevented. Allowable catches for stocks in the monitored stock category are set well below maximum sustainable yield (MSY) levels to ensure overfishing does not occur. As a result, monitored stocks have been adequately managed by tracking landings and examining available abundance indices. In contrast, the annual catch limits (ACLs) for stocks in the active category are set much closer to their respective overfishing limit (OFL)/MSY levels due to the higher certainty in their OFLs. Species in both categories may be subject to management measures such as catch allocation, gear regulations, closed areas, or closed seasons. For example, trip limits and a limited entry permit program apply to all CPS finfish. The prohibited harvest species category is comprised only of krill, which is subject to a complete prohibition on targeting and retention.

In September 2011, NMFS approved Amendment 13 to the CPS FMP, which modified the framework process used to set and adjust fishery specifications and for setting ACLs and accountability measures (AMs). Amendment 13 conformed the CPS FMP with the 2007 amendments to the Magnuson-Stevens Act and the Magnuson-Stevens Act National Standard 1 guidelines at 50 CFR 600.310, which for the first time required ACLs be established for management unit species (with exceptions). Specifically, Amendment 13 maintained the existing reference points and the primary harvest control rules for the monitored stocks (jack mackerel, northern anchovy, and market squid), including the large uncertainty buffer built into the acceptable biological catch (ABC) control rule for the finfish stocks. Amendment 13 established a management framework under which the OFL for each monitored stock is set equal to its existing MSY value, if available, and ABC values are set at 25 percent of the OFL to provide a 75 percent scientific uncertainty buffer. It was recognized at the time that these OFLs would be uncertain, therefore the Council's Scientific and Statistical Committee (SSC) recommended that a large uncertainty buffer be used (*i.e.,* 75 percent reduction) to prevent overfishing. ACLs are then set either equal to or lower than the ABC; annual catch targets (ACTs), if deemed necessary, can be set less than or equal to the ACL, primarily to account for potential management uncertainty.

Compared to the management framework for stocks in the active category, which uses annual estimates of biomass to calculate annual harvest levels, the ACLs for the monitored finfish stocks are not based on annual estimates of biomass or any single estimate of biomass. As described previously, ACLs for monitored finfish are set at the ABC levels, which are no higher than 25 percent of the OFL. OFLs are set equal to estimates of MSY—an estimate that is intended to reflect the largest average fishing mortality rate or yield that can be taken from a stock over

[1] 16 U.S.C. 1851(a)(1) and (2); *see also,* 50 CFR 600.310 and 600.315.

[2] Market squid is statutorily exempt from the general requirement to be managed using an ACL because of its short life-cycle.

the long term (if available) or set based on a stock-specific method if deemed more appropriate. Although the control rules and harvest policies for monitored CPS stocks are simpler than the active category control rules, the inclusion of a large non-discretionary buffer between the OFL and ABC both protects the stock from overfishing and allows for a relatively small sustainable harvest. In recognition of the low fishing effort and landings for these stocks, the Council chose this type of management framework for some finfish stocks in the FMP because it has proven sufficient to prevent overfishing while allowing for sustainable annual harvests, even when the year-to-year biomasses of these stocks fluctuate. This management framework comports with Magnuson-Stevens Act's National Standard 1 guidelines, which provide Councils the jurisdiction to develop ABC control rules and risk policies according to their fishery management objectives (ecological, economic, and social) for the respective FMP. The extent of risk aversion the Council decides is based on social, economic, biological, and ecological factors. To comply with the Magnuson-Stevens Act's National Standard 1 guidelines, the Council's ABC must account for scientific uncertainty in the OFL and, at a minimum, their ABC risk policy must provide at least a 50 percent chance of preventing overfishing when the stock's catch is equal to the ABC. Although this ABC control rule is not subject to this rulemaking, NMFS has determined that the ABC control rule for the central subpopulation of northern anchovy (hereafter referred to as ''central anchovy'') appropriately takes into account uncertainty in its OFL level. Additionally, the central anchovy fishery is subject to strict catch accounting and monitoring, therefore the fishery is able to be closed before exceeding the ABC level further ensuring that overfishing does not occur.

Although the allowable catch levels are not required to be adjusted each year for stocks in the monitored category, the Council's Coastal Pelagic Species Management Team is required by regulation to provide the Council an annual Stock Assessment and Fishery Evaluation report, which documents significant trends or changes in the resource, marine ecosystems, and fishery over time, and assesses the relative success of existing State and Federal fishery management programs (see 50 CFR 600.315(d)).[3] The report documents trends in landings, changes in fishery dynamics and available population, and biological information for all CPS stocks and is available for Council review each November. The purpose of this report is to provide the Council the ability to react to the best scientific information available and propose new catch limits if and when changes to management are needed to prevent overfishing or achieve the OY. A similar process is used for other stocks managed throughout the U.S. for which catch limits are not adjusted annually.

The 2016 Rule and *Oceana I*

On October 26, 2016, NMFS published a final rule (hereafter referred to as the ''2016 Rule'') (81 FR 74309) that established ACLs and, where necessary, other reference points (*i.e.,* OFL and ABC) for stocks in the monitored category of the CPS FMP. The 2016 Rule included an ACL of 25,000 mt for central anchovy.[4] As described earlier in Background on CPS Management for Monitored Stocks ACLs for the monitored finfish stocks are not based on annual estimates of biomass or any single estimate of biomass. Accordingly, the OFL for central anchovy established in Amendment 13 to the CPS FMP was set equal to the long-term MSY estimate previously established in Amendment 8 to the CPS FMP. This long-term MSY estimate was calculated based on biomass estimates from 1964–1990 (Conrad 1991[5]). In accordance with the ABC control rule for monitored stocks, the ABC was then reduced to 25,000 mt by a precautionary 75 percent buffer to account for scientific uncertainty in the OFL, which is primarily tied to the population volatility of small pelagic fishes. This buffer and resulting ABC were recommended by the Council's SSC and approved by the Council (see 16 U.S.C. 1852(g)).[6] The ACL was set equal to the ABC at 25,000 mt because there was no additional management uncertainty to justify setting the ACL lower than the ABC.

Oceana subsequently challenged the 2016 Rule in *Oceana* v. *Ross, et al.,* Case No. 16–CV–06784–LHK (N.D. Cal.) (hereafter referred to as ''*Oceana I*''), in part, because a recent publication at the time, MacCall et al. 2016[7] (hereafter referred to as the ''MacCall publication''), purported that recent biomass levels (2009–2011) had been below the ACL implemented in the 2016 Rule and remained low in 2015. In approving the ACL for the 2016 Rule, NMFS considered this information, but ultimately rejected the low biomass estimates in the MacCall publication despite their being the only estimates for the more recent time period, because NMFS determined that the biomass estimates were not credible estimates for the entire central anchovy stock. The primary rationale for NMFS making this determination was that multiple public scientific reviews by NMFS and other outside scientists, including the Council's SSC, had determined that the statistical method used in the MacCall publication to calculate adult anchovy biomass from counts of anchovy eggs and larvae was not suitable for estimating the total abundance of anchovy (which is necessary in this context for calculating an OFL) and that using data from only a portion of the California Cooperative Fisheries Investigation (CalCOFI) survey also does not allow for estimating total anchovy biomass. The reason for this latter point is that the spatial scale of the data used does not encompass the entire population range of central anchovy. The authors of the MacCall publication themselves reported high uncertainty in the estimates and cautioned against using them as independent measures of biomass. Additionally, at the time of the 2016 Rule, the actual anchovy catch by the fishery in certain years had exceeded the publication's biomass estimate for those years, reinforcing NMFS' determination that the estimates were not reliable.

The Court found, however, that the 2016 Rule for central anchovy, including the ACL it established, violated the Magnuson-Stevens Act and the Administrative Procedure Act (APA). The Court also found that the values for the OFL and ABC on which the ACL was based were arbitrary and capricious because, in the Court's determination, they were outdated. In particular, the Court found that, ''the OFL, ABC, and ACL are arbitrary and capricious because Plaintiff has presented substantial evidence that the OFL, ABC, and ACL are not based on the best scientific information available.'' The Court also found that, ''it was arbitrary and capricious for the

[3] *See* 50 CFR 600.315(d).

[4] The 2016 Rule only implemented an ACL for central anchovy. The OFL and ABC for central anchovy were implemented via Amendment 13 to the CPS FMP in 2011 based on values established in Amendment 8 to the CPS FMP in 2000. However, since the 2016 ACL was calculated based on the previously implemented OFL and ABC, the Court vacated all three reference points.

[5] Conrad, J.M. 1991. A Bioeconomic Model of the Northern Anchovy. Administrative Report LJ–91–26. La Jolla, CA: NMFS Southwest Fisheries Science Center.

[7] MacCall, A.D., W.J. Sydeman, P.C. Davison, and J.A. Thayer. 2016. Recent collapse of northern anchovy biomass off California. *Fisheries Research* 175: 87–94.

Service to fail to consider whether the OFL, ABC, and ACL still prevented overfishing in light of their direct reliance on a [maximum sustainable yield] estimate from a 1991 study that evidence in the administrative record indicated was out of date.'' On January 18, 2018, the Court granted Oceana's motion for summary judgment. On January 18, 2019, the Court granted Oceana's motion to enforce the judgment and ordered NMFS to promulgate a new rule in compliance with the Magnuson-Stevens Act and the APA by April 18, 2019.

The 2019 Rule and *Oceana II*

As a result of the Court's decision in *Oceana I,* which vacated the 2016 Rule, NMFS was charged with determining and implementing a new OFL, ABC and ACL unilaterally (*i.e.,* outside of the Council process). In determining these new reference points, NMFS considered the District Court's opinion, which indicated that the vacated reference points were not reflective of recent biomass levels. This conclusion was despite the fact that the vacated 2016 reference points were set using long-term information and thus were representative of the long-term population structure and variability of central anchovy. To address the Court's concern, NMFS examined ways to use recent abundance estimates in the 2019 Rule (84 FR 25196). However, NMFS also determined that a new OFL and ABC that significantly deviated from the management approach set in the CPS FMP for stocks in the monitored category would not be in accordance with the CPS FMP. After reviewing various methods and data, NMFS determined that with the limited time available to analyze more complex approaches for setting new reference points, the most appropriate path for setting an OFL for central anchovy in accordance with the CPS FMP was to use an approach similar to the one used by the Council and approved by NMFS for developing an OFL and ABC for the northern subpopulation of northern anchovy (NSNA) in 2010. This method had been previously approved by the Council's SSC and NMFS and would allow the use of recent biomass estimates.

Consistent with the approach used to set NSNA reference points, the OFL, ABC, and ACL set in the 2019 Rule were based on averaging three of the four estimates of relative abundance for central anchovy available from recent NMFS surveys and a recent estimate of the rate of fishing mortality for central anchovy at MSY or E_{MSY}.[8] The three abundance estimates NMFS used were from NMFS' 2016 and 2018 acoustic-trawl method (ATM) surveys, which were 151,558 mt and 723,826 mt respectively, and NMFS' 2017 daily egg production method (DEPM) survey, which was 308,173 mt. NMFS excluded from further consideration a fourth available abundance estimate, an ATM estimate for 2017, because the ATM survey in the summer of 2017 was focused on the northern portion of the U.S. West Coast as well as the west coast of Vancouver Island, British Columbia, Canada, and was not designed to sample the complete range of central anchovy. The principal objectives of that survey were to gather data on the northern stock of Pacific sardine and, to some extent, the NSNA, and therefore the survey chose not to sample south of Morro Bay, California, which is an area where central anchovy are typically found.

The fishing mortality rate estimate was from an analysis that the Southwest Fisheries Science Center (SWFSC) completed in 2016 as part of an effort examining minimum stock size thresholds for CPS. For potentially deriving an E_{MSY}, this analysis used the most current time-series data available, which comes from the last model-based stock assessment for central anchovy completed for formal management purposes (Jacobson et al. 1995 [9]). This analysis produced estimates of F_{MSY} based on eight alternative models. NMFS used the average of the four best fitting models from that work to calculate an E_{MSY} of 0.239. This methodology resulted in an OFL of 94,290 mt, an ABC of 23,573 mt, and an ACL of 23,573 mt.

In determining whether to use the previously described abundance estimates to develop the reference points for the 2019 Rule, NMFS considered scientific reviews presented to the Council at its April 2018 meeting,[10] which stated that ATM estimates cannot be considered absolute estimates of biomass and should not be used to directly inform management on their own. Specifically, these reviews concluded that, unless ATM estimates are used as a data source in an integrated stock assessment model, two things would need to occur before they could be used to directly inform management: (1) Addressing the area shoreward of the survey that is not sampled; and (2) conducting a management strategy evaluation to determine the appropriate way to incorporate an index of abundance into a harvest control rule. However, NMFS was comfortable at that time with using the ATM estimates from 2016 and 2018, because they represent recent information on the stock and can be considered minimum estimates of the total stock size, and using these estimates in a time series to set an OFL, in combination with reducing the OFL by 75 percent to set the ABC and ACL, would prevent overfishing. Therefore, NMFS determined that using these ATM estimates in the manner described earlier represented use of the best scientific information available for determining the reference points in the 2019 Rule and took the concerns previously expressed by the Court into account.

In determining whether the new reference points were based on the best scientific information available and that the best scientific information available supported that they would prevent overfishing, NMFS again considered the data in the MacCall publication, as well as other existing data sources, including a publication by Thayer et al. 2017 [11] (hereafter referred to as the ''Thayer publication''), historical estimates of biomass from the last stock assessment NMFS completed for central anchovy in 1995, and more recent estimates of relative abundance from NMFS' ATM and DEPM surveys. Additionally, by this time NMFS also had a better understanding of the anomalous oceanographic conditions that had occurred between 2013–2016 that had caused major shifts in fish distributions during that time.[12]

After NMFS' second review and consideration of the MacCall publication and its results, NMFS found

[8] The calculation uses an E_{MSY}, which is the exploitation rate for deterministic equilibrium MSY and although similar in context is slightly different than a calculation of F_{MSY}.

[9] Jacobson L.D., N.C.H. Lo, and S.F. Herrick Jr. 1995. Spawning Biomass of the Northern Anchovy in 1995 and Status of the Coastal Pelagic Fishery During 1994. Administrative Report LJ–95–11. La Jolla, CA: NMFS Southwest Fisheries Science Center.

[10] *See* Methodology Review Panel Report: Acoustic Trawl Methodology Review for use in Coastal Pelagic Species Stock Assessments. This report is available on the Pacific Fishery Management Council website at: *https://www.pcouncil.org/documents/2018/04/agenda-item-c-3-attachment-2.pdf/.*

See Center for Independent Experts Independent Peer Review of the Acoustic Trawl Methodology (ATM). This report is available on the Pacific Fishery Management Council website at: *https://www.pcouncil.org/documents/2018/04/agenda-item-c-3-supplemental-attachment-3.pdf/.*

[11] Thayer, J.A., A.D. MacCall, and W.J. Sydeman. 2017. California anchovy population remains low, 2012–2015. CalCOFI Report Vol. 58.

[12] *See* New Marine Heatwave Emerges off West Coast, Resembles ''the Blob'' Available at: *https://www.fisheries.noaa.gov/feature-story/new-marine-heatwave-emerges-west-coast-resembles-blob.*

that it was not the best scientific information available on historical and recent abundance, nor on annual changes in abundance over time. NMFS maintained that the flaws identified in the 2016 review rendered the biomass estimates as unreliable and too uncertain. NMFS also found the Thayer publication was not the best scientific information available for determining appropriate 2019 reference points because the Thayer publication used the same methodology as the MacCall publication to calculate biomass estimates, and so suffered from the same deficiencies. NMFS concluded that its own, more recent estimates of abundance, which contained high and low abundance estimates, constituted the best scientific information available for setting 2019 reference points and preventing overfishing. Oceana once again challenged the OFL, ABC, and ACL established in the 2019 Rule, in *Oceana* v. *Ross, et al.,* Case No. 19–CV–03809–LHK (N.D. Cal.) (hereafter referred to as ''*Oceana II*''). The Court ultimately vacated the 2019 Rule, finding that: (1) NMFS failed to discredit the evidence put forth by Oceana (*i.e.,* the MacCall and Thayer publications); (2) the OFL, ABC, and ACL were not based on the best scientific information available and therefore violated National Standard 2; and (3) the 2019 Rule violated National Standard 1's requirement to prevent overfishing. The Court also concluded that, based on the record presented of the 2019 Rule, the MacCall and Thayer publications constituted the best scientific information available regarding recent anchovy abundance estimates and anchovy population fluctuations and that the OFL, ABC, and ACL set in the 2019 Rule were therefore arbitrary and capricious because they did not account for this best scientific information available. The Court further concluded that NMFS' dismissal of McCall and Thayer was arbitrary and capricious because it is ''so implausible that it could not be ascribed to a difference in view or the product of the agency's expertise.'' The Court pointed specifically to one of the reasons NMFS had cited for dismissing McCall and Thayer; namely, that Thayer is unreliable because it updated MacCall's estimate for 2015 but failed to correct its estimates for 2009–2014. Finally, the Court concluded that, ''the fact that NMFS calculated unchanging OFL, ABC, and ACL values for an indefinite period of time based on data from 2016 to 2018 (years in which the anchovy population was drastically increasing) demonstrates that NMFS did not consider the best scientific information available from MacCall and Thayer.''

Purpose of the Final Rule

On September 2, 2020, in *Oceana II,* the U.S. District Court for the Northern District of California vacated and remanded to NMFS the May 31, 2019 final rule (hereafter referred to as the ''2019 Rule'') (84 FR 25196) setting the OFL, ABC, and ACL for central anchovy. The Court ordered NMFS to promulgate a new rule in compliance with the Magnuson-Stevens Act and the APA within 120 days of the Court's order. As described above, NMFS had issued the 2019 Rule pursuant to a 2018 decision from the same Court in *Oceana I,* in which the Court had vacated the ACL established in a 2016 final rule. NMFS provided additional background information on *Oceana I* and *Oceana II* in the preamble to the proposed rule (85 FR 73446).

NMFS is issuing this rule in accordance with the Court's order in *Oceana II* to promulgate a new rule in compliance with the Magnuson-Stevens Act and the APA. To ensure compliance, NMFS is setting an OFL, ABC, and ACL for central anchovy in accordance with the CPS FMP and in a manner that will protect the stock from overfishing and accommodate the needs of fishing communities. Although NMFS is issuing this rule and revising the values from the 2019 Rule as required by the *Oceana II* order, NMFS has appealed that order to the Ninth Circuit Court of Appeals. If the Court of Appeals reverses the decision in *Oceana II,* then NMFS will reinstate the reference points from the 2019 Rule through a notice in the **Federal Register**.

NMFS' 2020 Review of the MacCall and Thayer Publications

Although reference points implemented in this rule are similar to those previously vacated, NMFS has determined that they are based on the best scientific information available and that the best scientific information available shows that they will prevent overfishing, in compliance with National Standard 1. In making this determination, NMFS carefully reviewed and considered estimates of abundance from the MacCall and Thayer publications. The purpose of this review was to determine whether those estimates could or should be considered the best scientific information available regarding recent anchovy abundance estimates and anchovy population fluctuations. NMFS also looked at other historical and recent anchovy biomass estimates that had been previously determined to be the best scientific information available on anchovy biomass for years that the MacCall and Thayer publications also calculated estimates.

As stated earlier, for multiple reasons, previous reviews by NMFS and other independent scientists determined that the abundance estimates from the MacCall publication do not represent the best scientific information available for annual estimates of total central anchovy population. Specifically, NMFS and other outside scientists had valid concerns regarding the method used to try to estimate the total abundance of all adult (or spawning adult) anchovy in any one year from counts of anchovy eggs and larvae from only a portion of the California coast where anchovy are found and without using biological information collected from adult anchovy that same year. These conclusions are documented in a report from a May 2016 workshop [13] that included CPS experts from around the world, as well as in an October 2016 report [14] from NMFS scientists. Both of these reports were also subsequently endorsed by the Council's independent scientific review body (*i.e.,* the SSC).

In light of the Court's finding in *Oceana II* that, based on the record at the time, the MacCall and Thayer publications constituted the best scientific information available regarding recent anchovy abundance estimates and anchovy population fluctuations, NMFS re-examined the conclusions of the previously discussed 2016 scientific reviews of those publications. Specifically, NMFS reviewed the results of the May 2016 workshop, which was focused on anchovy and the data available to assess the status of the population. This workshop included experts from around the world on coastal pelagic species and was held as a direct result of the MacCall publication, as well as other evidence at the time that anchovy abundance was likely low (*e.g.,* Leising et al. 2015 [15]). The focus of the workshop was to review the available information on the abundance of

[13] *See* Report of the NOAA Southwest Fisheries Science Center & Pacific Fishery Management Council Workshop on CPS Assessments (May 2–5, 2016). This report is available on the Pacific Fisheries Management Council website, at *https://www.pcouncil.org/documents/2016/09/e2a_workshop_rpt_sept2016bb.pdf/.*

[14] *See* Egg and Larval Production of the Central Subpopulation of Northern Anchovy in the Southern California Bight (October 24, 2016). This report is available on the Pacific Fisheries Management Council website at *https://www.pcouncil.org/documents/2016/11/agenda-item-g-4-a-swfsc-report.pdf/.*

[15] Leisling, A.W. et al. State of the California Current 2013–14: El Nino Looming. CalCOFI Report Vol. 55.

anchovy and provide recommendations for conducting stock assessments or other ways of estimating total anchovy abundance that could be used for management, as well as to potentially provide input to the Council on the status of anchovy for their upcoming November 2016 meeting. One of the conclusions of this workshop was that although information on the total abundance of anchovy did not currently exist, and the best way to assess the population would be through a full stock assessment that integrates multiple data sources, there was nevertheless value in attempting to turn trends from eggs and larvae information from the CalCOFI survey into estimates of total anchovy abundance. This approach, called DEPM-lite, was viewed as an extension of the approach used by the MacCall publication, but with an attempt to correct for various issues identified in the calculations contained in the MacCall publication. Between May 2016 and October 2016, NMFS scientists attempted to correct for some of the technical issues originally expressed at the May 2016 workshop. Ultimately, however, NMFS scientists determined that the technical weaknesses could not be overcome and that it would be inappropriate to expand the egg and larval data from CalCOFI into adult biomass in the manner done in the MacCall publication. NMFS presented this analysis to the Council at its November 2016 meeting,[16] and the Council's SSC agreed with NMFS' analysis of the technical weaknesses.[16] Specifically, the SSC stated:

> The egg and larval production indices presented in the SWFSC report represent the best available science for trends in spawning biomass in the CalCOFI survey area. However, the report did not expand the trend information to estimate absolute spawning biomass in that area. The SSC agrees that this expansion is not appropriate, because it would require scaling the egg and larval indices using the Daily Egg Production Methods estimates for the 1980s. Neither the winter nor spring survey is conducted at the right time to fully capture spawning of CSNA, and the degree of mismatch may vary through time due to changing oceanographic conditions. A proper expansion from eggs and larvae to spawning biomass would require data on sex ratio, mean female weight, and fecundity. Variability in the timing of spawning may also complicate interpretation of the egg and larval time series as an index of relative abundance. The spatial extent of the CalCOFI survey is limited (by depth and latitude) relative to the distribution of the broader CSNA population. The proportion of the population contained in the survey area at any given time is unknown and changes through time due, in large part, to oceanographic conditions. As trends in the CalCOFI survey area may not be representative of the broader population, it is difficult to infer population-level trends.

After this review, NMFS remains confident that those scientific reviews from 2016 were thorough and unbiased and finds no reason to disagree with their logic or conclusions.

Although the previously-discussed technical rationale is sound in concluding that neither the MacCall publication nor the Thayer publication using the same methods is the best scientific information available, NMFS acknowledges that those publications contain the only explicit biomass estimates from 2009–2014. NMFS also acknowledges that those publications show that the stock during that time decreased to a very low level and that the ''drastic anchovy population fluctuations'' contained in the publications ''are only (emphasis added) documented by MacCall (2016) and Thayer et al. (2017).'' NMFS notes that it has never disputed whether the anchovy population was relatively low during the 2009–2014 time period, at least in the core CalCOFI region; rather, NMFS disputes whether the population was as low as the flawed MacCall and Thayer estimates suggest and whether the adult population was as high as reported in the year preceding the purported decline. The methodological concerns with the MacCall and Thayer publications, combined with the additional uncertainty added by instances of combined fishery catches and predator consumption estimates (Warzybok et al. 2018) [17] well exceeding MacCall and Thayer estimates for some years, have led NMFS to consistently conclude that the year-specific estimates in the MacCall and Thayer publications are not appropriate to use as independent measures for determining reference points for central anchovy and whether those reference points will prevent overfishing.

The authors of the MacCall and Thayer publications themselves cautioned against using their annual estimates as independent measures, stating, ''. . . . therefore estimates for recent single years are imprecise and should not be used individually for interpretation.'' Because of this, the Thayer publication suggests looking at the average of the last 4 years (2012–2015) provided in that publication, which is 24,300 mt, as evidence of the extremely low level of the stock. In 2018, however, as a result of newer data, the authors of the Thayer publication revised their estimated biomass for 2015,[18] which increased the 4-year average for 2012–2015 to approximately 46,000 mt. While 46,000 mt may still be considered relatively low, that low average is driven mainly by the anomalously low 2012 and 2013 estimates of 9,400 mt and 7,500 mt, respectively. It is also worth noting that 2013 is the year in which fishery catches of central anchovy exceeded the Thayer publication estimate of 7,500 mt—in other words, fishermen actually caught more anchovy than Thayer had estimated even existed. The estimates for the other years in Thayer's 4-year average were the 2014 estimate of 75,300 mt and the revised 2015 estimate of 92,100 mt. NMFS originally raised the point of the revised 2015 estimate to the Court because it changed the narrative of how low the stock may have been, and for how long, and the importance of having accurate estimates, not, as the Court suggested, because it made other estimates unreliable.

During the preparation of the proposed rule, NMFS again examined the MacCall and Thayer publications to ensure their complete consideration in making a determination on appropriate new reference points for central anchovy and whether they would prevent overfishing. Specifically, NMFS freshly reviewed the publications' annual estimates to determine whether, notwithstanding the high degree of uncertainty NMFS has previously determined those estimates contain, they should be relied on as evidence of both: (1) Anchovy abundance for the extraordinarily low years for which NMFS does not have comparable competing estimates; and (2) anchovy population fluctuations for the recent large annual changes in biomass.

As part of this review, NMFS compared overlapping estimates of biomass from the 1961–1994 time series of spawning stock biomass produced in NMFS' 1995 central anchovy stock assessment and recent NMFS ATM and

[16] *See* Scientific and Statistical Committee Report on Northern Anchovy Stock Assessment and Management Measures. This document is available on the Pacific Fishery Management Council website at: *https://www.pcouncil.org/documents/2016/11/agenda-item-g-4-a-supplemental-ssc-report.pdf/.*

[17] Warzybok P., J.A. Santora, D.G. Ainley, R.W. Bradley, J.C. Field, P.J. Capitolo, R.D. Carle et al. 2018. Prey switching and consumption by seabirds in the central California Current upwelling ecosystem: Implications for forage fish management. *Journal of Marine Systems* 185: 25–39.

[18] *See* Updated Biomass Estimates of CSNA. This document is available on the Pacific Fishery Management Council website at: *https://pfmc.psmfc.org/CommentReview/DownloadFile?p=e982e162-4ec2-4b3b-8f1a-1da42a0bb81e.pdf&fileName=FI%20Letter%20to%20PFMC%20for%20Nov%202018%2C%20CSNA%20biomass%20update.pdf.*

DEPM estimates with estimates in the 1951–2017 Thayer publication's time series. The referenced NMFS stock assessment had been subject to a formal scientific review and determined to be the best scientific information available on the biomass of central anchovy. Although NMFS does not have alternative or competing estimates for 2009–2014, the years in which the Thayer publication estimated historically low anchovy abundance, NMFS does have competing estimates for 24 other years between 1961 and 2017. For these overlapping years, NMFS can find no reason that the estimates from the MacCall or Thayer publications should be considered the best scientific information available over existing NMFS estimates. In comparing the estimates for the historical time period (pre-1994), NMFS found that the average per-year difference in biomass estimates between Thayer and NMFS' estimates is over 550,000 mt, with the largest difference in any given year being nearly 1.8 million mt. The significant differences in these comparable estimates raises additional valid concerns about the reliability of the estimates found in the MacCall and Thayer publications, and further supports NMFS' rationale for concluding that, for those years for which data only exist from the MacCall and Thayer publications, that data cannot be considered the best scientific information available for making determinations about catch limits for anchovy.

A primary reason for the discrepancy between NMFS' estimates and the MacCall and Thayer estimates is likely the various methodological issues with the calculations found in those publications, which are described earlier in this preamble. These methodological issues are best highlighted when looking at the discrepancy in the estimates for 2017. In 2017, NMFS scientists estimated the spawning biomass of central anchovy to be 308,173 mt using DEPM. The Thayer publication's spawning biomass estimate for this same year is 1,169,400 mt—a difference of more than 860,000 mt. The DEPM method used by NMFS, like the method used in the MacCall and Thayer publications, uses egg and larval data; however, unlike the method used in the MacCall and Thayer publications, the DEPM method uses information from adult fish and eggs and larvae from the same year, and therefore does not need to expand egg and larval data into adult biomass using biological data from a different time period (which in the case of MacCall and Thayer, was the 1980s). This method of expansion was the primary technical flaw identified with the MacCall and Thayer methodology, rendering the estimates from those publications unreliable for estimating total biomass. NMFS' 2017 DEPM estimate does not suffer from this same deficiency because it is a direct calculation derived using reproductive information from adult fish collected in the same year and same ship-based survey as the egg and larval information.

By using biological data from adult fish and eggs collected in the same year, as NMFS did in 2017, there was no need to expand the egg data into estimates of biomass-based adult information from a different time period, as done in the MacCall and Thayer publications. In addition, the 2017 DEPM estimate developed by NMFS was derived using egg data from more than just the core CalCOFI region, as was used in the MacCall and Thayer publications. The survey data used for this estimate was from north of San Francisco, California, to San Diego, California, and therefore covered the majority of the U.S. range of central anchovy. By comparison, the northern extent of the CalCOFI data used in the MacCall and Thayer estimates is near Point Conception, California, which is well south of San Francisco, and therefore includes less than half of the coastline covered in the NMFS survey. Despite using survey data from a larger region and using a scientifically-validated method to calculate the biomass of small pelagics, NMFS' biomass estimate for 2017 was nevertheless over 860,000 mt lower than the Thayer estimate for that year. This degree of difference in abundance can have a large impact when explicit values are needed to calculate reference points like is being done through this action. Which is why previous scientific reviews of the estimates in MacCall and Thayer stated that although they provided information on trends or relative abundance levels, they should not be used as total estimates. For example, if NMFS were to replace the 2017 estimate used in this rulemaking with that from the Thayer publication it would result in a nearly 13,000 mt difference in the ABC calculation.

These discrepancies in comparable data from both the historical and recent estimates, as well as the other biological and technical issues stated above, render the estimates from MacCall and Thayer unreliable as a measure of the actual population size of central anchovy. These estimates are therefore not the best scientific information available on the historical annual biomass estimates of anchovy in any given year to be used for management purposes. However, even if NMFS were to consider the 1951–2015 time series from MacCall and Thayer as best scientific information available for the annual abundance of central anchovy, which it does not, NMFS notes that during that 57-year time frame over which the MacCall and Thayer publications presented biomass estimates, the biomass only dropped below 100,000 mt 15 times, or 26 percent of the time, and more importantly, only stayed below 100,000 mt for more than one year twice over those 57 years: Once during the referenced 2009–2015 time period and once during the early 1950s. NMFS notes further, however, that for the period of purported low abundance in the early 1950s, catch of central anchovy in one of those years was over double the estimated biomass and three times greater in another. Therefore, those biomass estimates are likely underestimated. Given the infrequency of such low biomass, NMFS' proposed referenced points would have at least a 50 percent chance of preventing overfishing over the long term.[19]

Final Reference Points

As noted previously, the Court ordered NMFS to promulgate a new rule within 120 days of its September 2, 2020, order. NMFS therefore determined that, with such limited time available to develop and analyze more complex approaches for setting these reference points, the most appropriate path at this time for setting an OFL for central anchovy in accordance with the CPS FMP is to use the same method as in the 2019 Rule, however updated with the most recent information on the current status of central anchovy, the SWFSC's 2019 ATM estimate (810,634 mt). This approach included averaging four estimates of relative abundance for central anchovy available from recent NMFS surveys and a recent estimate of the rate of fishing mortality for central anchovy at MSY or E_{MSY}.[20] The four abundance estimates NMFS used were from NMFS' 2016, 2018, and 2019 ATM surveys, which were 151,558 mt, 723,826 mt, and 810,634 mt respectively, and NMFS' 2017 DEPM survey, which was 308,173 mt. The fishing mortality rate estimate was from an analysis that the Southwest Fisheries Science Center (SWFSC) completed in 2016 as part of an effort examining minimum stock size thresholds for CPS.

[19] *See* 50 CFR 600.310(f)(2).

[20] The calculation uses an E_{MSY}, which is the exploitation rate for deterministic equilibrium MSY and although similar in context is slightly different than a calculation of F_{MSY}.

For potentially deriving an E_{MSY}, this analysis used the most current time-series data available, which comes from the last model-based stock assessment for central anchovy completed for formal management purposes (Jacobson et al. 1995).[21] This analysis produced estimates of F_{MSY} based on eight alternative models. NMFS used the average of the four best fitting models from that work to calculate an E_{MSY} of 0.239. More information on the selection of this data and the calculations is provided in the preamble to the proposed rule.

In making this decision, NMFS considered the Court's two primary findings in *Oceana II*: That the McCall and Thayer publications constituted the best scientific information available and that NMFS's 2019 ACL would not prevent overfishing in all years, based on the evidence presented to the Court at that time. NMFS thoroughly reviewed the data in these two publications during the preparation of the proposed rule and this final rule, and has determined that they do not constitute the best scientific information available for setting or determining appropriate reference points for central anchovy. Additionally, even if NMFS were to consider that information as best scientific information available, it would not change NMFS' determination that the data we have used, in combination with the CPS FMP's ABC control rule risk policy for stocks in the monitored category, result in reference points that are consistent with the dual mandates of National Standard 1 (preventing overfishing while achieving, on a continue basis, OY) and other Magnuson-Stevens Act provisions.

The 2019 method for calculating reference points results in an OFL of 119,153 mt and an ABC of 29,788 mt. Although previous ACLs for northern anchovy have been set equal to the calculated AC level, for this action NMFS is implementing an ACL less than the ABC level at 25,000 mt. Although there is no management uncertainty that requires reducing the ACL from the ABC, prior environmental analyses have only analyzed an ACL up to 25,000 mt, which is also the Council's previous determination of OY for the stock.

In the proposed rule, NMFS notified the public that the proposed reference points might change if finalized ATM estimates for 2015 and 2017 could be incorporated into the OFL calculation. Although a reexamination and review of an estimate for 2015 has begun, that process is still ongoing to determine whether one can be finalized and therefore NMFS was not able to consider it as part of this rulemaking. As part of this process NMFS is also reexamining its 2016 ATM estimate, however at this point in time the 2016 estimate used to calculate the OFL in this rulemaking is still considered best scientific information available for that calculation. With regards to 2017 information, NMFS determined it was appropriate to only use the DEPM estimate from 2017 as was done in the 2019 rule. Therefore, NMFS is implementing the OFL, ABC and ACL from the proposed rule of 119,153 mt, 29,788 mt, and 25,000 mt.

If the ACL is reached, the fishery will be closed until the beginning of the next fishing season. The NMFS West Coast Regional Administrator will publish a notification in the **Federal Register** announcing the date of any such closure.

Potential Additional Management Measures for Central Anchovy

The CPS FMP states that ACLs for stocks in the monitored stocks category are specified for multiple years until such time as the species becomes actively managed or new scientific information becomes available to warrant a change to them. However, in the proposed rule, NMFS solicited public comment on the potential to limit the effectiveness of the final rule to 3 or 4 years. Additionally, NMFS solicited public comment on the potential of setting a biomass threshold whereby the ACL would automatically be reduced if the anchovy population were to fall below that threshold for a certain period of time. After further review of these potential measures, and in consideration of the public comments received, NMFS has decided not to explicitly limit the effective period of the ACL or implement a minimum biomass threshold in this rule. The primary reason for this decision is that NMFS has determined that the OFL, in combination with the ABC and ACL finalized in this rule, are sufficient to prevent overfishing over the long term and are based on the best scientific information available.

Although NMFS is not implementing an explicit expiration of the ACL in this action, it is NMFS' expressed intent to work with the Council to have the reference points being implemented through this action be replaced by Council recommended ones sometime within the next two years. To accomplish this, NMFS intends to ask the Council to schedule an agenda item in the spring of 2022 to develop recommendations to NMFS. Under the timelines the Court imposed for promulgating both this rule and the 2019 Rule it replaced, it was not possible to thoroughly engage the Council in setting a multi-year ACL for this stock. Instead, NMFS had to develop and implement these actions unilaterally pursuant to the general Secretarial authority of the Section 305(d) of the Magnuson-Stevens Act (16 U.S.C. 1855(d)), without recommendation from the Council. NMFS views the Council process, both the public engagement and scientific review aspects, as important steps in determining and setting appropriate catch levels for a fishery. This is the expressed design and purpose of the Councils. Because of the compressed timelines under which NMFS had to promulgate both this rule and the 2019 Rule, the Council did not have the opportunity to conduct its normal public meeting process and make formal recommendations to NMFS. Additionally, the Council had limited time to review and provide feedback to NMFS on this rule or the 2019 Rule. The Council highlighted this time-constraint in their public comment on the 2019 Rule and during their November 2020 Council meeting where the proposed rule published mid-meeting, not allowing some advisory bodies to review and comment on the proposed rule, which led the Council to decline to provide public comments on this action. During both Council meetings the Council also generally expressed that they also would prefer that rulemakings such as this action go through the Council process instead of unilaterally by NMFS. Although NMFS cannot require the Council to take action over the next two years, NMFS intends to engage and work with the Council to move towards them taking their own action on this stock. Such a subsequent rule may not necessarily result in reference points that are different from those being implemented in this final rule, however they will have the benefit of having been recommended through the public Council process.

Related to NMFS' intention to work with the Council in the near future to develop a recommendation that would replace the reference points set through this action, is potential for new data and biological information on northern anchovy may become available over the next 6 to 18 months in the form of new or revised ATM estimates from 2015

[21] Jacobson L.D., N.C.H. Lo, and S.F. Herrick Jr. 1995. Spawning Biomass of the Northern Anchovy in 1995 and Status of the Coastal Pelagic Fishery During 1994. Administrative Report LJ–95–11. La Jolla, CA: NMFS Southwest Fisheries Science Center.

and 2016,[22] as well as through a research stock assessment. NMFS expects that if any of this work is completed it will raise questions as to whether the reference points finalized through this action will need to be revised. Although NMFS will review this information to determine whether it warrants a revision to the reference points set through this rule, as stated above, NMFS believes that the Council process is the more appropriate arena for decisions on these reference points to be made. If and when available, NMFS will present this information to the Council to allow them to make such a decision. NMFS hopes that, given there will likely be questions as to potential revisions to the catch levels based on this new information, having the Council take action in the near term will reduce some uncertainty in terms of the timing of a potential change for the affected fishing industry that relies on a certain level of stability to be able to plan for the future and maintain certain markets.

NMFS' desire to have the Council replace this rule in the near future however, should not be seen as an indication that NMFS has any concerns about the ability of the reference points being implemented through this action to protect against overfishing in 2023 and beyond or an indication that a subsequent rule will necessarily result in reference points that are different than those being implemented in this final rule. As always, the decision to revise the reference points will be guided by the best scientific information available and compliance with Magnuson-Stevens Act and other applicable laws.

Public Comments and Responses

On November 18, 2020, NMFS published a proposed rule for this action and solicited public comments (85 FR 73446), with a public comment period that ended on December 3, 2020. NMFS received only two comment letters on the proposed rule, each containing multiple comments. One letter was submitted by the California Wetfish Producers Association (CWPA) and expressed support for the proposed reference points. The other letter one was submitted jointly by two environmental non-governmental organizations, Oceana and Earthjustice, and expressed concern over aspects of the proposed rule and its ability to prevent overfishing. NMFS notes that some components of the comment letter from Oceana and Earthjustice included recommendations to change the default ABC control rule for monitored stocks and the central anchovy management framework, but such measures were not within the scope of this rulemaking, and therefore NMFS did not respond to those comments. NMFS encourages Oceana and Earthjustice to continue bringing concerns over the central anchovy management framework to the Council. NMFS summarizes and provides responses to the relevant components of both comments below. NMFS made no changes to the proposed rule in response to the comments received.

Comment 1: The CWPA, a primary CPS industry representative, submitted a public comment in support of the proposed reference points for central anchovy and NMFS's process for their development. In regards to the potential additional management measures, the CWPA stated that they are not opposed to the concept of additional management measures for central anchovy, but feel those concepts should be developed stepwise through the Council process with scientific and stakeholder input as opposed to enforced via a unilateral action by NMFS.

Response: NMFS agrees that the appropriate process for making changes to anchovy management, including the additional management measures described in the proposed rule, is through the traditional Council process.

Comment 2: Oceana and Earthjustice stated that the proposed reference points were not set using the best scientific information available, and the rule therefore violates Magnuson-Stevens Act National Standard 2. Specifically, the commenters faulted NMFS for not using the biomass estimates from 2009–2014 that were published in the MacCall and Thayer publications, which the commenters contend constitute the best scientific information available for past populations sizes of central anchovy and fluctuations in those sizes from one year to the next. The commenters spent considerable time in their submission explaining why they believe NMFS' reasoning for not using the biomass estimates in the McCall and Thayer publications is baseless.

Response: NMFS used the best scientific information available to determine the OFL for central anchovy and the best scientific information available supports NMFS determination that the reference points, in particular the OFL and ABC, being set by this action are consistent with the dual mandates of National Standard 1 (preventing overfishing while achieving, on a continuing basis, OY) and other Magnuson-Stevens Act provisions. As described in the preamble of the proposed rule, NMFS disagrees that the MacCall and Thayer publications constitute the best scientific information available for setting central anchovy reference points or that they provide novel information on the biology or population dynamics of northern anchovy, factors that are already included in the risk policy of the ABC control rule, that invalidate the reference points set through this rule. NMFS has repeatedly stated that it agrees that the MacCall and Thayer biomass estimates are useful in that they demonstrate and support the general trend that NMFS has also observed in the naturally fluctuating central anchovy abundance; however, their high degree of uncertainty, which the commenter regularly points out in their comment letter, makes them inappropriate for use as single point biomass estimates in any given year upon which to base catch levels. As stated in the preamble to this rule however, out of a desire to be deferential to the Court's decision and to ensure full consideration of all the information, NMFS re-reviewed both MacCall and Thayer publications to evaluate whether their biomass estimates could be used to calculate new reference points or whether the information included in them somehow invalidated NFMS reference points. To this end, NMFS provided new, extensive analysis to better explain its decision to not use the MacCall and Thayer biomass estimates—see NMFS' 2020 Review of the MacCall and Thayer Publications in the preamble to the proposed rule and this final rule. After a thorough review and additional consultation with the SWFSC, NMFS has found rational basis for not using their biomass estimates, and has determined that the biomass estimates in these publications do not invalidate the references being set through this action. NMFS has instead determined that the best scientific information available for setting new reference points under the timeline provided by the Court, as well as to address the Court's concerns from *Oceana I,* is the SWFSC' recent ATM and DEPM abundance estimates described in the Final Reference Points section of this rule.

[22] In the proposed rule, NMFS stated that the SWFSC was investigating the possibility to finalize an ATM estimate for 2015. Since the proposed rule was published, the SWFSC is also investigating the possibility of revising its 2016 ATM estimate. Despite this potential reexamination, it is NMFS' determination that the existing 2016 estimate, the one used in this rulemaking, represents the best scientific information for the population size in that year.

Contrary to Oceana and Earthjustice's assertion, these values were not chosen arbitrarily and include both relatively high *and* low abundance estimates. For example, the 2016 ATM estimate (151,558 mt) and the 2017 DEPM estimate (308,173 mt) are lower than 60 and 50 percent of the 57 years of biomass estimates in the Thayer publication, respectively. NMFS also points out that if we were to use the average from the biomass estimates provided in appendix I of Oceana and Earthjustice's comment letter (500,293 mt) it would result in an OFL of 119,570 mt; a value slightly higher than the OFL being implemented by NMFS.

Comment 3: Oceana and Earthjustice stated that the proposed reference points will not prevent overfishing over the long term without the implementation of additional management measures, and the rule therefore violates Magnuson-Stevens Act National Standard 1. Oceana and Earthjustice specifically stated that the proposed reference points should be effective for only one year, or at most two, and if the effective period is greater than one year, then NMFS should include a minimum biomass threshold below which the directed fishery is closed and the ACL is reduced.

Response: The commenters misunderstand the requirements of the Magnuson-Stevens Act and the intent of the National Standard 1 guidelines. Under Oceana and Earthjustice's premise, if NMFS sets a multi-year ACL, it must set a drastically low ACL simply because the stock dropped to low levels once in the last 63 years to ensure that over the next 63 years, there is a 100 percent chance that overfishing will never occur. The National Standard 1 guidelines state that, ''the Council's risk policy for the ABC control could be based on an acceptable probability (at least 50 percent) that catch equal to the stock's ABC will not result in overfishing, but other appropriate methods can be used.'' NMFS demonstrated in the preamble to the proposed rule and this final rule that the new reference points more than satisfy this legal requirement. As part of the commenters' claim that the reference points set through this rule will not prevent overfishing is a statement that central anchovy biomass frequently drops to less than 10 percent of long-term averages; however, based on the long-term average biomass estimate from the Thayer publication, the biomass only dropped below that long-term average in 9 over the 57-year time series, which does not seem to qualify as ''frequently.'' Therefore, even if NMFS were to consider the MacCall and Thayer biomass estimates as the best scientific information available for analyzing long-term trends in central anchovy abundance, the 25,000-mt ACL would still meet the mandates of Magnuson-Stevens Act standards. Furthermore, if the 1951–2015 published time series from MacCall and Thayer was used, NMFS notes that during that 57-year time frame over which the MacCall and Thayer publications presented biomass estimates, the biomass only dropped below 100,000 mt 15 times, or 26 percent of the time, and only stayed below 100,000 mt for more than one year twice over those 57 years: Once during the referenced 2009–2015 time period and once during the early 1950s. Although the ABC control rule used in this action is not subject to this rulemaking, it is NMFS' determination that the risk policy incorporated into that control rule, more than accounts for the infrequent potential for the stock to decline to such low levels.

Regarding Oceana and Earthjustice's specific requests for additional management measures, see the Potential Additional Management Measures section earlier in this preamble. Although NMFS solicited public comment on potential additional management measures, NMFS has determined that they are not necessary to prevent overfishing, for all the reasons stated in that section.

Comment 4: Oceana and Earthjustice stated that the reference points will not provide adequate forage for marine predators, including ESA-listed marine predators when central anchovy abundance is low.

Response: Per the Magnuson-Stevens Act's National Standard 1, NMFS must set catch limits such that the fishery achieves OY, which is defined as, ''the greatest overall benefit to the Nation, particularly with respect to food production and recreational opportunities, and taking into account the protection of marine ecosystems.'' The 119,153-mt OFL was already substantially reduced to an ABC of 29,788 mt because of the 75 percent scientific uncertainty buffer, which includes ecological considerations like predator consumption. The ABC was then further reduced to an ACL of 25,000 mt. NMFS reasonably determined that no further reduction to the ACL was necessary because there is no evidence that harvest up to the ACL over the long term will cause harm to anchovy predator species through prey removal. Central anchovy biomass is driven primarily by environmental conditions, not by the small commercial take in the central anchovy fishery. Oceana has in multiple instances claimed that NMFS's central anchovy reference points do not provide adequate forage for marine predators, yet has never presented any direct evidence that the small commercial fishery for central anchovy results in a lack of forage availability for any species, even in circumstances of low anchovy biomass. For example, there was no evidence of direct competition between the fishery and anchovy predators during the years Oceana and Earthjustice purport that the anchovy population was low. Although it is true that some predators in southern california experienced decreased food availability during the 2014–2015 time period, these predators, such as the Brown Pelican and California sea lions, neither of which are endangered species, have evolved explicit reproductive and foraging strategies in response to the natural fluctuations of their prey. NMFS notes that the time frame for which the commenters highlight adverse effects to some marine predators are the same years when highly unusual environmental conditions shifted many fish stocks out of their typical geographic range, as was the case for central anchovy in 2014 and 2015.

Much of Oceana and Earthjustice's commentary about ESA analysis addresses concerns beyond the scope of the proposed action. Relevant to this action, the commenters did not introduce any new scientific information that would require NMFS to reinitiate consultation under ESA. NMFS determined that these harvest specifications fall well within the scope of impacts to ESA-listed species, including listed marine predators, considered under prior consultations for the CPS FMP, and that fishing activities pursuant to this rule are not likely to jeopardize the continued existence of any endangered or threatened species under the jurisdiction of NMFS or result in the destruction or adverse modification of critical habitat of any such species.

Comment 5: Oceana and Earthjustice criticized NMFS' decision to base the proposed catch limits on biomass estimates from 2016–2019, claiming that NMFS purposefully omitted data from the previous 7 years of low abundance—*i.e.,* MacCall and Thayer's biomass estimates from 2009–2014 and NMFS' own ATM estimate from 2015.

Response: After extensive scientific review and additional consultation with the SWFSC, NMFS has determined that the SWFSC's 2016, 2018, and 2019 ATM abundance estimates and 2017 DEPM abundance estimate constitute the best

scientific information available for setting new central anchovy reference points that will prevent overfishing over the long term. The commenters are correct that NMFS omitted the SWFSC's draft 2015 ATM estimate and the 2009–2014 MacCall/Thayer biomass estimates. NMFS did not use the SWFSC's 2015 ATM estimate because that 2015 estimate was the SWFSC's first attempt at an ATM estimate for central anchovy, and that estimate did not complete NMFS' formal review process to be finalized. However, the SWFSC is currently reviewing a new 2015 estimate, which may make it available for use in a potential future revision to central anchovy reference points if finalized. NMFS has stated in many previous instances that NMFS has determined that biomass estimates from the MacCall and Thayer publications do not constitute the best scientific information available for setting new central anchovy reference points. The commenters are also correct that NMFS does not have its own 2009–2014 biomass estimates; NMFS stated this in the preamble to the proposed rule and this final rule. However, NMFS has enough information on the biology and historical population sizes of central anchovy to support its determination that the reference points in this rule can prevent overfishing. As NMFS has also repeatedly stated, the idea that the central anchovy population can go to very low levels and that its size can fluctuate are not new concepts: This type of biology is the reason the risk policy included in the ABC control rule for this stock and other similar stocks in the CPS FMP includes the unprecedented buffer that it has.

Classification

NMFS is issuing these regulations under Magnuson-Stevens Act 305(d), 16 U.S.C. 1855(d), without a recommendation from the Council. The reason for using this regulatory authority is because this final rule must be published under an extremely aggressive timeline ordered by the U.S. District Court for the Northern District of California, which does not allow for compliance with the framework provisions of the CPS FMP.

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

This final rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

A final regulatory flexibility analysis (FRFA) was prepared pursuant to 5 U.S.C. 604(a), and is included in this final rule. The FRFA incorporates the initial regulatory flexibility analysis (IRFA). NMFS did not receive any public comments on the IRFA or regulatory flexibility analysis (RFA) process. The FRFA describes the economic impact this final rule may have on small entities. The results of the analysis are stated below. A copy of this analysis is available from NMFS (see **ADDRESSES**).

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a notification email to relevant stakeholders that also serves as small entity compliance guide (the guide) was prepared. Copies of this final rule are available from the West Coast Regional Office, and the guide, *i.e.,* the notification letter, will be emailed to all stakeholders.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (*see* 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide.

The action being implemented through this rule is the establishment of a new OFL, ABC, and ACL for the central anchovy subpopulation.

The small entities that would be affected by this action are primarily the vessels that harvest central anchovy as part of the West Coast CPS purse seine fleet. The average annual per vessel revenue in 2017 for the West Coast CPS finfish small purse seine fleet was below $11 million; therefore, all of these vessels are considered small businesses under the RFA. Because each affected vessel is a small business, this rule is considered to equally affect all of these small entities in the same manner. Therefore, this rule would not create disproportionate costs between small and large vessels/businesses. To evaluate whether this rule could potentially reduce the profitability of affected vessels, NMFS compared current and average recent historical landings to the proposed ACL (*i.e.,* the maximum fishing level for each year). The final ACL for central anchovy is 25,000 mt, which is slightly higher than the vacated ACL (23,573 mt). In 2019, approximately 10,162 mt of central anchovy were landed. The annual average harvest from 2010 to 2019 for central anchovy was approximately 7,950 mt. Central anchovy landings have been well below the proposed ACL in 8 of the past 10 years. Therefore, although the establishment of a new ACL for this stock is considered a new management measure for the fishery, this action should not result in changes in current fishery operations. As a result, the ACL implemented in this rule is unlikely to limit the potential profitability to the fleet from catching central anchovy and therefore would not impose significant economic impacts.

The central anchovy fishery is a component of the CPS purse seine fishery off the U.S. West Coast, which generally fishes a complex of species that also includes the fisheries for Pacific sardine, Pacific mackerel, jack mackerel, and market squid. Currently there are 58 vessels permitted in the Federal CPS limited entry fishery off California. Annually, 32 of these 58 CPS vessels landed anchovy in recent years.

CPS finfish vessels typically harvest a number of other species, including Pacific sardine, Pacific mackerel, and market squid, making the central anchovy fishery only one component of a multi-species CPS fishery. Therefore, the revenue derived from this fishery is only part of what determines the overall revenue for a majority of the vessels in the CPS fleet, and the economic impact to the fleet from the action cannot be viewed in isolation. CPS vessels typically rely on multiple species for profitability because abundance of the central anchovy stock, like the other CPS stocks, is highly associated with ocean conditions and seasonality. Variability in ocean conditions and season results in variability in the timing and location of CPS harvest throughout the year. Because each species responds to ocean conditions in its own way, not all CPS stocks are likely to be abundant at the same time. Therefore, as abundance levels and markets fluctuate, the CPS fishery as a whole has relied on a group of species for its annual revenues.

NMFS reviewed and evaluated options for other methods and data sources to update the estimate of MSY or develop a new long-term OFL. However, NMFS had limited time to fully review these types of methods; therefore, an alternative such as this was

not fully developed. Additionally, this action maintains the management approach set in the FMP for stocks in the monitored category, which dictates how the OFL and ABC can be set, thereby limiting the alternatives for these values. The CPS FMP states that the ACL is set equal to the ABC or lower if determined necessary to prevent overfishing or for other OY considerations not already built into the ABC control rule. Although there is no management uncertainty that requires reducing the ACL from the ABC, prior environmental analyses have only analyzed an ACL up to 25,000 mt, which is also the Council's previous determination of OY for the stock. As previously stated, NMFS does not expect the proposed reduction in the ABC to negatively impact regulated fishermen, as the proposed ACL (25,000 mt) is higher than the vacated ACL (23,573 mt).

During the proposed rule stage, NMFS proposed the option of implementing a biomass threshold whereby, if the best scientific information available indicates the stock's abundance drops below this threshold, then the ACL would be automatically reduced. A reduced ACL resulting from the this type of management measure would have potential to impact regulated fishermen through a consequent reduction in fishing opportunity, but the extent of economic impact would depend on a variety of factors, including the percentage of the reduction. NMFS decided to not to implement this management measure because NMFS determined it was not necessary in order to prevent overfishing over the long term. Therefore, NMFS did not further analyze potential economic impacts from this type of management measure during the final rule stage.

Thus, no significant alternatives to this final rule exist that would accomplish the stated objectives of the applicable statutes while minimizing any significant economic impact of this final rule on the affected small entities. However, as stated above, this final rule is not expected to have a significant economic impact on the regulated fishermen.

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 660

Fisheries, Fishing, Indians, Recreation and recreation areas, Reporting and recordkeeping requirements, Treaties.

Dated: December 23, 2020.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

■ 2. In § 660.511, revise paragraph (k)(1) to read as follows:

§ 660.511 Catch restrictions.

* * * * *

(k) * * *

(1) Northern Anchovy (Central Subpopulation): 25,000 mt.

* * * * *

[FR Doc. 2020–28901 Filed 12–30–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 200221–0062; RTID 0648–XA759]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod in the Gulf of Alaska

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

ACTION: Temporary rule; modification of closure.

SUMMARY: NMFS is opening directed fishing for Pacific cod by various sectors in the Gulf of Alaska (GOA). This action is necessary to fully use the 2021 total allowable catch (TAC) of Pacific cod in the GOA.

DATES: Effective 0001 hours, Alaska local time (A.l.t.), January 1, 2021 through 2400 hours, A.l.t., December 31, 2021. Comments must be received at the following address no later than 4:30 p.m., A.l.t., January 15, 2021.

ADDRESSES: You may submit comments, identified by *NOAA–NMFS–2019–0102,* by either of the following methods:

- *Federal e-Rulemaking Portal:* Go to *https://www.regulations.gov/docket?D=NOAA-NMFS-2019-0102,* click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Records Office. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council (Council) under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

Pursuant to the final 2020 and 2021 harvest specifications for groundfish in the GOA (85 FR 13802, March 10, 2020), NMFS closed directed fishing for Pacific cod in the GOA in accordance with § 679.20(d)(1)(iii) through December 31, 2021.

As of December 17, 2020, NMFS has determined that 5,590 metric tons (mt) in the Western Regulatory Area and 10,242 mt in the Central Regulatory Area of the GOA of Pacific cod TAC is available in 2021. This is based on the Council's December 2020 recommendation for the 2021 Pacific cod TAC in the GOA. NMFS issued an inseason adjustment to adjust the 2021 Pacific cod TAC to reflect the Council's recommendations (85 FR 83834, December 23, 2020). The adjusted 2021 Pacific cod TACs are sufficient to allow for directed fishing for Pacific cod by vessels using jig gear, vessels using pot gear, and catcher/processors (CPs) using hook-and-line gear in the Western Regulatory Area of the GOA. The adjusted 2021 Pacific cod TACs also are

sufficient to allow for directed fishing for Pacific cod by vessels using jig gear, vessels using pot gear, catcher vessels using hook-and-line gear, and CPs using hook-and-line gear in the Central Regulatory Area of the GOA.

Therefore, in accordance with § 679.25(a)(1)(i), (a)(2)(i)(C), and (a)(2)(iii)(D), and to fully utilize the 2021 Pacific cod TAC in the Western Regulatory Area of the GOA, NMFS is terminating the previous closures and is opening directed fishing for Pacific cod by vessels using jig gear, vessels using pot gear, and CPs using hook-and-line gear.

Additionally, in accordance with § 679.25(a)(1)(i), (a)(2)(i)(C), and (a)(2)(iii)(D), and to fully utilize the 2021 Pacific cod TAC in the Central Regulatory Area of the GOA, NMFS is terminating the previous closures and is opening directed fishing for Pacific cod by vessels using jig gear, vessels using pot gear, catcher vessels less than 50 feet length overall (LOA) using hook-and-line gear, catch vessels greater than or equal to 50 feet LOA using hook-and-line gear, and CPs using hook-and-line gear.

This action will enhance the socioeconomic well-being of harvesters in this area. The Administrator, Alaska Region (Regional Administrator) considered the following factors in reaching this decision: (1) The adjusted 2021 Pacific cod TAC in the GOA and (2) the harvest capacity and stated intent on future harvesting patterns of vessels in participating in this fishery.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the opening of directed fishing for Pacific cod in the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of December 23, 2020.

Without this inseason adjustment, NMFS could not allow the fishery for Pacific cod in the GOA to be harvested in an expedient manner and in accordance with the regulatory schedule.

Under § 679.25(c)(2), interested persons are invited to submit written comments on this action to the above address until January 15, 2021.

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

Dated: December 28, 2020.

Jennifer M. Wallace,

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

[FR Doc. 2020–28967 Filed 12–30–20; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 85, No. 251
Thursday, December 31, 2020

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.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 703 and 721

RIN 3133–AF26

Mortgage Servicing Rights

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) proposes to amend its investment regulation to permit federal credit unions (FCUs) to purchase mortgage servicing rights from other federally insured credit unions under certain conditions. Under the proposed rule, eligible FCUs may purchase the mortgage servicing rights of loans that the FCU is otherwise empowered to grant, provided these investments are consistent with safety and soundness and made in accordance with the FCU's policies and procedures that address the risk of these investments and servicing practices.

DATES: Comments must be received on or before February 1, 2021.

ADDRESSES: You may submit written comments, identified by RIN 3133–AF26, by any of the following methods (*Please send comments by one method only*):

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (703) 518–6319. Include ''[Your Name]—Comments on Proposed Rule: Mortgage Servicing Rights'' in the transmittal.
- *Mail:* Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

Public Inspection: You may view all public comments on the Federal eRulemaking Portal at *http://www.regulations.gov* as submitted, except for those we cannot post for technical reasons. The NCUA will not edit or remove any identifying or contact information from the public comments submitted. Due to social distancing measures in effect, the usual opportunity to inspect paper copies of comments in the NCUA's law library is not currently available. After social distancing measures are relaxed, visitors may make an appointment to review paper copies by calling (703) 518–6540 or emailing *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Mayfield, Senior Capital Markets Specialist; Lou V. Pham, Senior Credit Specialist, Office of Examination & Insurance, or Ian Marenna, Associate General Counsel; Chrisanthy Loizos, Senior Trial Attorney, Office of General Counsel, at 1775 Duke Street, Alexandria, VA 22314 or telephone: (703) 518–6300 or (703) 581–6540.

SUPPLEMENTARY INFORMATION:

I. Background
II. Legal Authority
III. Summary of the Proposed Rule
IV. Regulatory Procedures

I. Background

Generally, when a lender originates a mortgage loan, the lender may retain the loan and the servicing function for the loan in its portfolio, sell the loan along with the mortgage servicing rights to another party, or separate the mortgage servicing rights (MSRs) from its mortgage loan and transfer only the loan or the MSRs to another party. This proposed rulemaking focuses on the purchase of MSRs, as assets that are apart from their underlying mortgage loans. The Board proposes to permit FCUs to purchase MSRs by removing MSRs from the list of prohibited investments [1] in the Investment and Deposit Activities Rule (investment rule) and adding the purchase of MSRs from other federally insured credit unions (FICUs) to the rule's list of permissible investments for FCUs.[2] Under the investment rule, MSRs are defined as ''a contractual obligation to perform mortgage servicing and the right to receive compensation for performing those services. Servicing is the administration of a mortgage loan, including collecting monthly payments and fees, providing recordkeeping and escrow functions, and, if necessary curing defaults and foreclosing.'' [3]

[1] 12 CFR 703.16.

[2] 12 CFR 703.14.

[3] 12 CFR 703.2.

While the Federal Credit Union Act specifies the statutory investment powers for FCUs,[4] the NCUA has adopted regulatory prohibitions against certain investments and investment activities on the basis of safety and soundness concerns, including investments in MSRs.[5]

Mortgage servicing rights can be derived through various processes. Because FCUs are currently prohibited from purchasing MSRs by regulation, they are primarily derived when an FCU originates a residential mortgage loan and sells the loan to investors on the secondary market or other purchasers while the retaining the corresponding servicing rights. Alternatively, and to a lesser degree, FCUs can retain MSRs if they later sell residential mortgage loans that they had purchased from the originating lender.

Mortgage loan servicers function as intermediaries between borrowers and owners of the mortgage loans. MSRs entitle the servicer to receive compensation from the owner of the mortgage loan in return for performing servicing activities for the underlying mortgage loan. These servicing functions are subject to a servicing agreement and consumer protection laws, as applicable.[6] These functions generally include collecting monthly payments and fees, providing recordkeeping, and performing escrow functions. Further, the servicer also works with borrowers to mitigate loss and pursues foreclosure, as authorized.

In guidance to examination staff, the Office of the Comptroller of the Currency describes MSRs or mortgage servicing assets (MSAs) as ''complex, intangible assets that arise from owning the rights to service mortgage loans that have been securitized or sold to third-party investors. The market value of MSAs is affected by market supply and demand factors. MSA values are economically represented as the discounted present value of estimated future net cash flows over the life of the underlying mortgage loans. MSAs expose servicers to interest rate, price, compliance, and operational risks. The risk of changes in the fair value of MSAs

[4] 12 U.S.C. 1757(7), (8), (14), (15).

[5] 62 FR 32989 (June 18, 1997); 66 FR 54168, 54169 (Oct. 26, 2001); 67 FR 78996, 78997 (Dec. 27, 2002); 12 CFR 703.16(a).

[6] For example, *see* 12 CFR 1024.17; 12 CFR part 1024, subpart C; 12 CFR 1026.20, .36, .40–.41.

due to changes in interest rates is normally considered interest rate risk. It could be considered price risk, however, if the bank is actively buying and selling its MSAs. MSAs pose operational risk because the servicing and valuation functions are operations intensive and model dependent.'' [7]

MSRs are generally capitalized at fair value and subsequently accounted for using the amortization or fair value method.[8] The fair value of MSRs is the net present value, using a market-based discount rate, of servicing revenue components (servicing fee, float income, ancillary income, etc.) less expenses, adjusted for prepayment speeds. Prepayment speeds in turn are generally highly dependent on prevailing interest rates. However, determining the fair value of MSRs can be a complex exercise given that their market prices are generally not readily observable. Hence, owners of MSRs typically depend on data-driven models, whether proprietary or purchased, and third party expertise to help them value their MSRs.

MSRs impact compliance and reputation risk due to the high touch nature of interactions with consumers and the attendant legal requirements imposed on mortgage servicers. For example, depending on the amount and types of mortgage loans serviced,[9] servicers must comply with a variety of regulatory requirements that implement the Dodd–Frank Wall Street Reform and Consumer Protection Act of 2010, including amendments to Regulation Z (implementing the Truth in Lending Act) and Regulation X (implementing the Real Estate Settlement Procedures Act),[10] as well as other applicable state and federal laws, such as the Servicemembers Civil Relief Act (SCRA),[11] the Fair Debt Collection Practices Act,[12] and Section 5 of the Federal Trade Commission Act, which prohibits unfair or deceptive acts or practices. To be successful, servicers need not only to understand complexities in determining the value of these assets, but should have effective information management systems, trained personnel, robust internal controls, and appropriate risk management to properly service the loans.

Over decades, the NCUA has issued many regulations and opinions that have recognized the authority of an FCU to engage in the servicing of loans in varying contexts. Since 1979, an FCU has been permitted ''to service any eligible obligation it purchases or sells in whole or in part'' under the NCUA's eligible obligations rule.[13] The incidental powers regulation [14] has also long provided that FCUs have the authority to provide correspondent services, including loan servicing, to other credit unions.[15] In adopting that regulation, the Board observed: ''Correspondent services are services or functions provided by an FCU to another credit union that the FCU is authorized to perform for its own members or as part of its operation.'' [16] During the part 721 rulemaking in 2001, the Board agreed with commenters that loan servicing and escrow services were examples of permitted correspondent services.[17] Furthermore, although the purchase of MSRs was to be prohibited under the investment rule, the Board recognized during the rulemaking that an FCU could perform servicing for a member engaged in making mortgage loans as a financial service to its member: ''For this activity to be permissible as a financial service to a member, the member must continue to own the loan during the time that the credit union provides servicing. In this context, the NCUA Board concludes that providing mortgage servicing is an appropriate exercise of a credit union's incidental powers to provide financial service to a member.'' [18] Therefore, the authority to provide mortgage loan servicing as a financial service to members, under the conditions above, has been in place since 2003.[19] FCUs are also permitted to provide mortgage loan servicing to others as a charitable contribution.[20] Further, under the NCUA's Credit Union Service Organization (CUSO) regulation, CUSOs [21] are expressly preapproved to provide loan support services, including loan servicing and debt collection services.[22]

The Board believes it is appropriate now to remove the prohibition against FCUs from purchasing MSRs as permissible investments while also maintaining safety and soundness. FCUs have long had experience originating and servicing residential mortgage loans. In fact, first lien residential mortgage loans account for over one third of outstanding credit union loans as of September 30, 2020, which is the single largest loan concentration in the system. FCUs accounted for $78 billion of the approximately $154 billion in first lien residential mortgage loans originated by all FICUs in 2019. Comparatively, FCUs accounted for $62 billion of the approximately $117 billion in first lien residential mortgage loans originated by all FICUs in 2018.[23]

Like many financial institutions involved in residential lending, FCUs engage in both origination and servicing activities related to residential lending. As of September 30, 2020, approximately 3,700 FICUs held $431 billion in aggregate outstanding first lien residential mortgage loans, with 2,166 FCUs accounting for $214 billion of the

[7] Comptroller's Handbook for Mortgage Banking, version 1 Feb. 2014 at p. 67.

[8] *See* Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 860—Transfer and Servicing of Financial Assets.

[9] Small servicers are exempt from numerous requirements that apply to mortgage servicing activities under Regulations X and Z. *See, e.g.* 12 CFR 1024.17; 12 CFR 1024.37–.41; 12 CFR 1026.41. Generally, to qualify as a small servicer, a servicer must service, together with any affiliates, 5,000 or fewer mortgage loans, for all of which the servicer (or an affiliate) is the creditor or assignee. *See* 12 CFR 1026.41(e)(4) for full definition.

[10] Note that on April 3, 2020, NCUA and the federal banking regulators issued the ''Joint Statement on Supervisory and Enforcement Practices Regarding the Mortgage Servicing Rules in Response to the COVID–19 Emergency and the CARES Act'' available at *https://files.consumerfinance.gov/f/documents/cfpb_interagency-statement_mortgage-servicing-rules-covid-19.pdf* and the Consumer Financial Protection Bureau (CFPB) issued frequently asked questions regarding its mortgage servicing rules related to the COVID–19 Emergency available at *https://files.consumerfinance.gov/f/documents/cfpb_mortgage-servicing-rules-covid-19_faqs.pdf. See also the CFPB's interim final rule, ''Treatment of Certain COVID–19 Related Loss Mitigation Options,'' 85 FR 39055 (June 30, 2020).*

[11] For example, the SCRA contains a strict liability provision that requires a court order before foreclosing on a mortgage during a period of military service, and for one year after a period of military service. 50 U.S.C. 3953.

[12] Note the CFPB recently issued a final rule implementing the FDCPA to address the activities of debt collectors, as that term is defined in the FDCPA, with a focus on debt collection communications and related practices by debt collectors. *See* 87 FR 76734 (Nov. 30, 2020).

[13] 12 CFR 701.23(e); 44 FR 27068 (May 9, 1979).

[14] 12 CFR part 721.

[15] 12 CFR 721.3(c).

[16] 66 FR 40845, 40850 (Aug. 6, 2001).

[17] *Id.; see also* NCUA OGC Opinion 09–0430 (August 2009) available at *https://www.ncua.gov/regulation-supervision/legal-opinions/2009/nonmember-loan-servicing.*

[18] 67 FR 78996, 78998 (Dec. 27, 2002).

[19] 68 FR 32960 (June 3, 2003).

[20] NCUA OGC Opinion 01–0502 (June 18, 2001) available at *https://www.ncua.gov/files/legal-opinions/OL2001-0502.pdf;* 12 CFR 721.3(b)(1).

[21] Generally, a CUSO is an entity in which a FICU has an ownership interest or to which a FICU has extended a loan, and that entity is engaged primarily in providing products or services to credit unions or credit union members. A CUSO also includes any entity in which a CUSO has an ownership interest of any amount, if that entity is engaged primarily in providing products or services to credit unions or credit union members. *See* 12 CFR 712.1(d).

[22] 12 CFR 712.5(j); *see also* NCUA OGC Opinion 09–0349 (May 2009) available at *https://www.ncua.gov/regulation-supervision/legal-opinions/2009/credit-union-service-organization-cuso-purchase-and-servicing-non-performing-loans.*

[23] NCUA Call Report Data as of December 31, 2018 and December 31, 2019.

outstanding amount.[24] These residential mortgage loans are considered ''portfolio'' mortgage loans because the FICU has not sold its loans and the FICU (or a related CUSO) provides mortgage servicing activities for said loans. There are no associated MSRs with portfolio mortgage loans from an asset and accounting perspective, but the responsibility to service the mortgage loan rests with the portfolio lender.

Credit unions, like many other lenders involved with mortgage finance, also actively engage in selling residential mortgage loans to investors on the secondary market or other purchasers. In 2019, approximately 1,100 FICUs collectively sold $63 billion in residential mortgage loans. Five hundred fifty-six (556) FCUs accounted for $39 billion of the $63 billion of mortgage loans sold in 2019. Comparatively, approximately 1,100 FICUs collectively sold $46 billion in residential mortgage loans in 2018, with 553 FCUs accounting for $26 billion of the total amount sold.

The NCUA began collecting data on MSRs owned by FICUs in 2003 and has found that the value of MSRs in the credit union system increased from approximately $330 million in 2004 to $1.8 billion in 2019. During this period, the amount of real estate loans sold where servicing was retained increased from $46 billion to $240 billion. As of September 30, 2020, more than 500 FICUs owned $1.9 billion in MSRs. Of this figure, 235 FCUs accounted for $1.1 billion in MSRs.[25]

The Board recognizes that MSRs have certain inherent attributes that can have an adverse impact on an FCU's financial condition. Mortgage servicing rights can carry operational risks due to a myriad of statutes and regulations to protect consumers, which can expose FCUs to reputational, legal, and compliance risk. In addition, MSRs can expose servicers to liquidity risk as certain mortgage loans which have been sold to investors require the servicer to remit payments to the investors even if borrowers do not make the monthly mortgage loan payments. The value of MSRs is highly dependent on prevailing interest rates. In a rapidly increasing or decreasing interest rate environment, this can introduce extreme volatility to a credit union's financial condition as the MSRs are periodically valued for accounting and reporting purposes. An FCU in poor financial condition may not be able to withstand the financial impact of a significant loss due to a write-down in the value of its MSRs.

The Board believes that FCUs have demonstrated experience originating and servicing residential mortgage loans. Furthermore, although valuing MSRs can be complex, FCUs have sufficient access to market resources and expertise to help them value MSRs when purchased or retained on an ongoing basis for accounting purposes. For these reasons, the Board believes removing the prohibition in the investment rule is appropriate and consistent with safety and soundness. The proposed rule would provide flexibility for FCUs to operate their mortgage loan business and would also provide FICUs another avenue to sell their MSRs, which could generate a higher selling price and keep the MSRs within the credit union system.

II. Legal Authority

Section 120(a) of the Federal Credit Union Act[26] authorizes the Board to prescribe rules and regulations for the administration of the statute.[27] In addition, section 206 of the Federal Credit Union Act provides the Board with broad authority to take enforcement action against a FICU or an ''institution-affiliated party''[28] that is engaging or has engaged, or the Board has reasonable cause to believe that it is about to engage, in an unsafe or unsound practice in conducting the business of such credit union.[29] Congress chose not to define ''unsafe or unsound practices'' in the Federal Credit Union Act, leaving determinations regarding which actions are unsafe or unsound to the Board.

The Federal Credit Union Act authorizes an FCU ''to sell all or a part of its assets to another credit union [and] to purchase all or part of the assets of another credit union. . . subject to regulations of the Board.''[30] Given that MSRs are financial assets that may be sold separately from their underlying mortgage loans, an FCU has the statutory authority to sell MSRs to, and purchase MSRs from, another credit union. Further, the Federal Credit Union Act authorizes an FCU ''to exercise such incidental powers as shall be necessary or requisite to enable it to carry on effectively the business for which it is incorporated.''[31] As such, NCUA's incidental powers regulation[32] has long provided that FCUs have the authority to provide correspondent services, including loan servicing, to other credit unions.[33] Similarly, the eligible obligations rule allows an FCU ''to service any eligible obligation it purchases or sells in whole or in part.''[34]

III. Summary of the Proposed Rule

As set out above, the Board proposes to remove the current prohibition on FCUs purchasing MSRs from the investment rule. The Board is proposing to amend § 703.14 to explicitly permit an FCU to purchase MSRs from other FICUs as an investment, provided: (1) The underlying mortgage loans of the MSRs are loans the FCU is empowered to grant; (2) the FCU purchases the MSRs within the limitations of the FCU's board of directors' written purchase policies; and (3) the board of directors or investment committee approves the purchase in advance.

To ensure that MSRs purchased by FCUs meet the same requirements and standards applicable to the loans that a buying FCU can make, the proposed rule would allow purchases of MSRs from FICUs only if the underlying mortgage loans from which the MSRs are derived meet the same conditions for loans the FCU is empowered to grant. This is the same standard applicable to FCUs when buying certain eligible obligations under § 701.23(b). The phrase ''empowered to grant'' refers to an FCU's authority to make the type of loans permitted by the FCU Act, NCUA regulations, FCU Bylaws, and an FCU's own internal policies.[35]

Consistent with § 701.23, the Board is also requiring MSRs be purchased within the limitations of the FCU's board of directors' written purchase policies and requiring the FCU's board of directors or investment committee approves the purchase in advance.

[24] NCUA Call Report Data as of September 30, 2020.

[25] NCUA Call Report Data as of September 30, 2020.

[26] 12 U.S.C. 1766(a).

[27] 12 U.S.C. 1751–1795k.

[28] *See* 12 U.S.C. 1786(r) (providing: ''For purposes of [the Federal Credit Union Act], the term 'institution-affiliated party'' means—(1) any committee member, director, officer, or employee of, or agent for, an insured credit union; (2) any consultant, joint venture partner, and any other person as determined by the Board (by regulation or on a case-by-case basis) who participates in the conduct of the affairs of an insured credit union; and (3) any independent contractor (including any attorney, appraiser, or account) who knowingly or recklessly participates in—(A) any violation of any law or regulation; (B) any breach of fiduciary duty; or (C) any unsafe or unsound practice, which caused or is likely to cause more than a minimal financial loss to, or a significant adverse effect on, the insured credit union.'').

[29] 12 U.S.C. 1786.

[30] 12 U.S.C. 1757(14).

[31] 12 U.S.C. 1757(17).

[32] 12 CFR part 721.

[33] 12 CFR 721.3(c).

[34] 12 CFR 701.23(e); 44 FR 27068 (May 9, 1979).

[35] NCUA OGC Op. 04–0713 (Oct. 25, 2004) available at *https://www.ncua.gov/files/legal-opinions/OL2004-0713.pdf,* 76 FR 81421, 81425 (December 28, 2011).

The proposed rule necessarily removes the current prohibition against MSRs purchases imposed in § 703.16(a) and reserves the paragraph to correspond to the change in § 703.14. The remaining provision in § 703.16(a), which recognizes an FCU's incidental powers authority to service the loans owned by a member engaged in mortgage lending, is transferred to part 721 as another example of loan-related product. While loan servicing is an incidental powers activity when performed for other credit unions under § 721.3(c) as a correspondent service, the proposed addition to paragraph (h) reflects the existing authority currently found in § 703.16(a) to provide loan-related services to members.

The Board invites comments on all aspects of the proposal [36] and, in addition, requests comment on the following questions. The questions raise issues the Board intends to incorporate in the final rule to ensure appropriate safeguards and limitations, and will consider the comments and supporting information it receives in response to this notice.

How would the proposed rule to permit an FCU to purchase MSRs from other FICUs benefit an FCU's mortgage loan servicing operations? The Board solicits feedback on whether the current prohibition against FCUs purchasing MSRs as financial assets from other mortgage lenders has impacted the ability of FCUs to achieve their strategic objectives.

If FCUs purchase volumes of MSRs from different FICUs, are they prepared to ensure they have effective compliance management systems for compliance with the consumer protection-related laws and regulations that apply to mortgage loan servicers? FCUs manage their exposure to compliance risk through a comprehensive compliance program, often referred to as a compliance management system (CMS). An FCU's CMS includes policies, procedures, processes, monitoring, and an audit function regarding compliance with all applicable laws and regulations, including those that apply to mortgage loan servicing activities. An effective CMS promotes compliance with consumer protection-related laws and regulations and prevents consumer harm. The Board solicits comment on to what extent FCUs may need to make appropriate adjustments to their CMS if they expand their mortgage loan servicing as provided under the proposed rule, particularly to comply with the consumer protections that apply to the transfer and servicing of mortgage loans, and how the NCUA can best ensure that FCUs purchasing MSRs do so.

Should the proposed rule include additional criteria for an FCU to be eligible to purchase MSRs? In particular, should the FCU be required to be ''well capitalized'' as defined in part 702? If so, similarly to the eligible obligations rule, should it be well capitalized for a minimum of the six quarters preceding its purchase of MSRs? Should the FCU be required to have a composite CAMEL rating of 1 or 2 with a Management rating of a 1 or 2 for at least the last two examination cycles? As detailed in this notice, MSRs carry a variety of risks. As such, the Board is considering certain safeguards that would apply before an FCU is eligible to purchase MSRs, in order to mitigate some of these risks. The Board is considering whether to incorporate one of, or a combination of, these elements in a final rule because it has found these standards to be prudent in other contexts, including the eligible obligations rule and investment rule in relation to investments in derivatives.[37] The Board solicits feedback on whether these proposed standards would mitigate risks inherent in the purchase of MSRs and help ensure that FCUs engage in this activity in a safe and sound manner.

Should the final rule include a limit on the amount of MSRs an FCU can hold to address concentration risk? Specifically, should a limit on the amount of MSRs held by an FCU be determined using the total amount of MSRs purchased by the FCU or, alternatively, the aggregate amount of MSRs purchased from other parties and MSRs retained after the sale of the underlying mortgage loans by the FCU? Should the rule limit the total amount of MSRs that an FCU may hold to no more than twenty-five percent (25%) of the FCU's net worth or would another standard, such as a concentration limit based on assets, be more appropriate to address concentration risk? High concentrations in a particular asset can expose a credit union to undue risk. The Board solicits feedback on whether a concentration limit for MSRs would help alleviate risks for FCUs that purchase or originate MSRs.

To address the liquidity risk of the purchasing FCU, should the final rule limit the amount of months an FCU is obligated to remit payments to the mortgage loan owner if the borrower fails to make payments? Specifically, should there be a maximum of three to six months of payments made to the mortgage loan owner when a borrower fails to make payment on the serviced mortgage loan? MSRs can carry liquidity risks if the servicer is required under the mortgage servicing contract to remit payments to owners of the mortgage loans even if the servicer is not receiving mortgage payments from borrowers. The Board solicits feedback on whether there should be a limit on MSRs with certain remittance structures to mitigate liquidity risks to FCUs that purchase MSRs.

Finally, the Board solicits comment on whether the safeguards and limitations applicable to FCUs in the final rule should be extended to all FICUs in light of the risks associated with the purchase of MSRs, as a requirement for obtaining and maintaining federal insurance.

Regulatory Procedures

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a notice of proposed rulemaking, an agency prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities. A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined for purposes of the RFA to include FICUs with assets less than $100 million) and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule. The proposed rule provides additional investment authority to FCUs that meet certain eligibility requirements due to the complexity and risk related to the purchase of MSRs. As of March 31, 2020, of the 3,256 credit unions with federal charters, only 17 FCUs with assets of less than $100 million had MSRs on their books. Accordingly, the NCUA certifies that the proposed rule will not have a significant economic impact on a substantial number of small credit unions.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency creates a new or amends existing information collection

[36] As noted, many FCUs have considerable experience in managing the servicing of mortgage loans, therefore the Board is not providing the usual 60-day comment period for this proposal which relieves a regulatory prohibition on investments in MSRs as assets. *See* NCUA Interpretive Ruling and Policy Statement (IRPS) 87–2, as amended by IRPS 03–2 and IRPS 15–1. 80 FR 57512 (Sept. 24, 2015), *available at https://www.ncua.gov/files/publications/irps/IRPS1987-2.pdf.*

[37] 12 CFR 701.23(b)(2), 703.108(a)(1).

requirements.[38] For the purpose of the PRA, an information collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement. The proposed rule does not contain information collection requirements that require approval by OMB under the PRA.[39] The proposed rule provides regulatory relief by allowing eligible FCUs to expand their investment authority to include the purchase of MSRs under similar standards applicable to the purchase of eligible obligations and other investments.

C. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, the NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. This rulemaking will not have a substantial direct effect on the states, on the connection between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The NCUA has determined that this proposal does not constitute a policy that has federalism implications for purposes of the executive order.

D. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.[40]

List of Subjects

12 CFR Part 703

Credit unions, Investments.

12 CFR Part 721

Credit unions, Functions, Implied powers.

By the National Credit Union Administration Board on December 17, 2020.

Melane Conyers-Ausbrooks,

Secretary of the Board.

For the reasons discussed above, the NCUA Board proposes to amend 12 CFR parts 703 and 721 as follows:

[38] 44 U.S.C. 3507(d); 5 CFR part 1320.

[39] 44 U.S.C. Chap. 35.

[40] Public Law 105–277, 112 Stat. 2681 (1998).

PART 703—INVESTMENT AND DEPOSIT ACTIVITIES

■ 1. The authority citation for part 703 is revised to read as follows:

Authority: 12 U.S.C. 1757(7), 1757(8), 1757(14) and 1757(15).

■ 2. Amend § 703.14 by adding paragraph (l) to read as follows:

§ 703.14 Permissible investments.

* * * * *

(l) *Mortgage servicing rights.* A Federal credit union may purchase mortgage servicing rights from other federally insured credit unions as an investment if all of the following conditions are met:

(1) The underlying mortgage loans of the mortgage servicing rights are loans the Federal credit union is empowered to grant;

(2) the Federal credit union purchases the mortgage servicing rights within the limitations of its board of directors' written purchase policies; and

(3) the board of directors or investment committee approves the purchase.

§ 703.16 [Amended]

■ 2. Amend § 703.16 by removing and reserving paragraph (a).

PART 721—INCIDENTAL POWERS

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

Authority: 12 U.S.C. 1757(17), 1766 and 1789.

■ 5. Amend § 721.3 paragraph (h) by revising the last sentence to read as follows:

§ 721.3 What categories of activities are preapproved as incidental powers necessary or requisite to carry on a credit union's business?

* * * * *

(h) * * * These products or activities may include debt cancellation agreements, debt suspension agreements, letters of credit, leases, and mortgage loan servicing functions for a member as long as the loan is owned by a member.

* * * * *

[FR Doc. 2020–28278 Filed 12–30–20; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[REG–114615–16]

RIN 1545–BP75

User Fee for Estate Tax Closing Letter

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations establishing a new user fee for authorized persons who wish to request the issuance of IRS Letter 627, also referred to as an estate tax closing letter. The Independent Offices Appropriations Act of 1952 authorizes charging user fees in appropriate circumstances. The proposed regulations affect persons who request an estate tax closing letter.

DATES: Written or electronic comments and requests for a public hearing must be received by March 1, 2021. Requests for a public hearing must be submitted as prescribed in the ''Comments and Requests for a Public Hearing'' section.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *http://www.regulations.gov* (indicate IRS and REG–114615–16) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The IRS expects to have limited personnel available to process public comments that are submitted on paper through mail. Until further notice, any comments submitted on paper will be considered to the extent practicable. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comment submitted electronically, and to the extent practicable on paper, to its public docket. Send paper submissions to: CC:PA:LPD:PR (REG–114615–16), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning submissions of comments and/or requests for a public hearing, Regina Johnson, at (202) 317–5177; concerning cost methodology, Michael Weber, at (202) 803–9738; concerning the proposed regulations, Juli Ro Kim, at (202) 317–6859 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

A. Overview

This document contains proposed amendments to the User Fee Regulations (26 CFR part 300) to establish a user fee applicable to requests for estate tax closing letters provided by the IRS to an authorized person. (The term ''authorized person'' is used herein to refer to a decedent's estate or other person properly authorized under section 6103 of the Internal Revenue Code (Code) to receive, and therefore, to request, an estate tax closing letter with respect to the estate.) The IRS issues estate tax closing letters upon request of an authorized person only after an estate tax return (generally, Form 706, United States Estate (and Generation-Skipping Transfer) Tax Return) has been accepted by the IRS (1) as filed, (2) after an adjustment to which the estate has agreed, or (3) after an adjustment in the deceased spousal unused exclusion (DSUE) amount. An estate tax closing letter informs an authorized person of the acceptance of the estate tax return and certain other return information, including the amount of the net estate tax, the State death tax credit or deduction, and any generation-skipping transfer tax for which the estate is liable.[1]

The IRS understands that knowledge of the acceptance by the IRS of the estate tax return—including the amount of the gross estate and the estate tax liability—is important to executors or other persons administering estates because of the unique nexus between an estate's Federal estate tax obligations and State and local law obligations to administer and close a probate estate. This knowledge aids an executor's ability to make the final division and distribution of estate assets and to avoid potential personal liability for unpaid estate tax in making such distribution. Personal liability can be imposed on an executor when the executor makes preferential payments to creditors or distributions to beneficiaries, leaving insufficient funds for the full payment of the tax owed to the government. See 31 U.S.C. 3713(b). On the other hand, an estate tax closing letter does not indicate whether any of the estate tax has been paid or the amount of estate tax that has been paid.

The estate tax closing letter also includes relevant procedural and substantive explanations. Addressing the potential for conflating an estate tax closing letter with a formal closing agreement, the letter confirms that it is not a formal closing agreement with the IRS that is described under section 7121 of the Code. Additionally, the estate tax closing letter explains that, consistent with Rev. Proc. 2005–32, 2005–1 C.B. 1206, the IRS will not reopen or examine the estate tax return to determine the estate tax liability of a decedent's estate unless the estate notifies the IRS of changes to the estate tax return or if there is (1) evidence of fraud, malfeasance, collusion, concealment, or misrepresentation of a material fact, (2) a clearly defined substantial error based upon an established IRS position, or (3) a serious administrative omission. However, the estate tax closing letter does not limit or foreclose future adjustments to the DSUE amount shown on the estate tax return, so the estate tax closing letter further explains that the IRS has authority to examine returns of a decedent in the context of determining the DSUE amount for portability purposes. (See part C of this section for a discussion of portability of the DSUE amount.) Finally, the estate tax closing letter includes explanations related to the potential application of sections 6166 and 6324A (installment payments and special extended lien), 2204 (discharge of personal liability), and 6324 (estate tax lien). Currently, the IRS does not charge for providing an estate tax closing letter to authorized persons.

B. June 2015 Change to IRS Practice in Issuing Estate Tax Closing Letters

The practice of issuing estate tax closing letters to authorized persons is not mandated by any provision of the Code or other statutory requirement. Instead, the practice is fundamentally a customer service convenience offered to authorized persons in view of the unique nature of estate tax return filings and the bearing of an estate's Federal estate tax obligations on the obligation to administer and close a probate estate under applicable State and local law. Essentially, the practice takes into account estates' and stakeholders' need for information regarding the status of an estate's Federal tax obligations in administering and closing a probate estate. Prior to June 2015, the IRS generally issued an estate tax closing letter for every estate tax return filed. However, for estate tax returns filed on or after June 1, 2015, the IRS changed its practice and now offers an estate tax closing letter only upon the request of an authorized person.

The IRS changed its practice of issuing estate tax closing letters for every filed Form 706 for two primary reasons. First, the volume of estate tax return filings increased at the same time that the IRS experienced additional budget and resource constraints. In particular, the number of estate tax filings increased dramatically due to the enactment in December 2010 of portability of a deceased spouse's unused applicable exclusion amount (DSUE amount) for the benefit of a surviving spouse. (See part C for a discussion of the impact of portability of the DSUE amount on estate tax filings.) Second, the IRS recognized that an account transcript with a transaction code and explanation of ''421—Closed examination of tax return'' is an available alternative to the estate tax closing letter. *See* Notice 2017–12, I.R.B. 2017–5 (describing the utility of the account transcript in lieu of the estate tax closing letter and its availability at no charge). Notwithstanding these considerations, the IRS was aware that executors, local probate courts, State tax departments, and others had come to rely on the convenience of estate tax closing letters and the return information and procedural and substantive explanations such letters provided for confirmation that the examination of the estate tax return by the IRS had been completed and the IRS file had been closed. Accordingly, in 2015 the IRS decided to continue providing the service of issuing estate tax closing letters, still at no charge, but only upon the request of an authorized person.

Until restrictions were added due to the ongoing Coronavirus Disease 2019 (COVID–19) pandemic, an authorized person was able to request an estate tax closing letter by telephone or fax. Now, due to the COVID–19 pandemic, an authorized person may request an estate tax closing letter only by fax (current procedure and details available at *http://www.irs.gov*).

C. The Continuing Impact of Portability on Estate Tax Return Filings

Portability of the DSUE amount became effective for estates of decedents dying after December 31, 2010, upon enactment of the Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010, Public Law 111–312, 124 Stat.

[1] In the context of a Form 706 (a ''return'' as defined in section 6103(b)(1)), the term ''return information'' is broadly defined in section 6103(b)(2) to include not only information appearing on the Form 706, but also whether the estate's return was, is being, or will be examined or subject to other investigation or processing, or any other data, received by, recorded by, prepared by, furnished to, or collected by the Secretary of the Treasury or his delegate (Secretary) with respect to the Form 706 or with respect to the determination of the existence, or possible existence, of liability (or the amount thereof) of any person under the Code for any tax, penalty, interest, fine, forfeiture, or other imposition, or offense.

3296, 3302 (Dec. 17, 2010), and became permanent upon enactment of the American Taxpayer Relief Act of 2012, Public Law 112–240, 126 Stat. 2313 (January 2, 2013). In order to elect portability of the DSUE amount for the benefit of the surviving spouse, the estate of the deceased spouse must timely file an estate tax return, even if the sum of the value of the gross estate and the amount of adjusted taxable gifts is insufficient to trigger a filing requirement under section 6018(a). In calendar year 2016, the number of estate tax returns filed solely to elect portability of the DSUE amount was approximately 20,000, compared to approximately 12,000 estate tax returns filed because of a filing requirement under section 6018(a).

D. Establishment of User Fee for Estate Tax Closing Letters

The IRS continues to experience significant budget and resource constraints that require the IRS to allocate its existing resources as efficiently as possible. The volume of estate tax return filings remains high (approximately 30,500 estate tax returns filed in 2018), in large part attributable to estate tax returns that are filed for estates having no tax liability or filing requirement under section 6018 and that are filed solely to elect portability of the DSUE amount for the benefit of the surviving spouse of a decedent.

While the practice of issuing estate tax closing letters is intended as a customer service convenience to authorized persons based on an understanding of the unique nexus between an estate's Federal estate tax obligations and the estate's obligations under applicable local law for State and local estate and inheritance taxes and to administer and close a probate estate, the Treasury Department and the IRS received feedback from taxpayers and practitioners that the procedure for requesting an estate tax closing letter can be inconvenient and burdensome. When requests had been accepted by telephone, a request could not be made until the IRS's examination of the estate tax return had been completed. Taxpayer representatives, therefore, often needed to repeat the telephone request, sometimes multiple times, before the request could be accepted by the IRS. Currently, the instructions on *http://www.irs.gov* advise that, prior to faxing a request, an account transcript should be requested and reviewed to ensure the transaction code and explanation of ''421—Closed examination of tax return'' are present. Account transcripts are available online to registered tax professionals using the IRS's Transcript Delivery System (TDS) or to authorized persons making requests using Form 4506–T.

In view of the resource constraints and purpose of issuing estate tax closing letters as a convenience to authorized persons, the IRS has identified the provision of estate tax closing letters as an appropriate service for which to establish a user fee to recover the costs that the government incurs in providing such letters. Accordingly, the Treasury Department and the IRS propose establishing a user fee for estate tax closing letter requests (see parts E and F for explanation of the authority to establish the user fee). As currently determined, the user fee is $67, as detailed in part H.

Guidance on the procedure for requesting an estate tax closing letter and paying the associated user fee is not provided in these proposed regulations. The Treasury Department and the IRS expect to implement a procedure that will improve convenience and reduce burden for authorized persons requesting estate tax closing letters by initiating a one-step, web-based procedure to accomplish the request of the estate tax closing letter as well as the payment of the user fee. As presently contemplated, a Federal payment website, such as *http://www.pay.gov,* will be used and multiple requests will not be necessary. The Treasury Department and the IRS believe implementing such a one-step procedure will reduce the current administrative burden on authorized persons in requesting estate tax closing letters and will limit the burden associated with the establishment of a user fee for providing such service.

E. User Fee Authority

The Independent Offices Appropriations Act of 1952 (IOAA) (31 U.S.C. 9701) authorizes each agency to promulgate regulations establishing the charge for services provided by the agency (user fees). The IOAA provides that these user fee regulations are subject to policies prescribed by the President and shall be as uniform as practicable. Those policies are currently set forth in the Office of Management and Budget (OMB) Circular A–25, 58 FR 38142 (July 15, 1993; OMB Circular).

The IOAA states that the services provided by an agency should be self-sustaining to the extent possible. 31 U.S.C. 9701(a). The OMB Circular states that agencies providing services that confer special benefits on identifiable recipients beyond those accruing to the general public must identify those services, determine whether user fees should be assessed for those services, and, if so, establish user fees that recover the full cost of providing those services.

As required by the IOAA and the OMB Circular, agencies are to review user fees biennially and update them as necessary to reflect changes in the cost of providing the underlying services. During these biennial reviews, an agency must calculate the full cost of providing each service, taking into account all direct and indirect costs to any part of the U.S. Government. The full cost of providing a service includes, but is not limited to, salaries, retirement benefits, rents, utilities, travel, and management costs, as well as an appropriate allocation of overhead and other support costs associated with providing the service.

An agency should set the user fee at an amount that recovers the full cost of providing the service unless the agency requests, and the OMB grants, an exception to the full cost requirement. The OMB may grant exceptions only where the cost of collecting the fees would represent an unduly large part of the fee for the activity, or where any other condition exists that, in the opinion of the agency head, justifies an exception. When the OMB grants an exception, the agency does not collect the full cost of providing the service and therefore must fund the remaining cost of providing the service from other available funding sources. When the OMB grants an exception, the agency, and by extension all taxpayers, subsidize the cost of the service to the recipients who otherwise would be required to pay the full cost of providing the service, as the IOAA and the OMB Circular directs.

F. Special Benefits Conferred by Issuance of Estate Tax Closing Letters

The issuance of an estate tax closing letter, and the return information and procedural and substantive explanations such letters provide, constitutes the provision of a service and confers special benefits on identifiable recipients beyond those accruing to the general public. Upon receipt of an estate tax closing letter, authorized persons can make use of the return information and procedural and substantive explanations provided in the letter for non-Federal tax purposes, for example, to facilitate the executor's ability to make the final distribution of estate assets and to respond as needed to non-Federal tax authorities and entities, such as local probate courts, State tax departments, and private stakeholders. Further, executors of such estates can make use of the return information pertaining to the estate's Federal tax

liability to avoid potential personal liability for payment of the tax under 31 U.S.C. 3713.

Moreover, letters comparable to estate tax closing letters are not universally available or provided to taxpayers filing Federal tax returns other than estate tax returns, upon request by authorized persons or otherwise. By comparison, account transcripts are universally provided by the IRS upon request to all taxpayers. After issuing Notice 2017–12 to publicize the availability and utility of an account transcript as an alternative in lieu of an estate tax closing letter, the feedback the IRS received from stakeholders reflects a definite preference for the return information and procedural and substantive explanations provided by the IRS in an estate tax closing letter. While the IRS will continue to offer transcripts as an alternative in lieu of estate tax closing letters at no charge, an authorized person may choose which service best supports their needs based upon the specific circumstances of the decedent's estate. Estate tax closing letters are uniquely available for authorized persons that have need of such special benefits.

For these reasons, the issuance of an estate tax closing letter constitutes the provision of a service and confers special benefits to authorized persons requesting such letters beyond those accruing to the general public. Accordingly, the IRS is authorized, pursuant to the IOAA and the OMB Circular, to charge a user fee for the issuance of an estate tax closing letter that reflects the full cost of providing this service. See also section 6103(p)(2)(B) (allowing for a reasonable fee for furnishing return information to any person).

G. Calculation of User Fees Generally

User fee calculations begin by first determining the full cost for the service. The IRS follows the guidance provided by the OMB Circular to compute the full cost of the service, which includes all indirect and direct costs to any part of the U.S. Government including but not limited to direct and indirect personnel costs, physical overhead, rents, utilities, travel, and management costs. The IRS's cost methodology is described later in this part G.

Once the total amount of direct and indirect costs associated with a service is determined, the IRS follows the guidance in the OMB Circular to determine the costs associated with providing the service to each recipient, which represents the average per unit cost of that service. This average per unit cost is the amount of the user fee that will recover the full cost of the service.

The IRS follows generally accepted accounting principles (GAAP), as established by the Federal Accounting Standards Advisory Board (FASAB), in calculating the full cost of providing services. The FASAB Handbook of Accounting Standards and Other Pronouncements, as amended, which is available at *http://files.fasab.gov/pdffiles/2019_fasab-handbook.pdf,* includes the Statement of Federal Financial Accounting Standards 4: Managerial Cost Accounting Standards and Concepts (SFFAS No. 4) for the Federal Government. SFFAS No. 4 establishes internal costing standards under GAAP to accurately measure and manage the full cost of Federal programs. The methodology described in the remainder of this part G is in accordance with SFFAS No. 4.

1. Cost Center Allocation

The IRS determines the cost of its services and the activities involved in producing them through a cost accounting system that tracks costs to organizational units. The lowest organizational unit in the IRS's cost accounting system is called a cost center. Cost centers are usually separate offices that are distinguished by subject-matter area of responsibility or geographic region. All costs of operating a cost center are recorded in the IRS's cost accounting system and are allocated to that cost center. The costs allocated to a cost center are the direct costs for the cost center's activities as well as all indirect costs, including overhead, associated with that cost center. Each cost is recorded in only one cost center.

2. Determining the per Unit Cost

To establish the per unit cost, the total cost of providing the service is divided by the volume of services provided. The volume of services provided includes both services for which a fee is charged as well as subsidized services. The subsidized services are those where OMB has approved an exception to the full cost requirement, for example, to charge a reduced fee to low-income taxpayers. The volume of subsidized services is included in the total volume of services provided to ensure that the IRS, and not those who are paying full cost, subsidizes the cost of the reduced-cost services.

3. Cost Estimation of Direct Labor and Benefits

Not all cost centers are fully devoted to only one service for which the IRS charges a user fee. Some cost centers work on a number of different services. In these cases, the IRS estimates the cost incurred in those cost centers attributable to the service for which a user fee is being calculated by measuring the time required to accomplish activities related to the service, and estimating the average time required to accomplish these activities. The average time required to accomplish these activities is multiplied by the relevant organizational unit's average labor and benefits cost per unit of time to determine the labor and benefits cost incurred to provide the service. To determine the full cost, the IRS then adds an appropriate overhead charge, as discussed in part G.4.

4. Calculating Overhead

Overhead is an indirect cost of operating an organization that cannot be immediately associated with an activity that the organization performs. Overhead includes costs of resources that are jointly or commonly consumed by one or more organizational unit's activities but are not specifically identifiable to a single activity.

These costs can include:

- General management and administrative services of sustaining and support organizations;
- Facilities management and ground maintenance services (security, rent, utilities, and building maintenance);
- Procurement and contracting services;
- Financial management and accounting services;
- Information technology services;
- Services to acquire and operate property, plants, and equipment;
- Publication, reproduction, and graphics and video services;
- Research, analytical, and statistical services;
- Human resources/personnel services; and
- Library and legal services.

To calculate the overhead allocable to a service, the IRS multiplies a corporate overhead rate (Corporate Overhead rate) by the direct labor and benefits costs determined as discussed above in part G.3. The Corporate Overhead rate is the ratio of the sum of the IRS's indirect labor and benefits costs from the supporting and sustaining organizational units—those that do not interact directly with taxpayers—and all non-labor costs to the IRS's labor and benefits costs of its organizational units that interact directly with taxpayers. The IRS calculates the Corporate Overhead rate annually based on cost elements underlying the Statement of Net Cost included in the IRS Annual Financial Statements, which are audited

by the Government Accountability Office.

The Corporate Overhead rate of 74 percent (rounded to the nearest hundredth) for costs reviewed during fiscal year (FY) 2018 was calculated based on (FY) 2017 costs, as follows:

Indirect Labor and Benefits Costs: $1,705,152,274
Non-Labor Costs: + $3,213,504,014
Total Indirect Costs: $4,918,656,288
Direct Labor and Benefits Costs: ÷ $6,640,044,003
Corporate Overhead Rate: 74.08%

H. Description and Tables Showing Full Cost Determination for Estate Tax Closing Letter

The IRS followed the guidance provided by the OMB Circular to compute the full cost of issuing estate tax closing letters to an authorized person. The OMB Circular explains that the full cost includes all indirect and direct costs to any part of the Federal Government including but not limited to direct and indirect personnel costs, physical overhead, rents, utilities, travel, and management costs.

1. Request Processing Costs

Requests for estate tax closing letters are processed by GS Grade 5 and Grade 8 customer service representatives. Grade 5 representatives perform 80 percent of the work and Grade 8 representatives perform the remaining 20 percent of the work. The customer service representative verifies that the request is authorized and that the address information is correct. Because a separate estate tax closing letter is prepared for each executor, responding to requests often requires more than one letter, with an average of three letters per request. It requires approximately 0.65 staff hours for a customer service representative to review the return, create the estate tax closing letters, and prepare the letters for mailing. The IRS received an average of 17,249 requests for estate tax closing letters in FY 2017 and FY 2018 requiring 11,154 staff hours.

Total hours allocated to the cost must also include indirect hours for campus employees. Indirect hours are calculated by multiplying the direct hours by the indirect rate for employees, which is 60 percent. Using this information, IRS determined the total staff hours to process requests for estate tax closing letters are 17,846 as follows:

Staff Hours: 11,154
Indirect Hours (60%): 6,692
Total Hours: 17,846

To determine the labor and benefits costs, IRS converted total hours to full time employees (FTE) by dividing the total hours by 2,080, which is the number of hours worked by a full time employee during the year, resulting in 8.58 FTE. IRS calculated the cost per FTE by adding 80 percent of the average salary and benefits for a GS 5 to 20 percent of the average salary and benefits for a GS 8 campus employee and determined the cost of labor and benefits related to this program is $ 578,831 (rounded to the nearest whole dollar), as follows:

GS–5 Salary and Benefits ($62,330 × 80%): $49,864
GS–8 Salary and Benefits ($87,993 × 20%): $17,599
Total Cost per FTE: $67,463
Total FTE: 8.58
Total Labor & Benefits for processing requests: $578,831

2. Quality Assurance Review Costs

Outgoing estate tax closing letters are subjected to quality review performed by GS 8 Grade quality assurance professionals. Specifically, five of every 100 estate tax closing letters mailed are reviewed for quality assurance. A quality assurance professional opens the return to (1) ensure the estate tax closing letter was authorized, (2) verify that the correct information was included in the letter, and (3) verify the address information. Quality assurance professionals then document their review. On average, quality assurance professionals spend .5 staff hours to review one estate tax closing letter. The estimated labor hours for quality assurance related to estate tax closing letters are 1,294, determined as follows:

Estimated Volume of Requests: 17,249
Average Number of Letters per Request: × 3
Total Letters Available for Review: 51,747
Estimated Letters Reviewed (5%): 2,587
Hours per Review: × 0.5
Estimated Quality Assurance Hours: 1,294
Indirect Hours (60%): 776
Total Quality Assurance Hours: 2,070
Total FTE: 1.00
Cost Per Grade 8: $87,993
Total Salary and Benefits for Quality Assurance: $87,563

3. Overhead Calculation

The IRS applied the Corporate Overhead rate to the labor and benefits costs to calculate the full cost for issuing an estate tax closing letter. The full cost of the program is $ 1,160,058, determined as follows:

Total Processing Labor & Benefits: $578,831
Total Quality Assurance Labor & Benefits: $87,563
Total Labor and Benefits: $666,394
Corporate Overhead (74.08%): + $493,664
Full Cost: $1,160,058

To calculate the cost per request, IRS divided $ 1,160,058 by the volume of 17,249 requests. The cost to issue an estate tax closing letter is $ 67 (rounded to the nearest whole dollar), determined as follows:

Full Cost: $1,160,058
Estimated Volume: ÷ 17,249
Cost Per Request: $67

Proposed Applicability Date

These regulations are proposed to apply to requests for an estate tax closing letter received by the IRS after the date that is 30 days after the date of publication in the **Federal Register** of a Treasury decision adopting these rules as final regulations.

Special Analyses

This regulation is not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations. Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. The proposed regulations, which prescribe a fee to obtain a particular service, affect decedents' estates, which generally are not ''small entities'' as defined under 5 U.S.C. 601(6). Thus, these regulations have no economic impact on small entities. In addition, the dollar amount of the fee ($67 as currently determined) is not substantial enough to have a significant economic impact on any entities that could be affected by establishing such a fee. Accordingly, the Secretary certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and IRS request

comments on all aspects of the proposed regulations. Any electronic comments submitted, and to the extent practicable any paper comments submitted, will be available at *http://www.regulations.gov* or upon request.

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments as prescribed in this preamble under the **DATES** heading. Requests for a public hearing are also encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**. Announcement 2020–4, 2020–17 I.R.B. 1, provides that until further notice, public hearings conducted by the IRS will be held telephonically. Any telephonic hearing will be made accessible to people with disabilities.

Drafting Information

The principal author of these regulations is Juli Ro Kim of the Office of Associate Chief Counsel (Passthroughs and Special Industries). Other personnel from the Treasury Department and the IRS participated in the development of the regulations.

Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings notices, and other guidance cited in this document are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

List of Subjects in 26 CFR Part 300

Estate taxes, Excise taxes, Gift taxes, Income taxes, Reporting and recordkeeping requirements, User fees.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 300 is proposed to be amended as follows:

PART 300—USER FEES

■ **Paragraph 1.** The authority citation for part 300 continues to read as follows:

Authority: 31 U.S.C. 9701.

■ **Par. 2.** Section 300.0 is amended by adding paragraph (b)(13) to read as follows:

§ 300.0 User fees; in general.

* * * * *

(b) * * *

(13) Requesting an estate tax closing letter.

■ **Par. 3.** Section 300.13 is added to read as follows:

§ 300.13 Fee for estate tax closing letter.

(a) *Applicability.* This section applies to the request by a person described in paragraph (c) of this section for an estate tax closing letter from the IRS.

(b) *Fee.* The fee for issuing an estate tax closing letter is $67.

(c) *Person liable for the fee.* The person liable for the fee is the estate of the decedent or other person properly authorized under section 6103 of the Internal Revenue Code to receive and therefore to request the estate tax closing letter with respect to the estate.

(d) *Applicability date.* This section applies to requests received by the IRS after [date that is 30 days after these regulations are published as final regulations in the **Federal Register**].

Douglas W. O'Donnell,

Acting Deputy Commissioner for Services and Enforcement.

[FR Doc. 2020–28931 Filed 12–29–20; 4:15 pm]

BILLING CODE 4830–01–P

SURFACE TRANSPORTATION BOARD

49 CFR Chapter X

[Docket No. EP 766]

Joint Petition For Rulemaking—Annual Revenue Adequacy Determinations

AGENCY: Surface Transportation Board.

ACTION: Petition for rulemaking.

SUMMARY: The Surface Transportation Board (Board or STB) opens a rulemaking proceeding to consider a petition by several Class I railroads to change the Board's procedures for annually determining whether Class I rail carriers are revenue adequate. The Board seeks public comment on the petition and several specific related issues.

DATES: Comments are due March 1, 2021; replies are due March 31, 2021.

ADDRESSES: Comments and replies may be filed with the Board via e-filing on the Board's website at *www.stb.gov* and will be posted to the Board's website.

FOR FURTHER INFORMATION CONTACT: Amy Ziehm at (202) 245–0391.

Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: On September 1, 2020, Union Pacific Railroad Company (UP), Norfolk Southern Railway Company, and the U.S. rail operating affiliates of Canadian National Railway Company (collectively, Joint Carriers) filed a joint petition for rulemaking to change the Board's procedures for determining which Class I rail carriers are earning adequate revenues under 49 U.S.C. 10704(a)(3).

The Board annually determines each Class I railroad's revenue adequacy in successive subdockets under Docket No. EP 552, most recently in *Railroad Revenue Adequacy—2019 Determination,* EP 552 (Sub-No. 24) (STB served Oct. 1, 2020).[1] Under the Board's procedures, ''a railroad is considered revenue adequate under 49 U.S.C. 10704(a) if it achieves a rate of return on net investment (ROI) equal to at least the current cost of capital for the railroad industry.'' *Id.* at 1.

The Joint Carriers propose two changes to the Board's procedures for annually determining revenue adequacy. First, the Joint Carriers propose that the Board determine whether a railroad is revenue adequate by comparing the extent by which its ROI exceeds the rail industry's cost of capital to the extent by which companies in the S&P 500 exceed their cost of capital—in short, to examine railroads in comparison with the larger universe of S&P 500 companies (the Comparison Proposal). (Pet. 3, 8.) The Joint Carriers contend that railroads compete against other firms for capital, and that the financial health of the railroad industry ''must be considered in relation to the competition railroads face in the capital markets from other, unregulated firms.'' (*Id.* at 3.) More specifically, the Joint Carriers argue that the Board should define annual revenue adequacy to mean that a railroad's ''Adjusted STB ROI''[2] exceeds the rail industry cost of capital by more than the median S&P 500 firm's ROI exceeds its cost of capital. (*Id.* at 20–21.) Under the Comparison Proposal, the Board would direct the Association of American Railroads to submit ''Adjusted STB ROI'' and cost of capital calculations for every S&P 500 company, and the Board ''would calculate the median difference between the Adjusted STB ROI and the cost of capital for all companies in the S&P 500, except for banking and real estate companies.''[3] (*Id.* at 21.) As part

[1] In that decision, the Board found five carriers (BNSF Railway Company, CSX Transportation, Inc. (CSXT), Norfolk Southern Combined Railroad Subsidiaries, Soo Line Corporation, and UP) revenue adequate in 2019. *R.R. Revenue Adequacy—2019 Determination,* EP 552 (Sub-No. 24), slip op. at 2.

[2] The petition also proposes certain modifications to the calculation of ROI, as discussed below. (*See also* Pet. 35–36.)

[3] The Joint Carriers state that banking and real estate companies were excluded from the comparison groups because they have different

of the Comparison Proposal, the Joint Carriers also propose including non-goodwill intangible assets in the railroads' and S&P 500 companies' asset bases. (*Id.* at 35.)

The second proposal from the Joint Carriers is that the Board change how it treats deferred taxes in the revenue adequacy determination (the Deferred Taxes Proposal). Rather than the Board's current ''utility method,'' which removes annual deferred taxes from net operating income and removes accumulated deferred taxes from a company's investment base, the Joint Carriers propose a flow-through approach, under which annual deferred taxes and accumulated deferred taxes would not be removed from net operating income and the investment base, respectively. (*Id.* at 38.) The Joint Carriers state that the practical effect would be ''an annual measurement that is on a cash basis, where the impact of any deferred taxes is captured by the measurement of financial health if and when those taxes come due.'' (*Id.* at 38–39.)

On September 21, 2020, the Board received three replies to the petition, one each from CSXT, the Western Coal Traffic League (WCTL), and a group of several shippers.[4] CSXT supports the petition, while WCTL and the Joint Shippers oppose it.

CSXT urges the Board to grant the petition because doing so ''would provide a more accurate picture of railroad financial performance.'' (CSXT Reply 2.) CSXT also urges the Board to consider the use of replacement costs when determining long-term revenue adequacy and argues that the Board should abandon the revenue adequacy constraint in determining whether individual rates are reasonable. (*Id.* at 3–8.)

WCTL argues that the petition misrepresents the role of revenue adequacy and is an attempt by the Joint Carriers to avoid being found revenue adequate and thus potentially subject to the revenue adequacy rate constraint. (WCTL Reply 4–5.) Regarding the Comparison Proposal, WCTL asserts that many S&P 500 firms have different capital structures than railroads and hundreds are not capital intensive. (*Id.* at 12.) WCTL also argues that the Comparison Proposal would result in revenue adequacy determinations at odds with the investment community's perception of railroads' financial health. (*Id.* at 13 (citing Joint Opening Comments of WCTL 11–12, Sept. 5, 2014, *R.R. Revenue Adequacy,* EP 722).) Regarding the Deferred Taxes Proposal, WCTL argues that the flow-through approach ignores tax deferrals and the fact that railroads pay taxes below the corporate rate. (*Id.* at 14–16.) WCTL also questions the relevance and accuracy of the Joint Carriers' examples of the utility and flow-through methods. (*Id.* at 17.)

The Joint Shippers argue that the Comparison Proposal would ''render all Class I railroads revenue-inadequate and likely maintain that status for decades to come.'' (Joint Shippers Reply 4.) They contend that the current annual revenue-adequacy determination already sets a conservatively high bar, (*id.* at 4–8), and assert that the Joint Carriers' rationales for the Comparison Proposal do not actually support the proposal, (*id.* at 11–12 (stating that the Joint Carriers' arguments ''assume a role for revenue adequacy as a measure of market power, competitive failure and monopoly profits that Congress never intended'')).

On October 13, 2020, the Joint Carriers filed a motion for leave to respond to the reply comments, along with a response addressing WCTL's and the Joint Shippers' arguments against both proposals.[5]

The Board will open a rulemaking proceeding to further consider the Joint Carriers' petition and the issues that it raises.[6] The Board invites comment on the issues raised in the petition generally as well as on the following specific questions:

General Considerations

1. With specificity, in what ways do each of the Joint Carriers' proposals advance or fail to advance each of the components of 49 U.S.C. 10704(a)(2)?[7]

2. Are there other ways in which the Board's current procedures could be modified to further advance the statutory goals of 10704(a)(2)?

The Comparison Proposal

1. As noted above, the Joint Carriers propose that Class I carriers be considered revenue adequate only if their ROI exceeds their cost of capital by more than the median S&P 500 firm's ROI exceed its cost of capital. Why is the median S&P 500 firm's differential an appropriate benchmark and not, for example, the 25th, 33rd, or 75th percentile? Does the Joint Carriers' proposal assume that below-median S&P 500 firms do not earn adequate revenues, and, if so, why is that assumption appropriate (or inappropriate)?

2. WCTL and the Joint Shippers criticize the proposal to use the S&P 500 as a comparison group. (*See* WCTL Reply 12; Joint Shippers Reply 9–10.) The Joint Carriers express openness to using a different comparison group and note that similar results are reached if railroads are compared to the S&P 500 Industrials sector group or a group of S&P 500 railroad customers. (*See* Joint Carriers Response 11–12.) Would any of these alternative comparison groups be an appropriate benchmark? Are there other comparison groups that might be appropriate? Is it appropriate to compare regulated entities like railroads with a group that includes a significant number of non-regulated entities, and—if not—is there a set of regulated companies that could be used as a comparison group?

3. A company is typically removed from the S&P 500 index if its market capitalization falls below a certain threshold. Does the changing constituency of the index pose a problem with respect to the Joint Carriers' proposed methodology?

The Deferred Taxes Proposal

In *Standards for Railroad Revenue Adequacy,* 3 I.C.C.2d 261 (1986), the Board's predecessor, the Interstate Commerce Commission (ICC), based its decision to adopt the utility method on several grounds, including analogizing

capital structures than other firms; railroads were also excluded. (Pet. 35.)

[4] The shippers are: The American Chemistry Council, Corn Refiners Association, American Fuel & Petrochemical Manufacturers, The National Industrial Transportation League, The Chlorine Institute, and The Fertilizer Institute (collectively, Joint Shippers).

[5] Under 49 CFR 1104.13(c), a reply to a reply is not permitted. However, in the interest of a more complete record, the Board will grant the Joint Carriers' motion and accept their reply into the record. *See City of Alexandria—Pet. for Declaratory Order,* FD 35157, slip op. at 2 (STB served Nov. 6, 2008) (allowing a reply to a reply ''[i]n the interest of compiling a full record'').

[6] The Board has also received testimony and comments in two informational dockets related to revenue adequacy. *See Hearing on Revenue Adequacy,* Docket No. EP 761; *R.R. Revenue Adequacy,* Docket No. EP 722.

[7] Under 49 U.S.C. 10704(a)(2), the Board shall maintain and revise as necessary standards and procedures for establishing revenue levels for rail carriers providing transportation subject to its jurisdiction under this part that are adequate, under honest, economical, and efficient management, for the infrastructure and investment needed to meet the present and future demand for rail services and to cover total operating expenses, including depreciation and obsolescence, plus a reasonable and economic profit or return (or both) on capital employed in the business. The Board shall make an adequate and continuing effort to assist those carriers in attaining revenue levels prescribed under this paragraph. Revenue levels established under this paragraph should: Provide a flow of net income plus depreciation adequate to support prudent capital outlays, assure the repayment of a reasonable level of debt, permit the raising of needed equity capital, and cover the effects of inflation; and attract and retain capital in amounts adequate to provide a sound transportation system in the United States.

captive rail shippers to utility customers, favoring an approach that conforms to Generally Accepted Accounting Principles (GAAP), and determining that removing the effect of deferred taxes led to a more accurate representation of railroad profitability. *See id.* at 272–75; *Consol. Rail Corp.* v. *United States,* 855 F.2d 78, 93 (3rd Cir. 1988) (affirming the ICC's decision and finding that the ''adjustment of its formula in the interests of accuracy is rational''). Does the ICC's reasoning for adopting the utility method remain valid, specifically with respect to analogizing captive shippers to utility customers, determining whether the utility method continues to conform with GAAP today, and finding that the utility method led to a more accurate representation of railroad profitability?

Additionally, the Joint Carriers will be requested to file workpapers sufficient to replicate the analysis underlying their proposals and to make those workpapers available, upon request, to other participants in this proceeding, under an appropriate protective order.

Interested persons may file comments by March 1, 2021. If any comments are filed, replies will be due by March 31, 2021.

It is ordered:

1. A rulemaking proceeding is initiated, as discussed above.

2. Comments are due March 1, 2021; replies are due March 31, 2021.

3. The Joint Carriers are requested to file workpapers sufficient to replicate the analysis underlying their proposals and to make those workpapers available, upon request, to other participants in this proceeding, under an appropriate protective order.

4. Notice of this decision will be published in the **Federal Register**.

5. This decision is effective on its service date.

Decided Date: December 22, 2020.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Andrea Pope-Matheson,

Clearance Clerk.

[FR Doc. 2020–28864 Filed 12–30–20; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 229 and 697

[Docket No. 201221–0351]

RIN 0648–BJ09

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Atlantic Large Whale Take Reduction Plan Regulations; Atlantic Coastal Fisheries Cooperative Management Act Provisions; American Lobster Fishery

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to amend the regulations implementing the Atlantic Large Whale Take Reduction Plan to reduce the incidental mortality and serious injury to North Atlantic right whales (*Eubalaena glacialis*), fin whales (*Balaenoptera physalus*), and humpback whales (*Megaptera novaeangliae*) in northeast commercial lobster and crab trap/pot fisheries to meet the goals of the Marine Mammal Protection Act and the Endangered Species Act. In addition, this action also proposes a small revision to Federal regulations implemented under the Atlantic State Marine Fisheries Commissions' Interstate Fishery Management Plan for Lobster to increase the maximum length of a lobster trap trawl groundline. This action is necessary to reduce the risks to North Atlantic right whales and other large whales associated with the presence of fishing gear in waters used by these animals.

DATES: Submit comments on or before March 1, 2021.

Public Hearings: Eight or more remote public meetings will be held during the public comment period. See **ADDRESSES** to obtain public hearing notification details.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2020–0031, by either of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0031,* click the ''Comment Now!'' icon and complete the required fields, and enter or attach your comments.

Instructions: All comments received that are timely and properly submitted are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. We will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). 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 us.

Oral Comments: Remote public meeting access information will be posted on the Plan website *fisheries.noaa.gov/ALWTRP* or contact Colleen Coogan for information on locations and dates. Contact information below.

Copies of this action, including the Draft Environmental Impact Statement (DEIS) and the Regulatory Impact Review/Initial Regulatory Flexibility Analysis (DEIS/RIR/IRFA) prepared in support of this action, are available via the internet at *https://www.regulations.gov/* or by contacting Colleen Coogan at the contact information below.

Several of the background documents for the Plan and the take reduction planning process can be downloaded from the Plan website. Copies of the DEIS/RIR/IRFA for this action can also be obtained from the Plan website. Information on the Decision Support Tool and Co-Occurrence model used to support the development and analysis of the proposed regulations can be found in appendices to the DEIS. The complete text of current regulations implementing the Plan can be found in 50 CFR 229.32 or downloaded from the Plan's website, along with outreach compliance guides to current regulations. The complete text of current regulations implementing the Lobster Plan can be found at 50 CFR part 697.

FOR FURTHER INFORMATION CONTACT: Colleen Coogan, NMFS, Greater Atlantic Regional Fisheries Office, 978–281–9181, *Colleen.Coogan@noaa.gov.*

SUPPLEMENTARY INFORMATION:

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Background

The Atlantic Large Whale Take Reduction Plan (ALWTRP, or Plan) was originally developed pursuant to section 118 of the Marine Mammal Protection Act (MMPA, 16 U.S.C. 1387 to reduce the level of mortality and serious injury of three stocks of large whales (fin, humpback, and North Atlantic right) interacting with Category I and II fisheries. Under the MMPA a strategic stock of marine mammals is defined as a stock: (1) For which the level of direct human-caused mortality exceeds the Potential Biological Removal (PBR) level; (2) which, based on the best available scientific information, is declining and is likely to be listed as a threatened species under the Endangered Species Act of 1973 (ESA) within the foreseeable future; or (3) which is listed as a threatened or endangered species under the ESA or is designated as depleted under the MMPA (16 U.S.C. 1362(19)). When incidental mortality or serious injury of marine mammals from commercial fishing is over the PBR level, NMFS convenes a take reduction team made up of stakeholders from the fishing industry, fishery management councils and commissions, state and Federal resource management agencies, the scientific community and conservation organizations.

The Atlantic Large Whale Take Reduction Team (ALWTRT or Team) was established in 1996 and is made up of 60 members, including about 22 trap/pot and gillnet fishermen or fishery representatives. Because both right whales and fin whales are listed as endangered, they are considered strategic stocks under the MMPA. Due to population growth, in 2016 certain stocks of humpback whales, which are taken in the Atlantic Category I and II fisheries regulated under the ALWTRP, are no longer listed as endangered or threatened under the Endangered Species Act (81 FR 62259). However, although they are not currently a strategic stock, they continue to be included in the Plan because they are taken in Category I fisheries and will continue to benefit from Plan requirements and proposed revisions.

Specific Category I and II fisheries addressed by the Plan include the Northeast sink gillnet, Northeast drift gillnet, Northeast anchored float gillnet, Southeast Atlantic gillnet, Mid-Atlantic gillnet, Southeastern U.S. Atlantic shark gillnet, Atlantic mixed species trap/pot, Atlantic blue crab trap/pot, and Northeast/Mid-Atlantic American lobster trap/pot. Proposed modifications for this rulemaking are limited in scope to the crab and trap/pot fisheries in the Northeast Region Trap/Pot Management Area (Northeast Region). The Northeast Region encompasses those waters where year-round trap/pot measures are required as described in 50 CFR 229.32. This area includes the Northern Inshore State Trap/Pot Waters, the Northern Nearshore Trap/Pot Waters Areas, the Massachusetts Restricted Area, the Great South Channel Restricted Trap/Pot Area, the Jordan Basin, Jeffreys Ledge, and Stellwagen Bank Restricted Areas and the northeast Offshore Trap/Pot Waters Area that are within the area bounded on the west by a straight line running south from the coast at 41°18.2′ N latitude, 71°51.5′ W longitude to 40°00′ N latitude, and then bounded on the south by a line running east along 40°00′ N latitude to the eastern edge of the Exclusive Economic Zone (EEZ) (Figure 1).

The background for the take reduction planning process and initial development of the Plan is provided in the preambles to the proposed (62 FR 16519, April 7, 1997), interim final (62 FR 39157, July 22, 1997), and final (64 FR 7529, February 16, 1999) rules that implemented the original plan.

Since its 1997 implementation, the Plan has been modified several times to reduce the risk of mortality and serious injury of large whales incidentally taken in commercial sink gillnet and trap/pot gear. The most recent final rule was published in May 2015 (80 FR 30367, May 28, 2015). Because of the declining population and the persistent incidental entanglement mortalities and serious injuries above the stock's PBR, Plan modifications have, and continue to be, directed primarily at reducing the risk of commercial fisheries on the North Atlantic right whale.

Right Whale Population Decline

In a peer-reviewed scientific paper published in 2017, Pace *et al.* (see References section at end of this preamble), confirmed that due to decreased calving rates and increased mortality, much of it unseen, the North Atlantic right whale population had been in decline since 2010 (Pace *et al.* 2017). Seventeen right whale mortalities were documented in 2017, causing NMFS to declare an Unusual Mortality Event, which continues through 2020. Although most right whale mortalities in 2017 occurred in Canadian waters and not all were confirmed to be entanglement related, three mortalities first seen in U.S. waters exhibited signs of entanglement. The evidence of a declining population exacerbated by high mortalities caused NMFS to convene subgroups of the ALWTRT in early 2018 to investigate the feasibility of risk reduction measures. A meeting of the full Team was held in October 2018 to develop recommendations for modifying the Take Reduction Plan.

As described in detail in Chapter 3 of the DEIS prepared in support of this action and very briefly below, the location and exact fishery in which each entanglement incident occurs can rarely be determined. However, over 95 percent of vertical buoy lines fished along the U.S. East Coast in waters not currently exempt from Plan requirements are fished by the lobster and Jonah crab trap/pot fishery—93 percent within the Northeast Region. For this reason and given the magnitude of the issue, NMFS is addressing this issue in phases to expedite rulemaking. The initial phase focused the scope of the Team meetings on developing recommendations for the Northeast Region lobster and Jonah crab trap/pot fisheries. In 2021, the ALWTRT will be asked to recommend modifications to the Take Reduction Plan to address risk in the remaining fixed gear fisheries that use buoy lines, including other trap/pot fisheries and gillnet fisheries coastwide. Table 2.3 in the DEIS provides additional information supporting prioritizing the lobster and Jonah crab trap/pot fisheries in the Northeast Region first.

Team members submitted risk reduction proposals for the October 2018 in-person ALWTRT meeting. The lack of agreement on whether or how much risk reduction was necessary, or metrics to compare the wide range of proposal elements, challenged the Team's ability to develop recommendations. In anticipation of a spring 2019 meeting, the Team created workplans for NMFS identifying data needs to support decision making on Plan modification recommendations.

While the MMPA establishes PBR as a goal for take reduction, the Team identified the need for a risk reduction target that better described what their recommendations should achieve. NMFS estimated that to reduce serious injury and mortality below PBR, entanglement risk across U.S. fisheries needs to be reduced by 60 to 80 percent. There is much uncertainty regarding the source of entanglement mortality to the North Atlantic right whale population. There is no gear present or retrieved from most documented incidents of dead or seriously injured right whales. When gear is retrieved, it can rarely be identified to a fishery or to a location.

For the years 2009 through 2018, an average of five entanglement-related serious injuries and mortalities a year were observed. Only 0.2 a year could be attributed with certainty to U.S. fisheries and only 0.7 a year to Canadian fisheries. An annual average of four documented incidental entanglement mortalities and serious injuries could not be attributed to a country.

NMFS' has produced *Guidelines for Assessing Marine Mammal Stocks* to address how to consider PBR for transboundary stocks if certain information is available. Those Guidelines specify that in transboundary situations where a stock's range spans international boundaries or the boundary of the U.S. Exclusive Economic Zone (EEZ), the best approach is to establish an international management agreement for the species and to evaluate all sources of human-caused mortality and serious injury (U.S. and non-U.S.) relative to the PBR for the entire stock range. In the interim, if a transboundary stock is migratory and it is reasonable to do so, the fraction of time the stock spends in U.S. waters should be noted, and the PBR for U.S. fisheries should be apportioned from the total PBR based on this fraction. For non-migratory transboundary stocks (*e.g.,* stocks with broad pelagic distributions that extend into international waters), if there are estimates of mortality and serious injury from U.S. and other sources throughout the stock's range, then PBR calculations should be based upon a range-wide abundance estimate for the stock whenever possible.

Therefore, if a stock spends half its time in U.S. waters, PBR would be divided by two, resulting in a U.S. PBR for right whales of 0.5. Thus, the U.S. fishery related mortality would need to be reduced to below 0.5 (instead of 0.9 as is currently the goal). The Atlantic Scientific Review Group (established under MMPA sec. 117) that advises NMFS on Stock Assessment Reports, including PBR calculations, does not support this approach yet because we do not have sufficient information to apportion time spent in U.S. versus Canadian waters. Therefore, the U.S. target goal remains 0.9; however, NMFS did consider the relative threat including the time right whales spend in U.S. and Canadian waters when apportioning the unattributed entanglement incidents to create the risk reduction target, as described below.

For the purposes of creating a risk reduction target, NMFS assigned half of these right whale entanglement incidents of unknown origin to U.S. fisheries. Under this assumption, a 60 percent reduction in serious injury or mortality would be needed to reduce right whale serious injury and mortality in U.S. commercial fisheries, from an annual average of 2.2 to a PBR of 0.9 per year.

The upper bound of the risk reduction target (80 percent) considered estimated but unseen right whale mortalities, generated by a new population model (described in Hayes *et al.* 2019). Because all observed mortalities that can be attributed to a source have been caused by either entanglements or vessel strikes (except for some natural neonate mortalities), estimated non-observed mortalities are likely caused primarily by entanglements and vessels strikes. However, there is no way to definitively apportion unseen but estimated mortality across causes or country of origin (United States or Canada). For the purposes of developing a conservative target, NMFS assumed that half of the unseen mortalities occurred in U.S. waters and were caused primarily by incidental entanglements.

However, given the additional sources of uncertainty in the 80 percent target, as well as the challenges achieving such a target without large economic impacts to the fishery, the Take Reduction Team focused on recommendations to achieve the lower 60 percent target.

Additionally, to support the April 2019 Team meeting, the NMFS Northeast Fisheries Science Center created a preliminary decision support tool (DST): A model for analyzing and comparing how various proposal elements contributed toward the target risk reduction.

Both the target risk reduction and the DST generated a common understanding of the scope of measures that NMFS determined were necessary to reduce mortality and serious injury to below the PBR level for right whales. After some discussion, there was general agreement that risk reduction should be shared across jurisdictions so that no one state or fishing area would bear the bulk of the restrictions. This encouraged adoption of measures across the Northeast Region that would be resilient to changes in North Atlantic right whale distribution within the region. All but one Team member agreed that NMFS should move forward on a framework of recommended modifications to achieve 60 percent risk reduction. The dissenting Team member did not believe that the recommended modifications were sufficient to achieve PBR. The Team's recommendations was essentially a framework, largely dependent on extensive buoy line reduction goals and expansive requirements to use weak rope or weak insertions with breaking strengths of 1,700 lbs. (771 kgs.) or less that would allow large whales to break free of gear before a serious injury or mortality can occur (Knowlton *et al.* 2016).

In acknowledgement of the regional diversity of the fisheries, New England states sought and were given the lead in developing measures and implementation details related to the Team's near-consensus recommendation. Maine, New Hampshire, Massachusetts, and Rhode Island conducted public meetings before and after drafting measures. NMFS also worked closely with the Team members that represent the Atlantic Offshore Lobster Association on measures for the northeast Offshore Trap/Pot Waters Area, widely referred to as Lobster Management Area (LMA) 3. NMFS conducted its own scoping in August 2019 (84 FR 37822, August 2, 2019), receiving over 130 unique written comments as well as over 89,000 form emails generated by about a dozen campaigns. Oral comments were also collected during eight public meetings attended by over 800 stakeholders. The measures proposed in this rule are drawn largely from proposals received from New England states. Those proposals can be found in Appendix 3.2 of the DEIS. As described in the DEIS associated with this action, some Plan modifications in state waters will be implemented by Maine and Massachusetts under state laws and so are not included in the proposed Federal measures. Additionally, some measures proposed by the states for this rulemaking were not adopted in the regulations proposed here because they were inconsistent between adjacent states. Public comments received during scoping were considered throughout the development of the DEIS and proposed rule (Appendix 3.3 of the DEIS).

It should be noted that a draft population estimate developed by the North Atlantic Right Whale Consortium for their October 2020 meeting indicates that the right whale population has declined further, to about 366 right whales as of January 2019. Further peer review of this preliminary estimate is anticipated during Scientific Review Group meetings in early 2021 in preparation for an updated stock assessment. The updated stock assessment information along with other updates and analyses will be considered in drafting the final rule and environmental impact statement.

Summary of Proposed Changes

NMFS proposes changes for lobster and crab trap/pot gear in the Northeast

Region. The proposed measures detailed below seek to reduce large whale entanglement largely through risk reduction measures consistent with the April 2019 Team recommendations, which can be found in Table 3.1 in the DEIS. The proposed changes fall into four primary categories: (1) Gear modifications to reduce the number of vertical lines; (2) seasonal restricted areas that allow ropeless fishing but would be seasonally closed to fishing with persistent buoy lines; (3) gear modifications to include replacement of buoy lines with weak rope or weak insertions placed in intervals in buoy lines; and (4) additional gear marking and expansion of gear marking requirements throughout the Northeast Region.

Gear configuration changes to reduce line numbers include increases to the minimum number of traps per trawl (trawling up) in varying degrees related to distance from shore and area fished. In LMA 3, an extension of the maximum trawl length (distance between endlines) is also proposed to accommodate the increase in traps per trawl proposed for that area. Modified gear configuration to require weak rope in buoy lines or weak insertion at prescribed intervals in buoy lines are proposed across the Northeast Region crab/lobster fisheries. An alternative to allow fishermen the option of moving the weak link at the buoy connection to the surface system connect below the buoy is also proposed.

We are co-proposing three alternatives, as described in more detail below, for consideration concerning seasonal restricted areas. Under the first alternative, analyzed in the DEIS, we propose two new seasonal restricted areas that would be open to harvest of lobster and Jonah crab using ropeless fishing technology that does not require the use of persistent buoy lines, as well as changes to existing Northeast Region seasonal restricted areas to allow fishing in those areas with ropeless technology. Northeast state-specific gear marking modifications are also proposed. Under the second alternative, there would be only one new seasonal restricted area south of Cape Cod and Nantucket Island. Under the third alternative, NMFS is co-proposing provisions under which the imposition of seasonal restrictions on fishing in an area proposed for seasonal restrictions in LMA1 offshore of Maine would be triggered only if certain determinations are made in the future. We are soliciting comment on the relative merits of the three co-proposed approaches, including comment concerning the factual justifications for each approach, the legal adequacy of each approach, and the impacts of each approach on fishermen and other affected stakeholders.

In addition to the proposed Federal regulatory measures reflected in the proposed rule, modifications to the Plan to achieve at least a 60 percent risk reduction includes some risk reduction measures that will be implemented by the states of Maine and Massachusetts in exempted or state waters. Specifically, in waters currently exempted from regulations under the ALWTRP, the Maine Department of Marine Resources (MEDMR) will require the use of a weak insertion that breaks at 1,700 lbs. (771 kgs.) or less halfway down the buoy line. Maine has already implemented gear marking requirements consistent with gear marking modifications proposed here. The gear marking changes in Maine become effective September 1, 2020 for all Maine lobster fishermen, including those in Maine exempted waters. The Massachusetts Department of Marine Fisheries (MADMF) will continue their recent practice of extending the state waters closure of the Massachusetts Restricted Area into May until surveys demonstrate right whales have left the area. The DEIS includes an analysis of the risk reduction of the Maine weak insertions and the Massachusetts closure of the state waters of the Massachusetts Restricted Area because they contribute to the required risk reduction. The economic impacts of state measures are not included in the economic analysis of the Federal rulemaking, however. Massachusetts will also restrict buoy line diameters to no greater than ⅜ inch (0.95 cm) within state waters to restrain the introduction of larger diameter line into the fishery. Even ⅜ inch (0.95 cm) diameter rope can break at strengths much greater than 1,700 lbs; therefore, while this measure may contribute to future risk reduction by constraining line diameter, that cannot be assumed, and it is difficult to estimate a quantitative risk reduction.

As described fully in Chapter 3 of the DEIS, there are three categories of measures that contribute toward the target 60 percent risk reduction relative to the 2017 baseline:

- The proposed measures in this rulemaking
- the risk reduction measures that will be implemented by Massachusetts and Maine, and
- the lobster fishery management measures in LMA2 and LMA3 that have been implemented or are on a parallel regulatory track with ALWTRP modifications

The measures in this proposed rule were selected because they include those developed by Maine, Massachusetts, and to a lesser extent Rhode Island after extensive stakeholder outreach, supplemented by additional proposed measures and estimated by the DST to, together with the state and existing and anticipated Federal fishery management measures, achieve the 60-percent risk reduction target. Additional analyses using a co-occurrence model developed by IEC Inc. for NMFS demonstrated that proposed plan modifications should reduce the co-occurrence of North Atlantic right whales with lobster and crab buoy lines in the Northeast Region by about 69 percent.

Estimating the risk reduction of the weak insertion measures is more difficult. Nearly all Northeast lobster and crab trap/pot buoy lines would be modified with weak insertion. However, following the state proposals, the proposed rule would not require the insertions at intervals of every 40 feet (12.2 m), which was discussed by the Team as the interval needed to ensure it is equivalent to weak rope. The depth of the lowest weak insertion is also significant, as a whale that encounters a line above the lowest weak insertion can break away from the trawl, reducing the burden of gear on the whale. The risk reduction analysis takes an average of a lower bound of risk reduction estimate that compares the number of insertions to the number that would be required to be equivalent to weak rope and an upper bound estimate that considers the amount of rope above the lowest weak insertion to be weak. By this estimate, the proposed weak rope measures would modify nearly 26 percent of the rope in buoy lines to break at 1,700 lbs. (771 kgs.) or less.

The economic analysis does not estimate the number of vessels affected under the Maine measures within Maine exempted waters. Beyond the Maine exemption area, 3,970 vessels would be impacted, with first year compliance costs estimated at $6.9 million to $15.4 million (DEIS Table 6.22). Over the first six years (selected as the average span of time between amendments and consistent with buoy line replacement timing), there will continue to be costs associated with catch losses due to trawl up and closure requirements. The average annual cost in those out years is estimated to be $5.7 million to $12.3 million at a three percent discount rate. If Maine and Massachusetts do not implement the state measures identified in their proposals, and upcoming LMA3 aggregated trap measures are not finalized, further modifications to the

Plan would be required to achieve at least the 60 percent target risk reduction in the Northeast Region lobster and Jonah crab trap/pot fisheries to reduce mortality and serious injury to below PBR for North Atlantic right whales. Compliance costs would increase if states did not take these actions and NMFS were to include in Federal regulation the Maine exemption area measures and the extension of the Massachusetts Restricted Area in state waters. As noted above, we are co-proposing three alternatives for consideration concerning seasonal restricted areas. As the first alternative, NMFS proposes two new seasonal restricted areas that would restrict buoy lines but would be open to ropeless fishing; that is, harvesting lobster and Jonah crabs would be allowed using trap/pot trawls that would be retrieved without the use of persistent buoy lines. The purpose of these restricted areas would be to achieve risk reduction and reduce mortalities and serious injuries to below PBR for right whales when combined with the other proposed measures described in this rulemaking. The addition of restricted areas open to ropeless fishing was not included in the ALWTRT framework recommendations, but a seasonal closure south of Cape Cod and Nantucket was proposed by the Commonwealth of Massachusetts to increase risk reduction in southern New England. A restricted area open to ropeless fishing in LMA1 was not included in any state proposal but is proposed here at § 229.32(c)(6)(ii) to achieve sufficient risk reduction in the northern Gulf of Maine.

While NMFS has included both seasonal restricted areas in the proposed regulatory text below, and analyzed them in the DEIS, NMFS has not yet made a final determination as to whether the LMA1 closure is necessary to meet the goal of a 60 percent risk reduction. Accordingly, NMFS is co-proposing two additional alternative options regarding this issue, and is seeking public comment as set forth below:

Alternative 1–A (second co-proposed alternative): Not Including the LMA1 Seasonal Restricted Area.

NMFS is seeking comment on the option to not include the LMA1 seasonal restricted area in the final rule. Commenters that believe this additional restricted area is not warranted to achieve PBR are encouraged to provide specific information or analysis in support of not including the restricted area in the final rule. If NOAA receives information indicating that we can achieve the 60 percent risk reduction without the restricted area, we would consider not including the restricted area in the final rule. Additionally, if commenters believe that information will be available after issuance of the final rule on this topic, commenters should articulate the nature of that information, describe how the information might affect the decision, and propose a mechanism for evaluating that information in determining whether or not to continue with the restricted area.

Alternative 1–B (third co-proposed alternative): Implementing the LMA1 Seasonal Restricted Areas Only If Certain Triggers are Met.

NMFS is seeking comment on a proposal to provide that the Regional Administrator may implement the LMA1 closure only if certain triggers are met in the future. This option would require the Regional Administrator to examine the available information in advance of October in any given year and determine whether the closure is necessary. Specifically, the Regional Administrator would implement the closure if he or she determines that the frequency of entanglements has not been reduced below 60 percent from the effective date of the final rule. NMFS is considering the following specific language to implement this provision and is interested in any comments on this textual change (see § 229.32(c)(6)(ii) Alternative 1–B).

The Regional Administrator may determine whether the frequency of entanglements from the trap/pot gear in the Northeast region has been reduced by 60 percent from [the effective date of this rule] within a time period that allows meaningful analysis. If the Regional Administrator determines that the frequency of such entanglements has not been reduced by 60 percent, then from October 1 to January 31, it shall be prohibited to fish with, set, or possess trap/pot gear in this area unless it is fished without buoy lines or with buoy lines that are stored on the bottom until they can be remotely released for hauling, or the trap/pot gear is stowed in accordance with § 229.2. Authorizations for fishing without buoy lines must be obtained if such fishing would not be in accordance with surface marking requirements of §§ 697.21 and 648.84.

As relevant to the first and third co-proposed alternatives, the proposed rule would also modify two existing restricted areas to allow fishing without buoy lines. This modification was also not in the Team recommendations or state proposals, but is proposed here to accelerate research and development of ropeless (buoyless) fishing methods so that in the future, commercial fishing using ropeless technology can be used instead of seasonal closures to allow trap pot fishing while protecting right whales. NOAA has invested a substantial amount of funding in the industry's development of ropeless gear, in specific geographic areas and in general. We anticipate that these efforts to facilitate and support the industry's development of ropeless gear will continue, pending appropriations.

Finally, a number of housekeeping edits were made in the existing regulatory text. The initiation point was added as the final endpoint to the table describing the Great South Channel Area (see table 11 at 50 CFR 229.32(c)(5)(i) in amended text) to fully enclose the restricted area. In a number of places, revisions were made describing the availability of guidance created to aid in compliance with gear configuration and marking measures. In a number of places, state abbreviations were replaced with the complete state names.

See **ADDRESSES** for information on access to the DEIS for a detailed analysis of the impacts of the proposed measures and other measures considered.

Changes Proposed To Reduce the Number of Vertical Buoy Lines

The proposed rule would reduce the number of vertical buoy lines fished outside of areas exempted under the Plan by increasing the minimum number of traps required per trawl (known as trawling-up), based on area fished and distance from shore as indicated in Table 1. Concerns have been raised that the trawling-up requirement of 45 traps per trawl in LMA3 may present a safety concern to a handful of LMA3 vessels that have insufficient deck space or rope storage capacity. NMFS requests LMA3 fishery participants and other reviewers' comments on the feasibility of permit-specific conditions that would result in an average of 45 traps per trawl in LMA3, to achieve the same buoy line reduction.

The trawling-up measures included in this proposed rule were proposed by the states or by LMA3 ALWTRT fishing industry participants. Outside of waters exempted from trawling up requirements under the ALWTRP, an estimated 19 percent reduction in buoy line numbers would be achieved by the proposed trawling-up measures described on Table 1. Note that MEDMR proposed an option for lobstermen to use fewer traps per trawl using one buoy line in a manner resulting in the same line proportion of buoy lines to pots (four traps on a single buoy between three and six miles, eight trap per single

buoy between 6 and 12 miles). NMFS is not proposing this at this time because past gear modifications allowing more than three pots per buoy were rescinded due to comments that those gear configurations resulted in gear conflicts and safety concerns. Outside of three miles, this option would also require modifications to regulations on lobster gear configuration found at 50 CFR 697.21(b)(2) requiring trawls of more than three traps to mark both ends of the trawl with buoys and radar reflectors. Although not proposed here, comments on this option are requested. Additionally, the proposed rule would require 45 traps per trawl in the Northeast LMA3 management area. This trawl configuration may pose logistic and safety concerns for a few smaller vessels permitted to fish in LMA3. Offshore lobster fishermen have suggested that they would consider individual permit conditions requiring some vessels to fish more traps/trawl to ensure that the average traps/trawl fished in the area, and therefore, the buoy line numbers will be the same as that analyzed for the proposed rule. Reviewers are asked to provide comments on whether equivalencies implemented through fishing permit conditions should be considered.

TABLE 1—PROPOSED REGULATORY CRAB/LOBSTER NORTHEAST REGION BUOY LINE REDUCTION MODIFICATIONS TO THE ATLANTIC LARGE WHALE TAKE REDUCTION PLAN

Component	Area	Distance from shore if applicable	Proposed measure
Modify minimum traps per trawl requirements.	Maine state waters	Maine Exemption line to 3 nmi (5.56 km).	3 traps/trawl.
	Offshore Maine	3 nmi (5.56 km) to the 6 mi line	8 traps/trawl.
	All LMA1	6 mi line to 12 nmi (22.22 km)	15 traps/trawl.
	LMA2 and Outer Cape Cod	3–12 nmi (5.56–22.22 km)	15 traps/trawl.
	LMA1 and LMA2	>12 nmi (22.22 km)	25 traps/trawl.
	Northeast LMA3		45 traps/trawl.
Increase maximum trawl length to accommodate traps/trawl.	Northeast LMA3		Extend maximum trawl length to 1.75 nm (3.24 km).

Note: See 50 CFR 229.32 for delineations of regulated waters and associated terms, such as exempted waters. The ''6-mile line'' refers to an approximation, described in 50 CFR 229.32(a)(2)(ii).

Changes to Restricted Areas

The proposed measures, summarized in Table 2, would modify current Northeast Region restricted areas to allow commercial trap/pot fisheries to harvest lobster and crabs if they fish with ropeless gear, without persistent buoy lines. The proposed modifications would affect two existing seasonal restricted areas currently closed to fishing: the Massachusetts Restricted Area (50 CFR 229.32(c)(3)) and the Great South Channel Restricted Trap/Pot Area (50 CFR 229.32(c)(4)). However, no changes are proposed to the surface system requirements (buoys and radar reflectors required at either end of lobster trawls or bottom tending fixed gear) under the Atlantic Coastal Fisheries Cooperative Management Act (ACFCMA), 16 U.S.C. 5101 *et seq. See* 50 CFR 697.21. Therefore, fishermen harvesting lobster in these areas would need to get authorization from the appropriate state or Federal agency to be exempted from these surface marking requirements.

This measure is not expected to introduce substantial fishing effort into the currently restricted areas, and any exempted fishing authorization would require methods, monitoring, and reporting that minimize the possibility of impacts on large whales. The purpose of this measure is to encourage fishermen to participate in the development of ropeless fishing, to improve operational feasibility and accelerate the timeline for adoption within commercial fishery operations. NMFS continues to prioritize ropeless fishing development and has initiated a pilot program to support ropeless experimentation and develop other innovative fishing gear technologies to reduce North Atlantic right whale entanglements in U.S. commercial fisheries as supported by fiscal year 2020 appropriations described in Senate Report 116–127. We anticipate that these efforts to facilitate and support the industry's development of ropeless gear will continue, pending appropriation. Reviewers are asked to comment on this proposed measure.

Two new seasonal restricted areas that would allow harvest of lobster and Jonah crab using bottom trap/pot trawl gear but without the use of persistent buoy lines are also proposed and summarized in Table 2 and illustrated in Figure 1: (1) Offshore of Maine along the LMA1 and LMA3 border and (2) south of Cape Cod and Nantucket. The first proposed new seasonal lobster and crab trap/pot buoy line restricted area from October through January about 30 miles (48 km) offshore of Maine along the LMA1 and LMA3 border was discussed with MEDMR but was not included in their proposal to NMFS. This buoy line restricted area is proposed at 229.32(c)(6)(ii) to ensure that the risk reduction measures in LMA1 approach the regional target risk reduction of 60 percent. The amount of risk reduction relative to the economic impact of the restricted area may vary in unpredictable ways during the restricted season. NMFS seeks comment as to whether restricted areas during certain months may have a disproportionately higher amount of economic impact. NMFS also seeks comment as to whether the proposed closure is necessary to achieve a sufficient level of risk reduction across the region or whether the buoy line closures should be excluded from the final rule. Additionally, as noted above and analyzed in the DEIS, while NMFS has included both proposed seasonal restricted areas in the proposed regulatory text below, NMFS has not yet made a final determination as to whether the LMA1 closure is necessary to meet the goal of a 60 percent risk reduction. As such, NMFS is also considering two alternative options regarding this requirement, and is seeking public comment on these two options as well as the proposed restricted area as set forth below:

Alternative Option 1–A. Invite Comment on not including the LMA1 Seasonal Restricted Area.

As an alternative to the proposed seasonal restricted areas, NMFS is also seeking comment on the option to not include the LMA1 seasonal restricted area. Commenters that believe this additional restricted area is not warranted to achieve PBR are encouraged to provide specific information or analysis in support of recommended removal of the restricted area from the proposed rule. If NOAA

receives information indicating that we can achieve the 60 percent risk reduction without the restricted area, we would consider not including the restricted area in the final rule. Additionally, if commenters believe that information will be available after issuance of the final rule on this topic, commenters should articulate the nature of that information, how the information might affect the decision, and propose a mechanism for evaluating that information in determining whether or not to continue with the restricted area.

Alternative Option 1–B: Invite Comment on not including the LMA1 Seasonal Restricted Areas Unless Certain Triggers are Met.

As an alternative to the proposed seasonal restricted areas, NMFS is also seeking comment on the option to modify the regulatory structure such that the Regional Administrator may implement the LMA1 closure if certain triggers are met in the future. This proposal would require the Regional Administrator to examine the available information in advance of October in any given year and determine whether the closure is necessary. Specifically, the Regional Administrator would implement the closure if he or she determines that the frequency of entanglements has not been reduced below 60 percent from the effective date of the final rule. NMFS is considering the following specific language to implement this provision and is interested in any comments on this textual change at § 229.32(c)(6)(ii) Alternative 1–B.

The Regional Administrator may determine whether the frequency of entanglements from the trap/pot gear in the Northeast region has been reduced by 60 percent from [the effective date of this rule] within a time period that allows meaningful analysis. If the Regional Administrator determines that the frequency of such entanglements has not been reduced by 60 percent, then from October 1 to January 31, it shall be prohibited to fish with, set, or possess trap/pot gear in this area unless it is fished without buoy lines or with buoy lines that are stored on the bottom until they can be remotely released for hauling, or the trap/pot gear is stowed in accordance with § 229.2. Authorizations for fishing without buoy lines must be obtained if such fishing would not be in accordance with surface marking requirements of §§ 697.21 and 648.84.

The second proposed new seasonal lobster and crab trap/pot buoy line closure area was proposed by MADMF south of Cape Cod and Nantucket from February through April. These seasonal restricted areas closures are proposed as closures to buoy lines so that ropeless fishing for lobster and crab could occur with appropriate exemptions, as described above in discussion of changes to closure current restricted areas.

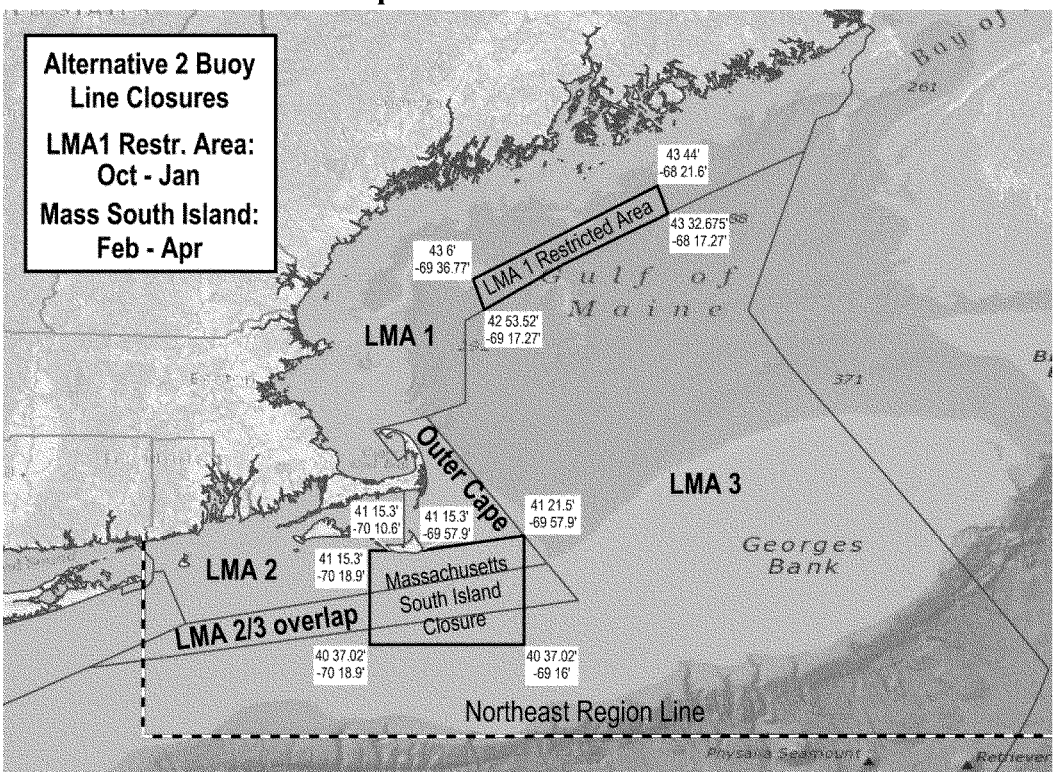
Rhode Island fishermen may also be affected by the Massachusetts South Island Restricted Area in LMA2, and a restriction of buoy lines was not included in the Rhode Island Division of Marine Fisheries (RIDMF) proposal. RIDMF instead proposed that LMA2 fishermen fish with two weak buoy lines (considered to be top 75 percent of the buoy line, allowing 25 percent chafing line where the line makes contact with the ocean floor) to achieve 60 percent risk reduction. Although weak buoy lines are analyzed within Alternative 3 in the DEIS, the Massachusetts South of Island closure was selected for proposed rulemaking due to the demonstrated value of the Massachusetts Restricted Area to North Atlantic right whale protection and recent use by right whales in the area south of Nantucket.

Through flexible state rulemaking, Massachusetts extends the current closure of state waters within the Massachusetts Restricted Area in May if whales remain. Taken together with line reduction measures and the two proposed buoy line closures, co-occurrence of trap/pot buoy lines with North Atlantic right whales would be reduced by an estimated 69 percent (Table 5.4, DEIS).

TABLE 2—PROPOSED REGULATORY CHANGES TO EXISTING NORTHEAST REGION RESTRICTED AREAS AND ADDITION OF TWO NEW AREAS PROHIBITING PERSISTENT BUOY LINES

Component	Proposed area	Measure
Northeast Region Lobster and Crab Trap/Pot Fishery seasonal closures to persistent buoy lines, open to harvest of lobster and Jonah crab using ropeless technology; Ropeless fishing would be allowed with appropriate state and Federal authorizations for exemption from Atlantic Coastal Fisheries Cooperative Management Act and the Magnuson-Stevens Fishery Conservation and Management Act surface marking requirements.	Massachusetts Restricted Area (50 CFR 229.32(c)(3)) and Great South Channel Restricted Trap/Pot Area (50 CFR 229.32(c)(4)).	Would change the trap/pot fishery restricted areas from complete fishing closures to closures to buoy lines. Would allow ropeless fishing for crab and lobster with appropriate state and Federal authorization for exemption from the remaining surface system marking requirements under the Atlantic Coastal Fisheries Cooperative Management Act and the Magnuson-Stevens Fishery Conservation and Management Act.
	New LMA1 Restricted Areas, across Maine Lobster Zones C/D/E.	October–January proposed restricted area; open to fishing with ropeless technology but closed to trap/pot fishing with persistent buoy lines. See Figure 1. Alternative 1–A No Closure. Alternative 1–B Open unless a determination is made by the Regional Administrator that the frequency of entanglements has not been reduced by 60 percent, in which case the area shall be open from October–January to fishing with ropeless technology but closed to trap/pot fishing with persistent buoy lines.
	New Massachusetts South Island Restricted Area.	February–April proposed restricted area; open to fishing with ropeless technology but closed to trap/pot fishing with persistent buoy lines. See Figure 1.

Figure 1 -- Northeast Region Trap/Pot Management Area, showing lobster management area boundaries and proposed LMA1 and Massachusetts South Island Seasonal Crab/Lobster Trap/Pot Restricted Areas



Gear Modifications To Include Weak Line or Weak Insertions in Buoy Lines

The proposed rule also identifies area-specific modifications to buoy lines to introduce weak rope or weak insertions breaking at 1,700 lbs. (771 kgs.) or less at various depths on the buoy line to increase the likelihood that a large whale would break the line prior to becoming entangled in a manner that causes a serious injury or mortality (Table 3). NMFS has confirmed with gear manufacturers that they can include one alternate color in three-strand buoy lines that are manufactured to break at less than 1,700 lbs. (771 kgs.) to distinguish them from strong line of the same diameter. Publication of this proposed rule would be an indicator of future market demand that may spur the production of weak line that can be visibly differentiated.

Weak insertions create places along the rope that have a breaking strength of 1,700 lbs. (771 kgs.) or less. The proposed regulations require a stipulation regarding the depths of weak insertions. Large whales including right whales appear to use the entire water column; therefore, encounters at depth can happen. We assume no risk reduction below the insertion. A large right whale encountering the rope above the weak insertion should be able to break free of the gear below the insertion with a lesser chance of serious injury. The closer the distance between weak insertions, the greater the benefit to right whales, with an ideal interval proposed by some Team members of 40 ft. (12.19 m), the average length of a right whale.

The proposed weak rope and weak insertion measures included in the proposed rule are taken directly from state proposals. MEDMR is evaluating the breaking strength of weak insertion devices, and some that have effectively broken at or below 1,700 lbs (771 kgs) include: Use of an engineered rope designed to have a tensile strength of up to 1,700 lbs. (771 kgs.); spliced insertion into a buoy line of a 3 to 6 ft. (0.91 to 1.83 m) long length of rope engineered to break at 1,700 lbs. (771 kgs.); and insertion of a 3 to 6 ft. (0.91 to 1.83 m) length of South Shore Lobster Fishermen's Association sleeve, a hollow braided sleeve that can be quickly integrated into typical three strand 5/16 and 3/8 inch (0.79 and 0.95 cm) diameter buoy line. Preliminary results of MEDMRs evaluations can be found in their proposal in Appendix 3.2 of the DEIS. Fishermen continue to test additional weak insertion configurations; therefore, additional options that demonstrate appropriate breaking strengths may be identified by the time of final rulemaking. The proposed rule requires inserts or weak line that has been demonstrated to break under forces greater than 1,700 lbs. (771 kgs.), but allows the Regional Administrator to approve new weak insertion devices as they are developed and proven effective to respond to the diversity in fishing practices and available materials across the Northeast Region.

The proposed requirements do not require weak insertions in the Maine exemption area because MEDMR will be requiring one insertion halfway down the buoy line in the exemption area through state regulations. The elements within the Preferred Alternative (Alternative 2) were selected because the DST estimated together they would achieve a greater than 60-percent risk reduction. The analysis includes Maine's intention to require a weak insertion in their exemption waters. The weak line and weak insertion modifications proposed below estimates that outside of the Maine exemption area, all buoy lines in the Northeast Region would be modified under the proposed rule and more than 26 percent

of the rope in crab and lobster buoy lines would be weakened to 1,700 lbs. (771 kgs.) or less. Planned state regulations would modify all buoy lines in Maine exempted waters so that an additional 31.7 percent of line would be equivalent to weak rope. If MEDMR does not implement weak insertion requirements in the exemption area, further modifications to the Plan may be needed to reduce risk of serious injury and mortality of North Atlantic right whales due to entanglement in the commercial Northeast Region lobster and crab trap/pot fisheries by 60 percent.

In addition to weak rope and weak insertions along the length of the buoy lines, the proposed rule would also modify the current weak link requirement at the buoy. The rule would allow fishermen the option of inserting the weak links (at current area-specific strengths) where the surface system connects to the buoy line rather than requiring it at the buoy itself. This modification was requested by fishermen for operational reasons rather than risk reduction reasons. The change would not increase risk, and may allow a whale to break away from entire surface system, which can include multiple lines, buoys, and radar reflectors, rather than just releasing the buoys. This may have a positive benefits due to a reduction in entanglement complexity. Comments from fishermen and the public on this measure specifically are encouraged.

We propose modifying the buoy weak link to provide fishermen with two options, the current connection close to the buoy or a weak link connecting the base of the surface system to the single buoy line. Moving the weak link to the base of the surface system could be required if there is information demonstrating this is a large risk reduction improvement. Finally, the non-preferred alternative in the DEIS (Alternative 3) considers removing the buoy weak link requirement for all buoy lines that would be required to have weak line or weak insertions farther down the buoy line. Under this configuration, a retained buoy could provide resistance that helps the buoy line to part lower down, or the buoy could pull the line away from the whale, increasing the possibility that it will fall from the whale. A retained buoy could also be helpful to large whale disentanglement responders, and buoys from commercial fisheries are usually required to be marked with vessel specific information that would provide information on the original location of entanglement. NMFS invites comments on all of these options.

TABLE 3—PROPOSED REGULATORY CHANGES TO REQUIRE WEAK ROPE, WEAK INSERTIONS ON BUOY LINES AND CHANGE TO WEAK LINK REQUIREMENT ON NORTHEAST REGION CRAB AND LOBSTER TRAP/POT BUOY LINES

Component	Area including distance from shore	Proposed measure
Weak line/Weak Insertion	From Maine exemption line to 3 nmi (5.56 km)	2 weak insertions, at 25 percent and 50 percent down buoy line.
	New Hampshire/Massachusetts/Rhode Island. From coast to 3 nmi (5.56 km).	1 weak insertion, at 50 percent down the buoy line.
	All Northeast Region. 3–12 nmi (5.56 km–22.22 km).	2 weak insertions, at 25 percent and 50 percent down line.
	LMA1, LMA2, and Outer Cape Cod. >12 nmi (22.22 km).	1 weak insertion, at 35 percent down the line.
	Northeast LMA 3	The top 75 percent of one buoy line weak.
Weak link placement option	Entire Northeast Region (Figure 1)	Allow option to place weak link as a connection between the surface system and the single buoy line.

Gear Marking Changes

Finally, the proposed rule would modify current gear marking requirements, introducing colored marks that identify state of permit issuance, as well as a 6-inch (15.24 cm) mark that distinguishes Northeast Region lobster and crab trap trawls in Federal waters from state waters. The rule would also add a 3 ft. (0.91 m) long mark within 2 fathoms of the buoys to increase the possibility of detection and identification to state fishery from vessels and aerial survey aircraft. Proposed modifications are summarized in Table 4. The gear markings are based on proposals received from or discussed with New England States. Maine has already published gear marking requirements analogous to these measures, requiring gear marking on every Maine permitted lobster buoy line, effective in September 2020. Maine's gear marks for Federal waters are mirrored in these regulations. Multiple marking methods would be allowed including paint, tape, or colored rope insertions.

While existing gear marking requirements have increased the amount of retrieved gear with marks, they do not provide sufficient entanglement location information. The proposed gear marking scheme would increase the number of marks present by approximately 56 percent (not including Maine exempt waters, which are regulated under state requirements and will substantially increase the number of marked lobster buoy lines there), increasing the chances that gear will be recovered with visible marks. The proposed gear marking would not impact the probability of whales becoming entangled in commercial fishing gear nor would they affect the severity of an entanglement should one occur. However, the markings would increase the information available regarding the fishery and state of origin of large whale entanglements to aid the efforts of NMFS and the ALWTRT in assessing, and if needed reducing, entanglements in U.S. commercial fisheries that cause mortalities and serious injuries of North Atlantic right whales and other large whales.

TABLE 4—PROPOSED REGULATORY CHANGES TO GEAR MARKING ON NORTHEAST CRAB AND LOBSTER TRAP/POT BUOY LINES

Area	Proposed gear marking measure
Entire Northeast Management Area (see figure 1) except Maine exemption area.	3-ft long state-specific mark (see color below) within 2 fathoms of the buoy. In Federal waters, an additional 6-inch green mark within 1 ft. of 3-ft mark.
Maine Exemption Area	3-ft long mark within 2 fathoms of the buoy. One or two additional 1-ft marks (depth dependent) through state regulation only.
Maine Non-Exempt	Purple. Three 1-ft marks: At top, middle and bottom of line. In Federal waters, an additional 6-inch green buoy line mark within 2 fathoms of buoy.
New Hampshire	Yellow. In state waters: Two 1-ft marks in the top half and bottom half of buoy line. Beyond state waters, three 1-ft marks: At top, middle and bottom of line. In Federal waters, an additional 6-inch green mark within 1 ft. of 3-ft mark within 2 fathoms of buoy.
Massachusetts	Red. In state waters: Two 1-ft marks in the top half and bottom half of buoy line. Beyond state waters three 1-ft marks: At top, middle and bottom of line. In Federal waters, an additional 6-inch green mark within 1 ft. of 3-ft mark within 2 fathoms of buoy.
Rhode Island	Silver/Gray. In state waters: Two 1-ft marks in the top half and bottom half of buoy line. Beyond state waters three 1-ft marks at top, middle and bottom of line. In Federal waters, an additional 6-inch green mark within 1 ft. of 3-ft mark within 2 fathoms of buoy.
LMA 3	Retain Black. In Federal waters add a 3-ft long mark within 2 fathoms of the buoy, and an additional 6-inch green mark within 1 ft. of 3-ft mark within 2 fathoms of buoy.

Addition to Definitions

To ensure clarity related to the management areas that are referenced but were developed for the American lobster fishery, a definition for ''Lobster Management Area'' is provided, citing the Atlantic Coastal Fisheries Cooperative Management Act regulations at 50 CFR 697.18.

For clarity related to proposed changes in weak link and gear marking requirements, the proposed rule would add a definition for ''surface system'' to the definitions in § 229.2.

Change in the Maximum Length of a Lobster Trap Trawl

In addition to changes to 50 CFR part 229, the proposed rule would revise Federal regulations implemented under the Atlantic State Marine Fisheries Commission's Interstate Fishery Management Plan for Lobster at 50 CFR 697.21. The proposed modification would increase the maximum length of a lobster trap trawl from 1.5 nm (2.78 km) to 1.75 nm (3.24 km) in LMA3 as measured from radar reflector to radar reflector, to accommodate a proposed increase in the minimum number of traps per trawl in LMA3.

Risk Reduction Target of 60 Percent

The proposed changes are intended to achieve a regional risk reduction target of at least 60 percent within the Northeast Region lobster and Jonah crab trap/pot fisheries. The Team will be convened to develop recommendations to modify the Plan to reduce risk in other U.S. Atlantic fisheries in meetings in 2021. A 60 percent risk reduction across U.S. commercial fisheries is the minimum that NMFS believes is necessary to reduce the incidental mortalities and serious injuries to below the potential biological removal level for right whales (0.9 potential biological removal level to 0.9 right whales (see Section 2.1.5 of the DEIS) based on documented serious injuries and mortalities. This rulemaking is intended to reduce the risk of entanglement within the Northeast Region lobster and Jonah crab fisheries by 60 percent, which fish about 93 percent of the buoy lines that occur in areas in the United States where right whales occur. NMFS will develop measures to reduce the risk within other fisheries by a similar amount so that the risk reduction target of 60 percent across U.S. commercial fisheries is achieved. NMFS seeks comment as to whether the allocation of risk reduction in the proposed rule is appropriate relative to other fixed gear fisheries (*e.g.,* gillnets) in the region that contribute to the risk of entanglement. Commenters that believe a lower target for risk reduction is warranted should provide specific information or analysis in support of any recommended level.

Classification

The NMFS Assistant Administrator has determined that this proposed rule is consistent with the Plan and the provisions of the Marine Mammal Protection Act, the Atlantic Coastal Fisheries Cooperative Management Act, and other applicable law, subject to further consideration after public comment.

National Environmental Policy Act

NMFS prepared a DEIS for this proposed rule that discusses the potential impacts of proposed changes to the ALWTRP on the environment. In addition to the status quo (Alternative 1), two alternatives are analyzed, Alternative 2 (preferred and the basis of this proposed rule) and Alternative 3. Alternatives 2 and 3 would both modify existing seasonal restricted areas from closure areas to areas closed to persistent buoy lines rather than closed to harvesting lobster and crab, reduce the number of vertical buoy lines fished in northeast lobster and crab trap/pot fisheries, deploy weak rope to allow whales to break free before being killed or seriously injured, seasonally close some areas to crab and lobster trap/pot fishing with persistent buoy lines, and increase gear marking requirements across the Northeast Region lobster and crab trap/pot fisheries. Alternative 2 would reduce buoy lines through an increase in minimum traps/trawl based on area fished. Alternative 3 would reduce lines by providing a line allocation in Federal waters capped at half the lines fished in 2017. While Alternative 2 weak buoy line provisions allow the use of a small number of weak insertions, under Alternative 3 those insertions would be required every 40 ft. along the buoy line or engineered weak rope would be required. Alternative 3 has more and larger seasonal restricted areas closed to buoy lines. An analysis of the impacts of the Federal portion of the two action alternatives estimates that Alternative 2 would reduce the co-occurrence of North Atlantic right whales and buoy lines in these fisheries by 69 percent and would modify 26 percent of the rope in vertical buoy lines to be weakened lines. Co-occurrence of humpback and fin whales with vertical lines would also be reduced by 19 and 27 percent, respectively. Alternative 3 would reduce the co-occurrence of North Atlantic right whales by 86

percent or greater and would modify 75 percent of rope in remaining vertical buoy lines to be weakened lines. Co-occurrence of fin and humpback whales with buoy lines would also be reduced by over 56 percent and 58 percent, respectively, in Alternative 3. Because of the extensive gear marking and weak rope provisions under both alternatives, 3,970 vessels would be affected. The estimated annualized compliance costs of each action alternative are $5.7 to $12.3 million for Alternative 2 and $16.3 to $31.8 million for Alternative 3. A copy of the DEIS is available in the docket or from NMFS (see **ADDRESSES**). Reviewers are asked to comment on and identify support for Alternative 1, 2 or 3.

Executive Order 12866, Regulatory Planning and Review, and Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This proposed rule has been determined significant for the purposes of Executive Order 12866. This proposed rule is expected to be an Executive Order 13771 regulatory action. Depending on the assumptions used, the estimated total cost of this rule over the first six years of implementation, in 2020 dollars, is between $24.5 and $53.5 million.

Regulatory Flexibility Act

NMFS prepared an IRFA as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A copy of this analysis is available in the docket or from NMFS (see **ADDRESSES**), and a summary follows.

Description and Estimate of Number of Small Entities To Which This Proposed Rule Would Apply

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (North American Industry Classification System (NAICS) code 11411) is classified by NMFS as including those businesses, including their affiliates, whose primary industry is commercial fishing and who have $11 million or less in annual gross receipts. This standard applies to all businesses classified under NAICS code 11411 for commercial fishing, including all businesses classified as commercial finfish fishing (NAICS 114111), commercial shellfish fishing (NAICS 114112), and other commercial marine fishing (NAICS 114119) businesses. Data are not available to ascertain non-ownership interests needed to confirm the Small Business Act definition of ''affiliations;'' therefore, the Social Sciences Branch (SSB) of the NMFS Northeast Fisheries Science Center created an affiliated database. There are three major components of this dataset: Vessel affiliation information, landing values by species, and vessel permits. All federally permitted vessels in the Northeast Region from 2016 to 2018 are included in this dataset. Vessels are affiliated into entities according to common owners. The entity definition used by the SSB uses only unique combinations of owners.

Since this proposed regulation applies only to the crab and lobster pot/trap vessels in the Northeast Region, entities that possess one or more of these permits are evaluated. For each affiliation, the revenues from all member vessels of the entity are summed into affiliation revenue in each year. On December 29, 2015, NMFS issued a final rule establishing a small business size standard of $11 million in annual gross receipts for all businesses primarily engaged in the commercial fishing industry (NAICS 11411) for RFA compliance purposes only. The $11 million standard became effective on July 1, 2016. Thus, the RFA defines a small business in the lobster fishery as a firm that is independently owned and operated with receipts of $11 million or less annually. Based on this size standard, if the three-year average (2016–2018) affiliation revenue is greater than $11 million, the fishing business is considered to be a large entity, otherwise it is a small entity.

Within the Northeast Fisheries Science Center (NEFSC) SSB database, 1,591 distinct entities were identified as regulated entities. Using landings data, four of these entities are considered large entities. Because the regulations will also affect fishermen holding only state permits, the vertical buoy line estimates within the NMFS/IEC Co-Occurrence model were used to identify an addition estimate of 1,913 active vessels fishing in state waters that would be regulated by the proposed rule. In total, therefore, there are 3,504 regulated entities.

While we do not have data to determine the dependence of state permitted vessels on lobster landings, if they are analogous to the small entities fishing under Federal permits, they are likely to be dependent on lobster landings, as further described below. To determine the number of impacted entities within the NEFSC data, we identified whether one or more members of an affiliation landed lobster in 2018. These are entities likely to be impacted by the proposed regulations. The determination of whether an entity is a large or small entity is based on three-year average affiliation revenue from 2016 to 2018. Based on these characteristics, we identified 1,591 distinct entities as regulated entities, including 259 entities with no fishing revenue in 2018, and 111 entities (one large, 110 small) with no 2018 lobster landings. That is, there are 1,221 federally permitted vessels that would be impacted by the proposed rule because at least one vessel in the entity landed lobster in the past year (Table 5). Only three of the affected entities would be considered large entities; 1,218 are Federally-permitted small entities. We assume that in addition to those, the 1,912 vessels in state waters would also be impacted, for a total of 3,130 impacted small entities.

As estimated in Chapter 9 of the DEIS, Table 5 displays the average profit for all large and small entities, compared to their mean total revenue. Results indicate the profitability for large entities is 1.77 percent and for small entities is 18.48 percent. As such, we could conclude that the action would not create more significant economic impact on small entities compared to large entities.

TABLE 5—PROFITABILITY OF LARGE AND SMALL ENTITIES

	Mean profit	Mean total revenue	Profitability (%)
Large Entity	$469,784	$26,485,600	1.77
Small Entity	52,235	282,586	18.48

Under Alternative Two, a few measures are proposed to reduce the probability of serious injury and mortality of North Atlantic right whales including weak ropes, minimum trawl length requirement, and restricted areas. A gear marking requirement is also proposed to increase the chance of threat identification. All these measures generate a series of compliance costs for small entities.

As discussed in Chapter 6 of the DEIS, we assume the rulemaking cycle is six years, considered the approximate replacement time for buoy lines. Table 6 displays the compliance costs for all affected entities from Year 1 to Year 6. Year 0 is the status quo, so the compliance cost is zero, and we do not include it in the table. The discount rate of three percent and seven percent are used for the annualized value calculation. Weak rope only generate costs in Year 1, while gear marking needs to be replaced every year. Trawling up and restricted area measures have costs in the subsequent years due to the catch reduction impacts. At seven percent discount rate, the trawling up measures have the highest annual cost of $2.8 to $9.4 million. Gear marking would cost $2.5 million each year. Weak rope and restricted areas (seasonal buoy line closures) cost less than half a million dollars annually. The total annual cost of all measures ranges from $5.9 million to $12.8 million. If applied to roughly 3,100 affected small entities, each entity would have to bear a compliance cost of $1,900 to $4,100 per year for six years. If we are applying a three percent discount rate, the final cost for each vessel would be around $1,700 to $3,600 per year. In terms of realized Year 1 costs, compliance costs would range between $2,200 and $5,000 but would be lower in Years 2–6. The Year 1 costs would result in an estimated reduction in profit ranging from 4.3 percent to 9.5 percent.

TABLE 6—YEARLY COMPLIANCE COST OF PREFERRED ALTERNATIVE

Year	Gear marking	Weak rope	Trawling up lower	Trawling up upper	Restricted area lower	Restricted area upper	Total lower	Total upper
1	$2,017,283	$2,152,497	$2,660,792	$10,957,354	$106,259	$315,300	$6,936,831	$15,442,434
2	2,017,283	0	4,239,722	12,236,593	106,259	315,300	6,363,264	14,569,176
3	2,017,283	0	3,179,791	9,517,350	106,259	315,300	5,303,333	11,849,933
4	2,017,283	0	2,119,861	6,798,107	106,259	315,300	4,243,403	9,130,690
5	2,017,283	0	1,059,930	4,078,864	106,259	315,300	3,183,472	6,411,447
6	2,017,283	0	0	1,359,621	106,259	315,300	2,123,542	3,692,204
PV	12,103,698	2,152,497	13,260,096	44,947,889	637,554	1,891,800	28,153,845	61,095,884
AV (3%)	2,234,312	397,346	2,447,781	8,297,268	117,691	349,222	5,197,129	11,278,147
AV (7%)	2,539,305	451,585	2,781,912	9,429,878	133,756	396,892	5,906,558	12,817,660

Notes: 1. Year 1 to year 6 values are in 2017 dollars.
2. PV represents net present value of year 1 to year 6, also in 2017 dollars.
3. AV represents annualized value of the net present value. It is an equalized yearly cost during the 6-year time period with 3% and 7% discount rate.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

Paperwork Reduction Act

The gear marking requirements in this proposed rule constitute a revision to the information collection burden estimates, subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), OMB Control Number 0648–0364. The DEIS includes two alternatives which both include gear marking modifications and on which NMFS is soliciting comment here.

Comments are requested on assumptions made in estimating the public reporting burden associated with gear marking, including proposed revisions. In addition to new marks that would be required under this proposed rulemaking, we have revised past assumptions that fishermen replace about 20 percent of their buoy lines each year and therefore replace 20 percent of the gear marks annually. Based on new information from a NMFS gear specialist, burden estimates now include an assumption that fishermen will recreate every mark each year. The estimated time required to mark buoy lines has also increased to account for the new marks required and based on new information that the estimated time to make each mark is about 8.4 minutes for each mark. We estimate an average of 334.4 marks for each vessel, for a total reporting burden of an average of 47 hours per year for each of the 1,670 vessels, including the time and costs in acquiring gear marking materials. The total labor cost is estimated to be $1,963,949. Previous burden estimates assumed that 3,672 fishermen (including Maine fishermen outside of the Maine exempted waters) would replace an average of about 47 marks per vessel each year, with each mark taking 5 minutes, and a total burden cost estimate of $199,540 per year.

Reviewers are asked to comment and provide data on whether this proposed revision to the collection of information is necessary for the proper performance and function of the agency, including: The practical utility of the information; the accuracy of the burden estimate; the opportunities to enhance the quality, utility, and clarity of the information to be collected; and the ways to minimize the burden of the collection of information, including the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to the NMFS Greater Atlantic Region at the **ADDRESSES** above. Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information is conducted under OMB Control Number 0648–0364.

Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

This action does not duplicate, overlap, or conflict with any other Federal rules.

Description of Significant Alternatives to the Proposed Action Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact on Small Entities

This rule proposes to amend the ALWTRP to reduce the incidental mortality and serious injury to North Atlantic right whales (*Eubalaena glacialis*), humpback (*Megaptera Novaeangliae*) and fin whales (*Balaenoptera physalus*) in the northeast commercial lobster and crab trap/pot fisheries to meet the goals of the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA). In addition, this action also proposes a small revision to Federal regulations

implemented under the Atlantic State Marine Fisheries Commissions' Interstate Fishery Management Plan for Lobster to increase the maximum length of a lobster trap trawl groundline to accommodate a gear configuration modification proposed in the Plan amendment.

Because incidental entanglement-related serious injury and mortality of North Atlantic right whales is above PBR, and the population is declining, the primary purpose of the proposed modifications is to reduce mortality and serious injury of right whales incidental to northeast U.S. crab and lobster trap/pot gear to below by greater than 60 percent. A reduction in entanglement incidents and serious injuries would also reduce sub-lethal impacts to right whales. NMFS estimated that to reduce mortality and serious injury to below PBR, entanglement risk across U.S. fisheries needs to be reduced by 60 to 80 percent. Non-preferred alternatives would likely not accomplish these objectives for this action or would be less cost effective.

Alternative 1 (status quo) would not modify the Plan or reduce the risk of mortality or serious injury of right whales to below its PBR level as required by the MMPA.

Alternative 3 would reduce the amount of line in the water via a line cap allocation to 50 percent of the lines fished in 2017, implemented in Federal and non-exempt waters except in LMA3. An increase in the minimum traps per trawl requirement would be implemented in LMA3. Under this alternative, existing closures to fishing would be modified to be closed to fishing with persistent buoy lines. The Massachusetts Bay Restricted area would also be extended with a soft closure through May, opening if surveys demonstrate that whales have left the restriction area. Three new seasonal restricted areas would allow ropeless fishing but be closed to buoy lines, including a longer restricted period for the LMA1 Restricted Area and a summer buoy line restriction in an area north of George's Bank at Georges Basin. Two alternative buoy line restricted area options are analyzed south of Cape Cod. Additional measures in Alternative 3 include conversion of a portion of the top 75 percent of all lobster and crab trap/pot vertical buoy lines to weaker rope with a maximum breaking strength of 1, 700 lbs. (771.1 kgs.). The Alternative also includes a more robust gear marking requirement that differentiates buoy lines by state and fishery and expands into areas previously exempt from gear marking.

Alternative 3 demonstrated better risk reduction than Alternative 2, but at a much greater cost. The DST estimated the preferred alternative proposed in this rulemaking would achieve over 60 percent risk reduction for lobster and crab trap/pot buoys in the Northeast Region, within the target established for reaching right whale PBR. The Co-Occurrence model suggested that co-occurrence would be reduced by over 69 percent and that more than 26 percent of the buoy lines in the regulated area would be modified to weak lines. The estimated cost of bringing gear into compliance and lost landings in the first year ranges from $6.04 to $14.5 million.

The DST estimated that Alternative 3 achieved a risk reduction score of nearly 70 percent, and the Co-occurrence Model estimated a co-occurrence reduction of greater than 86 percent. This alternative would increase the likelihood of reducing mortality and serious injury to below PBR for right whales even when taking into account cryptic mortality (estimated but unseen). However, the estimated costs associated with Alternative Three are substantially higher; ranging from $35.0 million to $53.6 million in first year implementation costs.

Alternative 2 was selected as the preferred alternative and is proposed for rule making because it addresses the Purpose and Need for Action stated in this DEIS, is made up primarily of measures proposed by New England states with extensive input from fishing industry stakeholders who will be directly affected by the measures, and includes measures that will help to conserve large whales by reducing the potential for and severity of interactions with commercial fishing gear that may lead to mortalities and serious injuries. In addition, NMFS believes that its preferred alternative achieves these goals while reducing, to the extent possible, the adverse socioeconomic impacts of the rule. On this basis, NMFS believes that Alternative 2 (Preferred) offers the best option for achieving compliance with MMPA requirements.

Coastal Zone Management

NMFS has determined that this action is consistent to the maximum extent practicable with the approved coastal management programs of the U.S. Atlantic coastal states. This determination has been submitted for review by the responsible state agencies under section 307 of the Coastal Zone Management Act.

Federalism

This proposed rule contains policies with federalism implications as that term is defined in Executive Order 13132. Accordingly, the Assistant Secretary for Legislative and Intergovernmental Affairs will provide notice and invite for appropriate participation in the proceedings for the proposed action to the appropriate official(s) of affected state, local, and/or tribal governments.

Endangered Species Act

An Endangered Species Act Section 7 consultation has been initiated and will be completed prior to publication of a final rule. Previously, NMFS completed an ESA Section 7 consultation on the implementation of the Plan on July 15, 1997, and concluded that the action was not likely to adversely affect any ESA-listed species under NMFS jurisdiction. Three subsequent consultations were concluded in 2004, 2008, 2014, and 2015, when NMFS amended the Plan. NMFS, as both the action agency and the consulting agency, reviewed the changes and determined that the measures as revised through rulemaking would not affect ESA-listed species under NMFS jurisdiction in a manner that had not been previously considered.

References

Knowlton, A.R., J. Robbins, S. Landry, H.A. McKenna, S.D. Kraus, and T.B. Werner. 2016. Effects of fishing rope strength on the severity of large whale entanglements. Conserv Biol 30:318–328.

Pace, R.M., 3rd, P.J. Corkeron, and S.D. Kraus. 2017. State-space mark-recapture estimates reveal a recent decline in abundance of North Atlantic right whales. Ecology and Evolution 7:8730–8741.

List of Subjects

50 CFR Part 229

Administrative practice and procedure, Confidential business information, Endangered species, Fisheries, Marine mammals, Reporting and recordkeeping requirements.

50 CFR Part 697

Fisheries, Fishing.

Dated: December 22, 2020.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, 50 CFR parts 229 and 697 are proposed to be amended as follows:

PART 229—AUTHORIZATION FOR COMMERCIAL FISHERIES UNDER THE MARINE MAMMAL PROTECTION ACT OF 1972

■ 1. The authority citation for 50 CFR part 229 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.;* § 229.32(f) also issued under 16 U.S.C. 1531 *et seq.*

■ 2. In § 229.2, add definitions for ''Lobster Management Area'' and ''Surface system'' in alphabetical order to read as follows:

§ 229.2 Definitions.

* * * * *

Lobster Management Area as used in this part means the management areas defined in the American Lobster Fishery regulations found at § 697.18 of this title.

* * * * *

Surface system, with reference to trap/pot and fixed gillnet gear, includes the components at the sea surface to identify the presence of stationary bottom fishing gear, and includes buoys, radar reflectors, and high flyers as well as the rope that connect these components to the vertical buoy line that connects to the bottom gear.

* * * * *

■ 3. Revise § 229.32 to read as follows:

§ 229.32 Atlantic large whale take reduction plan regulations.

(a) *Purpose and scope*—(1) *Whales and fixed gear fisheries.* The purpose of this section is to implement the Atlantic Large Whale Take Reduction Plan to reduce incidental mortality and serious injury of fin, humpback, and right whales in specific Category I and Category II commercial fisheries from Maine through Florida. Specific Category I and II commercial fisheries within the scope of the Plan are identified and updated in the annual List of Fisheries. The measures identified in the Atlantic Large Whale Take Reduction Plan are also intended to benefit minke whales, which are not designated as a strategic stock, but are known to be taken incidentally in gillnet and trap/pot fisheries. The gear types affected by this plan include gillnets (*e.g.,* anchored, drift, and shark) and traps/pots. The Assistant Administrator may revise the requirements set forth in this section in accordance with paragraph (i) of this section.

(2) *Regulated waters*—(i) *U.S. Atlantic waters.* The regulations in this section apply to all U.S. waters in the Atlantic except for the areas exempted in paragraph (a)(3) of this section.

(ii) *Six-mile line.* The six-mile line referred to in paragraph (c)(2)(iv) of this section is a line connecting the following points (Machias Seal to Provincetown):

TABLE 1 TO PARAGRAPH (a)(2)(ii)

44°31.98′ N lat., 67°9.72′ W long (Machias Seal)
44°3.42′ N lat., 68°10.26′ W long (Mount Desert Island)
43°40.98′ N lat., 68°48.84′ W long (Matinicus)
43°39.24′ N lat., 69°18.54′ W long (Monhegan)
43°29.4′ N lat., 70°5.88′ W long (Casco Bay)
42°55.38′ N lat., 70°28.68′ W long (Isle of Shoals)
42°49.53′ N lat., 70°32.84′ W long
42°46.74′ N lat., 70°27.70′ W long
42°44.18′ N lat., 70°24.91′ W long
42°41.61′ N lat., 70°23.84′ W long
42°38.18′ N lat., 70°24.06′ W long
42°35.39′ N lat., 70°25.77′ W long
42°32.61′ N lat., 70°27.91′ W long
42°30.00′ N lat., 70°30.60′ W long
42°17.19′ N lat., 70°34.80′ W long
42°12.48′ N lat., 70°32.20′ W long
42°12.27′ N lat., 70°25.98′ W long
42°11.62′ N lat., 70°16.78′ W long
42°12.27′ N lat., 70°10.14′ W long
42°12.05′ N lat., 70°54.26′ W long
42°11.20′ N lat., 70°17.86′ W long
42°09.55′ N lat., 69°58.80′ W long (Provincetown)

(iii) *Maine pocket waters.* The pocket waters referred to in paragraph (c)(2)(iv) of this section are defined as follows:

TABLE 2 TO PARAGRAPH (a)(2)(iii)

West of Monhegan Island in the area north of the line 43°42.17′ N lat., 69°34.27′ W long and 43°42.25′ N lat., 69°19.3′ W long
East of Monhegan Island in the area located north of the line 43°44′ N lat., 69°15.08′ W long and 43°48.17′ N lat., 69°8.02′ W long
South of Vinalhaven Island in the area located west of the line 43°52.31′ N lat., 68°40′ W long and 43°58.12′ N lat., 68°32.95′ W long
South of Bois Bubert Island in the area located northwest of the line 44°19.27′ N lat., 67°49.5′ W long and 44°23.67′ N lat., 67°40.5′ W long

(3) *Exempted waters*—(i) *COLREGS demarcation line.* The regulations in this section do not apply to waters landward of the 72 COLREGS demarcation lines (International Regulations for Preventing Collisions at Sea, 1972), as depicted or noted on nautical charts published by the National Oceanic and Atmospheric Administration (Coast Charts 1:80,000 scale), and as described in 33 CFR part 80 with the exception of the COLREGS lines for Casco Bay (Maine), Portsmouth Harbor (New Hampshire), Gardiners Bay and Long Island Sound (New York), and the State of Massachusetts.

(ii) *Other exempted waters*—(A) *Maine.* The regulations in this section

do not apply to waters landward of a line connecting the following points (Quoddy Narrows/U.S.-Canada border to Odiornes Pt., Portsmouth, New Hampshire):

TABLE 3 TO PARAGRAPH (a)(3)(ii)(A)

44°49.67′ N lat., 66°57.77′ W long. (R N "2", Quoddy Narrows)
44°48.64′ N lat., 66°56.43′ W long. (G "1" Whistle, West Quoddy Head)
44°47.36′ N lat., 66°59.25′ W long. (R N "2", Morton Ledge)
44°45.51′ N lat., 67°02.87′ W long. (R "28M" Whistle, Baileys Mistake)
44°37.70′ N lat., 67°09.75′ W long. (Obstruction, Southeast of Cutler)
44°27.77′ N lat., 67°32.86′ W long. (Freeman Rock, East of Great Wass Island)
44°25.74′ N lat., 67°38.39′ W long. (R "2SR" Bell, Seahorse Rock, West of Great Wass Island)
44°21.66′ N lat., 67°51.78′ W long. (R N "2", Petit Manan Island)
44°19.08′ N lat., 68°02.05′ W long. (R "2S" Bell, Schoodic Island)
44°13.55′ N lat., 68°10.71′ W long. (R "8BI" Whistle, Baker Island)
44°08.36′ N lat., 68°14.75′ W long. (Southern Point, Great Duck Island)
43°59.36′ N lat., 68°37.95′ W long. (R "2" Bell, Roaring Bull Ledge, Isle Au Haut)
43°59.83′ N lat., 68°50.06′ W long. (R "2A" Bell, Old Horse Ledge)
43°56.72′ N lat., 69°04.89′ W long. (G "5TB" Bell, Two Bush Channel)
43°50.28′ N lat., 69°18.86′ W long. (R "2 OM" Whistle, Old Man Ledge)
43°48.96′ N lat., 69°31.15′ W long. (GR C "PL", Pemaquid Ledge)
43°43.64′ N lat., 69°37.58′ W long. (R "2BR" Bell, Bantam Rock)
43°41.44′ N lat., 69°45.27′ W long. (R "20ML" Bell, Mile Ledge)
43°36.04′ N lat., 70°03.98′ W long. (RG N "BS", Bulwark Shoal)
43°31.94′ N lat., 70°08.68′ W long. (G "1", East Hue and Cry)
43°27.63′ N lat., 70°17.48′ W long. (RW "WI" Whistle, Wood Island)
43°20.23′ N lat., 70°23.64′ W long. (RW "CP" Whistle, Cape Porpoise)
43°04.06′ N lat., 70°36.70′ W long. (R N "2MR", Murray Rock)
43°02.93′ N lat., 70°41.47′ W long. (R "2KR" Whistle, Kittery Point)
43°02.55′ N lat., 70°43.33′ W long. (Odiornes Pt., Portsmouth, New Hampshire)

(B) *New Hampshire.* New Hampshire State waters are exempt from the minimum number of traps per trawl requirement in paragraph (c)(2)(iv) of this section. Harbor waters landward of the following lines are exempt from all the regulations in this section.

TABLE 4 TO PARAGRAPH (a)(3)(ii)(B)

A line from 42°53.691′ N lat., 70°48.516′ W long. to 42°53.516′ N lat., 70°48.748′ W long. (Hampton Harbor)
A line from 42°59.986′ N lat., 70°44.654′ W long. to 42°59.956′ N, 70°44.737′ W long. (Rye Harbor)

(C) *Rhode Island.* Rhode Island State waters are exempt from the minimum number of traps per trawl requirement in paragraph (c)(2)(iv) of this section. Harbor waters landward of the following lines are exempt from all the regulations in this section.

TABLE 4 TO PARAGRAPH (a)(3)(ii)(C)

A line from 41°22.441′ N lat., 71°30.781′ W long. to 41°22.447′ N lat., 71°30.893′ W long. (Pt. Judith Pond Inlet)
A line from 41°21.310′ N lat., 71°38.300′ W long. to 41°21.300′ N lat., 71°38.330′ W long. (Ninigret Pond Inlet)
A line from 41°19.875′ N lat., 71°43.061′ W long. to 41°19.879′ N lat., 71°43.115′ W long. (Quonochontaug Pond Inlet)
A line from 41°19.660′ N lat., 71°45.750′ W long. to 41°19.660′ N lat., 71°45.780′ W long. (Weekapaug Pond Inlet)
A line from 41°26.550′ N lat., 71°26.400′ W long. to 41°26.500′ N lat., 71°26.505′ W long. (Pettaquamscutt Inlet)

(D) *New York.* The regulations in this section do not apply to waters landward of a line that follows the territorial sea baseline through Block Island Sound (Watch Hill Point, RI, to Montauk Point, NY).

(E) *Massachusetts.* The regulations in this section do not apply to waters landward of the first bridge over any embayment, harbor, or inlet in Massachusetts. The following Massachusetts State waters are exempt from the minimum number of traps per trawl requirement in paragraph (c)(2)(iv) of this section:

(*1*) *Exempt waters of Massachusetts Bay and Outer Cape.* Heading From the New Hampshire border to 70° W longitude south of Cape Cod, waters in EEZ Nearshore Management Area 1 and the Outer Cape Lobster Management Area (as defined in the American Lobster Fishery regulations under § 697.18 of this title), from the shoreline to 3 nautical miles from shore, and including waters of Cape Cod Bay southeast of a straight line connecting 41°55.8′ N lat., 70°8.4′ W long. and 41°47.2′ N lat., 70°19.5′ W long.

(*2*) *Exempt waters of southern Massachusetts.* Heading From 70° W longitude south of Cape Cod to the Rhode Island border, all Massachusetts State waters in EEZ Nearshore Management Area 2 and the Outer Cape Lobster Management Area (as defined in the American Lobster Fishery regulations under § 697.18 of this title), including Federal waters of Nantucket Sound west of 70° W longitude.

(F) *South Carolina.* The regulations in this section do not apply to waters landward of a line connecting the following points from 32°34.717′ N lat.,

80°08.565′ W long. to 32°34.686′ N lat., 80°08.642′ W long. (Captain Sams Inlet).

(4) *Sinking groundline exemption.* The fisheries regulated under this section are exempt from the requirement to have groundlines composed of sinking line if their groundline is at a depth equal to or greater than 280 fathoms (1,680 ft or 512.1 m).

(5) *Net panel weak link and anchoring exemption.* The anchored gillnet fisheries regulated under this section are exempt from the requirement to install weak links in the net panel and anchor each end of the net string if the float-line is at a depth equal to or greater than 280 fathoms (1,680 ft or 512.1 m).

(6) *Island buffer.* Those fishing in waters within ¼ nautical miles of the following Maine islands are exempt from the minimum number of traps per trawl requirement in paragraph (c)(2)(iv) of this section: Monhegan Island, Matinicus Island Group (Metinic Island, Small Green Island, Large Green Island, Seal Island, Wooden Ball Island, Matinicus Island, Ragged Island), and Isles of Shoals Island Group (Duck Island, Appledore Island, Cedar Island, Smuttynose Island).

(b) *Gear marking requirements*—(1) *Specified area*s. Except for when fishing in LMA3 and Maine exempted waters, Maine, New Hampshire, Massachusetts, and Rhode Island lobster and crab trap/pot fishermen will follow the color code scheme assigned to the state that permits their vessel, indicated in paragraph (b)(3) of this section. For all other trap/pot and gillnet gear, excluding shark gillnet, the following areas are specified for gear marking purposes: Northern Inshore State Trap/Pot Waters, Cape Cod Bay Restricted Area, Massachusetts Restricted Area, Stellwagen Bank/Jeffreys Ledge Restricted Area, Northern Nearshore Trap/Pot Waters Area, Great South Channel Restricted Trap/Pot Area, Great South Channel Restricted Gillnet Area, Great South Channel Sliver Restricted Area, Southern Nearshore Trap/Pot Waters Area, Offshore Trap/Pot Waters Area, Other Northeast Gillnet Waters Area, Mid/South Atlantic Gillnet Waters Area, Other Southeast Gillnet Waters Area, Southeast U.S. Restricted Areas, and Southeast U.S. Monitoring Area.

(i) *Jordan Basin.* The Jordan Basin Restricted Area is bounded by the following points connected by straight lines in the order listed:

TABLE 5 TO PARAGRAPH (b)(1)(i)

Point	N lat.	W long.
JBRA1	43°15′	68°50′
JBRA2	43°35′	68°20′

TABLE 5 TO PARAGRAPH (b)(1)(i)—Continued

Point	N lat.	W long.
JBRA3	43°25′	68°05′
JBRA4	43°05′	68°20′
JBRA5	43°05′	68°35′
JBRA1	43°15′	68°50′

(ii) *Jeffreys Ledge Restricted Area.* The Jeffreys Ledge Restricted Area is bounded by the following points connected by a straight line in the order listed:

TABLE 6 TO PARAGRAPH (b)(1)(ii)

Point	N lat.	W long.
JLRA1	43°15′	70°25′
JLRA2	43°15′	70°00′
JLRA3	42°50′	70°00′
JLRA4	42°50′	70°25′
JLRA1	43°15′	70°25

(2) *Markings.* All specified gear in specified areas must be marked with the color code shown in paragraph (b)(3) of this section. The color must be permanently marked on or along the line or lines specified under paragraphs (b)(2)(i) through (iii) of this section. Each colored mark must be clearly visible when the gear is hauled or removed from the water, including if the color of the rope is the same as or similar to the respective color code.

(i) *Northeast crab and lobster buoy line markings.* For all Northeast Region crab and lobster trap/pot gear regulated under this section, the surface system ropes must be marked with a solid 36-inch mark (91.4 cm) within two-fathoms (3.7 m) of the buoy. When fishing in Federal waters, all Northeast Region crab and lobster trap/pot surface system lines must have an additional 6-inch (15.24 cm) green mark one-foot (30.05 cm) below the 36-inch (91.4 cm) mark. These surface system marks must be solid marks that may be dyed, painted, or heat-shrink tubing, insertion of a colored rope or braided sleeve, or the line may be marked as approved in writing by the Assistant Administrator. When fishing in state waters, the buoy line must be marked at least two additional times (top half, bottom half) and each mark must total 12-inches (30.5 cm) for a total of four marks in state waters. When in Federal waters, the buoy line must be marked at least three additional times (top, middle, and bottom) and each mark must total 12-inches (30.5 cm) for a total of five marks in Federal waters. In marking or affixing the color code for buoy line below the surface system for gear regulated under this paragraph (b)(2)(i), the line may be: Dyed; painted, marked with thin colored whipping line, thin colored plastic, or heat-shrink tubing; spliced in insertion of a colored rope or braided sleeve or other material, or a thin line may be woven into or through the line; or the line may be marked as approved in writing by the Assistant Administrator.

(ii) *Other buoy line markings.* For all other trap/pot and gillnet gear regulated under this section, the buoy line must be marked at least three times (top, middle, bottom) and each mark must total 12 inches (30.5 cm) in length. If the mark consists of two colors then each color mark may be 6 inches (15.25 cm) for a total mark of 12 inches (30.5 cm). In marking or affixing the color code for gear regulated under this paragraph (b)(2)(ii), the line may be: Dyed, painted, marked with thin colored whipping line, thin colored plastic, or heat-shrink tubing, spliced in insertion of a colored rope or braided sleeve or other material, or a thin line may be woven into or through the line, or the line may be marked as approved in writing by the Assistant Administrator. An outreach guide illustrating the techniques for marking gear is available from the Regional Administrator, NMFS, Greater Atlantic Region upon request and posted on the NMFS, Greater Atlantic Region Atlantic Large Whale Take Reduction Plan website *https://www.fisheries.noaa.gov/new-england-mid-atlantic/marine-mammal-protection/atlantic-large-whale-take-reduction-plan#outreach.*

(iii) *Net panel markings.* Shark gillnet gear net panels in the Southeast U.S. Restricted Area S, Southeast U.S. Monitoring Area and Other Southeast Gillnet Waters is required to be marked. The net panel must be marked along both the floatline and the leadline at least once every 100 yards (91.4 m).

(iv) *Surface buoy markings.* Trap/pot and gillnet gear regulated under this section must mark all surface buoys to identify the vessel or fishery with one of the following: The owner's motorboat registration number, the owner's U.S. vessel documentation number, the Federal commercial fishing permit number, or whatever positive identification marking is required by the vessel's home-port state. When marking of surface buoys is not already required by state or Federal regulations, the letters and numbers used to mark the gear to identify the vessel or fishery must be at least 1 inch (2.5 cm) in height in block letters or Arabic numbers in a color that contrasts with the background color of the buoy. An outreach guide illustrating the techniques for marking gear is available from the Regional

Administrator, NMFS, Greater Atlantic Region upon request and posted on the NMFS, Greater Atlantic Region Atlantic Large Whale Take Reduction Plan website *https://www.fisheries.noaa.gov/new-england-mid-atlantic/marine-mammal-protection/atlantic-large-whale-take-reduction-plan#outreach.*

(3) *Color code.* Gear must be marked with the appropriate colors to designate gear types and areas as follows.

TABLE 7 TO PARAGRAPH (b)(3)

Color code scheme	
Plan management area	Color
Northeast Region, Lobster and Crab Trap/Pot Gear	
Trawls fished by vessels permitted by the state of Maine when fished in state waters	Purple.
Trawls fished by vessels permitted by the state of Maine when fished in Federal LMA 1 waters	Purple, Green (Surface System).
Trawls fished by vessels permitted by the state of New Hampshire when fished in state waters	Yellow.
Trawls fished by vessels permitted by the state of New Hampshire when fished in Federal LMA 1 waters.	Yellow, Green (Surface System).
Trawls fished by vessels permitted by the state of Massachusetts when fished in state waters	Red.
Trawls fished by vessels permitted by the state of Massachusetts in Federal waters of LMA 1, OC, LMA 2 (including ⅔ overlap).	Red, Green (Surface System).
Trawls fished by vessels permitted by the state of Rhode Island in state waters	Silver/Gray.
Trawls fished by vessels permitted by the state of Rhode Island in Federal waters of LMA 2 (including ⅔ overlap).	Silver/Gray Green (Surface System).
Trawls fished in the Northeast EEZ Offshore Management Area 3 (LMA3) excluding the ⅔ overlap	Black, Green (Surface system).
Northeast Region, Other Trap/Pot Gear	
Massachusetts Restricted Area	Red.
Northern Nearshore	Red.
Northern Inshore State	Red.
Stellwagen Bank/Jeffreys Ledge Restricted Area	Red.
Great South Channel Restricted Area overlapping with LMA 2 and/or Outer Cape	Red.
Exempt Rhode Island state waters (single traps)	Red and Blue.
Exempt Massachusetts state waters in LMA 1 (single traps)	Red and White.
Exempt Massachusetts state waters in LMA 2 (single traps)	Red and Black.
Exempt Massachusetts state waters in Outer Cape (single traps)	Red and Yellow.
Isles of Shoals, ME (single traps)	Red and Orange.
Great South Channel Restricted Area overlapping with LMA 2/3 and/or LMA 3	Black.
Jordan Basin	Black and Purple (LMA 3), Red and Purple (LMA 1).
Jeffreys Ledge	Red and Green.
Trap/Pot Gear	
Southern Nearshore	Orange.
Southeast Restricted Area North (State Waters)	Blue and Orange.
Southeast Restricted Area North (Federal Waters)	Green and Orange.
Offshore	Black.
Gillnet Excluding Shark Gillnet	
Cape Cod Bay Restricted Area	Green.
Stellwagen Bank/Jeffreys Ledge Restricted Area	Green.
Great South Channel Restricted Area	Green.
Great South Channel Restricted Sliver Area	Green.
Other Northeast Gillnet Waters	Green.
Jordan Basin	Green and Yellow.
Jeffreys Ledge	Green and Black.
Mid/South Atlantic Gillnet Waters	Blue.
Southeast U.S. Restricted Area South	Yellow.
Other Southeast Gillnet Waters	Yellow.
Shark Gillnet (With Webbing of 5″ or Greater)	
Southeast U.S. Restricted Area South	Green and Blue.
Southeast Monitoring Area	Green and Blue.
Other Southeast Waters	Green and Blue.

(c) *Restrictions applicable to trap/pot gear in regulated waters*—(1) *Universal trap/pot gear requirements.* In addition to the gear marking requirements listed in paragraph (b) of this section and the area-specific measures listed in paragraphs (c)(2) through (12) of this section, all trap/pot gear in regulated waters, including the Northern Inshore State Trap/Pot Waters Area, must comply with the universal gear

requirements listed in paragraphs (c)(1)(i) through (iii) of this section.[1]

(i) *No buoy line floating at the surface.* No person or vessel may fish with trap/pot gear that has any portion of the buoy line floating at the surface at any time when the buoy line is directly connected to the gear at the ocean bottom. If more than one buoy is attached to a single buoy line or if a high flyer and a buoy are used together on a single buoy line, floating line may be used between these objects.

(ii) *No wet storage of gear.* Trap/pot gear must be hauled out of the water at least once every 30 days.

(iii) *Groundlines.* All groundlines must be composed entirely of sinking line. The attachment of buoys, toggles, or other floatation devices to groundlines is prohibited.

(2) *Area specific gear requirements.* Trap/pot gear must be set according to the requirements outlined in paragraphs (c)(2)(i) through (iii) of this section and in Table 8 to paragraph (c)(2)(iv) of this section.

(i) *Single traps and multiple-trap trawls.* All traps must be set according to the configuration outlined in Table 8 to paragraph (c)(2)(iv) of this section. Trawls up to and including five traps must only have one buoy line unless specified otherwise in Table 8 to paragraph (c)(2)(iv) of this section.

(ii) *Buoy line weak links.* All buoys, flotation devices and/or weights (except traps/pots, anchors, and leadline woven into the buoy line), such as surface buoys, high flyers, radar reflectors, subsurface buoys, toggles, window weights, etc., must be attached to the buoy line with a weak link placed either as close to each individual buoy, flotation device and/or weight as operationally feasible, or at the base of the surface system where the surface system attaches to the single buoy line, and that meets the following specifications:

(A) *Weak link breaking strengths.* The breaking strength of the weak links must not exceed the breaking strength listed in paragraph (c)(2)(iv) of this section for a specified management area.

(B) *Approved weak links.* The weak link must be chosen from the following list approved by NMFS: Swivels, plastic weak links, rope of appropriate breaking strength, hog rings, rope stapled to a buoy stick, or other materials or devices approved in writing by the Assistant Administrator. An outreach guide illustrating the techniques for making weak links is available from the Regional Administrator, NMFS, Greater Atlantic Region upon request and posted on the NMFS, Greater Atlantic Region Atlantic Large Whale Take Reduction Plan website *https://www.fisheries.noaa.gov/new-england-mid-atlantic/marine-mammal-protection/atlantic-large-whale-take-reduction-plan#outreach.*

(C) *Clean breaks.* Weak links must break cleanly leaving behind the bitter end of the line. The bitter end of the line must be free of any knots when the weak link breaks. Splices are not considered to be knots for the purposes of this paragraph (c)(2)(ii)(C).

(iii) *Weak buoy lines and weak insertion devices.* All crab and lobster trap buoy lines in the management areas and configurations outlined in Table 8 to paragraph (c)(2)(iv) of this section must use weak line or must insert weak devices along the buoy line as described in Table 8 to paragraph (c)(2)(iv). The weak line and weak insert devices must meet the following specifications:

(A) *Breaking strength.* The breaking strength of the weak buoy lines and weak insert devices must not exceed 1,700 lbs. (771 kgs.).

(B) *Distance between weak insertions.* Weak insertion devices must be inserted in the specified intervals from the surface system and must be devices chosen from the following list approved by NMFS: Three-foot long hollow braided sleeves such as those known as the South Shore Sleeve, spliced insert of three-foot long weak buoy line that is no thinner than five sixteenths inches (8mm) in diameter, three-foot (.91 m) long ''lazy splice'' loop and double tuck of three eighths inch (9.5 mm) diameter line with three eighths inch (9.5 mm) diameter line, or a loop and double tuck (lazy splice) of three eighths inch (9.5mm) diameter line with five sixteenths inch (8 mm) diameter line, or other materials or devices approved in writing by the Assistant Administrator. An outreach guide illustrating the techniques for making weak insert devices is available from the Regional Administrator, NMFS, Greater Atlantic Region upon request and posted on the NMFS, Greater Atlantic Region Atlantic Large Whale Take Reduction Plan website *https://www.fisheries.noaa.gov/new-england-mid-atlantic/marine-mammal-protection/atlantic-large-whale-take-reduction-plan#outreach.*

(C) *Clean breaks.* Weak line and weak inserts must break cleanly leaving behind the bitter end of the line. The bitter end of the line must be free of any knots when the weak insert breaks. Splices are not considered to be knots for the purposes of this paragraph (c)(2)(iii)(C).

(iv) *Table of area specific trap/pot gear requirements.*

TABLE 8 TO PARAGRAPH (c)(2)(iv)

Mgmt area; location	Minimum number traps/trawl	Weak link strength	Weak rope or weak insertion configuration
Northeast Lobster/Crab Trap/Pot			
Northern Inshore State; Maine State and Pocket Waters [1].	3 (1 buoy line)	≤600 lbs	Weak line for the top 50 percent of the buoy line or two weak insertion devices, one at 25 percent and one at 50 percent buoy line length from top.
Northern Nearshore; Maine Zones A–G (3–6 miles).	8	≤600 lbs	Weak line for the top 50 percent of the buoy line or two weak insertion devices, one at 25 percent and one at 50 percent buoy line length from top.
Northern Inshore State and Massachusetts Restricted Area; Massachusetts State Waters [2].	No minimum number of traps per trawl. Trawls up to and including 3 or fewer traps must only have one buoy line.	≤600 lbs	Weak line for the top 50 percent of the buoy line or one weak insertion device at 50 percent buoy line length from top.

[1] Fishermen are also encouraged to maintain their buoy lines to be as knot-free as possible. Splices are considered to be less of an entanglement threat and are thus preferable to knots.

TABLE 8 TO PARAGRAPH (c)(2)(iv)—Continued

Mgmt area; location	Minimum number traps/trawl	Weak link strength	Weak rope or weak insertion configuration
Northern Inshore State and Massachusetts Restricted Area; Other Massachusetts State Waters.	2 (1 buoy line) Trawls up to and including 3 or fewer traps must only have one buoy line.	≤600 lbs	Weak line for the top 50 percent of the buoy line or one weak insertion device at 50 percent buoy line length from top.
Northern Inshore State; New Hampshire State Waters.	No minimum trap/trawl	≤600 lbs	Weak line for the top 50 percent of the buoy line or one weak insertion device at 50 percent buoy line length from top.
Northern Nearshore; New Hampshire and Massachusetts (3–6 miles).	10	≤600 lbs	Weak line for the top 50 percent of the buoy line or two weak insertion devices, one at 25 percent and one at 50 percent buoy line length from top.
Northern Nearshore, Massachusetts Restricted Area, and Stellwagen Bank/Jeffreys Ledge Restricted Area; LMA 1 (6–12 miles).	15	≤600 lbs	Weak line for the top 50 percent of the buoy line or two weak insertion devices, one at 25 percent and one at 50 percent buoy line length from top.
Northern Nearshore and LMA1 Restricted Area; LMA1 (12 + miles).	25	≤600 lbs	Weak line for the top 35 percent of the buoy line or one weak insertion device at 35 percent buoy line length from top.
Northern Inshore State and Massachusetts Restricted Area; LMA1/OC Overlap (0–3 miles).	No minimum number of traps per trawl	≤600 lbs	Weak line for the top 50 percent of the buoy line or one weak insertion device at 50 percent buoy line length from top.
Northern Inshore State, Massachusetts Restricted Area, and Massachusetts South Island Restricted Area; OC (0–3 miles).	No minimum number of traps per trawl	≤600 lbs	Weak line for the top 50 percent of the buoy line or one weak insertion device at 50 percent buoy line length from top.
Northern Nearshore and Massachusetts Restricted Area; OC (3–12 miles).	15	≤600 lbs	Weak line for the top 50 percent of the buoy line or two weak insertion devices, one at 25 percent and one at 50 percent buoy line length from top.
Northern Nearshore and Great South Channel Restricted Area; OC (12 + miles).	20	≤600 lbs	Weak line for the top 35 percent of the buoy line or one weak insertion device at 35 percent buoy line length from top.
Northern Inshore State; RI State Waters	No minimum number of traps per trawl	≤600 lbs	Weak line for the top 50 percent of the buoy line or one weak insertion device at 50 percent buoy line length from top.
Northern Nearshore; LMA 2 (3–12 miles).	15	≤600 lbs	Weak line for the top 50 percent of the buoy line or two weak insertion devices, one at 25 percent and one at 50 percent buoy line length from top.
Northern Nearshore, Great South Channel Restricted Area, and Massachusetts South of Island Restricted Area; LMA 2 (12 + miles).	25	≤600 lbs	Weak line for the top 35 percent of the buoy line or one weak insertion device at 35 percent buoy line length from top.
Offshore, Great South Channel Restricted Area, and Massachusetts South Island Restricted Area; LMA ⅔ Overlap (12 + miles).	25	≤1500 lbs (2,000 lbs if red crab trap/pot).	Weak line for the top 35 percent portion of the buoy line or one weak insertion device at 35 percent buoy line length from top.
Northeast Offshore waters North of 40°, Great South Channel Restricted Area, and Massachusetts South Island Restricted Area; LMA 3 (12 + miles).	45	≤1500 lbs (2,000 lbs if red crab trap/pot).	Weak line for the top 75 percent of the buoy line.
Other Trap/Pot			
Northern Inshore State; Maine State and Pocket Waters [1].	2 (1 buoy line)	≤600 lbs.	
Northern Nearshore; Maine Zones A–G (3–6 miles) [1].	3 (1 buoy line)	≤600 lbs.	
Northern Nearshore; Maine Zones A–C (6–12 miles) [1].	5 (1 buoy line)	≤600 lbs.	
Northern Nearshore; Maine Zones D–G (6–12 miles) [1].	10	≤600 lbs.	
Northern Nearshore, Offshore, and LMA1 Restricted Area; Maine Zones A–E (12 + miles).	15	≤600 lbs (≤1500 lbs in offshore, 2,000 lbs if red crab trap/pot).	

TABLE 8 TO PARAGRAPH (c)(2)(iv)—Continued

Mgmt area; location	Minimum number traps/trawl	Weak link strength	Weak rope or weak insertion configuration
Northern Nearshore, Offshore, and LMA1 Restricted Area; Maine Zones F–G (12 + miles).	15 (Mar 1–Oct 31) 20 (Nov 1–Feb 28/29).	≤600 lbs (≤1500 lbs in offshore, 2,000 lbs if red crab trap/pot).	
Northern Inshore State and Massachusetts Restricted Area; Massachusetts State Waters [2].	No minimum number of traps per trawl. Trawls up to and including 3 or fewer traps must only have one buoy line.	≤600 lbs.	
Northern Inshore State, Massachusetts Restricted Area, and Massachusetts South Island Restricted Area; Other Massachusetts State Waters.	2 (1 buoy line) Trawls up to and including 3 or fewer traps must only have one buoy line.	≤600 lbs.	
Northern Inshore State; New Hampshire State Waters.	No minimum trap/trawl	≤600 lbs.	
Northern Nearshore and Massachusetts Restricted Area and Stellwagen Bank/Jeffreys Ledge Restricted Area; LMA 1 (3–12 miles).	10	≤600 lbs.	
Northern Nearshore and LMA1 Restricted Area; LMA 1 (12 + miles).	20	≤600 lbs.	
Northern Inshore State and Massachusetts Restricted Area; LMA1/OC Overlap (0–3 miles).	No minimum number of traps per trawl	≤600 lbs.	
Northern Inshore State and Massachusetts Restricted Area; OC (0–3 miles).	No minimum number of traps per trawl	≤600 lbs.	
Northern Nearshore and Massachusetts Restricted Area; OC (3–12 miles).	10	≤600 lbs.	
Northern Nearshore and Great South Channel Restricted Area; OC (12 + miles).	20	≤600 lbs.	
Northern Inshore State; Rhode Island State Waters.	No minimum number of traps per trawl	≤600 lbs.	
Northern Nearshore, and Massachusetts South Island Restricted Area; LMA 2 (3–12 miles).	10	≤600 lbs.	
Northern Nearshore, Great South Channel Restricted Area; LMA 2 (12 + miles).	20	≤600 lbs.	
Northeast Offshore and Great South Channel Restricted Area, and Massachusetts South Island Restricted Area; LMA ⅔ Overlap (12 + miles).	20	≤1500 lbs (2,000 lbs if red crab trap/pot).	
Northeast Offshore waters, Great South Channel Restricted Area, and Massachusetts South Island Restricted Area; LMA 3 (12 + miles).	20	≤1500 lbs (2,000 lbs if red crab trap/pot).	
Southern Nearshore; LMA 4,5,6		≤600 lbs.	
Southeast U.S. Restricted Area North; [3] Florida State Waters.	1	≤200 lbs.	
Southeast U.S. Restricted Area North; [3] Georgia State Waters.	1	≤600 lbs.	
Southeast U.S. Restricted Area North; [3] South Carolina State Waters.	1	≤600 lbs.	
Southeast U.S. Restricted Area North; [3] Federal Waters off Florida, Georgia, South Carolina.	1	≤600 lbs.	

[1] The pocket waters and 6-mile line are defined in paragraphs (a)(2)(ii) and (iii) of this section.
[2] Massachusetts State waters as defined as paragraph (a)(3)(ii) of this section.
[3] See paragraph (f)(1) of this section for description of area.

(3) *Massachusetts Restricted Area*—(i) *Area.* The Massachusetts Restricted Area is bounded by the following points connected by straight lines in the order listed, and bounded on the west by the shoreline of Cape Cod, Massachusetts.

TABLE 9 TO PARAGRAPH (c)(3)(i)

Point	N lat.	W long.
MRA1	42°12′	70°44′
MRA2	42°12′	70°30′
MRA3	42°30′	70°30′
MRA4	42°30′	69°45′
MRA5	41°56.5′	69°45′

TABLE 9 TO PARAGRAPH (c)(3)(i)—Continued

Point	N lat.	W long.
MRA6	41°21.5′	69°16′
MRA7	41°15.3′	69°57.9′
MRA8	41°20.3′	70°00′

TABLE 9 TO PARAGRAPH (c)(3)(i)—Continued

Point	N lat.	W long.
MRA9	41°40.2′	70°00′
MRA1	42°12′	70°44′

(ii) *Closure to fishing with buoy lines.* From February 1 to April 30, it is prohibited to fish with, set, or possess trap/pot gear in the area in paragraph (c)(3)(i) unless it is fished without buoy lines or with buoy lines that are stored on the bottom until it can be remotely released for hauling, or it is stowed in accordance with § 229.2. Authorizations for fishing without buoy lines must be obtained if such fishing would not be in accordance with surface marking requirements of §§ 697.21 and 648.84 of this chapter.

(iii) *Area-specific gear or vessel requirements.* From May 1 through January 31, no person or vessel may fish with or possess trap/pot gear in the Massachusetts Restricted Area unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, and the area-specific requirements listed in paragraph (c)(2) of this section, or unless the gear is stowed as specified in § 229.2.

(4) *Massachusetts South Island Restricted Area*—(i) *Area.* The Massachusetts South Island Restricted Area is bounded by the following points connected by straight lines in the order listed, and bounded on the north by the shoreline of Nantucket, Massachusetts.

TABLE 10 TO PARAGRAPH (c)(4)(i)

Point	N lat.	W long.
MSI1	41°15.3′	70°18.9′
MSI2	41°15.3′	70°10.6′
MSI3	41°15.3′	69°57.9′
MSI4	41°21.5′	69°16′
MSI5	40°37.02′	69°16′
MSI6	40°37.02′	70°18.9′
MSI1	41°15.3′	70°18.9′

(ii) *Closure to fishing with buoy lines.* From February 1 to April 30, it is prohibited to fish with, set, or possess trap/pot gear in the area in paragraph (c)(4)(i) unless it is fished without buoy lines or with buoy lines that are stored on the bottom until they can be remotely released for hauling, or the trap/pot gear is stowed in accordance with § 229.2. Authorizations for fishing without buoy lines must be obtained if such fishing would not be in accordance with surface marking requirements of §§ 697.21 and 648.84 of this chapter.

(iii) *Area-specific gear or vessel requirements.* From May 1 through January 31, no person or vessel may fish with or possess trap/pot gear in the Massachusetts South Island Restricted Area unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, and the area-specific requirements listed in paragraph (c)(2) of this section, or unless the gear is stowed as specified in § 229.2.

(5) *Great South Channel Restricted Trap/Pot Area*—(i) *Area.* The Great South Channel Restricted Trap/Pot Area consists of the area bounded by the following points.

TABLE 11 TO PARAGRAPH (c)(5)(i)

Point	N Lat.	W Long.
GSC1	41°40′	69°45′
GSC2	41°0′	69°05′
GSC3	41°38′	68°13′
GSC4	42°10′	68°31′
GSC1	41°40′	69°45′

(ii) *Closure to fishing with buoy lines.* From April 1 through June 30, it is prohibited to fish with, set, or possess trap/pot gear in the area in paragraph (c)(5)(i) unless it is fished without buoy lines or with buoy lines that are stored on the bottom until they can be remotely released for hauling, or the trap/pot gear is stowed in accordance with § 229.2. Authorizations for fishing without buoy lines must be obtained if such fishing would not be in accordance with surface marking requirements of §§ 697.21 and 648.84 of this chapter.

(iii) *Area-specific gear or vessel requirements.* From July 1 through March 31, no person or vessel may fish with or possess trap/pot gear in the Great South Channel Restricted Trap/Pot Area unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, and the area-specific requirements listed in paragraph (c)(2) of this section, or unless the gear is stowed as specified in § 229.2.

(6) *Lobster Management Area One Restricted Area*—(i) *Area.* The Lobster Management Area One Restricted Area (LMRA1) is bounded by the following points connected by straight lines in the order listed.

TABLE 12 TO PARAGRAPH (c)(6)(i)

Point	N lat.	W long.
LMRA1 1	43°06′	69°36.77′

TABLE 12 TO PARAGRAPH (c)(6)(i)—Continued

Point	N lat.	W long.
LMRA1 2	43°44′	68°21.6′
LMRA1 3	43°32.68′	68°17.27′
LMRA1 4	42°53.52′	69°32.16′
LMRA1 1	43°06′	69°36.77′

(ii) *Restrictions to fishing with buoy lines.* From October 1 to January 31, it is prohibited to fish with, set, or possess trap/pot gear in the area in paragraph (c)(6)(i) unless it is fished without buoy lines or with buoy lines that are stored on the bottom until they can be remotely released for hauling, or the trap/pot gear is stowed in accordance with § 229.2. Authorizations for fishing without buoy lines must be obtained if such fishing would not be in accordance with surface marking requirements of §§ 697.21 and 648.84 of this chapter.

Alternative 1–A (for Paragraph (c)(6)(ii))

(ii) *Restrictions to fishing with buoy lines.* There are no seasonal restrictions to fishing with buoy lines.

Alternative 1–B (for Paragraph (c)(6)(ii))

(ii) *Restrictions to fishing with buoy lines.* The Regional Administrator may determine whether the frequency of entanglements from trap/pot gear in the Northeast region has been reduced by 60 percent from [effective date of the final rule] within a time period that allows for meaningful analysis. If the Regional Administrator determines that the frequency of such entanglements has not been reduced by 60 percent, then from October 1 to January 31, it shall be prohibited to fish with, set, or possess trap/pot gear in the area in paragraph (c)(6)(i) unless it is fished without buoy lines or with buoy lines that are stored on the bottom until they can be remotely released for hauling, or the trap/pot gear is stowed in accordance with § 229.2. Authorizations for fishing without buoy lines must be obtained if such fishing would not be in accordance with surface marking requirements of §§ 697.21 and 648.84 of this chapter.

(iii) *Area-specific gear or vessel requirements.* From February 1 through September 30, no person or vessel may fish with or possess trap/pot gear in the Lobster Management Area One Restricted Area unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, and the area-specific requirements listed in paragraph (c)(2) of this section, or

unless the gear is stowed as specified in § 229.2.

(7) *Stellwagen Bank/Jeffreys Ledge Restricted Area*—(i) *Area.* The Stellwagen Bank/Jeffreys Ledge Restricted Area includes all Federal waters of the Gulf of Maine, except those designated as the Massachusetts Restricted Area in paragraph (c)(3) of this section, that lie south of 43°15′ N lat. and west of 70°00′ W long.

(ii) *Year round area-specific gear or vessel requirements.* No person or vessel may fish with or possess trap/pot gear in the Stellwagen Bank/Jeffreys Ledge Restricted Area unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, and the area-specific requirements listed in paragraph (c)(2) of this section, or unless the gear is stowed as specified in § 229.2.

(8) *Offshore Trap/Pot*[2] *Waters Area*—(i) *Area.* The Offshore Trap/Pot Waters Area includes all Federal waters of the EEZ Offshore Management Area known as Lobster Management Area 3, including the area known as the Area ⅔ Overlap and Area ⅗ Overlap as defined in the American Lobster Fishery regulations at § 697.18 of this title, with the exception of the Great South Channel Restricted Trap/Pot Area and Southeast Restricted Area, and extending south along the 100-fathom (600-ft or 182.9-m) depth contour from 35°14′ N lat. South to 27°51′ N lat., and east to the eastern edge of the EEZ.

(ii) *Year-round area-specific gear or vessel requirements.* No person or vessel may fish with or possess trap/pot gear in the northeast portion of Offshore Trap/Pot Waters Area that overlaps an area from the U.S./Canada border south to a straight line from 41°18.2′ N lat., 71°51.5′ W long. (Watch Hill Point, RI) south to 40°00′ N lat., and then east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, and the area-specific requirements listed in paragraph (c)(2) of this section, or unless the gear is stowed as specified in § 229.2.

(iii) *Seasonal area-specific gear or vessel requirements.* From September 1 to May 31, no person or vessel may fish with or possess trap/pot gear in the Offshore Trap/Pot Waters Area that overlaps an area bounded on the north by a straight line from 41°18.2′ N lat., 71°51.5′ W long. (Watch Hill Point, RI) south to 40°00′ N lat. and then east to the eastern edge of the EEZ, and bounded on the south by a line at 32°00′ N lat., and east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, and area-specific requirements in paragraph (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(iv) *Seasonal area-specific gear or vessel requirements.* From November 15 to April 15, no person or vessel may fish with or possess trap/pot gear in the Offshore Trap/Pot Waters Area that overlaps an area from 32°00′ N lat. south to 29°00′ N lat. and east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(v) *Seasonal area-specific gear or vessel requirements.* From December 1 to March 31, no person or vessel may fish with or possess trap/pot gear in the Offshore Trap/Pot Waters Area that overlaps an area from 29°00′ N lat. south to 27°51′ N lat. and east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) in this section, or unless the gear is stowed as specified in § 229.2.

(vi) [Reserved]

(9) *Northern Inshore State Trap/Pot Waters Area*—(i) *Area.* The Northern Inshore State Trap/Pot Waters Area includes the State waters of Rhode Island, Massachusetts, New Hampshire, and Maine, with the exception of Massachusetts Restricted Area and those waters exempted under paragraph (a)(3) of this section. Federal waters west of 70°00′ N lat. in Nantucket Sound are also included in the Northern Inshore State Trap/Pot Waters Area.

(ii) *Year-round area-specific gear or vessel requirements.* No person or vessel may fish with or possess trap/pot gear in the Northern Inshore State Trap/Pot Waters Area unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(10) *Northern Nearshore Trap/Pot Waters Area*—(i) *Area.* The Northern Nearshore Trap/Pot Waters Area includes all Federal waters of EEZ Nearshore Management Area 1, Area 2, and the Outer Cape Lobster Management Area (as defined in the American Lobster Fishery regulations at § 697.18 of this title), with the exception of the Great South Channel Restricted Trap/Pot Area, Massachusetts Restricted Area, Stellwagen Bank/Jeffreys Ledge Restricted Area, and Federal waters west of 70°00′ N lat. in Nantucket Sound (included in the Northern Inshore State Trap/Pot Waters Area) and those waters exempted under paragraph (a)(3) of this section.

(ii) *Year-round area-specific gear or vessel requirements.* No person or vessel may fish with or possess trap/pot gear in the Northern Nearshore Trap/Pot Waters Area unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) of this section, or unless the gear is stowed as specified in § 229.2.

(11) *Southern Nearshore*[3] *Trap/Pot Waters Area*—(i) *Area.* The Southern Nearshore Trap/Pot Waters Area includes all State and Federal waters that fall within EEZ Nearshore Management Area 4, EEZ Nearshore Management Area 5, and EEZ Nearshore Management Area 6 (as defined in the American Lobster Fishery regulations in § 697.18 of this title, and excluding the Area ⅗ Overlap), and inside the 100-fathom (600-ft or 182.9-m) depth contour line from 35°30′ N lat. south to 27°51′ N lat. and extending inshore to the shoreline or exemption line, with the exception of those waters exempted under paragraph (a)(3) of this section and those waters in the Southeast Restricted Area defined in paragraph (f)(1) of this section.

(ii) *Year-round area-specific gear or vessel requirements.* No person or vessel may fish with or possess trap/pot gear in the Southern Nearshore Trap/Pot Waters Area that is east of a straight line from 41°18.2′ N lat., 71°51.5′ W long. (Watch Hill Point, RI) south to 40°00′ N

[2] Fishermen using red crab trap/pot gear should refer to paragraph (c)(12) of this section for the restrictions applicable to the red crab trap/pot fishery.

[3] Fishermen using red crab trap/pot gear should refer to paragraph (c)(12) of this section for the restrictions applicable to the red crab trap/pot fishery.

lat., unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(iii) *Seasonal area-specific gear or vessel requirements.* From September 1 to May 31, no person or vessel may fish with or possess trap/pot gear in the Southern Nearshore Trap/Pot Waters Area that overlaps an area bounded on the north by a straight line from 41°18.2′ N lat., 71°51.5′ W long. (Watch Hill Point, RI) south to 40°00′ N lat. and then east to the eastern edge of the EEZ, and bounded on the south by 32°00′ N lat., and east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(iv) *Seasonal area-specific gear or vessel requirements.* From November 15 to April 15, no person or vessel may fish with or possess trap/pot gear in the Southern Nearshore Trap/Pot Waters Area that overlaps an area from 32°00′ N lat. south to 29°00′ N lat. and east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(v) *Seasonal area-specific gear or vessel requirements.* From December 1 to March 31, no person or vessel may fish with or possess trap/pot gear in the Southern Nearshore Trap/Pot Waters Area that overlaps an area from 29°00′ N lat. south to 27°51′ N lat. and east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(vi) [Reserved]

(12) *Restrictions applicable to the red crab trap/pot fishery*—(i) *Area.* The red crab trap/pot fishery is regulated in the waters identified in paragraphs (c)(6)(i) and (c)(9)(i) of this section.

(ii) *Year-round area-specific gear or vessel requirements.* No person or vessel may fish with or possess red crab trap/pot gear in the area identified in paragraph (c)(12)(i) of this section that overlaps an area from the U.S./Canada border south to a straight line from 41° 18.2′ N lat., 71°51.5′ W long. (Watch Hill Point, RI) south to 40°00′ N lat., and then east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(iii) *Seasonal area-specific gear or vessel requirements.* From September 1 to May 31, no person or vessel may fish with or possess red crab trap/pot gear in the area identified in paragraph (c)(12)(i) of this section that overlaps an area bounded on the north by a straight line from 41°18.2′ N lat., 71°51.5′ W long. (Watch Hill Point, RI) south to 40°00′ N lat. and then east to the eastern edge of the EEZ, and bounded on the south by a line at 32°00′ N lat., and east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(iv) *Seasonal area-specific gear or vessel requirements.* From November 15 to April 15, no person or vessel may fish with or possess red crab trap/pot gear in the area identified in paragraph (c)(12)(i) of this section that overlaps an area from 32°00′ N lat. south to 29°00′ N lat. and east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(v) *Seasonal area-specific gear or vessel requirements.* From December 1 to March 31, no person or vessel may fish with or possess red crab trap/pot gear in the area identified in paragraph (c)(12)(i) of this section that overlaps an area from 29°00′ N lat. south to 27°51′ N lat. and east to the eastern edge of the EEZ, unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, the area-specific requirements in paragraph (c)(2) of this section or unless the gear is stowed as specified in § 229.2.

(vi) [Reserved]

PART 697—ATLANTIC COASTAL FISHERIES COOPERATIVE MANAGEMENT

■ 4. The authority citation for 50 CFR part 697 continues to read as follows:

Authority: 16 U.S.C. 5101 *et seq.*

■ 5. In § 697.21, revise paragraph (b)(3) to read as follows:

§ 697.21 Gear identification and marking, escape vent, maximum trap size, and ghost panel requirements.

* * * * *

(b) * * *

(3) No American lobster trap trawl shall exceed 1.5 nautical miles (2.78 km) in length, as measured from radar reflector to radar reflector, except in the EEZ Offshore Management Area 3 where the maximum length of a lobster trap trawl shall not exceed 1.75 nautical miles (3.24 km).

* * * * *

[FR Doc. 2020–28775 Filed 12–30–20; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 85, No. 251

Thursday, December 31, 2020

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

Food and Nutrition Service

Summer Food Service Program; 2021 Reimbursement Rates

AGENCY: Food and Nutrition Service, Department of Agriculture (USDA).

ACTION: Notice.

SUMMARY: This notice informs the public of the annual adjustments to the reimbursement rates for meals served in the Summer Food Service Program for Children. These adjustments address changes in the Consumer Price Index, as required under the Richard B. Russell National School Lunch Act. The 2021 reimbursement rates are presented as a combined set of rates to highlight simplified cost accounting procedures. The 2021 rates are also presented individually, as separate operating and administrative rates of reimbursement, to show the effect of the Consumer Price Index adjustment on each rate.

DATES: Implemented January 1, 2021.

FOR FURTHER INFORMATION CONTACT: J. Kevin Maskornick, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, United States Department of Agriculture, 1320 Braddock Place, Suite 401, Alexandria, Virginia 22314, 703–305–2537.

SUPPLEMENTARY INFORMATION: The Summer Food Service Program (SFSP) is listed in the Catalog of Federal Domestic Assistance under No. 10.559 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR part 415 and final rule-related notice published at 48 FR 29114, June 24, 1983.)

In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520, no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

This notice is not a rule as defined by the Regulatory Flexibility Act, 5 U.S.C. 601–612, and thus is exempt from the provisions of that Act. Additionally, this notice has been determined to be exempt from formal review by the Office of Management and Budget under Executive Order 12866.

Definitions

The terms used in this notice have the meaning ascribed to them under 7 CFR part 225 of the SFSP regulations.

Background

This notice informs the public of the annual adjustments to the reimbursement rates for meals served in SFSP. In accordance with sections 12(f) and 13, 42 U.S.C. 1760(f) and 1761, of the Richard B. Russell National School Lunch Act (NSLA) and SFSP regulations under 7 CFR part 225, the United States Department of Agriculture announces the adjustments in SFSP payments for meals served to participating children during calendar year 2021.

The 2021 reimbursement rates are presented as a combined set of rates to highlight simplified cost accounting procedures. Reimbursement is based solely on a ''meals times rates'' calculation, without comparison to actual or budgeted costs.

Sponsors receive reimbursement that is determined by the number of reimbursable meals served, multiplied by the combined rates for food service operations and administration. However, the combined rate is based on separate operating and administrative rates of reimbursement, each of which is adjusted differently for inflation.

Calculation of Rates

The combined rates are constructed from individually authorized operating and administrative reimbursements. Simplified procedures provide flexibility, enabling sponsors to manage their reimbursements to pay for any allowable cost, regardless of the cost category. Sponsors remain responsible, however, for ensuring proper administration of the Program, while providing the best possible nutrition benefit to children.

The operating and administrative rates are calculated separately. However, the calculations of adjustments for both cost categories are based on the same set of changes in the *Food Away From Home* series of the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics of the United States Department of Labor. They represent a 3.8 percent increase in this series for the 12-month period, from November 2019 through November 2020 (from 287.255 in November 2019 to 298.253 in November 2020).

Table of 2021 Reimbursement Rates

Presentation of the 2021 maximum per meal rates for meals served to children in SFSP combines the results from the calculations of operational and administrative payments, which are further explained in this notice. The total amount of payments to State agencies for disbursement to SFSP sponsors will be based upon these adjusted combined rates and the number of meals of each type served. These adjusted rates will be in effect from January 1, 2021 through December 31, 2021.

These changes are reflected below.

All States except Alaska and Hawaii—Rural or Self-prep Sites—Breakfast—2 dollars and 46.25 cents (8.75 cent increase from the 2020 reimbursement rate), Lunch or Supper—4 dollars and 31.75 cents (16.5 cent increase), Snack—1 dollar and 2 cents (4.25 cent increase); All Other Types of Sites—Breakfast—2 dollars and 41.5 cents (8.5 cent increase), Lunch or Supper—4 dollars and 25 cents (16.25 cent increase), Snack—99.75 cents (4.25 cent increase).

Alaska—Rural or Self-prep Sites—Breakfast—3 dollars and 99 cents (14.25 cent increase), Lunch or Supper—6 dollars and 99.25 cents (25.5 cent increase), Snack—1 dollar and 65 cents (5.75 cent increase); All Other Types of Sites—Breakfast—3 dollars and 91.5 cents (14 cent increase), Lunch or Supper—6 dollars and 88 cents (25 cent increase), Snack—1 dollar and 61.25 cents (5.5 cent increase).

Hawaii—Rural or Self-prep Sites—Breakfast—2 dollars and 88 cents (11 cent increase), Lunch or Supper—5 dollars and 4.75 cents (18.75 cent increase), Snack—1 dollar and 19 cents (4.5 cent increase); All Other Types of Sites—Breakfast—2 dollars and 82.5 cents (10.75 cent increase), Lunch or Supper—4 dollars and 96.75 cents (18.5 cent increase), Snack—1 dollar and 16.25 cents (4.25 cent increase).

2021 REIMBURSEMENT RATES (COMBINED)

Per meal rates in whole or fractions of U.S. dollars	All States except Alaska and Hawaii		Alaska		Hawaii	
Site types	Rural or self-prep sites	All other types of sites	Rural or self-prep sites	All other types of sites	Rural or self-prep sites	All other types of sites
Breakfast	2.4625	2.4150	3.9900	3.9150	2.8800	2.8250
Lunch or Supper	4.3175	4.2500	6.9925	6.8800	5.0475	4.9675
Snack	1.0200	0.9975	1.6500	1.6125	1.1900	1.1625

Operating Rates

The portion of the SFSP rates for operating costs is based on payment amounts set in section 13(b)(1) of the NSLA, 42 U.S.C. 1761(b)(1). They are rounded down to the nearest whole cent, as required by section 11(a)(3)(B)(iii) of the NSLA, 42 U.S.C. 1759a(a)(3)(B)(iii).

These changes are reflected below.

All States except Alaska and Hawaii—Breakfast—2 dollars and 24 cents (8 cents increase from the 2020 reimbursement rate), Lunch or Supper—3 dollars and 91 cents (15 cents increase), Snack—91 cents (4 cents increase).

Alaska—Breakfast—3 dollars and 63 cents (13 cents increase), Lunch or Supper—6 dollars and 33 cents (23 cents increase), Snack—1 dollar and 47 cents (5 cents increase).

Hawaii—Breakfast—2 dollars and 62 cents (10 cents increase), Lunch or Supper—4 dollars and 57 cents (17 cents increase), Snack—1 dollar and 6 cents (4 cents increase).

OPERATING COMPONENT OF 2021 REIMBURSEMENT RATES

Operating rates in U.S. dollars, rounded down to the nearest whole cent	All States except Alaska and Hawaii	Alaska	Hawaii
Breakfast	2.24	3.63	2.62
Lunch or Supper	3.91	6.33	4.57
Snack	0.91	1.47	1.06

Administrative Rates

The administrative cost component of the reimbursement is authorized under section 13(b)(3) of the NSLA, 42 U.S.C. 1761(b)(3). Rates are higher for sponsors of sites located in rural areas and for ''self-prep'' sponsors that prepare their own meals at the SFSP site or at a central facility instead of purchasing them from vendors. The administrative portion of SFSP rates are adjusted, either up or down, to the nearest quarter-cent.

These changes are reflected below.

All States except Alaska and Hawaii—Rural or Self-prep Sites—Breakfast—22.25 cents (0.75 cent increase from the 2020 reimbursement rate), Lunch or Supper—40.75 cents (1.5 cent increase), Snack—11 cents (0.25 cent increase); All Other Types of Sites—Breakfast—17.5 cents (0.5 cent increase), Lunch or Supper—34 cents (1.25 cent increase), Snack 8.75 cents (0.25 cent increase).

Alaska—Rural or Self-prep Sites—Breakfast—36 cents (1.25 cent increase), Lunch or Supper—66.25 cents (2.5 cent increase), Snack—18 cents (0.75 cent increase); All Other Types of Sites—Breakfast—28.5 cents (1 cent increase), Lunch or Supper—55 cents (2 cent increase), Snack—14.25 cents (0.5 cent increase).

Hawaii—Rural or Self-prep Sites—Breakfast—26 cents (1 cent increase), Lunch or Supper—47.75 cents (1.75 cent increase), Snack—13 cents (0.5 cent increase); All Other Types of Sites—Breakfast—20.5 cents (0.75 cent increase), Lunch or Supper—39.75 cents (1.5 cent increase), Snack—10.25 cents (0.25 cent increase).

ADMINISTRATIVE COMPONENT OF 2021 REIMBURSEMENT RATES

Administrative rates in U.S. dollars, adjusted, up or down, to the nearest quarter-cent	All States except Alaska and Hawaii		Alaska		Hawaii	
Site types	Rural or self-prep sites	All other types of sites	Rural or self-prep sites	All other types of sites	Rural or self-prep sites	All other types of sites
Breakfast	0.2225	0.1750	0.3600	0.2850	0.2600	0.2050
Lunch or Supper	0.4075	0.3400	0.6625	0.5500	0.4775	0.3975
Snack	0.1100	0.0875	0.1800	0.1425	0.1300	0.1025

Authority: Sections 9, 13, and 14, Richard B. Russell National School Lunch Act, 42 U.S.C. 1758, 1761, and 1762a, respectively.

Pamilyn Miller,

Administrator, USDA Food and Nutrition Service.

[FR Doc. 2020–29093 Filed 12–30–20; 8:45 am]

BILLING CODE 3410–30–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the New Jersey Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the New Jersey Advisory Committee to the Commission will convene by conference call, on Friday, January 22, 2021 at 1:00

p.m. (ET). The purpose of the meeting is continued project about civil rights project on the collateral consequences that a criminal record has on criminal asset forfeitures and access to employment, especially occupational licensing.

DATES: Friday, January 22, 2021, at 1:00 p.m. (ET).

Public Call-In Information: Conference call number: 1–800–667–5617 and conference call ID number: 7386659.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call number: 1–800–667–5617 and conference call ID number: 7386659. Please be advised that before placing them into the conference call, the conference call operator may ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number herein.

Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Federal Relay Service operator with the conference call-in numbers: 1–800–667–5617and conference call ID number: 7386659.

Members of the public are invited to make statements during the Public Comment section of the meeting or to submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be emailed to the Eastern Regional Office, Ivy Davis at *ero@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing, as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or contact the Eastern Regional Office at the above email address.

Agenda: Friday, January 22, 2021 at 1:00 p.m. (ET)

I. Roll Call
II. Welcome
III. Project Planning
IV. Other Business
V. Next Meeting
VI. Public Comments
VII. Adjourn

Dated: December 23, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–28908 Filed 12–30–20; 8:45 am]

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DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2109]

Production Authority Not Approved, Foreign-Trade Zone 8, Arbor Foods Inc. (Blended Syrup), Toledo, Ohio

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Toledo-Lucas County Port Authority, grantee of FTZ 8, has requested production authority on behalf of Arbor Foods Inc. (Arbor), within FTZ 8 in Toledo, Ohio (B–63–2019, docketed October 10, 2019);

Whereas, notice inviting public comment has been given in the **Federal Register** (84 FR 55549, October 17, 2019) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the finding and recommendation of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations have not been satisfied;

Now, therefore, the Board hereby does not approve the application requesting production authority under zone procedures within FTZ 8 for Arbor, as described in the application and **Federal Register** notice.

Dated: December 28, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2020–28976 Filed 12–30–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 201228–0359]

RIN 0694–XC068

Change in Deadline for Public Comments on Condition of the Public Health Industrial Base and Recommend Policies and Actions To Strengthen the Public Health Industrial Base To Ensure Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States

AGENCY: Bureau of Industry and Security, Office of Technology Evaluation, U.S. Department of Commerce.

ACTIONS: Notice on reopening comment period for previously published notice of request for public comments.

SUMMARY: On December 2, 2020, the Bureau of Industry and Security (BIS) within the Department of Commerce (Commerce), published the *Notice of Request for Public Comments on Condition of the Public Health Industrial Base and Recommend Policies and Actions to Strengthen the Public Health Industrial Base to Ensure Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States.* The December 2 notice invited interested parties to submit written comments, data, analyses, or other information pertinent to the investigation to BIS. The deadline for written comments was December 23, 2020. In response to requests from the public for additional time, this notice reopens the deadline for the submission of public comment until January 15, 2021. Comments previously submitted need not be resubmitted and will be fully considered.

DATES: The comment period for the document published at 85 FR 77428 on December 2, 2020, is reopened. The due date for filing comments is January 15, 2021.

ADDRESSES: *Submissions:* All written comments on the notice must be addressed to PHIB Study and filed through the Federal eRulemaking Portal: *http://www.regulations.gov.* To submit comments via *http://www.regulations.gov,* enter docket number BIS–2020–0034 on the home page and click ''search.'' The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice and click on the link entitled ''Comment Now!'' (For further information on using *http://www.regulations.gov,* please consult the

resources provided on the website by clicking on ''How to Use This Site.'')

FOR FURTHER INFORMATION CONTACT: Jason Bolton at 202–482–5936 or via email *Jason.Bolton@bis.doc.gov; PHIBstudy@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

On December 2, 2020, BIS published the *Notice of Request for Public Comments on Condition of the Public Health Industrial Base and Recommend Policies and Actions to Strengthen the Public Health Industrial Base to Ensure Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States* (85 FR 77428) (December 2 notice). The December 2 notice specified that on August 6, 2020, President Trump issued Executive Order 13944, *Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States* (E.O. 13944). Among other directives, E.O. 13944 directed that, by February 2, 2021, the Secretary of Commerce shall submit a report to the Director of the Office of Management and Budget, the Assistant to the President for National Security Affairs, the Director of the National Economic Council, and the Director of the Office of Trade and Manufacturing Policy, describing any change in the status of the Public Health Industrial Base (PHIB) and recommending initiatives to strengthen the PHIB. The December 2 notice requested comments from the public to assist Commerce in preparing this report on the status and condition of the PHIB and recommending policies and actions to strengthen it. (*See* the December 2 notice for additional details on E.O. 13944 and the request for public comments.)

Change in Public Comment Deadline

The December 2 notice included a comment period deadline of December 23, 2020. Commerce has determined that an extension of the comment period is warranted, following requests from the public on the matter. While comments may be submitted at any time, this notice specifies that comments must be received by January 15, 2021, to be considered in the drafting of the final report. This notice reopens the comment period to allow for additional time for the public to submit comments. Comments previously submitted need not be resubmitted and will be fully considered.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–29036 Filed 12–29–20; 4:15 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–946]

Final Results of Expedited Sunset Review of Countervailing Duty Order: Prestressed Concrete Steel Wire Strand From the People's Republic of China

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

SUMMARY: As a result of this second sunset review, the Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on prestressed concrete steel wire strand (PC strand) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of a countervailable subsidy at the level indicated in the ''Final Results of Review'' section of this notice.

DATES: Applicable December 31, 2020.

FOR FURTHER INFORMATION CONTACT: John Hoffner, 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) 482–3315.

SUPPLEMENTARY INFORMATION:

Background

On September 1, 2020, Commerce initiated a second sunset review of the *Order* [1] pursuant to section 751(c)(2) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.218(c).[2] On September 14, 2020, Commerce received a timely notification of intent to participate from Insteel Wire Products Company, Sumiden Wire Products Corporation, and Wire Mesh Corporation (collectively, domestic parties or the petitioners), filed in accordance with 19 CFR 351.218(d)(1)(i).[3] On September 30, 2020, Commerce received a substantive response from the petitioners, timely filed in accordance with 19 CFR 351.218(d)(3)(i).[4] Commerce did not receive a substantive response from the Government of China (GOC) or company respondent interested parties.

Pursuant to 19 CFR 351.218(e)(1)(ii)(C)(2) and section 751(c)(3)(B) of the Act, when there are inadequate responses from respondent interested parties, Commerce will conduct an expedited sunset review and, not later than 120 days after the date of publication in the **Federal Register** of the notice of initiation, issue final results of review based on the facts available. Commerce did not receive a substantive response from the GOC or any Chinese producers or exporters. Accordingly, we conducted an expedited (120-day) sunset review of the *Order.*[5]

Scope of the Order

The scope of the *Order* is PC strand. PC strand is steel wire strand, other than of stainless steel, which is suitable for use in, but not limited to, pre-stressed concrete (both pre-tensioned and post-tensioned) applications. The scope of the *Order* encompasses all types and diameters of PC strand whether uncoated (uncovered) or coated (covered) by any substance, including but not limited to, grease, plastic sheath, or epoxy. This merchandise includes, but is not limited to, PC strand produced to the American Society for Testing and Materials (ASTM) A–416 specification, or comparable domestic or foreign specifications. PC strand made from galvanized wire is excluded from the scope if the zinc and/or zinc oxide coating meets or exceeds the 0.40 oz./ft^2 standard set forth in ASTM–A–475.

The PC strand subject to the *Order* is currently classifiable under subheadings 7312.10.3010 and 7312.10.3012 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the *Order* is dispositive.

Analysis of Comments Received

All issues raised in this review are addressed in the accompanying Issues and Decision Memorandum, which is

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[1] *See Pre-Stressed Concrete Steel Wire Strand from the People's Republic of China: Notice of Amended Final Affirmative Countervailing Duty Determination and Notice of Countervailing Duty Order,* 75 FR 38977 (July 7, 2010) (*Order*).

[2] *See Initiation of Five-Year ''Sunset'' Review,* 85 FR 54343 (September 1, 2020).

[3] *See* Domestic Parties' Letter, ''Prestressed Concrete Steel Wire Strand from the People's Republic of China—Domestic Industry's Notice of Intent to Participate,'' dated September 14, 2020.

[4] *See* Domestic Parties' Letter, ''Prestressed Concrete Steel Wire Strand from the People's Republic of China—Domestic Industry's Substantive Response,'' dated September 30, 2020.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on September 1, 2020,'' dated October 27, 2020.

hereby adopted by this notice.[6] 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.* A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. In addition, a complete version of the Issues and Decision Memorandum can be accessed at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Issues and Decision Memorandum are identical in content.

Final Results of Review

Pursuant to sections 752(b)(1) and (3) of the Act, Commerce finds that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies, at the following rates:

Producer/exporter	Net subsidy rate
Fasten Group Corporation (Fasten Corp.), Fasten Group Import & Export Co., Ltd. (Fasten I&E), Jiangyin Hongsheng Co. Ltd. (Hongsheng), Jiangyin Fasten Steel Products Co., Ltd. (Fasten Steel), Jiangyin Hongyu Metal Products Co., Ltd. (Hongyu Metal), and Jiangyin Walsin Steel Cable Co., Ltd. (Walsin) (Collectively, the Fasten Companies).	9.42 percent *ad valorem.*
Xinhua Metal Products Company Ltd. (Xinhua), Xinyu Iron and Steel Joint Stock Limited Company (Xinyu), and Xingang Iron and Steel Joint Stock Limited Liability Company (Xingang) (Collectively the Xinhua Companies).	45.85 percent *ad valorem.*
All Others	27.64 percent *ad valorem.*

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to 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. Timely notification of return/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 the results and notice in accordance with sections 751(c), 752, and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: December 28, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

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

[FR Doc. 2020–28984 Filed 12–30–20; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Second Sunset Review of the Countervailing Duty Order on Prestressed Concrete Steel Wire Strand from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–900]

Diamond Sawblades and Parts Thereof From the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review

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

SUMMARY: On November 20, 2020, the Department of Commerce (Commerce) published the initiation and preliminary results of a changed circumstances review (CCR) of the antidumping duty order on diamond sawblades and parts thereof (diamond sawblades) from the People's Republic of China (China). For these final results, Commerce continues to find that Protech Diamond Tools Inc. (Protech) and Gogo International Inc. (Gogo) are affiliated. Additionally, Commerce continues to find that Protech is eligible to participate in a certification process because Protech has demonstrated that it can identify diamond sawblades that it produced in Canada using non-Chinese cores and Chinese segments.

DATES: Applicable December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Michael A. Romani, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9180.

SUPPLEMENTARY INFORMATION:

Background

On February 20, 2020, Commerce found ''that diamond sawblades made with Chinese cores and Chinese segments joined in Canada by Protech and then subsequently exported from Canada to the United States are circumventing the antidumping duty order on diamond sawblades from China.'' [1] In the *Final Determination,* Commerce found that diamond sawblades ''assembled or completed in Canada using non-Chinese origin cores and/or non-Chinese origin segments are not subject to this anti-circumvention inquiry.'' However, because Protech was unable ''to identify diamond sawblades produced with non-Chinese origin cores and/or non-Chinese origin segments,'' Commerce decided not to ''implement a certification process for diamond sawblades already suspended,'' and required ''cash deposits on all entries of diamond sawblades produced and exported by Protech in Canada.'' [2] We indicated that Protech could, at some future point request reconsideration of Commerce's denial of the certification process in, *e.g.,* a CCR.[3]

On August 19, 2020, Protech submitted a request for a CCR, in which Protech claimed that it is able to identify and segregate diamond sawblades made with non-Chinese cores and Chinese segments joined in Canada by Protech and then subsequently

[1] *See Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Determination of Anti-Circumvention Inquiry,* 85 FR 9737, 9738 (February 20, 2020) (*Final Determination*); *see also Diamond Sawblades and Parts Thereof from the People's Republic of China and the Republic of Korea: Antidumping Duty Orders,* 74 FR 57145 (November 4, 2009).

[2] *See Final Determination,* 85 FR at 9739.

[3] *Id.*

exported from Canada by Protech, its affiliate Gogo, or a third party, to the United States.[4] Protech requested that Commerce find it eligible for certification of these diamond sawblades as non-subject merchandise. On August 26, 2020, the Diamond Sawblades Manufacturers' Coalition (DSMC) submitted a letter supporting the CCR Request.[5] In response to our request for additional information, Protech submitted its supplemental responses on September 15, 2020,[6] and October 1, 2020.[7]

Commerce preliminarily determined that Protech is able to track and certify the country of origin of the diamond sawblade cores used in the production of diamond sawblades produced at its facility in Canada. Commerce further determined that diamond sawblades produced in Canada by Protech, using Chinese cores and Chinese segments, and exported by Protech or its affiliate, Gogo, to the United States are subject to the antidumping duty order on diamond sawblades from China.[8]

No party commented on the *Initiation and Preliminary Results* regarding Commerce's analysis of Protech's practices to track the country of origin of the cores it uses to produce diamond sawblades which are exported to the United States, the determination that Protech and Gogo are affiliated, the sufficiency of the certification process, or the certification language.

Scope of the Order

The products covered by the order are all finished circular sawblades, whether slotted or not, with a working part that is comprised of a diamond segment or segments, and parts thereof, regardless of specification or size, except as specifically excluded below. Within the scope of the order are semi-finished diamond sawblades, including diamond sawblade cores and diamond sawblade segments. Diamond sawblade cores are circular steel plates, whether or not attached to non-steel plates, with slots. Diamond sawblade cores are manufactured principally, but not exclusively, from alloy steel. A diamond sawblade segment consists of a mixture of diamonds (whether natural or synthetic, and regardless of the quantity of diamonds) and metal powders (including, but not limited to, iron, cobalt, nickel, tungsten carbide) that are formed together into a solid shape (from generally, but not limited to, a heating and pressing process).

Sawblades with diamonds directly attached to the core with a resin or electroplated bond, which thereby do not contain a diamond segment, are not included within the scope of the order. Diamond sawblades and/or sawblade cores with a thickness of less than 0.025 inches, or with a thickness greater than 1.1 inches, are excluded from the scope of the order. Circular steel plates that have a cutting edge of non-diamond material, such as external teeth that protrude from the outer diameter of the plate, whether or not finished, are excluded from the scope of the order. Diamond sawblade cores with a Rockwell C hardness of less than 25 are excluded from the scope of the order. Diamond sawblades and/or diamond segment(s) with diamonds that predominantly have a mesh size number greater than 240 (such as 250 or 260) are excluded from the scope of the order.

Merchandise subject to the order is typically imported under heading 8202.39.00.00 of the Harmonized Tariff Schedule of the United States (HTSUS). When packaged together as a set for retail sale with an item that is separately classified under headings 8202 to 8205 of the HTSUS, diamond sawblades or parts thereof may be imported under heading 8206.00.00.00 of the HTSUS. On October 11, 2011, Commerce included the 6804.21.00.00 HTSUS classification number to the customs case reference file, pursuant to a request by U.S. Customs and Border Protection (CBP).[9] Pursuant to requests by CBP, Commerce included to the customs case reference file the following HTSUS classification numbers: 8202.39.0040 and 8202.39.0070 on January 22, 2015, and 6804.21.0010 and 6804.21.0080 on January 26, 2015.[10]

The tariff classification is provided for convenience and customs purposes; however, the written description of the scope of the order is dispositive.

Final Results of Changed Circumstances Review

Commerce is conducting this CCR in accordance with sections 751(b)(1) and 777(i) of the Act and 19 CFR 351.216. For the reasons stated in the *Initiation and Preliminary Results,* and because we received no comments from interested parties, Commerce continues to find that, since the publication of the *Final Determination,* Protech has demonstrated in its CCR request and supplemental responses that it is able to identify and segregate diamond sawblades produced in Canada by Protech, using non-Chinese cores and Chinese segments and exported to the United States. Based on information provided by Protech, we also continue to find that Protech and Gogo are affiliated, in accordance with section 771(33)(F) of the Act and 19 CFR 351.102(b)(3).[11] Therefore, we continue to find that diamond sawblades produced in Canada by Protech using Chinese cores and Chinese segments and exported by Gogo to the United States are subject to the antidumping duty order on diamond sawblades from China.

Accordingly, effective on the publication date of these final results, Protech, Gogo and their importers will be eligible, where appropriate, to certify that the diamond sawblades produced in Canada by Protech and exported by either Protech or Gogo were produced using non-Chinese cores and Chinese segments. Attached as an appendix to this notice is the final certification language. Commerce also determines, based on the request in this CCR, that no other exporters are eligible for this certification process.[12]

Suspension of Liquidation and Certification Requirements

In accordance with 19 CFR 351.225(l)(3), the suspension of liquidation instructions will remain in effect until further notice. Commerce will direct CBP to suspend liquidation and to require a cash deposit of

[4] *See* Protech's Letters, ''Request for Changed Circumstances Review,'' dated August 19, 2020 (CCR Request) at 1–2; *see also* ''Response of Protech Diamond Tools Inc. to the Department's September 1, 2020, Supplemental Questionnaire'' dated September 15, 2020 (Protech's First Supplemental Response) at 1.

[5] *See* DSMC's Letter, ''Comments in Support of Protech's Request for Changed Circumstances Review,'' dated August 26, 2020. DSMC is the petitioner in this proceeding.

[6] *See* Protech's First Supplemental Response.

[7] *See* Protech's Letter, ''Response of Protech Diamond Tools Inc. to the Department's September 28, 2020, Second Supplemental Questionnaire,'' dated October 1, 2020.

[8] *See Diamond Sawblades and Parts Thereof from the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 85 FR 74315 (November 20, 2020) (*Initiation and Preliminary Results*).

[9] *See Diamond Sawblades and Parts Thereof from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 76128 (December 6, 2011).

[10] *See Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 64331 (December 14, 2018), and accompanying Issues and Decision Memorandum at 3.

[11] *See* Memorandum, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: Affiliation of Protech Diamond Tools Inc. and Gogo International Inc.'' dated November 17, 2020, for details containing Protech's business proprietary information.

[12] The circumvention determination covered diamond sawblades produced in Canada by Protech with Chinese cores and Chinese segments and exported by Protech. *See Final Determination,* 85 FR at 9738. Other exporters are not covered by the circumvention determination.

estimated duties on unliquidated entries of diamond sawblades produced (*i.e.,* assembled or completed) using Chinese cores and Chinese segments by Protech in Canada and exported by Gogo that were entered, or withdrawn from warehouse, for consumption on or after November 20, 2020, the date of initiation of the CCR.[13]

Diamond sawblades produced by Protech in Canada using non-Chinese cores and Chinese segments and exported from Canada by either Protech or Gogo are not subject to the antidumping duty order on diamond sawblades from China. However, imports of such merchandise are subject to certification requirements, and cash deposits may be required if the certification requirements are not satisfied. Accordingly, if an importer imports finished diamond sawblades produced in Canada by Protech and exported from Canada by either Protech or Gogo and claims that the finished diamond sawblades were produced from non-Chinese cores and Chinese segments, in order not to be subject to cash deposit requirements, the importer and exporter are required to meet the certification and documentation requirements described herein and in the certifications contained in the appendix to this notice. Where no certification is provided for an entry of diamond sawblades produced by Protech in Canada and exported by Protech or Gogo to the United States, and the antidumping duty order on diamond sawblades from China potentially applies to that entry, Commerce intends to instruct CBP to suspend the entry and collect cash deposits at the China-wide rate of 82.05 percent of the entered value of the merchandise.[14] For shipments and/or entry summaries made on or after the date of publication of the initiation of the CCR through 30 days after the date of publication of the final results of CCR for which certifications are required, importers and exporters should complete the required certification within 30 days after the publication of the final results of this CCR in the **Federal Register**. Accordingly, where appropriate, the relevant bullet in the certification should be edited to reflect that the certification was completed within the time frame specified above. For such entries/shipments, importers and exporters each have the option to complete a blanket certification covering multiple entries/shipments, individual certifications for each entry/shipment, or a combination thereof. For shipments and/or entries made on or after 31 days after the date of publication of the final results of this CCR in the **Federal Register**, for which certifications are required, importers should complete the required certification at or prior to the date of entry summary, and exporters should complete the required certification and provide it to the importer at or prior to the date of shipment.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(b)(1) and 777(i) of the Act, and 19 CFR 351.216 and 351.222.

Dated: December 28, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

Exporter Certification

Special Instructions: The party that made the sale to the United States should fill out the exporter certification. Only Protech Diamond Tools Inc., and Gogo International Inc., are eligible for this certification process.

I hereby certify that:

(A) My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF EXPORTING COMPANY}, located at {ADDRESS};

(B) I have direct personal knowledge of the facts regarding the production and exportation of the finished diamond sawblades identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own books and records. For example, an exporter should have direct personal knowledge of the producer's identity and location.

(C) Finished diamond sawblades produced in Canada and covered by this certification were not manufactured using cores produced in China.

(D) This certification applies to the following sales to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}. (repeat this block as many times as necessary):

Foreign Seller's Invoice # to U.S. Customer:

Foreign Seller's Invoice to U.S. Customer Line item #:

Producer Name: Protech Diamond Tools Inc.

Producer's Address: Unit 105, 1626 –115 Avenue NE, Calgary, Alberta, Canada T3K 2E4

Producer's Invoice # to Foreign Seller: (If the foreign seller and the producer are the same party, put NA here.)

(E) The finished diamond sawblades covered by this certification were shipped to {NAME OF U.S. PARTY TO WHOM MERCHANDISE WAS SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

(F) I understand that {NAME OF EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, *etc.*) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries.

(G) I understand that {NAME OF EXPORTING COMPANY} must provide a copy of this Exporter Certification to the U.S. importer by the date of shipment.

(H) I understand that {NAME OF EXPORTING COMPANY} is required to provide a copy of this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce).

(I) I understand that the claims made herein, and the substantiating documentation are subject to verification by CBP and/or Commerce.

(J) I understand that failure to maintain the required certification and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all sales to which this certification applies are within the scope of the antidumping duty order on diamond sawblades and parts thereof from the People's Republic of China. I understand that such finding will result in:

(i) suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and

(ii) the requirement that the importer post applicable antidumping duty cash deposits (as appropriate) equal to the rates as determined by Commerce; and

(iii) the revocation of {NAME OF EXPORTING COMPANY}'s privilege to certify future exports of finished diamond sawblades from Canada as not manufactured using cores from China.

(K) This certification was completed at or prior to the date of shipment;

(L) I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

NAME OF COMPANY OFFICIAL
TITLE
DATE

Importer Certification

I hereby certify that:

(A) My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF IMPORTING COMPANY}, located at {ADRESS OF IMPORTING COMPANY}.

(B) I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of finished diamond sawblades produced in Canada that entered under entry summary

[13] *See Final Determination,* 85 FR at 9739.

[14] *See, e.g., Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 64331, 64332 (December 14, 2018).

number(s) identified below and are covered by this certification. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the importation of the product (*e.g.,* the name of the exporter) in its records.

(C) If the importer is acting on behalf of the first U.S. customer, complete this paragraph, if not put ''NA'' at the end of this paragraph: finished diamond sawblades covered by this certification were imported by {NAME OF IMPORTING COMPANY} on behalf of {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

(D) Finished diamond sawblades covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS FIRST SHIPPED IN THE UNITED STATES}, located at {ADDRESS OF SHIPMENT}.

(E) I have personal knowledge of the facts regarding the production of the finished diamond sawblades identified below. ''Personal knowledge'' includes facts obtained from another party, (*e.g.,* correspondence received by the importer (or exporter) from the producer regarding the country of manufacture of the imported products).

(F) Finished diamond sawblades covered by this certification were not manufactured using cores produced in China.

(G) This certification applies to the following entries (repeat this block as many times as necessary):

Entry Summary #:
Entry Summary Line Item #:
Foreign Seller:
Foreign Seller's Address:
Foreign Seller's Invoice #:
Foreign Seller's Invoice Line Item #:
Producer: Protech Diamond Tools Inc.
Producer's Address: Unit 105, 1626 –115 Avenue NE, Calgary, Alberta, Canada T3K 2E4

(H) I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, *etc.*) for the later of (1) a period of five years from the date of entry, or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries.

(I) I understand that {NAME OF IMPORTING COMPANY} is required to provide this certification and supporting records to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce), upon request by the respective agency.

(J) I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of the exporter's certification (attesting to the production and/or export of the imported merchandise identified above), and any supporting records provided by the exporter to the importer, for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

(K) I understand that {NAME OF IMPORTING COMPANY} is required, upon request, to provide a copy of the exporter's certification and any supporting records provided by the exporter to the importer, to CBP and/or Commerce.

(L) I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

(M) I understand that failure to maintain the required certifications, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all entries to which this certification applies are within the scope of the antidumping duty order on diamond sawblades and parts thereof from the People's Republic of China. I understand that such finding will result in:

(i) suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the requirement that the importer post applicable antidumping duty cash deposits (as appropriate) equal to the rates determined by Commerce; and

(iii) the revocation of {NAME OF IMPORTING COMPANY}'s privilege to certify future imports of diamond sawblades from Canada as not manufactured using cores from China.

(N) I understand that agents of the importer, such as brokers, are not permitted to make this certification. Where a broker or other party was used to facilitate the entry process, {NAME OF IMPORTING COMPANY} obtained the entry summary number and date of entry summary from that party.

(O) This certification was completed at or prior to the date of entry summary.

(P) I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

NAME OF COMPANY OFFICIAL
TITLE
DATE

[FR Doc. 2020–28980 Filed 12–30–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–945]

Prestressed Concrete Steel Wire Strand From the People's Republic of China: Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order

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

SUMMARY: The Department of Commerce (Commerce) finds that revocation of the antidumping duty order on prestressed concrete steel wire strand (PC strand) from the People's Republic of China (China) 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 31, 2020.

FOR FURTHER INFORMATION CONTACT: Emily Halle, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0176.

SUPPLEMENTARY INFORMATION:

Background

On June 29, 2010, the Department of Commerce (Commerce) published the antidumping duty order on PC strand from China.[1] On September 1, 2020, Commerce initiated the second sunset review of the *Order* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On September 14, 2020, Commerce received a notice of intent to participate in this sunset review from Insteel Wire Products Company, Sumiden Wire Products Corporation, and Wire Mesh Corporation (collectively, ''Domestic Industry''), within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The members of the Domestic Industry claimed interested party status under section 771(9)(C) of the Act as producers of the domestic like product in the United States. On September 30, 2020, Commerce received a substantive response from the Domestic Industry within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] Commerce received no substantive responses from respondent interested parties, nor was a hearing requested. On October 27, 2020, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent

[1] *See Notice of Antidumping Duty Order: Prestressed Concrete Steel Wire Strand from the People's Republic of China,* 75 FR 37382 (June 29, 2010) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 54348 (September 1, 2020).

[3] *See* Domestic Industry's Letter, ''Prestressed Concrete Steel Wire Strand from the People's Republic of China—Domestic Industry's Notice of Intent to Participate,'' dated September 14, 2020.

[4] *See* Domestic Industry's Letter, ''Prestressed Concrete Steel Wire Strand from the People's Republic of China—Domestic Industry's Substantive Response,'' dated September 30, 2020.

interested parties.[5] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order.*

Scope of the Order

The product covered by the *Order* is PC strand, produced from wire of non-stainless, non-galvanized steel, which is suitable for use in prestressed concrete (both pretensioned and post-tensioned) applications. The product definition encompasses covered and uncovered strand and all types, grades, and diameters of PC strand. PC strand is normally sold in the United States in sizes ranging from 0.25 inches to 0.70 inches in diameter. PC strand made from galvanized wire is only excluded from the scope if the zinc and/or zinc oxide coating meets or exceeds the 0.40 oz./ft^2 standard set forth in ASTM–A–475. Imports of the subject merchandise are currently classifiable under subheadings 7312.10.3010 and 7312.10.3012 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Analysis of Commerce Received

All issues raised in this review, including the likelihood of continuation or recurrence of dumping in the event of revocation and the magnitude of the margins likely to prevail if the order were revoked, are addressed in the accompanying Issues and Decision Memorandum. A list of topics discussed in the Issues and Decision Memorandum is included 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 *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic version of the Issues and Decision Memorandum are identical in content.

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 antidumping duty order on PC strand from China would likely lead to continuation or recurrence of dumping at the following weighted-average margins and that the margins of dumping likely to prevail would be weighted-average margins of up to 193.55 percent.[6]

Administrative Protective Order (APO)

This notice serves as the only reminder to interested parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: December 28, 2020.

Jeffrey I. Kessler,

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. History of the Order
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margins Likely to Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2020–28979 Filed 12–30–20; 8:45 am]

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[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on September 1, 2020,'' dated October 27, 2020.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order on Prestressed Concrete Steel Wire Strand from the People's Republic of China,'' dated concurrently with this notice.

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Substantive Submissions Made During Prosecution of the Trademark Application

The United States Patent and Trademark Office (USPTO) 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. The USPTO invites comment on this information collection renewal, which helps the USPTO assess the impact of its information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on October 23, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: United States Patent and Trademark Office, Department of Commerce.

Title: Substantive Submissions Made During Prosecution of the Trademark Application

OMB Control Number: 0651–0054.

Forms: (PTO = Patent and Trademark Office)

- *PTO 1553 (Allegation of Use (Statement of Use/Amendment to Allege Use))*
- *PTO 1581 (Request for Extension of Time to File a Statement of Use)*
- *PTO 2194 (Petition to Revive Abandoned Application—Failure to Respond Timely to Office Action)*
- *PTO 2195 (Petition to Revive Abandoned Application—Failure to File Timely Statement of Use or Extension Request)*
- *PTO 2200 (Request to Delete Section 1(b) Basis, Intent to Use)*
- *PTO 2202 (Request for Express Abandonment (Withdrawal) of Application)*
- *PTO 2301 (Petition to Director)*

Type of Review: Extension and revision of a currently approved information collection.

Number of Respondents: 337,382 respondents per year.

Average Hour per Response: The USPTO estimates that it will take the public from approximately 25 minutes (0.4 hours) to 65 minutes (1.1 hours) to complete a response, depending on the complexity of the situation. This

includes the time to gather the necessary information, prepare the appropriate documents, and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 211,639 hours.

Estimated Total Annual Non-Hour Cost Burden: $39,702,140.

Needs and Uses: The United States Patent and Trademark Office administers the Trademark Act, 15 U.S.C. 1051 *et seq.,* which provides for the Federal registration of trademarks, service marks, collective trademarks and service marks, collective membership marks, and certification marks. Individuals and businesses that use or intend to use such marks in commerce may file an application to register their mark with the USPTO. Such individuals and businesses may also submit various communications to the USPTO during the prosecution of an application.

This information collection covers the various communications that may be submitted by the applicant, including providing additional information needed to process a request to delete a particular filing basis from an application or to divide an application identifying multiple goods and/or services into two or more separate applications. This information collection also covers requests for a 6-month extension of time to file a statement that the mark is in use in commerce or petitions to revive an application that abandoned for failure to submit a timely response to an office action or a timely statement of use or extension request. In some circumstances, an applicant may expressly abandon an application by filing a written request for withdrawal of the application.

The USPTO amended its regulations to set, increase, or decrease certain trademark fees, to become effective January 2, 2021, including the fees in this information collection.

Affected Public: Private sector; individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce, USPTO information collections currently under review by OMB.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 0651–0054.

Further information can be obtained by:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0054 information request'' in the subject line of the message.
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–28991 Filed 12–30–20; 8:45 am]

BILLING CODE 3510–16–P

COUNCIL ON ENVIRONMENTAL QUALITY

Guiding Principles for Sustainable Federal Buildings and Associated Instructions

AGENCY: Council on Environmental Quality.

ACTION: Notice of availability.

SUMMARY: Consistent with Executive Order, ''Efficient Federal Operations,'' and the ''Implementing Instructions for Executive Order 13834 Efficient Federal Operations,'' the Council on Environmental Quality (CEQ) has issued updated guidance to Federal agencies titled, ''Guiding Principles for Sustainable Federal Buildings and Associated Instructions'' (Guidance).

DATES: CEQ issued the Guiding Principles for Sustainable Federal Buildings and Associated Instructions on December 23, 2020.

ADDRESSES: The Guiding Principles for Sustainable Federal Buildings and Associated Instructions are available at *https://www.sustainability.gov/resources.html.*

FOR FURTHER INFORMATION CONTACT: Dee Siegel, Deputy Chief Sustainability Officer, Office of Federal Sustainability, at *dee_s_siegel@ceq.eop.gov* or (202) 395–5750.

SUPPLEMENTARY INFORMATION: Consistent with Executive Order 13834, ''Efficient Federal Operations,'' [1] and the ''Implementing Instructions for Executive Order 13834 Efficient Federal Operations,'' [2] CEQ has issued Guidance number CEQ–OFS–2020–1 to assist Federal agencies in designing, locating, constructing, maintaining, and operating Federal buildings in a sustainable manner that increases efficiency and optimizes performance, consistent with their missions. The Guidance provides new flexibilities regarding the use of third-party green building certification systems, and provides a consistent government-wide portfolio approach for Federal agencies to design, mitigate, and measure the impact of their buildings. The Guidance replaces and supersedes the following CEQ guidance documents: (1) ''Guiding Principles for Sustainable Federal Buildings and Associated Instructions'' (February 2016); (2) ''Guidance for Federal Agencies on Sustainable Practices for Designed Landscapes'' (October 2011) and addendum titled ''Supporting the Health of Honey Bees and Other Pollinators'' (October 2014); and (3) ''Implementing Instructions—Sustainable Locations for Federal Facilities'' (September 2011). CEQ rescinds these prior guidance documents. The Guidance applies only to Federal agencies, operations, and programs. Agencies are expected to follow the ''Guiding Principles for Sustainable Federal Buildings and Associated Instructions'' as part of their compliance with E.O. 13834.

(Authority: E.O. 13834, 83 FR 23771)

Mary B. Neumayr,

Chairman.

[FR Doc. 2020–28928 Filed 12–30–20; 8:45 am]

BILLING CODE 3225–F1–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket DARS–2020–0047; OMB Control Number 0750–0003]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Requests for Reimbursement Under Section 3610 of the CARES Act

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

[1] 83 FR 23771 (May 22, 2018).

[2] 84 FR 19056 (May 3, 2019), *https://www.sustainability.gov/pdfs/eo13834_instructions.pdf.*

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. *DoD invites comments on:* Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; the accuracy of the 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 the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection requirement for use through February 28, 2021. DoD proposes that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD will consider all comments received by March 1, 2021.

ADDRESSES: You may submit comments, identified by OMB Control Number 0750–0003, using any of the following methods:

○ *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

○ *Email: osd.dfars@mail.mil.* Include OMB Control Number 0750–0003 in the subject line of the message.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Carrie Moore, OUSD(A&S)DPC/DARS, Room 3B938, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Moore, 571–372–6093.

SUPPLEMENTARY INFORMATION:

Title and OMB Control Number: Defense Federal Acquisition Regulation Supplement (DFARS), Requests for Reimbursement under Section 3610 of the CARES Act; OMB Control Number 0750–0003.

Type of Request: Extension of a currently approved collection.

Obligation to Respond: Required to obtain or retain benefits.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Number of Respondents: 16,224.

Responses per Respondent: 1.5 approximately.

Annual Responses: 24,337.

Average Burden per Response: 63 hours approximately.

Annual Burden Hours: 1,523,053.

Reporting Frequency: On Occasion.

Needs and Uses: Section 3610 of the Coronavirus Aid, Relief and Economic Security (CARES) Act (Pub. L. 116–136), enacted on March 27, 2020, authorizes, but does not require, contracting officers to modify contracts and other agreements, without consideration, to reimburse contractors for paid leave a contractor provides to keep its employees or subcontractors in a ready state, including to protect the life and safety of Government and contractor personnel, during the public health emergency declared for Coronavirus Disease (COVID–19).

A contractor request for reimbursement under section 3610 must include sufficient documentation to support the request and enable the contracting officer to determine whether a contractor is eligible for reimbursement under section 3610 and, if so, the amount of reimbursement to provide to a contractor. Contractors' requests for reimbursement under section 3610 will vary in dollar amount and complexity; as such, so will the amount and type of information needed from a contractor to support their reimbursement request. Based on this variation, contracting officers will use one of three DoD reimbursement checklists to advise contractors of the information needed to support their request. The information described in the checklists is necessary to collect from contractors in order to ensure that contracting officers are able to determine whether to approve the request for reimbursement and expediently modify the affected contract(s) for the authorized reimbursement amount.

Section 3610 also requires that any reimbursements made under its authority are reduced by the amount of credit a contractor is allowed under other provisions of the CARES Act and division G of the Families First Coronavirus Response (FFRCA) (Pub. L. 116–127). As the status of such credits may not be known at the time of reimbursement, DFARS clause 252.243–7999, Section 3610 Reimbursement (Deviation 2020–O0021), requires contractors to notify the contracting officer of any credits received after receiving reimbursement under section 3610 and make any repayment, as necessary, to comply with the requirements of section 3610. This information is necessary so that contracting officers may comply with the provisions of section 3610.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2020–28965 Filed 12–30–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2020–0046; OMB Control Number 0704–0214]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement Part 217, Special Contracting Methods, and Related Clauses at 252.217

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. *DoD invites comments on:* Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; the accuracy of the 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 the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection requirement for use through April 30, 2021. DoD proposes that OMB extend its approval for three additional years beyond the current expiration date.

DATES: DoD will consider all comments received by March 1, 2021.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0214, using any of the following methods:

○ *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

○ *Email: osd.dfars@mail.mil.* Include OMB Control Number 0704–0214 in the subject line of the message.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Carrie Moore, OUSD(A&S)DPC(DARS), 3060 Defense Pentagon, Room 3B938, Washington, DC 20301–3060.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Moore, 571–372–6093.

SUPPLEMENTARY INFORMATION:

Title and OMB Control Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 217, Special Contracting Methods, and related clauses at 252.217; OMB Control Number 0704–0214.

Type of Request: Extension.

Obligation to Respond: Required to obtain or retain benefits.

Affected Public: Businesses or other for-profit and not-for- profit institutions.

Number of Respondents: 5,859.

Responses per Respondent: 5.

Annual Responses: 29,295.

Average Burden per Response: 8.

Annual Burden Hours: 234,360.

Reporting Frequency: On occasion.

Needs and Uses: DFARS part 217 prescribes policies and procedures for acquiring supplies and services by special contracting methods. Contracting officers use the required information as follows:

DFARS 217.7004(a)—When solicitations permit the exchange (or trade-in) of personal property and application of the exchange allowance to the acquisition of similar property, offerors must provide the prices for the new items being acquired both with and without any exchange. Contracting officers use the information to make an informed decision regarding the reasonableness of the prices for both the new and trade-in items.

DFARS 217.7404–3(b)—When awarded an undefinitized contract action, contractors are required to submit a qualifying proposal in accordance with the definitization schedule provided in the contract. Contracting officers use this information to complete a meaningful analysis of a contractor's proposal in a timely manner.

DFARS 217.7505(d)—When responding to sole source solicitations that include the acquisition of replenishment parts, offerors submit price and quantity data on any Government orders for the replenishment part(s) issued within the most recent 12 months. Contracting officers use this information to evaluate recent price increases for sole source replenishment parts.

DFARS clause 252.217–7012—Included in master agreements for repair and alteration of vessels, paragraph (d) of the clause requires contractors to show evidence of insurance under the agreement. Contracting officers use this information to ensure contractor is adequately insured when performing work under the agreement. Paragraphs (f) and (g) of the clause require contractors to notify the contracting officer of any property loss or damage for which the Government is liable under the agreement and submit a request, with supporting documentation, for reimbursement of the cost of replacement or repair. Contracting officers use this information to stay informed of lost or damaged property for which the Government is liable, and to determine the appropriate course of action for replacement or repair of the property.

DFARS provision 252.217–7026—Included in certain solicitations for supplies that are being acquired under other than full and open competition, the provision requires the apparently successful offeror to identify their sources of supply so that competition can be enhanced in future acquisitions.

DFARS clause 252.217–7028—When performing under contracts for overhaul, maintenance, and repair, contractors must submit a work request and proposal for ''over and above'' work that is within the scope of the contract, but not covered by the line item(s) under the contract, and necessary in order to satisfactorily complete the contract. This requirement allows the Government to review the need for pending work before the contractor begins performance.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2020–28964 Filed 12–30–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–714–000]

Indiana Crossroads Wind Farm LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Indiana Crossroads Wind Farm LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 12, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call

toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: December 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–28972 Filed 12–30–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–2118–009; ER10–1849–023; ER10–1852–048; ER10–1951–030; ER11–2642–018; ER11–4428–024; ER11–4462–051; ER12–1228–024; ER12–1880–023; ER12–2227–023; ER12–569–024; ER12–895–022; ER13–2474–018; ER13–712–025; ER14–2707–019; ER14–2708–020; ER14–2709–019; ER14–2710–019; ER15–1925–017; ER15–2676–016; ER15–30–017; ER15–58–017; ER16–1440–013; ER16–1672–014; ER16–2190–013; ER16–2191–013; ER16–2240–013; ER16–2241–012; ER16–2275–012; ER16–2276–012; ER16–2297–012; ER16–2453–014; ER17–2152–010; ER17–838–026; ER18–1981–008; ER18–2003–008; ER18–2032–008; ER18–2066–004; ER18–2067–005; ER18–2182–008; ER18–2314–004; ER18–882–009; ER19–1128–002; ER19–2495–004; ER19–2513–004; ER20–637–002.

Applicants: Armadillo Flats Wind Project, LLC, Blackwell Wind, LLC, Brady Interconnection, LLC, Brady Wind, LLC, Brady Wind II, LLC, Breckinridge Wind Project, LLC, Cedar Bluff Wind, LLC, Chaves County Solar, LLC, Cimarron Wind Energy, LLC, Cottonwood Wind Project, LLC, Elk City Wind, LLC, Elk City Renewables II, LLC, Ensign Wind, LLC, Florida Power & Light Company, FPL Energy South Dakota Wind, LLC, High Majestic Wind II, LLC, Kingman Wind Energy I, LLC, Kingman Wind Energy II, LLC, Lorenzo Wind, LLC, Mammoth Plains Wind Project, LLC, Minco Wind II, LLC, Minco Wind III, LLC, Minco Wind Interconnection Services, LLC, Minco Wind IV, LLC, Minco IV & V Interconnection, LLC, Minco Wind V, LLC, Ninnescah Wind Energy, LLC, NEPM II, LLC, NextEra Energy, Marketing, LLC, NextEra Energy Services Massachusetts, LLC, Osborn Wind Energy, LLC, Palo Duro Wind Energy, LLC, Palo Duro Wind Interconnection Services, LLC, Pratt Wind, LLC, Roswell Solar, LLC, Rush Springs Energy Storage, LLC, Rush Springs Wind Energy, LLC, Seiling Wind, LLC, Seiling Wind II, LLC, Seiling Wind Interconnection Services, LLC, Sholes Wind Energy, LLC, Steele Flats Wind Project, LLC, Wessington Springs Wind, LLC, Wildcat Ranch Wind Project, LLC, Wilton Wind Energy I, LLC, Wilton Wind Energy II, LLC.

Description: Notice of Change in Status of NextEra Resources Entities.

Filed Date: 12/21/20.

Accession Number: 20201221–5498.

Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER20–491–003.

Applicants: Lake Lynn Generation, LLC.

Description: Compliance filing: Settlement Compliance Filing to be effective 1/1/2020.

Filed Date: 12/23/20.

Accession Number: 20201223–5033.

Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER20–492–003.

Applicants: York Haven Power Company, LLC.

Description: Compliance filing: Settlement Compliance Filing to be effective 1/1/2020.

Filed Date: 12/23/20.

Accession Number: 20201223–5034.

Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER20–2186–002.

Applicants: Fern Solar LLC.

Description: Compliance filing: compliance to 4 to be effective 12/11/2020.

Filed Date: 12/23/20.

Accession Number: 20201223–5076.

Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–723–000.

Applicants: Red Horse Wind 2, LLC.

Description: Tariff Cancellation: Cancellation of Rate Schedule Tariff to be effective 12/24/2020.

Filed Date: 12/23/20.

Accession Number: 20201223–5016.

Comments Due: 5 p.m. ET 1/4/21.

Docket Numbers: ER21–724–000.

Applicants: Red Horse III, LLC.

Description: Tariff Cancellation: Cancellation of Rate Schedule Tariff to be effective 12/24/2020.

Filed Date: 12/23/20.

Accession Number: 20201223–5017.

Comments Due: 5 p.m. ET 1/4/21.

Docket Numbers: ER21–725–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: WPA For Shelter Cove Resort Improvement District No. 1 WDT SA 382 to be effective 2/22/2021.

Filed Date: 12/23/20.

Accession Number: 20201223–5020.

Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–726–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to OATT Sch. 12-Appendices re: 2021 RTEP Annual Cost Allocations to be effective 1/1/2021.

Filed Date: 12/23/20.

Accession Number: 20201223–5025.

Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–727–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2020–12–23_SA 3422 Termination of ITC-Three Waters Wind Farm Sub GIA (J720) to be effective 2/22/2021.

Filed Date: 12/23/20.

Accession Number: 20201223–5026.

Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–728–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: Certificates of Concurrences ANPP Hassayampa Sun Streams PVS & Sun Streams 4 to be effective 11/1/2020.

Filed Date: 12/23/20.

Accession Number: 20201223–5029.

Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–729–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: E&P Agreement for Caballero CA Storage TO SA 2100 EP–28 to be effective 2/23/2021.

Filed Date: 12/23/20.

Accession Number: 20201223–5035.

Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–730–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: E&P Agreement for Chalan CA Solar Storage SA 2100 EP–29 to be effective 2/23/2021.

Filed Date: 12/23/20.

Accession Number: 20201223–5036.

Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–731–000.

Applicants: Mid-Atlantic Interstate Transmission, LLC, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: MAIT submits Six ECSAs, SA Nos. 5776, 5780, 5781, 5782, 5784, 5785 to be effective 2/22/2021.

Filed Date: 12/23/20.

Accession Number: 20201223–5047.

Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–732–000.

Applicants: American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: ATSI submits ECSA, SA No. 5783 to be effective 2/22/2021.

Filed Date: 12/23/20.
Accession Number: 20201223–5058.
Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–733–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original WMPA SA No. 5874; Queue No AF1–006 to be effective 11/30/2020.
Filed Date: 12/23/20.
Accession Number: 20201223–5059.
Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–734–000.
Applicants: Public Service Company of New Mexico.
Description: § 205(d) Rate Filing: Certificate of Concurrence with APS Rate Schedule Nos. 303 and 304 to be effective 2/1/2021.
Filed Date: 12/23/20.
Accession Number: 20201223–5075.
Comments Due: 5 p.m. ET 1/13/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–28975 Filed 12–30–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL19–80–000]

ITC Great Plains, LLC; Notice of Refund Report

Take notice that on December 18, 2020, ITC Great Plains, LLC, (Petitioner), submitted a Refund Report pursuant to the Federal Energy Regulatory Commission's July 16, 2020 Order.[1]

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on January 8, 2021.

Dated: December 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–28974 Filed 12–30–20; 8:45 am]

BILLING CODE 6717–01–P

[1] *Kansas Corp. Comm'n* v. *ITC Great Plains, LLC, 172FERC 61,037 (2020) (July 16 Order).*

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:

Docket Number: PR21–11–000.
Applicants: Columbia Gas of Ohio, Inc.
Description: Tariff filing per 284.123(b),(e)/: COH Rates effective Nov 25 2020 to be effective 11/25/2020 Filing Type: 980.
Filed Date: 12/22/20.
Accession Number: 202012225073.
Comments Due: 5 p.m. ET 1/12/2021.

Docket Numbers: RP21–326–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Volume No. 2—SWN Energy Services Company, LLC SP102504 to be effective 2/1/2021.
Filed Date: 12/22/20.
Accession Number: 20201222–5009.
Comments Due: 5 p.m. ET 1/4/21.

Docket Numbers: RP21–327–000.
Applicants: Enable Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing—January 1, 2021 SWEPCO 1006349 to be effective 1/1/2021.
Filed Date: 12/22/20.
Accession Number: 20201222–5087.
Comments Due: 5 p.m. ET 1/4/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–28970 Filed 12–30–20; 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 rate filings:

Docket Numbers: ER10–1781–003.
Applicants: Northern Indiana Public Service Company.
Description: Triennial Market Power Analysis for Central Region of Northern Indiana Public Service Company LLC.
Filed Date: 12/21/20.
Accession Number: 20201221–5457.
Comments Due: 5 p.m. ET 2/19/21.

Docket Numbers: ER10–2502–008; ER10–2472–007; ER10–2473–007; ER11–2724–008; ER11–4436–006; ER18–2518–003; ER19–645–002.
Applicants: Black Hills Colorado Electric, LLC, Black Hills Colorado IPP, LLC, Black Hills Colorado Wind, LLC, Black Hills Electric Generation, LLC, Black Hills Power, Inc., Black Hills Wyoming, LLC, Cheyenne Light Fuel & Power Company.
Description: Notice of Non-Material Change in Status of Black Hills Colorado Electric, LLC, et al.
Filed Date: 12/21/20.
Accession Number: 20201221–5451.
Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER10–2739–029; ER10–1859–010; ER10–1872–010; ER10–1892–016; ER12–995–008; ER16–1652–017; ER20–660–004.
Applicants: LS Power Marketing, LLC, Bolt Energy Marketing, LLC, Cherokee County Cogeneration Partners, LLC, Columbia Energy LLC, LifeEnergy, LLC, Mobile Energy, LLC, Santa Rosa Energy Center, LLC.
Description: Triennial Market Power Analysis for Southeast Region of LS Power Development, LLC.
Filed Date: 12/21/20.
Accession Number: 20201221–5453.
Comments Due: 5 p.m. ET 2/19/21.

Docket Numbers: ER10–3125–014; ER10–3100–014; ER10–3102–014; ER10–3107–014; ER15–1447–006; ER15–1657–012.
Applicants: AL Sandersville, LLC, Effingham County Power, LLC, Mid-Georgia Cogen L.P., MPC Generating, LLC, SEPG Energy Marketing Services, LLC, Walton County Power, LLC.
Description: Triennial Market Power Analysis for Southeast Region of AL Sandersville, LLC, et. al.
Filed Date: 12/21/20.
Accession Number: 20201221–5454.
Comments Due: 5 p.m. ET 2/19/21.

Docket Numbers: ER15–2028–010.
Applicants: Southwest Power Pool, Inc.
Description: Compliance filing: Compliance Filing in Response to Order issued in ER15–2028–006 (Corn Belt) to be effective 10/1/2015.
Filed Date: 12/23/20.
Accession Number: 20201223–5015.
Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER16–1275–002; ER16–759–001; ER17–2342–001; ER17–2343–001; ER18–348–001.
Applicants: Innovative Solar 46, LLC, Innovative Solar 43, LLC, Shoe Creek Solar, LLC, Bladen Solar, LLC, Bullock Solar, LLC.
Description: Notice of Non-Material Change in Status of Cypress Creek MBR Sellers.
Filed Date: 12/21/20.
Accession Number: 20201221–5456.
Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER16–1404–006.
Applicants: New York Independent System Operator, Inc.
Description: Compliance filing: Errata filing re: BSM Self Supply Exemption compliance filing to be effective 2/20/2021.
Filed Date: 12/22/20.
Accession Number: 20201222–5117.
Comments Due: 5 p.m. ET 1/12/21.

Docket Numbers: ER18–1077–002; ER13–1430–010; ER13–1561–010; ER15–1218–009; ER16–2501–003; ER16–2502–003; ER16–38–007; ER16–39–006; ER17–2341–003 ER17–2453–003; ER18–1076–002; ER18–713–002.
Applicants: GASNA 36P, LLC, GASNA 6P, LLC, CA Flats Solar 150, LLC, CA Flats Solar 130, LLC, Imperial Valley Solar 3, LLC, Kingbird Solar A, LLC, Kingbird Solar B, LLC, Solar Star California XIII, LLC, Nicolis, LLC, Tropico, LLC, Arlington Valley Solar Energy II, LLC, Centinela Solar Energy, LLC.
Description: Notice of Non-Material Change in Status of GASNA 36P, LLC, et. al.
Filed Date: 12/21/20.
Accession Number: 20201221–5450.
Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER19–2901–005; ER10–1852–047; ER10–1951–029; ER10–1966–015; ER11–4462–050; ER12–2225–014; ER12–2226–014; ER14–2138–011; ER17–838–025; ER18–2091–007; ER19–2389–005; ER20–1417–003.
Applicants: Bronco Plains Wind, LLC, Florida Power & Light Company, Grazing Yak Solar, LLC, Limon Wind, LLC, Limon Wind II, LLC, Limon Wind III, LLC, Logan Wind Energy, LLC, NextEra Energy Marketing, LLC, NextEra Energy Services Massachusetts, LLC, NEPM II, LLC, Roundhouse Renewable Energy, LLC, Titan Solar, LLC.
Description: Notice of Change in Status of NextEra Entities.
Filed Date: 12/21/20.
Accession Number: 20201221–5455.
Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER21–712–000.
Applicants: New England Hydro-Transmission Electric Company, Inc., New England Hydro-Transmission Corporation., New England Electric Transmission Corporation, VERMONT ELECTRIC TRANSMISSION COMPANY, IRH Management Committee.
Description: Pre-Arranged/Pre-Agreed (Settlement and Settlement Agreement) Filing of New England Hydro-Transmission Electric Company, Inc.
Filed Date: 12/18/20.
Accession Number: 20201218–5379.
Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–716–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Correction to Original ISA, SA No. 5692; Queue No. AF1–198 (amend) to be effective 6/30/2020.
Filed Date: 12/22/20.
Accession Number: 20201222–5123.
Comments Due: 5 p.m. ET 1/12/21.

Docket Numbers: ER21–718–000.
Applicants: Rainbow Energy Marketing Corporation.
Description: Notice of Cancellation of Multiple Inactive Legacy Electric Service Agreements and Rate Schedules of Rainbow Energy Marketing Corporation.
Filed Date: 12/21/20.
Accession Number: 20201221–5458.
Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER21–719–000.
Applicants: MidAmerican Central California Transco, LLC.
Description: § 205(d) Rate Filing: MCCT Annual Update TRBAA Filing to be effective 1/1/2021.
Filed Date: 12/23/20.
Accession Number: 20201223–5004.
Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–720–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2020–12–23_SA 3595 ITC Midwest-Heartland Divide Wind FSA (J583) to be effective 2/22/2021.
Filed Date: 12/23/20.
Accession Number: 20201223–5006.
Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–721–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2020–12–23_SA 3596 ITC Midwest-Walleye Wind FSA (J569) to be effective 2/22/2021.

Filed Date: 12/23/20.
Accession Number: 20201223–5007.
Comments Due: 5 p.m. ET 1/13/21.

Docket Numbers: ER21–722–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2020–12–23_SA 3597 ITC Midwest-Emmons Logan Wind FSA (J302 J503) to be effective 2/22/2021.
Filed Date: 12/23/20.
Accession Number: 20201223–5010.
Comments Due: 5 p.m. ET 1/13/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–28973 Filed 12–30–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–706–000]

Paulsboro Refining Company LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Paulsboro Refining Company LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 12, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: December 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–28977 Filed 12–30–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7883–019]

Powerhouse Systems, Inc.; Notice of Intent To File License Application, Filing of Pre-Application Document, and Approving Use of the Traditional Licensing Process

a. *Type of Filing:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 7883–019.

c. *Date Filed:* September 11, 2020.

d. *Submitted By:* Powerhouse Systems, Inc. (Powerhouse).

e. *Name of Project:* Weston Dam Project.

f. *Location:* On the Upper Ammonoosuc River in Coos County, New Hampshire. No federal lands are occupied by the project works or located within the project boundary.

g. *Filed Pursuant to:* 18 CFR 5.3 and 5.5 of the Commission's regulations.

h. *Potential Applicant Contact:* Deborah A. Allen, Powerhouse Systems, Inc., 1 Middle St., Suite 303, Lancaster, NH 03584; (603) 991–7757; email at *WestonDam.FERCrelicensing@gmail.com.*

i. *FERC Contact:* John Baummer at (202) 502–6827; or email at *john.baummer@ferc.gov.*

j. Powerhouse filed its request to use the Traditional Licensing Process on September 11, 2020, and provided public notice of its request on November 18, 2020. In a letter dated December 23, 2020, the Director of the Division of Hydropower Licensing approved Powerhouse's request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service and NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR part 402; and NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920. We are also initiating consultation with the New Hampshire State Historic Preservation Officer, as required by section 106 of the National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. On September 11, 2020, Powerhouse filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the

Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

m. A copy of the PAD may be viewed and/or printed on the Commission's website (*http://www.ferc.gov*), using the eLibrary link. Enter the docket number, excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

n. The licensee states its unequivocal intent to submit an application for a subsequent license for Project No. 7883. Pursuant to 18 CFR 16.20, each application for a subsequent license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by September 30, 2023.

o. Register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: December 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–28969 Filed 12–30–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0687; FRL–10016–58–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Submission of Unreasonable Adverse Effects Information Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 6(a)(2) (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), Submission of Unreasonable Adverse Effects under FIFRA Section 6(a)(2) (EPA ICR Number 1204.14, OMB Control Number 2070–0039) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through February 28, 2021. Public comments were previously requested via the **Federal Register** on August 17, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before February 1, 2021.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OPP–2017–0687, online using *www.regulations.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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: Carolyn Siu, Mission Support Division (7101M), Office of Program Support, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 347–0159; email address: *siu.carolyn@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 6(a)(2) requires pesticide registrants to submit information to the Agency which may be relevant to the balancing of the risks and benefits of a pesticide product. The statute requires the registrant to submit any factual information that it acquires regarding adverse effects associated with its pesticidal products, and it is up to the Agency to determine whether or not that factual information constitutes an unreasonable adverse effect. In order to limit the amount of less meaningful information that might be submitted to the Agency, the EPA has limited the scope of factual information that the registrant must submit. The Agency's regulations at 40 CFR part 159 provide a detailed description of the reporting obligations of registrants under FIFRA section 6(a)(2).

Form Numbers: None.

Respondents/affected entities: Pesticide and other agricultural chemical manufacturing.

Respondent's obligation to respond: Mandatory under FIFRA section 6(a)(2).

Estimated number of respondents: 1,452 (total).

Frequency of response: On occasion.

Total estimated burden: 301,118 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $19,999,815 (per year), includes no annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no change in the total estimated respondent burden compared with the ICR currently approved by OMB.

Dated: December 16, 2020.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2020–28995 Filed 12–30–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2016–0465, FRL–10018–57–OMS]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Information Requirements for Boilers and Industrial Furnaces (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Information Requirements for Boilers and Industrial Furnaces (EPA ICR Number 1361.18, OMB Control Number 2050–0073) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through January 31, 2021. Public comments were previously requested via the **Federal Register** on March 26, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before February 1, 2021.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OLEM–2016–0465, online using *www.regulations.gov* (our preferred method), by email to *rcra-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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: Peggy Vyas, Office of Resource Conservation and Recovery (mail code 5303P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 703–308–5477; fax number: 703–308–8433; email address: *vyas.peggy@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: EPA regulates the burning of hazardous waste in boilers, incinerators, and industrial furnaces (BIFs) under 40 CFR parts 63, 264, 265, 266 and 270. This ICR describes the paperwork requirements that apply to the owners and operators of BIFs. This includes the general facility requirements at 40 CFR parts 264 and 265, subparts B thru H; the requirements applicable to BIF units at 40 CFR part 266; and the RCRA Part B permit application and modification requirements at 40 CFR part 270.

Form Numbers: None.

Respondents/affected entities: Business or other for-profit.

Respondent's obligation to respond: Mandatory (per 40 CFR 264, 265, and 270).

Estimated number of respondents: 36 (total).

Frequency of response: On occasion.

Total estimated burden: 39,758 hours per year. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $5,499,098 (per year), which includes $0 in annualized capital/startup, and $2,823,120 in annualized operation & maintenance costs.

Changes in the Estimates: There is a decrease of 231,600 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to a decrease in the size of the universe, from 105 facilities to 36 facilities. This decrease is due partly to closures of boilers in both permitted and interim status facilities, but is mostly due to a clean-up of the data, because previously there had been double-counting of facilities as being both permitted and interim status. The reason for the double-counting was that one facility could have both permitted boilers and non-permitted boilers (*i.e.*, in interim status). Currently, however, there are no boilers in interim status; they are either permitted or they have been closed.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2020–28994 Filed 12–30–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2020–0193; FRL 10017–31–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Effluent Limitation Guidelines and Standards for the Dental Category (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Effluent Limitation Guidelines and Standards for the Dental Category (OMB Control Number 2040–0287; EPA ICR Number 2514.03), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through November 30, 2020. Public comments were previously requested via the **Federal Register** on April 30, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is provided in the Executive Summary.

DATES: Additional comments may be submitted on or before February 1, 2021.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OW–2020–0193 online using *www.regulations.gov* (our preferred method), by email to *ow-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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: Joshua Baehr, National Program Branch, Water Permits Division, OWM Mail

Code: 4203M, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–0742; email address: *Baehr.Joshua@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This ICR calculates the burden and costs associated with reporting and record-keeping activities required under the Final Effluent Limitations Guidelines (ELG) and Standards for the Dental Category. For purposes of this estimate, EPA assumed all existing dentists affected by the original rulemaking would have complied with the One-Time Compliance Reporting by the time of this ICR renewal. This estimate includes the effort for One-Time Compliance Reporting for new dental offices which open during the ICR period and those which transfer ownership and conduct annual recordkeeping. This estimate is based on average total compensation labor rates from the Bureau of Labor Statistics for the dental office personnel involved in collecting and reporting the information required. This estimate also includes the effort for control authorities to review the information submitted by dentists that certify they meet the requirements of the final rule. EPA estimates that there will be no start-up or capital costs associated with the information described above. Respondent reports may contain confidential business information. If a respondent does consider this information to be of a confidential nature, the respondent may request that such information be treated as confidential. All confidential data will be handled in accordance with 40 CFR 122.7, 40 CFR part 2, and EPA's Security Manual part III, chapter 9, dated August 9, 1976.

Form Numbers: None.

Respondents/affected entities: Dentists, Control Authorities.

Respondent's obligation to respond: Mandatory (40 CFR 403 & 441).

Estimated number of respondents: 124,378 annual average (122,741 permittees and 1,637 Publicly Owned Treatment Works and States/Tribes/Territories).

Frequency of response: One time.

Total estimated burden: 392,646 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $11,065,904 (per year), includes $9,671 in non-labor costs (*i.e.,* postage and file storage).

Changes in the Estimates: There is a decrease of 39,467 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. The burden decrease is based on the assumption that all existing dental offices which place or remove amalgam submitted the required One-Time Compliance Report during the prior ICR period. EPA is assuming a one percent growth rate in dental offices and that only new dental offices and dental offices transferring ownership will be doing the One-Time Compliance Reporting.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2020–28998 Filed 12–30–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9054–6]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed December 17, 2020 10 a.m. EST Through December 23, 2020 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20200263, Draft, DOE, ID, Draft Versatile Test Reactor Environment Impact Statement, Comment Period Ends: 02/16/2021, Contact: James Lovejoy 208–526–6805.

EIS No. 20200264, Draft, NMFS, ME, Regulatory Impact Review, and Initial Regulatory Flexibility Analysis for Amending the Atlantic Large Whale Take Reduction Plan: Risk Reduction Rule, Comment Period Ends: 03/01/2021, Contact: Colleen Coogan 978–281–9181.

Amended Notice

EIS No. 20200199, Draft, USA, AK, Heat and Electrical Upgrades at Fort Wainwright, Alaska, Comment Period Ends: 02/22/2021, Contact: Laura Sample 907–361–6323. Revision to FR Notice Published 10/09/2020; Extending the Comment Period from 12/08/2020 to 02/22/2021.

Dated: December 23, 2020.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2020–28940 Filed 12–30–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10018–12–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Public Health Emergency Workplace Response System (New)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Public Health Emergency Workplace Response System (EPA ICR Number 2676.01, OMB Control Number 2030–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for emergency approval of a new collection. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

FOR FURTHER INFORMATION CONTACT: Daniel Coogan, Office of Resource and Business Operations, Office of Mission Support, Environmental Protection Agency; telephone number: 202–564–1862; email address: *coogan.daniel@epa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 3507(j) of the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), as implemented in the Office of Management and Budget (OMB) regulations at 5 CFR 1320.13, EPA is hereby requesting emergency processing of an information collection necessary for contact tracing EPA employees, contractors and grantee recipients that perform work in EPA facilities.

Abstract: Because of the substantial risk to life, safety, or health of the workforce and the public, EPA requests an emergency approval to collect the necessary information from Federal employees, detailees, interns, volunteers, grantee recipients and contractors that perform work in EPA facilities to implement an effective COVID–19 Contact Tracing program.

Each item of information requested is based on CDC and industry best practice for Contact Tracing. This information is necessary to identify individuals in the workforce who are COVID- 19 positive and to notify and trace persons in the workforce who were in close contact with the COVID–19 positive employee. Including contractors, interns, grantees, and volunteers, enables EPA to capture the total workforce and take appropriate action.

The following information will be collected for COVID Contact Testing:

—Name;

—Work location;

—Contact information;

—Supervisor;

—Health status;

—Close contacts (as defined by CDC) when in the office; and

—Building and floors visited during period of possible transmission (as defined by CDC).

Form Numbers: None.

Respondents/affected entities: EPA's Contract Tracing Program participants, including detailees, interns, volunteers, grantee recipients and contractors.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 250 (total).

Frequency of response: Once.

Total estimated burden: 63 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $0 (per year), which includes annualized capital or operation & maintenance costs.

Changes in the Estimates: This is a new collection for information necessary for contact tracing EPA employees, contractors and grantee recipients that perform work in EPA facilities.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2020–28993 Filed 12–30–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2016–0122; FRL–10014–20–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Notice of Arrival of Pesticides and Devices Under Section 17(c) of FIFRA (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Notice of Arrival of Pesticides and Devices under section 17(c) of FIFRA (EPA ICR Number 0152.13 and OMB Control Number 2070–0020) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through December 31, 2020. Public comments were previously requested via the **Federal Register** on May 8, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before February 1, 2021.

ADDRESSES: Submit your comments to EPA, referencing Docket ID Number EPA–HQ–OPP–2016–0122, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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: Connie Hernandez, FEAD (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 305–5190; email address: *hernandez.connie@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The U.S. Customs and Border Protection (Customs) regulations at 19 CFR 12.112 require that an importer desiring to import a pesticide or device into the United States shall, prior to the shipment's arrival in the United States, submit a Notice of Arrival (NOA) of Pesticides and Devices (EPA Form 3540–1 or its Customs-authorized electronic equivalent) to EPA. Once EPA receives the NOA, EPA will determine the disposition of the shipment upon its arrival in the United States. Upon completing its review, the EPA response is sent to the importer of record or licensed customs broker, who must present the NOA to Customs upon arrival of the shipment at the port of entry. This is necessary to ensure that EPA is notified of the arrival of pesticides and pesticidal devices as required under section 17(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and that EPA has the ability to examine such shipments to determine compliance with FIFRA. Customs compares entry documents for the shipment with the NOA and notifies the EPA regional office of any discrepancies. Alternatively, importers may submit NOA information electronically through Customs' Automated Commercial Environment (ACE). Most of the electronic filings are automatically processed, and an early indication is provided to the filer if the initial reporting requirements have been met and if the shipment can be released upon arrival at the port of entry. For those filings that do not meet the reporting requirements, automatic checks will be performed to notify the filer of errors. For filings that require

non-automated checks, EPA staff can review and provide feedback notifications through ACE to the filer on what information is needed that has not been provided.

Form Numbers: None.

Respondents/Affected Entities: Pesticide importers, which includes many types of business entities ranging from Commercial and Institutional Building Construction (NAICS 236220) to Pesticide and Other Agricultural Chemical Manufacturing (NAICS 325300) and even Public Administration: Executive Offices (NAICS 921110). Other business and institutions that import pesticides include Agriculture, Forestry, Fishing and Hunting (Sector 11), Wholesale Trade, (Sector 42).

Respondent's obligation to respond: Mandatory (FIFRA sections 3 and 25; 40 CFR 152.25(f)).

Estimated number of respondents: 92,133 (total).

Frequency of response: On occasion.

Total estimated burden: 40,880 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $ 2,753,522 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the estimates: There is an increase of 24,540 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to an increase in the annual number of NOAs submitted. The new electronic system for submitting NOA filings, ACE, has contributed to the increase in the number of NOAs. The annual number of NOAs submitted to EPA increased from 38,000 for the previous ICR renewal to 92,133 for this ICR renewal. The average burden hours per response increased slightly from the previous ICR renewal of 0.43 hours to the current 0.44 per response. This change is an adjustment.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2020–29098 Filed 12–30–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL TRADE COMMISSION

[File No. 202 3094]

Epichouse, LLC (First Class Herbalist CBD); Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before February 1, 2021.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write ''Epichouse, LLC (First Class Herbalist LLC); File No. 202 3094'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Keith Fentonmiller (202–326–2775), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained at *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before February 1, 2021. Write ''Epichouse, LLC (First Class Herbalist LLC); File No. 202 3094'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of the public health emergency in response to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

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Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual

and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing the proposed settlement. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 1, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing a consent order with Epichouse, LLC (''Epichouse''), also doing business as First Class Herbalist CBD, Cobalt Serum, Cobalt Enhance, and Cobalt Cream, and John Le, individually and as an officer of Epichouse (collectively, ''Respondents'').

The proposed consent order (''order'') has been placed on the public record for 30 days so that interested persons may submit comments. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves Respondents' advertising for products containing cannabidiol (''CBD Products''), including First Class Herbalist CBD oil. The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that their CBD Products, among other things: Are safe for all users; treat pain better than prescription medicine like OxyContin; prevent and treat numerous serious health conditions, including age-related cognitive decline, cancer, chronic pain, diabetes, heart disease, hypertension, and migraines; and are scientifically proven to improve many serious health conditions.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food that Respondents sell or market, including CBD Products.

Part I prohibits Respondents from making any representation about the efficacy of any covered product, including that such product:

A. treats, alleviates, or cures age-related cognitive decline, neurodegeneration, or prostate problems;

B. prevents age-related cognitive decline, pain, hypertension, or migraines;

C. treats, alleviates, or cures any disease, including but not limited to adult acne; Alzheimer's disease; arthritis, autoimmune disorder; bipolar disorder; cancer; pain, including neuropathic pain, pain from spinal cord injuries, and pain from diseases like arthritis; colitis; Crohn's disease; depression; diabetes; endocrine disorders; heart disease; high blood pressure; migraines; multiple sclerosis; obesity; Parkinson's disease; psoriasis; rheumatism; strokes; or schizophrenia;

D. replaces the need for prescription painkillers like oxycontin; or

E. is safe for all consumers, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) Randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety, or side effects of any covered product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, ''competent and reliable scientific evidence'' means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III requires that, with regard to any human clinical test or study (''test'') upon which Respondents rely to substantiate any claim covered by the order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part IV prohibits Respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research or that any benefit of any covered product is scientifically or clinically proven.

Part V provides Respondents a safe harbor for making claims approved by the Food and Drug Administration (''FDA'').

Parts VI and VII require Respondents to pay the Commission $30,000.00 and describes the procedures and legal rights related that payment.

Part VIII requires Respondents to send email notices to consumers who purchased First Class Herbalist Relief CBD oil informing them about the settlement. Part IX requires Respondents to submit an acknowledgement of receipt of the order; serve the order on certain individuals, including all officers or directors of any business Respondents control and employees having managerial responsibilities for conduct related to the subject matter of the order; and obtain acknowledgements from each individual or entity to which

Respondents have delivered a copy of the order.

Part X requires Respondents to file compliance reports with the Commission and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. Part XI contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance or non-compliance with the order. Part XII contains other requirements related to the Commission's monitoring of Respondents' order compliance. Part XIII provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

Statement of Commissioner Rohit Chopra [1]

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish—and unlawful—claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine ''a competitor's ability to compete'' on honest attributes.[2]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID–19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[3] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer Americans into high-cost, subpar treatment centers, and some even hire intermediaries—so-called ''body brokers''—who collect kickbacks from this harmful practice.[4]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[5] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[6]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[7] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[8] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[9] Under the Penalty Offense Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[10] For example,

[1] *In the Matter of EasyButter, LLC et al.,* Comm'n File No. 2023047; *In the Matter of Reef Industries, Inc. et al.,* Comm'n File No. 2023064; *In the Mater of Steves Distributing, LLC et al.,* Comm'n File No. 2023065; *In the Matter of CBD Meds, Inc. et al.,* Comm'n File No. 2023080; *In the Matter of Epichouse, LLC et al.,* Comm'n File No. 2023094; *In the Matter of Bionatrol Health, LLC et al.,* Comm'n File No. 2023114.

[2] *In re Pfizer, Inc.,* 81 F.T.C. 23, 62 (1972).

[3] *See, e.g.,* Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic,* WALL STREET J. (Sept. 8, 2020), *https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic,* American Medical Association (last updated on Oct. 31, 2020), *https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.*

[4] For example, recent reporting describes the ''Florida Shuffle,'' where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America,* VOX (Mar. 2, 2020), *https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-bri-jayne. See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), *https://www.ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid* (calling on the FTC to do more to tackle this problem).

[5] Public Law. 115–271 §§ 8021–8023 (codified in 15 U.S.C. 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

[6] Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), *https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.*

[7] Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), *https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.*

[8] In one of these matters, the respondents are paying nothing.

[9] 15 U.S.C. 45(m)(1)(b).

[10] *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256.* Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can

Continued

the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[11] and apprising firms of these findings—along with a warning that noncompliance can result in penalties—makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a ''high level of voluntary compliance achieved quickly and at a low cost.'' [12] Going forward, we should pursue this strategy.

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.[13]

Concurring Statement of Commissioner Christine S. Wilson

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication. The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters [1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo-controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain conditions—specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that ''[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to

safeguard the Commission's ability to seek strong remedies against lawbreakers.

[11] This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc., supra* note 2 (finding that ''[f]airness to the consumer, as well as fairness to competitors'' compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.,* 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (DC Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that ''a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.'' *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.,* 155 F.T.C. 1, 6 (2013).

[12] Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an ''extremely effective and efficient way to enforce the law.'' Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), *https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.*

[13] My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

[1] Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions,* Oct. 22, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims;* Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis,* Sept. 10, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused;* Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases,* Apr. 2, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.*

[2] Press Release, *FTC Order Stops the Marketer of ''Thrive'' Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID–19,* July 10, 2020, available at *https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.*

[3] *See, e.g.,* Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

[4] *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.*

[5] *See, e.g.,* Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC* v. *Avrom Boris Lasarow, et al.* (Feb. 2015), *https://www.ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health;* Statement of Commissioner Joshua D. Wright, *FTC* v. *Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), *https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin;* Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru;* Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part;* Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC* v. *Springtech 77376, et al.* (July 2013), *https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12–49 (May 2012), available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.*

compete' on honest attributes.'' [6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

[FR Doc. 2020–29001 Filed 12–30–20; 8:45 am]

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[6] *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

FEDERAL TRADE COMMISSION

[File No. 202 3080]

CBD Meds, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before February 1, 2021.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write ''CBD Meds, Inc.; File No. 202 3080'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Barbara Chun (310–824–4312), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained at *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before February 1, 2021. Write ''CBD Meds, Inc.; File No. 202 3080'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

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Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing the proposed settlement. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 1, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement

containing a consent order with CBD Meds, Inc.; G2 Hemp, Inc.; and Lawrence Moses, a/k/a Lawrence D. Moses, Jr., individually and as an officer of CBD Meds, Inc. and G2 Hemp, Inc. (''Respondents'').

The proposed consent order (''order'') has been placed on the public record for 30 days so that interested persons may submit comments. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves the Respondents' advertising of products containing cannabidiol (''CBD Products). The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements that claimed: (1) CBD treats, prevents, or reduces the risk of artery blockage, dementia, blood sugar levels, seizures and convulsions, psoriasis, HIV dementia, cancer, age-related bone disease, arthritis, blood pressure conditions, diabetes, gastrointestinal disorders, glaucoma, strokes, Alzheimer's disease, multiple sclerosis, Parkinson's disease, epilepsy, autism, post-traumatic stress disorder, bipolar disorders, and schizophrenia; (2) clinical trials, studies, or scientific research prove that CBD treats or prevents seizures, cancer, strokes, Alzheimer's disease, Parkinson's disease, and HIV dementia, and may make chemotherapy more effective; (3) a U.S. government study has shown that CBD may make chemotherapy more effective; and (4) the U.S. government has stated that CBD is scientifically proven to have antioxidant and neuroprotectant properties.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food Respondents sell or market, including CBD Products.

Part I prohibits Respondents from making any representation about the efficacy of any covered product, including that such product will: (1) Treat blood pressure conditions or gastrointestinal disorders; (2) reduce seizures and convulsions; (3) reduce blood sugar levels; or (4) cure, mitigate or treat any disease in humans, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) Randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety or side effects of any covered product, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, ''competent and reliable scientific evidence'' means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III requires that, with regard to any human clinical test or study (''test'') upon which Respondents rely to substantiate any claim covered by the order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part IV prohibits Respondents from misrepresenting: (1) That any covered product is scientifically proven to (a) prevent seizures; (b) treat cancer; (c) treat or prevent strokes, Alzheimer's disease, Parkinson's disease, or HIV dementia; or (d) make chemotherapy more effective and increase cancer cell death without harming normal cells; (2) that the performance or benefits of any covered product is scientifically or clinically proven; (3) the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research; (4) that a U.S. government study showed that any covered product makes chemotherapy more effective, or (5) that the U.S. government has stated that any covered product is scientifically proven to have antioxidant and neuroprotectant properties, limit neurological damage following ischemic insults, and treat neurogenerative diseases. Part V provides Respondents a safe harbor for making claims approved by the Food and Drug Administration (''FDA'').

Part VI requires Respondents to send notices to consumers who purchased their CBD products informing them about the settlement. Part VII requires Respondents to submit an acknowledgement of receipt of the order, and for the individual Respondent to serve the order on certain individuals, including all officers or directors of any business the individual Respondent controls and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which a Respondent has delivered a copy of the order.

Part VIII requires Respondents to file compliance reports with the Commission and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. Part IX contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance with the order. Part X contains other requirements related to the Commission's monitoring of Respondents' order compliance. Part XI provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

Statement of Commissioner Rohit Chopra [1]

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish—and unlawful—claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine ''a competitor's ability to compete'' on honest attributes.[2]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID–19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[3] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer Americans into high-cost, subpar treatment centers, and some even hire intermediaries—so-called ''body brokers''—who collect kickbacks from this harmful practice.[4]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[5] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[6]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[7] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[8] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[9] Under the Penalty Offense Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[10] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[11] and apprising firms of these findings—along with a warning that noncompliance can result in penalties—makes it significantly more

[1] *In the Matter of EasyButter, LLC et al.,* Comm'n File No. 2023047; *In the Matter of Reef Industries, Inc. et al.,* Comm'n File No. 2023064; *In the Mater of Steves Distributing, LLC et al.,* Comm'n File No. 2023065; *In the Matter of CBD Meds, Inc. et al.,* Comm'n File No. 2023080; *In the Matter of Epichouse, LLC et al.,* Comm'n File No. 2023094; *In the Matter of Bionatrol Health, LLC et al.,* Comm'n File No. 2023114.

[2] *In re Pfizer, Inc.,* 81 F.T.C. 23, 62 (1972).

[3] *See, e.g.,* Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic,* WALL STREET J. (Sept. 8, 2020), *https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic,* American Medical Association (last updated on Oct. 31, 2020), *https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.*

[4] For example, recent reporting describes the ''Florida Shuffle,'' where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America,* VOX (Mar. 2, 2020), *https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-bri-jayne. See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), *https://www.ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid* (calling on the FTC to do more to tackle this problem).

[5] Public Law 115–271 §§ 8021–8023 (codified in 15 U.S.C. 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

[6] Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), *https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.*

[7] Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), *https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.*

[8] In one of these matters, the respondents are paying nothing.

[9] 15 U.S.C. 45(m)(1)(b).

[10] *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256.* Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

[11] This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc., supra* note 2 (finding that ''[f]airness to the consumer, as well as fairness to competitors'' compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.,* 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (DC Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that ''a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.'' *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.,* 155 F.T.C. 1, 6 (2013).

likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a ''high level of voluntary compliance achieved quickly and at a low cost.'' [12] Going forward, we should pursue this strategy.

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.[13]

Concurring Statement of Commissioner Christine S. Wilson

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication. The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters [1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo-controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain conditions—specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that ''[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes.'' [6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

[FR Doc. 2020–29002 Filed 12–30–20; 8:45 am]

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[12] Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an ''extremely effective and efficient way to enforce the law.'' Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), *https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.*

[13] My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

[1] Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions,* Oct. 22, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims;* Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis,* Sept. 10, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused;* Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases,* Apr. 2, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.*

[2] Press Release, *FTC Order Stops the Marketer of ''Thrive'' Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID–19,* July 10, 2020, available at *https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.*

[3] *See, e.g.,* Part I of Proposed Order, *In the Matter of Bionatrol Health, LLC, et al.* (Dec. 2020).

[4] *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.*

[5] *See, e.g.,* Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC* v. *Avrom Boris Lasarow, et al.* (Feb. 2015), *https://www.ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health;* Statement of Commissioner Joshua D. Wright, *FTC* v. *Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), *https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin;* Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru;* Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part;* Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC* v. *Springtech 77376, et al.* (July 2013), *https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12–49 (May 2012), available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.*

[6] *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

FEDERAL TRADE COMMISSION

[File No. 202 3064]

Reef Industries, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before February 1, 2021.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write ''Reef Industries, Inc.; File No. 202 3064'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Nicholas Coates (415–848–5125), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained at *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before February 1, 2021. Write ''Reef Industries, Inc.; File No. 202 3064'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of the public health emergency in response to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Reef Industries, Inc.; File No. 202 3064'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing the proposed settlement. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 1, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing a consent order with Reef Industries, Inc., a corporation; Cannatera, Inc., a corporation; AndHemp, Ltd., a limited company; and Andrew M. Bouchie, John R. Cavanaugh, and Shaun Paquette, individually and as officers and/or owners of Reef Industries, Inc., Cannatera, Inc., and/or AndHemp, Ltd. (collectively, ''Respondents'').

The proposed consent order (''Order'') has been placed on the public record for 30 days so that interested persons may submit comments. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Order and the comments received, and will decide whether it should withdraw the Order or make it final.

This matter involves the respondent's advertising of cannabidiol (CBD), a cannabinoid compound found in hemp and cannabis. The complaint alleges that respondent violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) CBD products can effectively prevent, cure, treat, or mitigate multiple diseases and other health conditions; and (2) studies or scientific research prove that CBD

products effectively prevent, cure, treat, or mitigate multiple diseases and other health conditions.

The Order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food the respondent sells, markets, promotes, or advertises.

Provision I requires randomized, double-blind, placebo-controlled clinical testing for the challenged claims or any disease treatment, mitigation, or cure claim for a Covered Product. The Order defines ''Covered Product'' as any dietary supplement, food, or drug including but not limited to CBD products or cannabigerol (CBG) products.

Provision II prohibits other misleading or unsubstantiated representations about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or essentially equivalent product. It also covers prevention claims not specifically included in Provision I.

Provision III requires the preservation of certain records for any testing Respondents rely upon as competent and reliable scientific evidence.

Provision IV addresses Respondents' false establishment claims and generally prohibits misrepresentations regarding the scientifically or clinically proven benefits of any product. Provision V provides a safe harbor for FDA-approved claims.

Provisions VI and VII contain monetary payment provisions.

Provisions VIII, IX, and X require the Respondents to provide customer information to the Commission and to provide notice of the order to customers, affiliates and other resellers. Provision XI requires an acknowledgement of receipt of the order. It also requires the individual Respondents to deliver a copy of the order to certain individuals in any business for which they are the majority owner or which they control directly or indirectly.

Provisions XII, XIII, and XIV provide the required reporting, recordkeeping, and compliance monitoring programs that Respondents must put in place.

Provision XV explains when the Order is final and effective.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

Statement of Commissioner Rohit Chopra [1]

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish—and unlawful—claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine ''a competitor's ability to compete'' on honest attributes.[2]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID–19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[3] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer Americans into high-cost, subpar treatment centers, and some even hire intermediaries—so-called ''body brokers''—who collect kickbacks from this harmful practice.[4]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[5] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[6]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[7] I am concerned that we

[1] *In the Matter of EasyButter, LLC et al.,* Comm'n File No. 2023047; *In the Matter of Reef Industries, Inc. et al.,* Comm'n File No. 2023064; *In the Mater of Steves Distributing, LLC et al.,* Comm'n File No. 2023065; *In the Matter of CBD Meds, Inc. et al.,* Comm'n File No. 2023080; *In the Matter of Epichouse, LLC et al.,* Comm'n File No. 2023094; *In the Matter of Bionatrol Health, LLC et al.,* Comm'n File No. 2023114.

[2] *In re Pfizer, Inc.,* 81 F.T.C. 23, 62 (1972).

[3] *See, e.g.,* Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic,* WALL STREET J. (Sept. 8, 2020), *https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic,* AMERICAN MEDICAL ASSOCIATION (last updated on Oct. 31, 2020), *https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.*

[4] For example, recent reporting describes the ''Florida Shuffle,'' where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America,* VOX (Mar. 2, 2020), *https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-bri-jayne. See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), *https://www.ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid* (calling on the FTC to do more to tackle this problem).

[5] Public Law 115–271 §§ 8021–8023 (codified in 15 U.S.C. 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

[6] Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), *https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.*

[7] Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising

have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[8] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[9] Under the Penalty Offense Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[10] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[11] and apprising firms of these findings—along with a warning that noncompliance can result in penalties—makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a ''high level of voluntary compliance achieved quickly and at a low cost.'' [12] Going forward, we should pursue this strategy.

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.[13]

Concurring Statement of Commissioner Christine S. Wilson

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication. The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters [1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo-controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain conditions—specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful

Complaint (Mar. 4, 2020), *https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.*

[8] In one of these matters, the respondents are paying nothing.

[9] 15 U.S.C. 45(m)(1)(b).

[10] *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256.* Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

[11] This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc., supra* note 2 (finding that ''[f]airness to the consumer, as well as fairness to competitors'' compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.,* 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (DC Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that ''a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.'' *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.,* 155 F.T.C. 1, 6 (2013).

[12] Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an ''extremely effective and efficient way to enforce the law.'' Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), *https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.*

[13] My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

[1] Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions,* Oct. 22, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims;* Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis,* Sept. 10, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused;* Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases,* Apr. 2, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.*

[2] Press Release, *FTC Order Stops the Marketer of ''Thrive'' Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID–19,* July 10, 2020, available at *https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.*

[3] *See, e.g.,* Part I of Proposed Order, *In the Matter of Bionatrol Health, LLC, et al.* (Dec. 2020).

[4] *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.*

information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that ''[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes.''[6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

[FR Doc. 2020–29003 Filed 12–30–20; 8:45 am]

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[5] *See, e.g.,* Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC* v. *Avrom Boris Lasarow, et al.* (Feb. 2015), *https://www.ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health;* Statement of Commissioner Joshua D. Wright, *FTC* v. *Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), *https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin;* Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru;* Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part;* Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC* v. *Springtech 77376, et al.* (July 2013), *https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12–49 (May 2012), available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.*

[6] *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–21–1277]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled The Childcare Survey of Activity and Wellness (C–SAW) Pilot Study to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on October 30, 2020 to obtain comments from the public and affected agencies. CDC received one public comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

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

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

The Childcare Survey of Activity and Wellness (C–SAW) Pilot Study (OMB Control No. 0920–1277, Exp. 12/31/2020)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) work to promote optimal nutrition, physical activity, and wellness in early care and education (ECE) facilities for children 0–5 years of age. Data collected from this pilot survey will be used to understand the current practices of ECE centers in a representative sample in four states. The survey will also be used to inform the development of a potential national surveillance system.

A sample of approximately 1,266 ECE centers across four states will be selected to participate in this one-time data collection effort. However, it is estimated that approximately 10% of the original sample will be out of business or otherwise ineligible yielding an actual sample of 1,140 ECEs to be recruited. Each center will receive a recruitment letter introducing the survey, and instructions for completing the survey. It is anticipated that most responses will be submitted through the web. However, paper surveys will be available upon request. It is also anticipated that the response rate will be approximately 55% based on a review of recent surveys of childcare centers conducted by the Federal government. Thus, we anticipate the number of completed surveys to be 627. CDC requests approval for a two year period with an estimated 513 total Burden Hours. Participation in this study is completely voluntary and there are no costs to the respondent other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
ECE Director or Administrator	Recruitment Letter	1,140	1	5/60
ECE Director or Administrator	Web/Mail Survey	627	1	40/60

Jeffery M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–28982 Filed 12–30–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Requirement for Negative Pre-Departure COVID–19 Test Result for All Airline Passengers Arriving Into the United States From the United Kingdom

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Agency Order.

SUMMARY: The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), announces an Agency Order requiring negative pre-departure COVID–19 test results for all airline passengers arriving into the United States from the United Kingdom (UK). This Order is issued to preserve human life; prevent the further introduction, transmission, and spread of the virus that causes COVID–19 into the United States, including new virus variants; preserve the health and safety of airline crew members, passengers, airport personnel, and communities; and preserve hospital, healthcare, and emergency response resources within the United States.

DATES: This Order was effective December 27, 2020 at 7:01 p.m. EST (12:01 a.m. December 28, 2020 GMT). See **SUPPLEMENTARY INFORMATION** for the conditions under which the Order will expire.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329. Email: *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION: On December 14, 2020, Public Health England announced that a new variant of SARS-CoV–2 had been identified across the southeast of England (*i.e.,* Kent and the surrounding areas). While it is known and expected that viruses change through mutation leading to the emergence of new variants, preliminary analysis in the UK suggests that this SARS–CoV–2 variant may be more transmissible than previously circulating variants. Pre-departure testing may detect travelers infected with SARS–CoV–2 before they initiate their travel and may reduce the risk of transmission. Therefore, urgent efforts are needed to mitigate the potential spread of this new virus variant into the United States.

This Order establishes requirements for (1) airlines arriving into the United States from the UK; and (2) passengers departing the United Kingdom with a final destination in the United States.

A copy of the Order and Attachment A are provided below and a copy of the signed order can be found at *https://www.cdc.gov/quarantine/testing-requirement-for-arriving-UK-air-travelers.html.*

Centers for Disease Control and Prevention Department of Health and Human Services

Order Under Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 Code of Federal Regulations 71.20 & 71.31(b)

Requirement for Negative Pre–Departure Covid–19 Test Result for All Airline Passengers Arriving Into the United States From the United Kingdom (UK)

Summary

Pursuant to 42 CFR 71.20 and as set forth in greater detail below, this Notice and Order prohibit the introduction into the United States of any airline passenger departing from the UK unless the passenger has a negative pre-departure test result for COVID–19. The test must be a viral test that was conducted on a specimen collected during the 3 calendar days preceding the flight's departure (Qualifying Test). Passengers must retain written or electronic documentation reflecting the negative Qualifying Test result presented to the airline and produce such results upon request to any U.S. government official or a cooperating state or local public health authority.

Pursuant to 42 CFR 71.31(b) and as set forth in greater detail below, this Notice and Order constitutes a controlled free pratique to any airline with an aircraft arriving into the United States from the UK. Pursuant to the controlled free pratique, the airline must comply with the following conditions in order to receive permission for the aircraft to enter and disembark passengers in the United States:

- Airline must verify that every passenger—2 years of age or older—onboard the flight has attested to having received a negative Qualifying Test result.
- Airline must confirm that every passenger onboard the aircraft has documentation reflecting a negative Qualifying Test result.

Statement of Intent

This Order shall be interpreted and implemented in a manner as to achieve the following paramount objectives:

- Preservation of human life;
- Preventing the further introduction, transmission, and spread of the virus that causes COVID–19 into the United States, including new virus variants;
- Preserving the health and safety of airline crew members, passengers, airport personnel, and communities; and
- Preserving hospital, healthcare, and emergency response resources within the United States.

Definitions

Airline shall have the same definition as under 42 CFR 71.1(b).

Attest/Attestation means having completed the attestation in Attachment A. Such attestation may be completed in written or electronic form. The attestation is a statement, writing, entry, or other representation under 18 U.S.C. 1001.

Confirm that every passenger onboard the aircraft has documentation reflecting a negative Qualifying Test result means confirmation that:

(1) The personal identifiers (*e.g.,* name and date of birth) on the Qualifying Test result match the

personal identifiers on the passenger's passport or other travel documents;

(2) the specimen was collected within 3 calendar days of the flight's departure;

(3) the test performed was a viral test (as defined below); and

(4) the test result states ''NEGATIVE,'' ''SARS–CoV–2 RNA NOT DETECTED,'' or ''SARS–CoV–2 ANTIGEN NOT DETECTED.''

Negative Pre-departure Test Result for COVID–19 or negative Qualifying Test result means documentation of a negative COVID–19 test taken within 3 calendar days of a flight's departure. Such documentation may be in paper or electronic formats as required by this Order. Testing must be performed using a viral test. The documentation must include sufficient verification information—such as the name and contact information for the laboratory or healthcare personnel who performed the test.

United Kingdom means the United Kingdom of Great Britain and Northern Ireland, commonly known as the United Kingdom and consisting of the countries of England, Scotland, Wales, and Northern Ireland.

United States has the same meaning as in 42 CFR 71.1(b).

Viral test means a viral detection test for current infection (*i.e.,* a nucleic acid amplification test or a viral antigen test) approved or authorized by the relevant national authority for the detection of SARS-CoV–2.

Exemptions

The following categories of individuals are exempt from the requirements of this Order:

- Airline crew members provided that they follow industry standard protocols for the prevention of COVID–19 as set forth in relevant Safety Alerts for Operators (SAFOs) issued by the Federal Aviation Administration (FAA).[1]
- Passengers who originate on flights outside the UK but connect through an airport in the UK on a transit flight with a connection time of no more than 24 hours.

Background

The COVID–19 pandemic has spread throughout the world. Individuals who travel may be at risk for exposure to SARS–CoV–2, the virus that causes COVID–19, before, during, and after travel. This could result in travelers further spreading the virus to others during travel, upon arrival in the United States, and at their destinations.

Over the last few weeks, the UK has faced a rapid increase in COVID–19 cases in South East England, leading to enhanced epidemiological and virological investigations. On December 14, 2020, Public Health England announced that a new variant of SARS–CoV–2 had been identified across the southeast of England (*i.e.,* Kent and the surrounding areas).[2]

While it is known and expected that viruses constantly change through mutation leading to the emergence of new variants, preliminary analysis in the UK suggests that this SARS-CoV–2 variant may be more transmissible than previously circulating variants, with an estimated potential to increase the reproductive number (R_0) by 0.4 or greater with an estimated increased transmissibility of up to 70 percent.[3] This new variant has emerged at a time of the year when there has traditionally been increased family and social mixing, and travel.

On December 19, 2020, in response to the emergence of this new variant, the countries comprising the UK announced stricter measures to be applied from December 20 and over the coming weeks, with affected areas going into a 'Tier 4' level with movement restrictions within and between more and less heavily affected areas. These measures have included recommendations for residents of the most affected areas to restrict movements and travel, including international travel, outside of these areas. The government of Scotland announced a travel ban between Scotland and the rest of the UK. In addition, the Netherlands issued a travel ban from the UK effective through January 1, 2021, and Belgium halted flight and train travel from the UK. Other countries have taken similar measures to restrict travel from the UK.[4]

On March 14, 2020, the United States issued a ''Proclamation on the Suspension of Entry as Immigrants and Nonimmigrants of Certain Additional Persons Who Pose a Risk of Transmitting Coronavirus'' applicable to the UK.[5] While this suspension remains in place and has slowed the introduction of travelers into the United States from the UK, the suspension does not apply to U.S. persons and contains other exemptions for eligible travelers. Thus, urgent efforts are needed to mitigate the potential spread of this new virus variant into the United States.

Pre-departure testing may detect travelers infected with SARS-CoV–2 before they initiate their travel. CDC recommends viral testing and receipt of results 1–3 days[6] before departure for international travelers, particularly those traveling long distances or passing through transportation hubs such as airports where social distancing may be challenging. Such testing may reduce the risk of SARS–CoV–2 transmission. Testing does not eliminate all risk, but when pre-departure testing is combined with other measures such as self-monitoring for symptoms of COVID–19, wearing masks, social distancing, and hand hygiene, it can make travel safer by reducing spread on conveyances and in transportation hubs.

CDC modeling indicates that pre-departure testing is most effective when combined with self-monitoring.[7] Testing before departure results in the greatest reduction of transmission risk during travel when the specimen is collected close to the time of departure. Earlier testing (*i.e.,* more than 3 days before travel) provides little benefit beyond what self-monitoring alone can provide. Travel should be delayed (*i.e.,* individuals should self-isolate) if symptoms develop or a pre-departure test result is positive.[8]

Action

For these reasons, I hereby determine that passengers covered by this Order are at risk of transmitting the new SARS–CoV–2 virus variant and that requiring such passengers to demonstrate negative COVID–19 test results is needed as a public health measure to protect the health of fellow travelers and U.S. communities.

[1] *https://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/safo/all_safos/media/2020/SAFO20009.pdf.*

[2] *https://www.gov.uk/government/news/phe-investigating-a-novel-variant-of-covid-19.*

[3] *https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom.*

[4] On December 20, 2020, Austria, Belgium, Italy, Ireland, Germany, France, and the Netherlands announced travel bans from the United Kingdom. The measures vary in scope and generally are short-term. The Republic of Ireland, Portugal, Latvia, Estonia, and Czech Republic also announced new travel restrictions, testing requirements, and quarantine rules. Bulgaria suspended flights to and from the UK until January 31, 2021, one of the longer bans announced. Greece issued new rules requiring a seven-day quarantine for travelers from the UK, rather than the current three-day period, starting December 21, 2020. Turkey has temporarily banned all flights from the UK, as has Switzerland.

[5] *https://www.whitehouse.gov/presidential-actions/proclamation-suspension-entry-immigrants-nonimmigrants-certain-additional-persons-pose-risk-transmitting-coronavirus-2/.*

[6] *https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-air-travel.html.*

[7] Johansson MA, Wolford H., Paul P., et al. Reducing travel-related SARS–CoV–2 transmission with layered mitigation measures: Symptom monitoring, quarantine, and testing, *available at https://www.medrxiv.org/content/10.1101/2020.11.23.20237412v1.*

[8] *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/end-home-isolation.html.*

1. Requirements for Airlines

Any airline operating aircraft with passengers arriving into the United States from the UK, for each passenger onboard the aircraft arriving into the United States, shall—

a. Verify that each passenger has attested to having received a negative Qualifying Test result. Airlines must retain a copy of each passenger attestation for 2 years. The attestation is attached to this order as Attachment A.

b. Confirm that each passenger aged 2 years or older has documentation of a negative Qualifying Test result.

c. Not board any passenger without verifying the attestation and confirming the documentation as set forth in 1.a–b.

Any airline that fails to comply with section 1, ''Requirement for Airlines,'' may be subject to criminal penalties under, *inter alia,* 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571.

2. Requirements for Passengers

Any passenger departing the UK with a final destination in the United States shall—

(a) Provide an attestation to the Centers for Disease Control and Prevention, through the airline, of having received a negative Qualifying Test result. The attestation is attached to this order as Attachment A. A parent or other legal guardian must attest on behalf of a passenger aged 2 to 17 years. An authorized individual may attest on behalf to any passenger who is unable to attest on his or her own behalf (*e.g.,* by reason of physical or mental impairment).

(b) Retain a copy of the negative Qualifying Test result in his/her possession and present it for inspection to the airline and upon request by an agent of the U.S. government or a cooperating state or local public health authority.

Any passenger who fails to comply with the requirements of section 2, ''Requirements for Passengers,'' may be subject to criminal penalties under, *inter alia,* 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia,* 18 U.S.C. 1001.

CDC may modify this Order by an updated publication in the **Federal Register** or by posting an advisory to follow at *www.cdc.gov.*

This Order shall be enforceable through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 271; and 42 CFR 71.2.

Effective Date

This Order shall enter into effect on Sunday, December 27, 2020 at 7:01 p.m. (EST) (12:01 a.m. on Monday, December 28, 2020 (GMT)) and shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID–19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) March 26, 2021.

Attachment A

Passenger Disclosure and Attestation to the United States of America

All airlines covered by the Order must provide the following disclosure to passengers and collect the attestation prior to embarkation.

Airline Disclosure Requirement

As required by United States federal law, all airlines are required to confirm a negative COVID–19 test result and collect a passenger attestation on behalf of the U.S. Centers for Disease Control and Prevention (CDC) for certain passengers on aircraft departing from the United Kingdom and arriving in the United States.

Each individual 2 years of age or older must provide a separate attestation. A parent or other legal guardian must attest on behalf of a passenger aged 2 to 17 years. An individual may attest on behalf of another passenger for whom the individual is authorized to submit the required information (for example, immediate family member(s), legal guardian, or travel agent), if that person is unable to attest on his or her own behalf (*e.g.,* because of physical or mental impairment).

The information provided must be accurate and complete to the best of the individual's knowledge.

Under United States federal law, each passenger must provide this attestation. Failure to provide this attestation, or submitting false or misleading information, could result in delay of travel, denial of boarding, denial of boarding on future travel, or put the passenger or other individuals at risk of harm, including serious bodily injury or death. Any passenger who fails to comply with these requirements may be subject to criminal penalties under, among others, 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. Willfully providing false or misleading information may lead to criminal fines and imprisonment under, among others, 18 U.S.C. 1001. Providing this information can help protect you, your friends and family, your communities, and the United States. CDC appreciates your cooperation.

Passenger Attestation Requirement

I [name of passenger or authorized representative] have read the disclosure pertaining to my obligation to obtain a negative pre-departure test result for COVID–19 in order to board an aircraft departing from the UK and arriving in the United States.

[ ] I attest that I have received a negative pre-departure test result for COVID–19. The test was a viral test that was conducted on a specimen collected from me during the 3 calendar days preceding the flight's departure.

[ ] On behalf of [_____], I attest that such person has received a negative pre-departure test result for COVID–19. The test was a viral test that was conducted on a specimen collected from that person during the 3 calendar days preceding the flight's departure.

Date

Privacy Act Statement

The United States (U.S.) Centers for Disease Control and Prevention (CDC) requires airlines to collect this information pursuant to 42 CFR 71.20, 71.31, and 71.32, as authorized by 42 U.S.C. 264. Providing this information is mandatory for all passengers arriving by air into the United States. Failure to provide this information may prevent you from boarding the plane. Additionally, passengers will be required to attest to providing complete and accurate information, and failure to do so may lead to other consequences, including criminal penalties. CDC will use this information to help prevent the introduction, transmission, and spread of communicable diseases by performing contact tracing investigations and notifying exposed individuals and public health authorities; and for health education, treatment, prophylaxis, or other appropriate public health interventions, including the implementation of travel restrictions.

The collection and use of this information is governed by The Privacy Act of 1974, 5 U.S.C. 552a. The information maintained by CDC will be covered by CDC's System of Records No. 09–20–0171, Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR parts 70 and 71. *See* 72 FR 70867 (Dec. 13, 2007), as amended by 76 FR 4485 (Jan. 25, 2011) and 83 FR 6591 (Feb. 14, 2018). CDC will only disclose information from the system outside the CDC and the U.S. Department of Health and Human

Services as the Privacy Act permits, including in accordance with the routine uses published for this system in the **Federal Register**, and as authorized by law. Such lawful purposes may include but are not limited to sharing identifiable information with state and local public health departments, and other cooperating authorities. CDC and cooperating authorities will retain, use, delete, or otherwise destroy the designated information in accordance with federal law and the System of Records Notice (SORN) set forth above. You may contact the system manager at *dgmqpolicyoffice@cdc.gov;* Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329, if you have questions about CDC's use of your data.

Authority

The authority for these orders is Sections 361 and 365 of the Public Health Service Act (42 U.S.C. 264) and 42 CFR 71.20 & 71.31(b).

Nina B. Witkofsky,

Acting Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2020–28981 Filed 12–28–20; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Generic Clearance for the Comprehensive Child Welfare Information System (CCWIS) Review and Technical Assistance Process (New Collection)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Children's Bureau (CB), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to establish a generic clearance to collect information to assess regulatory requirements of title IV–E agencies' Comprehensive Child Welfare Information System (CCWIS) and ensure that the CCWIS is utilized for purposes consistent with the efficient, economical, and effective administration of the title IV–B and IV–E plans. The information collected is intended to be used for review and technical assistance processes.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: This initial request is to establish an overarching generic for CCWIS Review and Technical Assistance (TA) information collections and includes six initial TA tools for title IV–E agencies to self-assess their conformity to CCWIS project and design requirements at 45 CFR 1355.52–3. The initial six TA tools include intake, investigation, case management, adoption, foster care and service provider management, and administration.

In the future, ACF will submit under this generic clearance mechanism additional TA tools for title IV–E agencies to self-assess design, data quality, usability, reporting, data exchanges, external systems, eligibility, finance, Child Welfare Contributing Agencies, and other tools, as needed, to assess new child welfare programs and modern system architecture.

The CCWIS requirements at 45 CFR 1355.55 require the review, assessment, and inspection of the planning, design, development, installation, operation, and maintenance of each CCWIS project on a continuing basis. The Advance Planning Document regulations at 45 CFR 95.621 require periodic reviews of state and local agency methods and practices to insure that information systems, including CCWIS, are utilized for purposes consistent with proper and efficient administration.

Respondents: Title IV–E agencies under the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
CCWIS Self-Assessment—Intake	55	1	10	550
CCWIS Self-Assessment—Investigation	55	1	10	550
CCWIS Self-Assessment—Case Management	55	1	10	550
CCWIS Self-Assessment—Adoption	55	1	10	550
CCWIS Self-Assessment—Foster Care and Service Provider Management	55	1	10	550
CCWIS Self-Assessment—Administration	55	1	10	550
Future Tools to be Developed	55	10	12	6,600

Estimated Total Annual Burden Hours: 9,900.

Authority: 5 U.S.C. 301; 42 U.S.C. 470, 620 *et seq.,* 622(b), 629b(a), 652(b), 654A, 670 *et seq.,* 671(a), 1302, and 1396a(a).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–28925 Filed 12–30–20; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0124 (Formerly Docket No. FDA–1975–N–0012)]

Consumer Antiseptic Rub Final Rule; Finding of Ineligibility for Inclusion in Final Monograph Questions and Answers; Guidance for Industry; Small Entity Compliance Guide; 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 ''Consumer Antiseptic Rub Final Rule Questions and Answers.'' We are issuing this guidance in accordance with the Small Business Regulatory Enforcement Fairness Act to help small businesses understand and comply with the Consumer Antiseptic Rub Final Rule; Finding of Ineligibility for Inclusion in Final Monograph (Consumer Antiseptic Rub FR). In the Consumer Antiseptic Rub FR, FDA established that 28 active ingredients used in nonprescription (also known as over-the-counter (OTC)) consumer antiseptic products intended for use without water (consumer antiseptic rubs) are not eligible for evaluation under FDA's OTC Drug Review, which was used to evaluate the safety and effectiveness of OTC drug products marketed in the United States on or before May 1972. The Consumer Antiseptic Rub FR also established that three active ingredients used in consumer antiseptic rubs are eligible for evaluation under the OTC Drug Review and granted requests to temporarily defer further rulemaking on these three eligible ingredients to allow for the development and submission of new safety and effectiveness data.

DATES: The announcement of the guidance is published in the **Federal Register** on December 31, 2020.

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–2016–N–0124 for ''Consumer Antiseptic Rub Final Rule Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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: Anita Kumar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5445, Silver Spring, MD 20993–0002, 301–796–1032.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Consumer Antiseptic Rub Final Rule

Questions and Answers.'' We are issuing this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28) [1] to help small businesses understand and comply with the Consumer Antiseptic Rub FR (84 FR 14847, April 12, 2019), which established that 28 active ingredients are not eligible for evaluation under FDA's OTC Drug Review for use in consumer antiseptic rubs. Drug products containing these ineligible active ingredients will require approval under a new drug application or abbreviated new drug application before they can be marketed. In this final action, FDA also established that three active ingredients used in consumer antiseptic rubs are eligible for evaluation under the OTC Drug Review and granted requests to temporarily defer further rulemaking on these three ingredients to allow interested parties to complete the studies necessary to fill the safety and effectiveness data gaps identified for these three ingredients.

This guidance reviews the content and effect of the final action, including identifying which active ingredients were found eligible and which were found not eligible for evaluation under the OTC Drug Review for use in consumer antiseptic rubs. In addition, this guidance explains when and how manufacturers must comply with the final action.

This Level 2 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on how small businesses can better understand and comply with the Consumer Antiseptic Rub FR. 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

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

[1] 5 U.S.C. 601 (note).

Dated: December 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28929 Filed 12–30–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Updates to the Bright Futures Periodicity Schedule

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Effective December 28, 2020, HRSA accepted a recommended update to the Bright Futures Periodicity Schedule, a HRSA-supported guideline for infants, children and adolescents, for purposes of health insurance coverage without cost sharing under the Public Health Service (PHS) Act. The update includes screening for Hepatitis C Virus Infection for individuals ages 18 to 21. Please see *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html* for additional information.

FOR FURTHER INFORMATION CONTACT: Bethany D. Miller, MSW, M.Ed., HRSA/Maternal and Child Health Bureau by calling (301) 495–5156 or by emailing at *BMiller@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The Bright Futures program has been funded by HRSA since 1990. A primary focus of this program is for the funding recipient to maintain and update the *Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents,* a set of materials and tools that provide theory-based and evidence-driven guidance for all preventive care screenings and well-child visits. One component of these tools is the Bright Futures Periodicity Schedule, a chart that identifies the recommended screenings, assessments, physical examinations, and procedures to be delivered within preventive checkups at each age milestone. Over the program's existence, the Bright Futures Periodicity Schedule has become the accepted schedule within the United States for preventive health services through the course of a child's development.

Section 2713 of the PHS Act requires that non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage provide coverage without cost sharing for certain preventive health services in four identified areas. Section 2713(a)(3) describes such services for infants, children, and adolescents as ''evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.'' HHS, along with the Departments of Treasury and Labor, issued an Interim Final Rule on July 19, 2010, (75 FR 41726–41760) that identified two specific resources as the comprehensive guidelines supported by HRSA for infants, children, and adolescents to be covered by insurance without cost sharing by non-grandfathered group health plans and health insurance issuers: (1) The Bright Futures Periodicity Schedule and (2) the Recommended Uniform Screening Panel of the Advisory Committee on Heritable Disorders in Newborns and Children. The Interim Final Rule provided that a future change to these comprehensive guidelines is considered to be issued for purposes of Section 2713 on the date on which it is accepted by the HRSA Administrator or, if applicable, adopted by the Secretary of HHS.

On December 28, 2020, the HRSA Administrator accepted the recommended update to the Bright Futures Periodicity Schedule. The Bright Futures recommendation included both a recommended clinical practice update and revisions to the footnotes on the Bright Futures Periodicity Schedule. The update includes screening for Hepatitis C Virus Infection for individuals age 18 to 21. The footnote revisions are applied to footnote 11 (Developmental Screening); footnote 12 (Autism Spectrum Disorder Screening) to update the title of the relevant revised policy statements and the electronic hyperlinks; and a new footnote referring to the supporting evidence for the recommendation for screening for hepatitis C virus infection. Therefore, all non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage must cover without cost-sharing the services and screenings listed on the updated Bright Futures Periodicity Schedule for plan years (in the individual market, policy years) beginning on or after December 28, 2021.

The updated Bright Futures Periodicity schedule can be accessed at the following link: *https://*

mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html.

Thomas J. Engels,

Administrator.

[FR Doc. 2020–28971 Filed 12–30–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) will hold public meetings for the 2021 calendar year (CY). Information about ACTPCMD, agendas, and materials for these meetings can be found on the ACTPCMD website at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html.*

DATES: ACTPCMD meetings will be held on

- March 2, 2021, 10:00 a.m.–5:00 p.m. Eastern Time (ET) and March 3, 2021, 10:00 a.m.–2:00 p.m. ET;
- November 2, 2021, 8:30 a.m.–5:00 p.m. ET and November 3, 2021, 8:30 a.m.–2:00 p.m. ET.

ADDRESSES: Meetings may be held in-person, by teleconference, and/or Adobe Connect webinar. For updates on how the meeting will be held, visit the ACTPCMD website 30 business days before the date of the meeting, where instructions for joining meetings either in-person or remotely will also be posted. In-person ACTPCMD meetings will be held at 5600 Fishers Lane, Rockville, Maryland 20857. For meeting information updates, go to the ACTPCMD website meeting page at *https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N142, Rockville, Maryland 20857; 301–443–5260; or *SRogers@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACTPCMD provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under Section 747 of Title VII of the

Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. The ACTPCMD prepares an annual report describing the activities of the committee, including findings and recommendations made by the committee concerning the activities under Section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary as well as the Chairman and ranking members of the Senate Committee on Health, Education, Labor and Pensions and the House of Representatives Committee on Energy and Commerce. The ACTPCMD develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C of the PHS Act, and recommends appropriation levels for programs under this Part. Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2021 meetings, agenda items may include, but are not limited to inter-professional team-based education, practice, and retention in underserved rural communities, as well as matters pertaining to policy, program development, and other matters of significance concerning medicine and dentistry activities authorized under Title VII of the PHS Act. Refer to the ACTPCMD website listed above for all current and updated information concerning the CY 2021 ACTPCMD meetings, including draft agendas and meeting materials that will be posted 30 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACTPCMD should be sent to Shane Rogers using the contact information above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Shane Rogers using the contact information listed above at least 10 business days before the meeting(s) they wish to attend.

If a meeting is held in-person, it will occur in a federal government building and attendees must go through a security check to enter. Non-U.S. citizen attendees must notify HRSA of their planned attendance at an in-person meeting at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–28919 Filed 12–30–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Nurse Education and Practice

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the National Advisory Council on Nurse Education and Practice (NACNEP) will hold public meetings for the 2021 calendar year (CY). Information about NACNEP, agendas, and materials for these meetings can be found on the NACNEP website at *https://www.hrsa.gov/advisory-committees/nursing/index.html.*

DATES: NACNEP meetings will be held on

- March 9, 2021, 8:30 a.m.–5:00 p.m. Eastern Time (ET) and March 10, 2021, 8:30 a.m.–2:00 p.m. ET;
- July 13, 2021, 8:30 a.m.–5:00 p.m. ET and July 14, 2021, 8:30 a.m.–5:00 p.m. ET;
- December 7, 2021, 8:30 a.m.–5:00 p.m. ET and December 8, 2021, 8:30 a.m.–5:00 p.m. ET.

ADDRESSES: Meetings may be held in-person, by teleconference, and/or Adobe Connect webinar. For updates on how the meeting will be held, visit the NACNEP website 30 business days before the date of the meeting, where instructions for joining meetings either in-person or remotely will also be posted. In-person NACNEP meetings will be held at 5600 Fishers Lane, Rockville, Maryland 20857. For meeting

information updates, go to the NACNEP website meeting page at *https://www.hrsa.gov/advisory-committees/nursing/meetings.html.*

FOR FURTHER INFORMATION CONTACT: Camillus Ezeike, Ph.D., JD, LLM, RN, PMP, Designated Federal Official, Division of Nursing and Public Health, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, 11N–120, Maryland 20857; 301–443–2866; or *BHWNACNEP@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The NACNEP provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities carried out under Title VIII of the Public Health Service (PHS) Act, including the range of issues relating to the nurse workforce, education, and practice improvement. NACNEP also prepares and submits an annual report to the Secretary of HHS and Congress describing its activities, including NACNEP's findings and recommendations concerning activities under Title VIII, as required by the PHS Act. Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2021 meetings, agenda items may include, but are not limited to, a review of federal nursing workforce programs, funding for nursing practice improvement and nursing education, and the response to the COVID–19 pandemic. Refer to the NACNEP website listed above for all current and updated information concerning the CY 2021 NACNEP meetings, including agendas and meeting materials that will be posted 30 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the NACNEP should be sent to Camillus Ezeike using the contact information above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Camillus Ezeike using the contact information listed above at least 10 business days before the meeting(s) they wish to attend.

If a meeting is held in-person, it will occur in a federal government building and attendees must go through a security check to enter. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at an in-person meeting at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–28920 Filed 12–30–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

RIN 0917–AA19

Reimbursement Rates for Calendar Year 2021

AGENCY: Indian Health Service (IHS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Notice is provided that the Director of the Indian Health Service has approved the rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2021.

SUPPLEMENTARY INFORMATION: The Director of the Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2021 for Medicare and Medicaid beneficiaries, beneficiaries of other federal programs, and for recoveries under the Federal Medical Care Recovery Act (42 U.S.C. 2651–2653). The inpatient rates for Medicare Part A are excluded from the table below. That is because Medicare inpatient payments for IHS hospital facilities are made based on the prospective payment system, or (when IHS facilities are designated as Medicare Critical Access Hospitals) on a reasonable cost basis. Since the inpatient per diem rates set forth below do not include all physician services and practitioner services, additional payment shall be available to the extent that those services are provided.

Inpatient Hospital Per Diem Rate (Excludes Physician/Practitioner Services)

Calendar Year 2021

Lower 48 States $3,631
Alaska $3,384

Outpatient Per Visit Rate (Excluding Medicare)

Calendar Year 2021

Lower 48 States $519
Alaska $808

Outpatient Per Visit Rate (Medicare)

Calendar Year 2021

Lower 48 States $414
Alaska $662

Medicare Part B Inpatient Ancillary Per Diem Rate

Calendar Year 2021

Lower 48 States $678
Alaska $1,039

Outpatient Surgery Rate (Medicare)

Established Medicare rates for freestanding Ambulatory Surgery Centers.

Effective Date for Calendar Year 2021 Rates

Consistent with previous annual rate revisions, the Calendar Year 2021 rates will be effective for services provided on/or after January 1, 2021, to the extent consistent with payment authorities, including the applicable Medicaid State plan.

Michael D. Weahkee,

Assistant Surgeon General, RADM, U.S. Public Health Service, Director, Indian Health Service.

[FR Doc. 2020–28950 Filed 12–30–20; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 National Advisory General Medical Sciences Council.

The meeting will be open to the public as indicated below, with a short public comment period at the end. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

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 Advisory General Medical Sciences Council.

Date: September 1–2, 2021.

Open: September 1, 2021, 9:30 a.m. to 12:00 p.m.

Agenda: For the discussion of program policies and issues; opening remarks; report of the Director, NIGMS; and other business of the Council.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Closed: September 1, 2021, 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Open: September 2, 2021, 9:30 a.m. to 12:00 p.m.

Agenda: For the discussion of program policies and issues; opening remarks; report of the Director, NIGMS; and other business of the Council.

Place: National Institutes of Health, Natcher Building, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: September 2, 2021, 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Erica L. Brown, Ph.D., Acting Associate Director for Extramural Activities, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 2AN24F, Bethesda, MD 20892, (301) 594–4499, *erica.brown@nih.gov*.

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: *http://www.nigms.nih.gov/About/Council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 23, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28902 Filed 12–30–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cell Biology Integrated Review Group; Cellular Signaling and Regulatory Systems Study Section.

Date: January 28–29, 2021.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, (301) 435–1022, *balasundaramd@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Biobehavioral Medicine and Health Outcomes Study Section.

Date: February 1–2, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Mark Allen Vosvick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110 Bethesda, MD 20892 (301) 402–4128, *mark.vosvick@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 23, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28936 Filed 12–30–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference Grant Applications.

Date: February 25, 2021.

Time: 11:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Video Meeting).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *yangj@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 23, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28935 Filed 12–30–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Communication Disorders Review Committee.

Date: February 11–12, 2021.

Time: 10:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center 6001 Executive Boulevard Rockville, MD 20852 (Virtual Meeting).

Contact Person: Kausik Ray, Ph.D. Scientific Review Officer National Institute on Deafness and Other Communication Disorders National Institute of Health 6001 Executive Blvd. Rockville, MD 20850 (301) 402–3587 *rayk@nidcd.nih.gov*.

Name of Committee: Communication Disorders Review Committee.

Date: June 17–18, 2021

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion 4300 Military Road NW, Washington, DC 20015.

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institute of Health, 6001 Executive Blvd., Rockville, MD 20850, (301) 402–3587, *rayk@nidcd.nih.gov*.

Name of Committee: Communication Disorders Review Committee.

Date: October 14–15, 2021.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion 4300 Military Road NW, Washington, DC 20015.

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institute of Health, 6001 Executive Blvd., Rockville, MD 20850, (301) 402–3587, *rayk@nidcd.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: December 23, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28903 Filed 12–30–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 National Advisory General Medical Sciences Council.

The meeting will be open to the public as indicated below, with a short public comment period at the end. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

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 Advisory General Medical Sciences Council.

Date: May 12–13, 2021.

Open: May 12, 2021, 8:30 a.m. to 12:00 p.m.

Agenda: For the discussion of program policies and issues; opening remarks; report of the Director, NIGMS; and other business of the Council.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Closed: May 12, 2021, 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Open: May 13, 2021, 8:30 a.m. to 5:00 p.m.

Agenda: For the discussion of program policies and issues; opening remarks; report of the Director, NIGMS; and other business of the Council.

Place: National Institutes of Health, Natcher Building, 45 Center Drive Bethesda, MD 20892 (Virtual Meeting).

Closed: May 13, 2021, 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Erica L. Brown, Ph.D., Acting Associate Director for Extramural Activities, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 2AN24F Bethesda, MD 20892, (301) 594–4499, *erica.brown@nih.gov*.

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: *http://www.nigms.nih.gov/About/Council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 23, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28934 Filed 12–30–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the

information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Project: 2021 Behavioral Health Workforce Surveys, Part of the Mental and Substance Use Disorder Practitioner Data Grant Funded by SAMHSA, Grant Number H79FG000028

SAMHSA is requesting from the Office of Management and Budget (OMB) approval to administer two surveys being developed as part of the Mental and Substance Use Disorder Practitioner Data grant: (1) A one-time survey to employers of behavioral health providers and, (2) a one-time survey of licensed clinical behavioral health providers. The information gathered by these surveys will be used to gain critical new insights into, and to document, challenges in recruiting and retaining behavioral health staffing and to assess the strength of available data on the clinical behavioral health workforce actively providing care for mental health and substance use disorders.

Employer Survey

The survey includes questions to assess the following measures: Facility type (*e.g.,* outpatient facility, inpatient, residential); type of behavioral health staff employed (*e.g.,* addiction medicine specialists, psychiatric Nurse Practitioners, marriage and family therapists); services offered (*e.g.,* assertive community treatment, partial hospitalization); roles and training needs of peer support specialists, case managers, care managers, and pharmacists (*e.g.,* certification, population served, paid status, reimbursement); professions with recruitment and retention challenges (*e.g.,* select from list of professions); reasons behind the challenges (*e.g.,* low wages, high case load) and work-arounds (*e.g.,* use of locum tenens); average wait-time for appointments (*e.g.,* new patient visits); staffing needed to address gaps in care (*e.g.,* estimated FTEs needed by profession type); use of telehealth (*e.g.,* percent of visits); patient mix (*e.g.,* immigrants, LGBTQ communities, number of clients); and form of payment (*e.g.,* percent commercial, Medicaid, self-pay). The survey will be administered online through Qualtrics.

The target population will be the 2,800 member organizations of the National Council of Behavioral Health (NCBH). NCBH members are healthcare organizations and management entities that offer treatment and supports to more than eight million adults and children living with mental illnesses and addictions.

Provider Survey

The survey will help identify how many licensed clinical behavioral health specialists (licensed psychologists, licensed clinical social workers, licensed marriage and family therapists, and licensed professional counselors) are seeing clients for behavioral health needs and the populations served. The survey includes questions to assess the following measures: Demographics (*e.g.,* age, race/ethnicity, sex); professional and practice setting (*e.g.,* self-employed, outpatient mental health clinic, zip code, hours worked); level of education (*e.g.,* Masters in Social Work, Doctorate in Social Work); types of services provided (*e.g.,* assertive community treatment); number of and type clients served (*e.g.,* Medicaid, Medicare, veteran, immigrants); telehealth use (*e.g.,* current or prior to COVID–19 outbreak); and career satisfaction and burnout (*e.g.,* very satisfied, ''I enjoy my work, I have no symptoms of burnout'').

The target population will be a random sample of 5,000 licensed clinical behavioral health providers (licensed psychologists, licensed clinical social workers, licensed marriage and family therapists, and licensed professional counselors) in states where email addresses are available with state licensure data.

The primary objectives of the surveys are to:

- Better understand factors associated with challenges in both recruitment and retention at behavioral health provider organizations.
- Estimate the workforce needed to better address gaps in care for mental health and substance use disorder.
- Obtain new insights on staffing models for treatment of serious mental illness, such as assertive community treatment.
- Collect new data on use of peer support specialists, care coordinators, and pharmacists in behavioral health care.
- Assess whether state licensure data is a reliable data source for building a comprehensive database on clinical behavioral health practitioners who are actively providing client services that require licensure.

EXHIBIT 1—TOTAL ESTIMATED ANNUALIZED BURDEN BY INSTRUMENT

Type of participant activity	Number of participants	Responses per participant	Total responses	Hours per response	Total burden hours	Wage rate	Total hour cost
Employer Survey	2,800	1	2,800	.25	700	$21.79	$15,253
Provider Survey	5,000	1	5,000	.25	1,250	21.79	27,237.50
Total	7,800	.....	7,800	.....	1,950	.....	42,490.50

Send comments Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–B, Rockville, Maryland 20857, *OR* email a copy to *Carlos.Graham@samhsa.hhs.gov.* Written comments should be received by March 1, 2021.

Carlos Graham,

Social Science Analyst.

[FR Doc. 2020–28921 Filed 12–30–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

New Dates for the April and October 2021 Customs Broker's License Examinations

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection has changed the dates on which the semi-annual examination for an individual broker's license will be held in April and October 2021.

DATES: The customs broker's license examination scheduled for April 2021 will be held on Wednesday, April 21, 2021, and the customs broker's license

examination scheduled for October 2021 will be held on Thursday, October 21, 2021.

FOR FURTHER INFORMATION CONTACT: Melba Hubbard, Acting Director, Commercial Operations, Revenue and Entry, Office of Trade, (202) 325–6986, or *brokermanagement@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 641 of the Tariff Act of 1930, as amended (19 U.S.C. 1641), provides that a person (an individual, corporation, association, or partnership) must hold a valid customs broker's license and permit in order to transact customs business on behalf of others, sets forth standards for the issuance of brokers' licenses and permits, and provides for the taking of disciplinary action against brokers that have engaged in specified types of infractions. This section also provides that an examination may be conducted to assess an applicant's qualifications for a license.

The regulations issued under the authority of section 641 are set forth in Title 19 of the Code of Federal Regulations, part 111 (19 CFR part 111). Part 111 sets forth the regulations regarding the licensing of, and granting of permits to, persons desiring to transact customs business as customs brokers. These regulations also include the qualifications required of applicants and the procedures for applying for licenses and permits. Section 111.11 of the CBP regulations (19 CFR 111.11) sets forth the basic requirements for a broker's license, and in paragraph (a)(4) of that section provides that an applicant for an individual broker's license must attain a passing grade (75 percent or higher) on the examination.

Section 111.13 of the CBP regulations (19 CFR 111.13) sets forth the requirements and procedures for the examination for an individual broker's license and states that the customs broker's license examinations will be given on the fourth Wednesday in April and October unless the regularly scheduled examination date conflicts with a national holiday, religious observance, or other foreseeable event.

Due to the limited availability of testing sites caused by state and local restrictions during the COVID–19 pandemic, CBP has changed the regularly scheduled dates of the examination. This document announces that CBP has scheduled the April 2021 customs broker's license examination for Wednesday, April 21, 2021, and the October 2021 customs broker's license examination for Thursday, October 21, 2021.

Dated: December 27, 2020.

Cynthia F. Whittenburg,

Acting Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2020–28966 Filed 12–30–20; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0016]

Meeting To Implement Pandemic Response Voluntary Agreement Under Section 708 of the Defense Production Act

AGENCY: Federal Emergency Management Agency, Department of Homeland Security (DHS).

ACTION: Announcement of meeting.

SUMMARY: The Federal Emergency Management Agency (FEMA) held a meeting remotely via web conference to implement the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic.

DATES: The meeting took place on Monday, December 21, 2020, from 11 a.m. to 12:30 p.m. Eastern Time (ET).

FOR FURTHER INFORMATION CONTACT: Robert Glenn, Office of Business, Industry, Infrastructure Integration, via email at *OB3I@fema.dhs.gov* or via phone at (202) 212–1666.

SUPPLEMENTARY INFORMATION: Notice of these meetings is provided as required by section 708(h)(8) of the Defense Production Act (DPA), 50 U.S.C. 4558(h)(8), and consistent with 44 CFR part 332.

The DPA authorizes the making of ''voluntary agreements and plans of action'' with, among others, representatives of industry and business to help provide for the national defense.[1] The President's authority to facilitate voluntary agreements was delegated to the Secretary of Homeland Security with respect to responding to the spread of COVID–19 within the United States in Executive Order 13911.[2] The Secretary of Homeland Security has further delegated this authority to the FEMA Administrator.[3]

On August 17, 2020, after the appropriate consultations with the Attorney General and the Chairman of the Federal Trade Commission, FEMA completed and published in the **Federal Register** a ''Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic'' (Voluntary Agreement).[4] Unless terminated prior to that date, the Voluntary Agreement is effective until August 17, 2025, and may be extended subject to additional approval by the Attorney General after consultation with the Chairman of the Federal Trade Commission. The Agreement may be used to prepare for or respond to any pandemic, including COVID–19, during that time.

On December 7, 2020, the first plan of action under the Voluntary Agreement—the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID–19 (Plan of Action)—was finalized.[5] The Plan of Action established the Personal Protective Equipment Sub-Committee to Define COVID–19 PPE Requirements (Sub-Committee).

The meetings covered by this notice were held by the Sub-Committee to implement the Voluntary Agreement. The meetings were chaired by the FEMA Administrator or his delegate, and attended by the Attorney General or his delegate and the Chairman of the Federal Trade Commission or his delegate. In implementing the Voluntary Agreement, FEMA adheres to all procedural requirements of 50 U.S.C. 4558 and 44 CFR part 332.

Meeting Objectives: The objectives of the meetings were to:

(1) Finalize the priority tasks that should be completed first under the Plan of Action;

(2) Identify which Sub-Committees should begin meeting in January 2021; and

(3) Identify additional Participants and Attendees who should be invited to participate in the Plan of Action.

Meetings Closed to the Public: By default, the DPA requires meetings held to implement a voluntary agreement or plan of action be open to the public.[6] However, attendance may be limited if

[1] 50 U.S.C. 4558(c)(1).

[2] 85 FR 18403 (Apr. 1, 2020).

[3] DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020); DHS Delegation Number 09052 Rev. 00 (Jan. 3, 2017).

[4] 85 FR 50035 (Aug. 17, 2020). The Attorney General, in consultation with the Chairman of the Federal Trade Commission, made the required finding that the purpose of the voluntary agreement may not reasonably be achieved through an agreement having less anticompetitive effects or without any voluntary agreement and published the finding in the **Federal Register** on the same day. 85 FR 50049 (Aug. 17, 2020).

[5] *See* 85 FR 78869 (Dec. 7, 2020). *See also* 85 FR 79020 (Dec. 8, 2020).

[6] *See* 50 U.S.C. 4558(h)(7).

the Sponsor[7] of the voluntary agreement finds that the matter to be discussed at a meeting falls within the purview of matters described in 5 U.S.C. 552b(c). The Sponsor of the Voluntary Agreement, the FEMA Administrator, found that these meetings to implement the Voluntary Agreement involved matters which fell within the purview of matters described in 5 U.S.C. 552b(c) and were therefore closed to the public.[8]

Specifically, the meetings to implement the Voluntary Agreement could have required participants to disclose trade secrets or commercial or financial information that is privileged or confidential. Disclosure of such information allows for meetings to be closed pursuant to 5 U.S.C. 552b(c)(4). In addition, the success of the Voluntary Agreement depends wholly on the willing and enthusiastic participation of private sector participants. Failure to close these meetings could have had a strong chilling effect on participation by the private sector and caused a substantial risk that sensitive information would be prematurely released to the public, resulting in participants withdrawing their support from the Voluntary Agreement and thus significantly frustrating the implementation of the Voluntary Agreement. Frustration of an agency's objective due to premature disclosure of information allows for the closure of a meeting to pursuant to 5 U.S.C. 552b(c)(9)(B).

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–29054 Filed 12–30–20; 8:45 am]

BILLING CODE 9111–19–P

[7] "[T]he individual designated by the President in subsection (c)(2) [of section 708 of the DPA] to administer the voluntary agreement, or plan of action." 50 U.S.C. 4558(h)(7).

[8] Under 50 U.S.C. 4558(h)(8), the Sponsor generally must publish in the **Federal Register** prior notice of any meeting held to carry out a voluntary agreement or plan of action. However, when the Sponsor finds that the matters to be discussed at such meeting fall within the purview of matters described in 5 U.S.C. 552b(c), notice of the meeting may instead be published in the **Federal Register** within ten days of the date of the meeting. *See* 50 U.S.C. 4558(h)(8).

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2020–0041; OMB No. 1660–0047]

Agency Information Collection Activities: Proposed Collection; Comment Request; Request for Federal Assistance Form—How To Process Mission Assignments in Federal Disaster Operations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, 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 Paperwork Reduction Act of 1995, this notice seeks comments concerning the collection of information necessary to allow FEMA to support the needs of State, Tribes, and Territories during disaster situation through the use of other Federal agency resources.

DATES: Comments must be submitted on or before March 1, 2021.

ADDRESSES: Submit comments at *www.regulations.gov* under Docket ID FEMA–2020–0041. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID. All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Pat Foster, (617) 913–6140 or *FEMA-MissionAssignments@fema.dhs.gov.* You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: According to the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. 5121 *et seq.,* FEMA is authorized to provide assistance before, during, and after a disaster has impacted a State, Tribe, or Territory. For a major disaster, the Stafford Act authorizes FEMA to direct any agency to utilize its existing authorities and resources in support of State, Tribe, and Territory assistance response and recovery efforts. *See* 42 U.S.C. 5170(a)(1). For an emergency, the Stafford Act authorizes FEMA to direct any agency to utilize its existing authorities and resources in support of State and local emergency assistance efforts. *See* 42 U.S.C. 5192(a)(1). FEMA may task other Federal agencies to assist during disasters and to support emergency efforts by State and local governments by issuing a mission assignment to the appropriate agency. *See* 44 CFR 206.5, 206.208. FEMA collects the information necessary to determine what resources are needed and if a mission assignment is appropriate. The information collected explains which States, Tribes, Territories require assistance, what needs to be accomplished, details any resource shortfalls, and explains what assistance is required to meet these needs.

Collection of Information

Title: Request for Federal Assistance Form—How to Process Mission Assignments in Federal Disaster Operations.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0047.

FEMA Forms: FEMA Form 010–0–7, Resource Request Form; FEMA Form 010–0–8, Mission Assignment; FEMA Form 010–0–8A, Mission Assignment Task Order.

Abstract: If a State, Tribe, or Territory determines that its capacity to respond to a disaster exceeds its available resources, it may submit to FEMA a request that the work be accomplished by a Federal agency. This request documents how the response requirements exceed the capacity for the State to respond to the situation on its own and what type of assistance is required. FEMA reviews this information and may issue a mission assignment to the appropriate Federal agency to assist the State in its response to the situation.

Affected Public: State, Tribe, or Territory Government.

Number of Respondents: 40

Number of Responses: 19,220.

Estimated Total Annual Burden Hours: 6,559 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $475,003. There are no annual costs to respondents for operations and maintenance costs for technical services. There are no annual start-up or

capital costs. The cost to the Federal Government is $41,643.

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.

Maile Arthur,

Acting, Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2020–28926 Filed 12–30–20; 8:45 am]

BILLING CODE 9111–19–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0124]

Agency Information Collection Activities; Withdrawal of 60-Day Notice: Consideration of Deferred Action for Childhood Arrivals

ACTION: Notice; withdrawal.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) is withdrawing the **Federal Register** Notice published on November 13, 2020.

DATES: December 31, 2020.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number.). It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 13, 2020 (85 FR 72682), ''Agency Information Collection Activities; Revision of a Currently Approved Collection; Consideration of Deferred Action for Childhood Arrivals'', USCIS requested comment on the information collection activity.

Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

USCIS recently announced that in compliance with an order of a United States District Court, effective December 7, 2020, USCIS is accepting first-time requests for consideration of deferred action under Deferred Action for Childhood Arrivals (DACA) based on the terms of the DACA policy in effect prior to September 5, 2017, and in accordance with the Court's December 4, 2020, order;. *See, Batalla Vidal et al* v. *Wolf et al,* 1:16–cv–04756–NGG–VMS (E.D. N.Y., Dec. 4, 2020). DHS will comply with the order while it remains in effect, but DHS may seek relief from the order. In light of these developments and their implications for revising the USCIS Form I–821D as planned with the November 13, 2020 **Federal Register** Notice, USCIS has decided not to seek to revise the collection of information at this time and will instead continue to maintain the form in its current state. USCIS will extend, without change, the currently approved collection of information and will use the notice provided on July 20, 2020 (85 FR 46882) that sought comments for 60 days. USCIS will be publishing a separate 30-day **Federal Register** notice seeking comment on the extension and submitting the information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

Dated: December 23, 2020.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2020–28924 Filed 12–30–20; 8:45 am]

BILLING CODE 9111–97–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–654–655 and 731–TA–1529–1532 (Final)]

Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe From Czechia, Korea, Russia, and Ukraine; Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–654–655 and 731–TA–1529–1532 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of seamless carbon and alloy steel standard, line, and pressure pipe from Czechia, Korea, Russia, and Ukraine, provided for in subheading 7304.19.10, 7304.19.50, 7304.31.60, 7304.39.00, 7304.51.50, 7304.59.60, and 7304.59.80 of the Harmonized Tariff Schedule of the United States, for which imports from Czechia have been preliminarily determined by the Department of Commerce (''Commerce'') to be sold at less-than-fair-value, imports from Korea and Russia have been preliminarily determined by Commerce to be subsidized by the Governments of Korea and Russia, and imports from Korea, Russia, and Ukraine are alleged to be sold at less-than-fair-value.

DATES: December 15, 2020.

FOR FURTHER INFORMATION CONTACT: Junie Joseph ((202) 205–3363), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.—For purposes of these investigations, Commerce has defined the subject merchandise as seamless carbon and alloy steel (other than stainless steel) pipes and redraw hollows, less than or equal to 16 inches (406.4 mm) in nominal outside diameter, regardless of wall-thickness, manufacturing process (*e.g.,* hot-finished or cold-drawn), end finish (*e.g.,* plain end, beveled end, upset end, threaded, or threaded and coupled), or surface finish (*e.g.,* bare, lacquered or coated). Redraw hollows are any unfinished carbon or alloy steel (other than stainless steel) pipe or ''hollow profiles'' suitable for cold finishing operations, such as cold drawing, to meet the American Society for Testing and Materials (ASTM) or American Petroleum Institute (API) specifications referenced below, or comparable specifications. Specifically included within the scope are seamless carbon and alloy steel (other than stainless steel) standard, line, and pressure pipes produced to the ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–589, ASTM A–795, ASTM A–1024, and the API 5L specifications, or comparable specifications, and meeting the physical parameters described above, regardless of application, with the exception of the exclusions discussed below.

Specifically excluded from the scope of the investigation are: (1) All pipes meeting aerospace, hydraulic, and bearing tubing specifications, including pipe produced to the ASTM A–822 standard; (2) all pipes meeting the chemical requirements of ASTM A–335, whether finished or unfinished; and (3) unattached couplings. Also excluded from the scope of the investigations are all mechanical, boiler, condenser and heat exchange tubing, except when such products conform to the dimensional requirements, *i.e.,* outside diameter and wall thickness, of ASTM A–53, ASTM A–106 or API 5L specifications.

Subject seamless standard, line, and pressure pipe are normally entered under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7304.19.1020, 7304.19.1030, 7304.19.1045, 7304.19.1060, 7304.19.5020, 7304.19.5050, 7304.31.6050, 7304.39.0016, 7304.39.0020, 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.51.5005, 7304.51.5060, 7304.59.6000, 7304.59.8010, 7304.59.8015, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, 7304.59.8055, 7304.59.8060, 7304.59.8065, and 7304.59.8070. The HTSUS subheadings and specifications are provided for convenience and customs purposes; the written description of the scope is dispositive.

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by Commerce that certain benefits which constitute subsidies within the meaning of § 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in Korea and Russia of seamless carbon and alloy steel standard, line, and pressure pipe, and that such products from Czechia are being sold in the United States at less than fair value within the meaning of § 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on July 8, 2020, by Vallourec Star, LP, Houston, Texas.

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on February 19, 2021, and a public version will be issued thereafter, pursuant to § 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on March 4, 2021. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.* Interested parties should check the Commission's website periodically for updates. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before February 25, 2021. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on March 1, 2021. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the

Commission's rules; the deadline for filing is February 26, 2021. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of § 207.25 of the Commission's rules. The deadline for filing posthearing briefs is March 11, 2021. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before March 11, 2021. On March 25, 2021, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before March 29, 2021, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to § 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: December 28, 2020.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2020–28986 Filed 12–30–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

[Docket No. 2020R–10W]

Objective Factors for Classifying Weapons With "Stabilizing Braces"; Withdrawal of Guidance

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives, Department of Justice.

ACTION: Notice; withdrawal.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms, and Explosives (''ATF'') is announcing the withdrawal of a notice and request for comments entitled ''Objective Factors for Classifying Weapons with 'Stabilizing Braces','' that was published on December 18, 2020.

DATES: The withdrawal is effective December 31, 2020.

ADDRESSES: This Notice also will be made available on the ATF website (*www.atf.gov*).

FOR FURTHER INFORMATION CONTACT: Andrew Lange, Office of Regulatory Affairs, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Ave. NE, Mail Stop 6N–518, Washington, DC 20226; telephone: (202) 648–7070 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Upon further consultation with the Department of Justice and the Office of the Deputy Attorney General, ATF is withdrawing, pending further Department of Justice review, the notice and request for comments entitled ''Objective Factors for Classifying Weapons with 'Stabilizing Braces','' that was published on December 18, 2020. 85 FR 82516. As explained in the notice, the proposed guidance was not a regulation. The notice informed and invited comment from the industry and public on a proposed guidance prior to issuing a final guidance document.

The withdrawal of the guidance does not change any law, regulation, or other legally binding requirement.

Marvin G. Richardson,

Associate Deputy Director.

[FR Doc. 2020–28930 Filed 12–30–20; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States, et al. v. Harvard Pilgrim Health Care, Inc., et al.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of New Hampshire in *United States and State of New Hampshire* vs. *Harvard Pilgrim Health Care, Inc. and Health Plan Holdings, Inc.,* Civil Action No. 1:20–cv–01183. On December 14, 2020, the United States filed a Complaint alleging that the proposed merger of Harvard Pilgrim Health Care, Inc. and Health Plan Holdings, Inc. (f/k/a Tufts Health Plan, Inc.) would violate Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed Final Judgment, filed at the same time as the Complaint, requires Health Plan Holdings to divest its New Hampshire subsidiary, Tufts Health Freedom Plans, Inc., along with certain tangible and intangible assets.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the District of New Hampshire. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be directed to Eric D. Welsh, Chief, Healthcare and Consumer Products Section, Antitrust Division, Department of Justice, 450 Fifth Street NW, Suite

4100, Washington, DC 20530 (telephone: 202–598–8681).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

United States District Court for the District of New Hampshire

United States of America and *State of New Hampshire,* Plaintiffs, vs. *Harvard Pilgrim Health Care, Inc.* and *Health Plan Holdings, Inc.,* Defendants.

Civil Action No.: 1:20–cv–01183–JL
Judge Joseph N. Laplante

Complaint

The United States of America and the State of New Hampshire bring this civil antitrust action to block the proposed merger of Harvard Pilgrim Health Care and Health Plan Holdings (f/k/a Tufts Health Plan). The combination of Harvard Pilgrim and Health Plan Holdings—two of the largest suppliers of health insurance in New Hampshire for certain employers purchasing group coverage for their employees—into one firm would likely lead to higher prices, lower quality, and reduced choice for consumers of commercial group health insurance in New Hampshire. To prevent this harm to consumers, the United States and the State of New Hampshire seek an injunction to stop the proposed merger. Plaintiffs allege as follows:

I. Introduction

1. Health insurance is an integral part of the American healthcare system. Americans collectively spend trillions of dollars on healthcare each year, and the cost of healthcare impacts almost every American. Consumers depend on health insurance to secure affordable access to doctors and hospitals and to protect themselves from the risk of medical expenses that could be financially devastating.

2. Half of all Americans obtain health insurance coverage through their employers. Employers purchase group health insurance plans for their employees from insurance companies such as Harvard Pilgrim and Health Plan Holdings. Competition between insurance companies like Harvard Pilgrim and Health Plan Holdings ensures that employers can purchase high-quality group health insurance plans for their employees at affordable prices.

3. Harvard Pilgrim sells commercial group health insurance plans to small and large employer groups in New Hampshire. Health Plan Holdings sells commercial group health insurance plans to small and large employer groups in New Hampshire through Tufts Health Freedom Plan, Inc. (''Tufts Freedom'').

4. In New Hampshire, Harvard Pilgrim and Tufts Freedom are two of the three top companies offering commercial group health insurance plans to (1) private small group employers with up to 50 full-time eligible employees (''small groups'') and (2) private large group employers with between 51 and 99 full-time eligible employees, a segment of commercial large group health insurance referred to as community rated by class or ''CRC'' by Defendants and others in the industry (''CRC groups''). Competition between Harvard Pilgrim and Tufts Freedom has resulted in lower premiums, richer (*i.e.,* more robust and comprehensive) plan benefits, and better service for small groups and CRC groups in New Hampshire.

5. Combining Harvard Pilgrim and Health Plan Holdings into one firm would eliminate this competition, likely raising the price and reducing the quality of commercial health insurance sold to small groups and to CRC groups in New Hampshire.

6. As a result, the proposed transaction is likely to substantially lessen competition for commercial health insurance sold to small groups and to CRC groups, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18. The Court, therefore, should enjoin this transaction.

II. Defendants and the Transaction

7. Harvard Pilgrim sells commercial group health insurance to small and large employer groups in four states: New Hampshire, Massachusetts, Connecticut, and Maine. Harvard Pilgrim's annual revenue in 2019 was approximately $3 billion, and it has over one million members.

8. Health Plan Holdings sells commercial group health insurance to small and large employer groups in New Hampshire through Tufts Freedom, which until September 2020 was a joint venture with the Granite Healthcare consortium consisting of several large New Hampshire health systems and now is solely owned by Health Plan Holdings. It also sells commercial group health insurance in Massachusetts and Rhode Island. Health Plan Holdings' annual revenue in 2019 was over $5.5 billion, and it has over one million members.

9. Defendants have agreed to a ''merger of equals,'' which was memorialized in a Combination Agreement dated August 9, 2019 (the ''Transaction'').

III. Jurisdiction and Venue

10. This Court has subject-matter jurisdiction under Section 15 of the Clayton Act, 15 U.S.C. 25, and 28 U.S.C. 1331, 1337(a), and 1345.

11. The State of New Hampshire brings this action in its sovereign capacity as *parens patriae* on behalf of and to protect the health and general welfare of its citizens and the general economy of the State under Section 16 of the Clayton Act, 15 U.S.C. 26 and under N.H. Rev. Stat. Ann. 356:4–a & 4–b, seeking injunctive and other relief from Defendants' violation of Section 7 of the Clayton Act, 15 U.S.C. 18 and state antitrust law.

12. Defendants are engaged in activities that substantially affect interstate commerce. Defendants sell health insurance and administrative services for which employers and consumers remit payments across state lines, and Defendants otherwise participate in interstate commerce.

13. Venue is proper under Section 12 of the Clayton Act, 15 U.S.C. 22, and under 28 U.S.C. 1391(b) and (c).

14. This Court has personal jurisdiction over each Defendant. Harvard Pilgrim is headquartered in Wellesley, Massachusetts and transacts business in this district. Health Plan Holdings is headquartered in Watertown, Massachusetts and transacts business in this district. Both Harvard Pilgrim and Health Plan Holdings have consented to personal jurisdiction and the acceptance of service of process in this district for purposes of this matter. The Transaction would also have effects on employers and consumers in this district.

IV. The Relevant Markets

15. Commercial group health insurance is sold by health insurance companies to employers to provide health insurance coverage to their employees and their employees' families. Employers cover at least a portion of the cost of the insurance for their employees, making it a cost-effective way for employees, and their families, to obtain health insurance.

16. Insurers offering commercial group health insurance plans to employers try to make them attractive by competing on price, product design, customer service, care management, wellness programs, and reputation. Insurers also compete based on the breadth of their network of healthcare providers, including doctors and hospitals, as employers seek an insurance plan that offers in-network access to medical providers that are close to where their employees live and

work. An insurer's ability to compete on price depends largely on medical costs, which are impacted significantly by the discounts the insurer obtains from medical providers.

17. In New Hampshire, Harvard Pilgrim and Health Plan Holdings compete vigorously with one another in the sale of commercial health insurance to small groups and to CRC groups.

18. The Transaction is likely to harm competition in two health insurance markets in New Hampshire: (1) The sale of commercial group health insurance to small groups and (2) the sale of commercial group health insurance to CRC groups. For both of these markets, employers tend to be local, with the majority of their employees based in New Hampshire, although some employers offer insurance to employees in multiple states. Competition to win small groups and CRC groups in New Hampshire is primarily driven by which insurer offers the lowest rates. Small groups and CRC groups, as defined in this complaint, do not include governmental employers (*e.g.,* municipalities, school districts) in New Hampshire with fewer than 100 employees, as historically almost all those employers have purchased health insurance through a trust instead of directly from an insurer.

A. Commercial Health Insurance Sold to Small Groups

19. The sale of commercial health insurance to small groups in New Hampshire is a relevant antitrust product market in which to analyze the effects of the Transaction. New Hampshire Insurance Department regulations define a ''small group'' as an employer with 50 or fewer full-time eligible employees. For small groups, health plans are typically fully insured, which means that the employer pays a premium to the insurance company and in return the company covers the employees' healthcare costs. Small groups tend to be local in nature, requiring a strong local provider network.

20. The commercial health insurance plans offered to small groups are governed by the New Hampshire Insurance Department and cannot be substituted with plans offered to New Hampshire employers with 51 or more full-time eligible employees, defined by statute as ''large group.'' Harvard Pilgrim and Health Plan Holdings also differentiate small group accounts separately from large group accounts internally and offer different pricing for small group accounts compared to large group accounts.

21. New Hampshire law does not require that an insurer offer a small group product statewide and therefore permits an insurer to offer small group plans only in certain counties. Accordingly, despite the fact that state law does not allow insurers to charge different prices for the same small group plans based on location, insurers can offer a more expensive set of small group plans in one part of the state, and a less expensive set of different small group plans in another part of the state. This allows insurers to charge different prices for different products to small groups based on where employees live and work. The Transaction is likely to substantially lessen competition for the sale of commercial health insurance to small groups in all seven of New Hampshire's Core Based Statistical Areas (''CBSA''): (1) The Manchester-Nashua CBSA, (2) the Concord CBSA, (3) the Laconia CBSA, (4) the Keene CBSA, (5) the Berlin CBSA, (6) the New Hampshire counties (Grafton and Sullivan) of the Lebanon NH–VT CBSA, and (7) the New Hampshire counties (Rockingham and Strafford) of the Boston-Cambridge-Newton MA–NH CBSA.

22. Each of these seven CBSAs is a relevant geographic market. A hypothetical monopolist over the sale of commercial health insurance to small groups in each of these markets would impose a small but significant and non-transitory increase in price, or SSNIP. A small group employer, faced with a significant price increase, cannot defeat the price increase by purchasing a large group product for which it is ineligible. This price increase would not be defeated by substitution outside the relevant market or by arbitrage (meaning a small group trying to repurchase insurance through another employer group).

B. Commercial Health Insurance Sold to CRC Groups

23. The sale of commercial health insurance to CRC groups is a relevant antitrust product market. In New Hampshire, employers with between 51 and 99 full-time eligible employees represent a distinct segment of large group and are referred to as CRC employers (or CRC groups). CRC groups have different needs and make different buying decisions than small groups or even larger employers. Harvard Pilgrim and Tufts Freedom employ different sales strategies for this segment than they do for other types of employers.

24. For CRC groups, similar to small groups, health plans are typically fully insured, which means that the employer pays a premium to the insurance company and in return the company covers the employees' healthcare costs. Insurers, including Harvard Pilgrim and Tufts Freedom, differentiate employers with 51 to 99 full-time eligible employees from other large group employers, and refer to these employers as the CRC segment. As with small groups, CRC groups also tend to be more local in nature than other large group employers, requiring a strong local provider network, as opposed to large group employers with more than 100 full-time eligible employees, which tend to require strong national provider networks.

25. Insurers offering commercial health insurance to CRC groups in New Hampshire can charge different prices to different employers. Group health plans for CRC groups, in contrast to larger group employers, are typically (although not exclusively) community rated by class, meaning that, when setting rates for CRC groups, the insurer first establishes a base rate determined by the medical costs of a class of similar groups, rather than upon the medical costs of the individual group seeking the plan. The insurer then uses this base rate, along with the individual employer's medical costs, to negotiate rates with the specific CRC group.

26. The Defendants target CRC groups directly through their sales efforts. For example, Tufts Freedom has focused its large group sales efforts on CRC groups since it began selling commercial health insurance in New Hampshire, and Harvard Pilgrim tracks CRC groups separately from other large group accounts. In addition, both Harvard Pilgrim and Tufts Freedom utilize specific pricing strategies for CRC groups. The Defendants have formulated these specific pricing strategies because CRC groups in New Hampshire are generally more price sensitive than large group employers with more than 100 full-time eligible employees.

27. As with commercial health insurance sold to small groups, New Hampshire law does not require that an insurer offer a CRC group product statewide and therefore permits an insurer to offer CRC plans only in certain counties. Accordingly, insurers can offer more expensive plans to CRC groups in one part of the state and less expensive plans in another part of the state. This allows insurers to charge different prices for different products to CRC groups based on where employees live and work. The Transaction is likely to substantially lessen competition for the sale of commercial health insurance to CRC groups in six separate CBSAs in New Hampshire: (1) The Manchester-Nashua CBSA, (2) the Concord CBSA,

(3) the Laconia CBSA, (4) the Keene CBSA, (5) the New Hampshire counties (Grafton and Sullivan) of the Lebanon NH–VT CBSA, and (6) the New Hampshire counties (Rockingham and Strafford) of the Boston-Cambridge-Newton MA–NH CBSA.

28. Each of these six CBSAs is a relevant geographic market. A hypothetical monopolist over the sale of commercial health insurance to CRC groups in each of these markets would impose a small but significant and non-transitory increase in price or SSNIP. This price increase would not be defeated by substitution outside the relevant market or by arbitrage.

V. The Transaction Is Presumptively Illegal

29. Mergers that significantly increase concentration in already concentrated markets are presumptively anticompetitive and therefore presumptively unlawful.

30. To measure market concentration, courts often use the Herfindahl-Hirschman Index (''HHI''). HHI is an accepted measure of market concentration. It is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of four firms with shares of 30 percent, 30 percent, 20 percent, and 20 percent, the HHI is 2,600 ($30^2 + 30^2 + 20^2 + 20^2 = 2{,}600$). The HHI recognizes the relative size distribution of the firms in a market, ranging from 0 in markets with no concentration to 10,000 in markets where one firm has 100 percent market share. *See* Horizontal Merger Guidelines § 5.3. Courts have found that mergers that increase the HHI by more than 200 and result in an HHI above 2,500 in any relevant market or line of commerce are presumed to be anticompetitive.

A. The Relevant Markets Are Highly Concentrated and the Transaction Would Significantly Increase Their Concentration

31. In the small group market, based upon 2018 data, the combined market shares for Harvard Pilgrim and Tufts Freedom would range from over 45% to over 60% in each of the seven CBSAs. The Transaction would reduce the number of small group health insurers from four to three, with the two largest insurers—Anthem and the merged Harvard Pilgrim/Tufts Freedom—possessing over 95% share in each of the seven CBSAs. The Transaction would result in an HHI increase ranging from over 350 points to over 1,600 points with post-transaction HHIs of between 4,500 points and 7,500 points for commercial health insurance sold to small groups in New Hampshire. Thus, the Transaction is presumptively unlawful.

32. For the CRC group market, based upon 2018 data, the combined market shares for Harvard Pilgrim and Tufts Freedom would range from more than 40% to over 65% in each of the six CBSAs. The Transaction would reduce the number of CRC group health insurers from four to three, with the two largest insurers—Anthem and the merged Harvard Pilgrim/Tufts Freedom—possessing over 95% share in each of the six CBSAs. The Transaction would result in an HHI increase ranging from over 200 to over 2,000 points in the CRC group market with post-transaction HHIs of just under 5,000 to almost 7,000 for CRC groups in New Hampshire. Thus, the Transaction is presumptively unlawful.

B. The Transaction Likely Would Harm Consumers in New Hampshire

33. Harvard Pilgrim and Tufts Freedom are particularly close competitors for commercial health insurance sold to small groups and CRC groups in New Hampshire with competition between the two insurers more robust for certain types of groups than the market shares would predict. This is in part because Harvard Pilgrim and Tufts Freedom—two strong local health insurers that have not built national provider networks—are more attractive to small groups and CRC groups with higher percentages of employees resident in New Hampshire. Similarly, because Harvard Pilgrim and Tufts Freedom have priced aggressively, the two appeal to small groups and CRC groups that have greater price sensitivity.

34. Tufts Freedom's entry into New Hampshire in 2016 was backed by its Granite Healthcare provider partners, which formed the core of Tufts Freedom's provider network and extended it substantially below-market rates, enabling it to price aggressively. Using a combination of competitive pricing and a strong provider network, Tufts Freedom significantly grew its small group market share throughout New Hampshire after entering the state in 2016, with its share reaching almost 20% by 2019. Tufts Freedom achieved much of this growth at the expense of Harvard Pilgrim. As a result, and as Harvard Pilgrim recognized, the New Hampshire small group market became a three-player market, consisting of Harvard Pilgrim, Tufts Freedom, and Anthem.

35. Tufts Freedom's aggressive pricing and growth caused Harvard Pilgrim to respond by significantly lowering prices and improving plan features to be more competitive with Tufts Freedom. This response included a strategy of targeting its competitors' ''sweet spots,'' meaning lowering its rates on plans that competed with the most popular offerings of its competitors. Tufts Freedom observed this competitive reaction and in turn responded by announcing lower than expected rate increases. The Transaction would eliminate this fierce competition between Harvard Pilgrim and Tufts Freedom and its resulting benefits to consumers in New Hampshire.

36. Direct competition between Harvard Pilgrim and Tufts Freedom in New Hampshire also has benefitted CRC groups. Again, Tufts Freedom entered New Hampshire pursuing a targeted pricing strategy that allowed it to gain market share. Harvard Pilgrim reacted to this competitive pressure resulting in lower health insurance prices for CRC groups.

37. In addition to this price competition, New Hampshire consumers also have benefitted from competition between Harvard Pilgrim and Tufts Freedom on plan features and quality of service for commercial health insurance sold to CRC groups. For example, in 2019, Harvard Pilgrim developed four new no-coinsurance plans, which limited out-of-pocket expenses to insureds and offered different features, with the express purpose of making them more attractive to the insureds. Just this year, Tufts Freedom offered consumers a novel telehealth option that included zero copayment in fully insured plans in order to drive innovation around this new emerging platform.

38. Harvard Pilgrim and Tufts Freedom have engaged in head-to-head competition on price, plan features, and quality of service in the sale of commercial health insurance to small groups and to CRC groups in New Hampshire. Eliminating this competition would likely result in higher prices, lower quality, and less customer choice in the sale of commercial health insurance to small groups and to CRC groups in New Hampshire.

VI. Absence of Countervailing Factors

39. Other firms are unlikely to enter or expand into the relevant markets in a manner that would be timely, likely, or sufficient to replace the competition that would be lost as a result of the Transaction.

40. Each of the relevant markets is characterized by high barriers to entry, including state licensing and regulatory

requirements, the cost of developing a comprehensive provider network where employees live and work, the inability of insurers without significant membership to obtain competitive discounts from providers, and the development of sufficient business to permit the spreading of risk.

41. The Transaction will not result in verifiable, transaction-specific efficiencies in the relevant markets sufficient to reverse the Transaction's likely anticompetitive effects.

VII. Violation Alleged

42. Plaintiffs allege and incorporate paragraphs 1 through 41 as if set forth fully herein.

43. Unless enjoined, the Transaction is likely to substantially lessen competition in the relevant markets, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

44. Among other things, the Transaction would:

(a) Eliminate present and future competition between Harvard Pilgrim and Health Plan Holdings in New Hampshire;

(b) likely cause prices for commercial health insurance sold to small groups and to CRC groups in New Hampshire to be higher than they would be otherwise; and

(c) likely reduce quality, service, choice, and innovation for commercial health insurance sold to small groups and to CRC groups in New Hampshire.

VIII. Request for Relief

45. Plaintiffs request that:

(a) The Transaction be adjudged to violate Section 7 of the Clayton Act, 15 U.S.C. 18;

(b) the Court permanently enjoin and restrain Defendants from entering into the Transaction contemplated in the Combination Agreement;

(c) Plaintiffs be awarded the costs of this action, including attorneys' fees to the State of New Hampshire; and

(d) Plaintiffs be awarded any other relief that the Court deems just and proper.

Dated: December 14, 2020.

Respectfully submitted,

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United States District Court for the District of New Hampshire

United States of America and State of New Hampshire, Plaintiffs, vs. Harvard Pilgrim Health Care, INC., and Health Plan Holdings, INC., Defendants.

Civil Action No. 1:20-cv-01183–JL
Judge Joseph N. Laplante

[Proposed] Final Judgment

Whereas, Plaintiffs, United States of America and the State of New Hampshire, filed their Complaint on December 14, 2020;

And whereas, Plaintiffs and Defendants, Harvard Pilgrim Health Care, Inc. and Health Plan Holdings, Inc. (f/k/a Tufts Health Plan, Inc.), have consented to entry of this Final Judgment without the taking of testimony, without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact or law;

And whereas, Defendants agree to make a divestiture to remedy the loss of competition alleged in the Complaint;

And whereas, Defendants represent that the divestiture and other relief required by this Final Judgment can and will be made and that Defendants will not later raise a claim of hardship or difficulty as grounds for asking the Court to modify any provision of this Final Judgment;

And whereas, the resolution of the interests of the State of New Hampshire through its Consumer Protection and Antitrust Bureau pursuant to Section 7 of the Clayton Act and the state antitrust law, N.H. Rev. Stat. Ann. Ch. 356, does not impact the jurisdiction or authority of the New Hampshire Insurance Department to pursue any interest authorized by law.

Now therefore, it is ordered, adjudged, and decreed:

I. Jurisdiction

The Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Defendants under Section 7 of the Clayton Act, as amended (15 U.S.C. 18).

II. Definitions

As used in this Final Judgment:

A. ''Harvard Pilgrim'' means Defendant Harvard Pilgrim Health Care, Inc., a Massachusetts nonprofit corporation with its headquarters in Wellesley, Massachusetts, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

B. ''Health Plan Holdings'' means Defendant Health Plan Holdings, Inc. (f/k/a Tufts Health Plan, Inc.), a Massachusetts nonprofit corporation with its headquarters in Watertown, Massachusetts, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

C. ''Tufts Health Freedom Plan'' means Tufts Health Freedom Plans, Inc., its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint

ventures, and their directors, officers, managers, agents, and employees.

D. ''Acquirer'' means UnitedHealth Group, Inc. or another entity approved by the United States of America in its sole discretion to whom Defendants divest the Divestiture Assets.

E. ''CRC'' means community rating by class, which refers to the sale of commercial group health insurance to private employers with between 51 and 99 full-time eligible employees.

F. ''Divestiture Assets'' means:

1. All Healthcare Provider Contracts;

2. All of Defendants' rights, title, and interests in and to all property and assets, tangible and intangible, wherever located, of Tufts Health Freedom Plan, including:

a. All licenses, permits, certifications, approvals, consents, registrations, waivers, and authorizations issued or granted by any governmental organization, and all pending applications or renewals;

b. All real property interests, including leases; and

c. All contracts, other than Healthcare Provider Contracts, to which Tufts Health Freedom Plan is a party, including contractual rights, membership, customer contracts, and all other agreements, commitments, and understandings.

3. All current and historical member records for the health plans that Tufts Health Freedom Plan offers or has offered, including contact information, claims information, clinical information, all underlying electronic data, and all files that contain any current or historical member records for those health plans;

4. All provider-furnished data related to members of health plans that Tufts Health Freedom Plan offers or has offered and all files that contain any provider-furnished data related to those health plans; and

5. An exclusive license to use the ''Tufts Health Freedom,'' ''Tufts Health Freedom Insurance Company,'' and ''Tufts Health Freedom Plan(s)'' brand names, and all associated trademarks, service marks, and service names, in New Hampshire from the date on which the Divestiture Assets are divested to Acquirer through December 31, 2021.

G. ''Granite Healthcare'' means Granite Healthcare Asset Holding Company, LLC, its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures as of July 1, 2020, and their members, directors, officers, managers, agents, and employees. Its members include Catholic Medical Center, Concord Hospital, Southern New Hampshire Health System, Wentworth-Douglass Hospital, and Delta Dental Plan of New Hampshire, Inc. d/b/a Northeast Delta Dental.

H. ''Granite Healthcare Provider Contracts'' means the contracts with Catholic Medical Center, Concord Hospital, Southern New Hampshire Health System, and Wentworth-Douglass Hospital, and any other hospitals that had an ownership interest in Granite Healthcare as of July 1, 2020, to which Tufts Health Freedom Plan is a signatory.

I. ''Healthcare Provider Contracts'' means contracts with healthcare providers to which Tufts Health Freedom Plan is a signatory, including the Granite Healthcare Provider Contracts.

J. ''Including'' means including but not limited to.

K. ''Recruitment Period'' means the period of 60 calendar days from the date on which the Divestiture Assets are divested to Acquirer.

L. ''Regulatory Approvals'' means any approvals or clearances pursuant to Health Plan Holdings' November 16, 2020 Form A filed with the Massachusetts Division of Insurance that are required for the proposed combination of Health Plan Holdings and Harvard Pilgrim to proceed.

M. ''Relevant Personnel'' means every employee of Health Plan Holdings based in or assigned to New Hampshire in calendar year 2020 who (1) holds the title of President; Senior Executive Assistant; Public Policy Manager; Small and Large Group Account Executive; Senior Account Executive; Sales and Account Associate; Small Group Account Manager; Key Account Manager; Large Group Account Manager; Senior Manager, Strategic Marketing; Senior Provider Group Manager; or Small Group Account Manager; and (2) has responsibility for Small Group or CRC for Tufts Health Freedom Plan. The United States, in its sole discretion, will resolve any disagreement regarding which employees are Relevant Personnel.

N. ''Run-out Services'' means services that are customarily provided following an operational transfer of health insurance plans and that require Defendants' ongoing support, including claims processing, claims reporting, administrative support, and routine investigations necessary for claims processing.

O. ''Small Group'' means the sale of commercial group health insurance to private employers with between 1 and 50 full-time eligible employees.

P. ''United'' means UnitedHealth Group, Inc., a Delaware corporation with its headquarters in Minnetonka, Minnesota, its successors and assigns, and its subsidiaries, including its subsidiary United Healthcare Services, Inc., divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

III. Applicability

A. This Final Judgment applies to Harvard Pilgrim and Health Plan Holdings, as defined above, and all other persons in active concert or participation with any Defendant who receive actual notice of this Final Judgment.

B. If, prior to complying with Section IV and Section V of this Final Judgment, Defendants sell or otherwise dispose of all or substantially all of their assets or of business units that include the Divestiture Assets, Defendants must require any purchaser to be bound by the provisions of this Final Judgment. Defendants need not obtain such an agreement from Acquirer.

IV. Divestiture

A. Defendants are ordered and directed, within 30 calendar days after the Court's entry of the Asset Preservation Stipulation and Order (''Stipulation and Order'') in this matter, to divest the Divestiture Assets in a manner consistent with this Final Judgment to United or to another Acquirer acceptable to the United States, in its sole discretion, after consultation with the State of New Hampshire.

B. If Defendants have not received all Regulatory Approvals within 30 calendar days after the Court's entry of the Stipulation and Order in this matter, the time period under Paragraph IV.A will be extended until 5 calendar days after all Regulatory Approvals are received. This extension allowed for securing Regulatory Approvals shall be no longer than 60 calendar days past the time period provided in Paragraph IV.A, unless the United States, in its sole discretion, consents to an additional extension.

C. Defendants must use their best efforts to divest the Divestiture Assets as expeditiously as possible and may not take any action to impede the permitting, operation, or divestiture of the Divestiture Assets.

D. Unless the United States otherwise consents in writing, divestiture pursuant to this Final Judgment must include the entire Divestiture Assets, and must be accomplished in such a way as to satisfy the United States, in its sole discretion, that the Divestiture Assets can and will be used by Acquirer as part of a viable, ongoing business to

compete effectively in Small Group and CRC in New Hampshire and that the divestiture to Acquirer will remedy the competitive harm alleged in the Complaint.

E. The divestiture must be made to an Acquirer that, in the United States' sole judgment, after consultation with the State of New Hampshire, has the intent and capability (including the necessary managerial, operational, technical, and financial capability) to compete effectively in Small Group and CRC in New Hampshire.

F. The divestiture must be accomplished so as to satisfy the United States, in its sole discretion, after consultation with the State of New Hampshire, that none of the terms of any agreement between Acquirer and Defendants gives Defendants the ability unreasonably to raise Acquirer's costs, to lower Acquirer's efficiency, or otherwise to interfere in the ability of Acquirer to compete effectively in Small Group and CRC in New Hampshire.

G. Defendants must permit Acquirer to have reasonable access to personnel and access, subject to customary confidentiality assurances, to any and all financial, operational, or other documents and information regarding the Divestiture Assets customarily provided as part of a due diligence process.

H. In the event Defendants are attempting to divest the Divestiture Assets to an Acquirer other than United, Defendants promptly must make known, by usual and customary means, the availability of the Divestiture Assets. Defendants must inform any person making an inquiry regarding a possible purchase of the Divestiture Assets that the Divestiture Assets are being divested in accordance with this Final Judgment and must provide that person with a copy of this Final Judgment. Defendants must offer to furnish and promptly provide to all prospective Acquirers, subject to customary confidentiality assurances, all information and documents relating to the Divestiture Assets that are customarily provided in a due-diligence process, including all information and documents provided to United; *provided, however,* that Defendants need not provide information or documents subject to the attorney-client privilege or work-product doctrine. Defendants must make all information and documents available to the United States at the same time that the information and documents are made available to any other person.

I. Defendants must cooperate with and assist Acquirer in identifying Relevant Personnel and, at the option of Acquirer, in hiring any Relevant Personnel, including:

1. No later than five business days following the filing of the Complaint in this matter, Defendants must provide to Acquirer and Plaintiffs, a list of all Relevant Personnel.

2. Following the filing of the Complaint in this matter, within seven business days following receipt of a request by Acquirer or the United States, Defendants must provide to Acquirer and Plaintiffs, additional information related to Relevant Personnel, including name, job title, reporting relationships, past experience, responsibilities, training and educational history, relevant certifications, job performance evaluations. Defendants must also provide to Acquirer current, recent, and accrued compensation and benefits, including most recent bonuses paid, aggregate annual compensation, current target or guaranteed bonus, if any, any retention agreement or incentives, and any other payments due, compensation or benefits accrued, or promises made to Relevant Personnel. If Defendants are barred by any applicable laws from providing any of this information, Defendants must provide, within seven business days following receipt of the request, the requested information to the full extent permitted by law and also must provide a written explanation of Defendants' inability to provide the remaining information, including specifically identifying the provisions of the applicable laws.

3. At the request of Acquirer, Defendants must promptly make Relevant Personnel available for private interviews with Acquirer during normal business hours at a mutually agreeable location.

4. Defendants must not interfere with any effort by Acquirer to employ any Relevant Personnel. Interference includes offering to increase the compensation or benefits of Relevant Personnel unless the offer is part of a company-wide increase in compensation or benefits granted that was announced prior to May 1, 2020, or has been approved by the United States, in its sole discretion. Defendants' obligations under this Paragraph I.4. will expire after the Recruitment Period.

5. For Relevant Personnel who elect employment with Acquirer during the Recruitment Period, Defendants must waive all non-compete and non-disclosure agreements; vest and pay to the Relevant Personnel (or to Acquirer for payment to the employee) on a prorated basis any bonuses, incentives, other salary, benefits, or other compensation fully or partially accrued at the time of the transfer of the employee to Acquirer; vest any unvested pension and other equity rights; and provide all other benefits that those Relevant Personnel otherwise would have been provided had the Relevant Personnel continued employment with Defendants, including any retention bonuses or payments. Defendants may maintain reasonable restrictions on disclosure by Relevant Personnel of Defendants' proprietary non-public information that is unrelated to the Divestiture Assets and not otherwise required to be disclosed by this Final Judgment.

6. Acquirer's right to hire Relevant Personnel under Paragraph IV.I. lasts throughout the duration of the Recruitment Period.

7. For a period of one year from the date on which the Divestiture Assets are divested to Acquirer, Defendants may not solicit to rehire Relevant Personnel who were hired by Acquirer during the Recruitment Period, unless (a) an individual is terminated or laid off by Acquirer or (b) Acquirer agrees in writing that Defendants may solicit to rehire that individual. Nothing in this Paragraph prohibits Defendants from advertising employment openings using general solicitations or advertisements and rehiring Relevant Personnel who apply for an employment opening through a general solicitation or advertisement.

J. Defendants must warrant to Acquirer that (1) the Divestiture Assets will be operational and without material defect on the date of their transfer to Acquirer; (2) there are no material defects in any permits pertaining to the operation of the Divestiture Assets; and (3) Defendants have disclosed all encumbrances on any part of the Divestiture Assets, including on intangible property. Following the sale of the Divestiture Assets, Defendants must not undertake, directly or indirectly, challenges to any permits pertaining to the operation of the Divestiture Assets.

K. Defendants must make best efforts to assist Acquirer to obtain all necessary licenses, registrations, and permits to operate the Divestiture Assets. Until Acquirer obtains the necessary licenses, registrations, and permits, Defendants must provide Acquirer with the benefit of Defendants' licenses, registrations, and permits to the full extent permissible by law.

L. Defendants must make best efforts to transition customers from the Health Plan Holdings operating platform to Acquirer's operating platform beginning July 1, 2021, and ending by December 31, 2021.

M. At the option of Acquirer, and subject to approval by the United States, in its sole discretion, on or before the date on which the Divestiture Assets are divested to Acquirer, Defendants must enter into one or more agreements to provide transition services for a period ending no later than December 31, 2021, or, if Acquirer is not United, for a period of one year from the date of divestiture, on terms and conditions reasonably related to market conditions and must fully perform the duties and obligations of such agreements. The transition services to be provided by Defendants to Acquirer under such agreements must encompass all services necessary for the Acquirer to operate the Divestiture Assets, including: (1) Providing the operational platform and systems infrastructure to run the Divestiture Assets, including appropriate hardware and software; (2) preparing regulatory plan submissions, including filing and securing regulatory approval, for product, rate, and other required submissions; (3) handling member services and enrollment, the processing and administration of claims, routine investigations, and member appeals and grievances; (4) providing and preparing claims reports; (5) performing accounting and billing, finance support, and payment integrity maintenance; (6) providing care management services; (7) providing regulatory compliance; (8) processing vendor costs; (9) providing benefits configuration; (10) providing broker and employer services; (11) handling provider services and appeals; (12) processing provider demographic, contract, and fee schedules updates; (13) maintaining coordination of benefits programs; (14) providing underwriting support services; and (15) making personnel available to assist Acquirer with operational questions and issues. Any amendments to or modifications of any provision of a transition services agreement are subject to approval by the United States, in its sole discretion. Acquirer may terminate a transition services agreement, or any portion of a transition services agreement, without cost or penalty at any time upon commercially reasonable notice. The employee(s) of Defendants tasked with providing transition services must not share any competitively sensitive information of Acquirer with any other employee of Defendants, unless such sharing is for the sole purpose of providing transition services to Acquirer.

N. At the option of Acquirer, and subject to approval by the United States in its sole discretion, on or before the date on which the Divestiture Assets are divested to Acquirer, Defendants must enter into one or more agreements to provide Run-out Services to Acquirer from the date of each customer's transition to Acquirer's operating platform to June 30, 2022. At Acquirer's option, after written notice to the United States, Defendants must extend any contract for Run-out Services for a total of up to an additional 90 days. Defendants must provide Run-out Services on terms and conditions reasonably related to market conditions. Any amendments to or modifications of any provision of a Run-out Services agreement are subject to approval by the United States, in its sole discretion. Acquirer may terminate a Run-out Services agreement, or any portion of a Run-out Services agreement, without cost or penalty at any time upon commercially reasonable notice. The employee(s) of Defendants tasked with providing Run-out Services must not share any competitively sensitive information of Acquirer with any other employee of Defendants, unless such sharing is for the sole purpose of providing Run-out Services to Acquirer.

O. Except for Healthcare Provider Contracts, Defendants must make any required notifications and use best efforts to obtain all necessary consents of the contracting party to the change of control of Tufts Health Freedom Plan to Acquirer. Defendants must not interfere with any negotiations between Acquirer and a contracting party.

P. Defendants warrant that as of the date on which the Divestiture Assets are divested to Acquirer, the Granite Healthcare Provider Contracts have not expired or terminated, will run through at least December 31, 2021, and will be on the same rates and terms that were in effect as of October 1, 2020, except for any increase in rates that is (a) no greater than a rate increase imposed on Health Plan Holdings between October 1, 2020 and April 1, 2021, and (b) reasonably related to market conditions.

Q. Defendants must make best efforts and must cooperate with and assist Acquirer to ensure that Acquirer will retain all of the Healthcare Provider Contracts. Best efforts includes the following:

1. For Healthcare Provider Contracts with Tufts Health Freedom Plan's fifteen largest healthcare providers in New Hampshire, as measured by Tufts Health Freedom Plan's 2019 claims volume, that do not require notification of a change in ownership or control of Tufts Health Freedom Plan, Defendants must ensure that as of the date on which the Divestiture Assets are divested to Acquirer, the contracts have not expired or terminated and include the same rates and terms that were in effect as of October 1, 2020, except for any increase in rates that is (a) no greater than a rate increase imposed on Health Plan Holdings between October 1, 2020 and April 1, 2021, and (b) reasonably related to market conditions.

2. For all Healthcare Provider Contracts that require a provider's consent to a change in ownership or control of Tufts Health Freedom Plan, or that allow a provider to terminate the contract upon notice of a change in ownership or control, Defendants must notify each such provider of the change in ownership or control within 30 calendar days of entering into an agreement to divest the Divestiture Assets to Acquirer. Except for Healthcare Provider Contracts for which the time to exercise any termination rights has expired without the provider terminating the contract or giving Defendants written notice of an intent to terminate, Defendants must use best efforts to obtain any necessary consent to a change in ownership or control or written acknowledgment that a provider will not terminate because of a change in ownership or control.

3. For any Healthcare Provider Contract that is terminated or for which a provider gives written notice of its intent to terminate within 90 days from the date on which the Divestiture Assets are divested to Acquirer, at Acquirer's request, Defendants must assist Acquirer to secure a new contract with that provider as expeditiously as possible by sharing information with Acquirer concerning the history of the provider's participation in the Tufts Health Freedom Plan, including the performance of the contract and any material disputes relating to the contract, and assisting Acquirer in developing strategies to retain or bring the provider in-network and on the same rates and terms that were in effect as of October 1, 2020, except for any increase in rates that is (a) no greater than a rate increase imposed on Health Plan Holdings between October 1, 2020 and April 1, 2021, and (b) reasonably related to market conditions.

4. If a provider terminates or gives written notice of its intent to terminate any Healthcare Provider Contract within 90 days from the date on which the Divestiture Assets are divested to Acquirer and Acquirer is unable to secure a contract with the provider before the contract terminates, and either (1) the provider is one of Tufts Health Freedom Plan's fifteen largest healthcare providers in New Hampshire, as measured by Tufts Health Freedom Plan's 2019 claims volume, or (2) the termination would result in Tufts

Health Freedom Plan not meeting provider network adequacy standards required by applicable law or regulation, at Acquirer's request, Defendants must, to the full extent permitted by the terms of Defendants' provider contracts, immediately enter into a rental, lease, or similar contract to provide Acquirer with in-network access to the relevant healthcare provider(s) for a period of 12 months from the date on which the Divestiture Assets are divested to Acquirer. Defendants may charge Acquirer no more than Defendants' costs paid to the relevant healthcare provider(s), without adding any mark-up, for the provision of such rental, lease, or similar contract.

5. For all Healthcare Provider Contracts that will expire between the filing of the Complaint in this matter and 90 days after the date on which the Divestiture Assets are divested to Acquirer, Defendants must use best efforts to expeditiously renew each contract to avoid a termination and out-of-network status for that provider, on the same rates and terms that were in effect as of October 1, 2020, except for any increase in rates that is (a) no greater than a rate increase imposed on Health Plan Holdings between October 1, 2020 and April 1, 2021, and (b) reasonably related to market conditions.

R. From the date on which the Divestiture Assets are divested to Acquirer through December 31, 2021, Defendants must not sell any commercial health insurance products in New Hampshire that use the ''Tufts Health'' or ''Tufts Health Plan'' brand(s) (and all associated trademarks, service marks, and service names). This Paragraph does not prohibit Defendants from using the ''Tufts Health'' or ''Tufts Health Plan'' brand(s) for group retiree plans, Medicaid plans, or Medicare plans in New Hampshire.

S. Beginning on the date on which the Divestiture Assets are divested to Acquirer, Defendants must not use the terms ''Health Freedom Plan(s),'' ''Freedom,'' and/or ''Freedom Plan(s)'' for any business name or to identify, market, or promote any products or services in New Hampshire.

T. If any term of an agreement between Defendants and Acquirer to effectuate the divestiture required by this Final Judgment varies from a term of this Final Judgment, to the extent that Defendants cannot fully comply with both, this Final Judgment determines Defendants' obligations.

V. Appointment of Divestiture Trustee

A. If Defendants have not divested the Divestiture Assets within the period specified in Paragraphs IV.A. and IV.B., Defendants must immediately notify Plaintiffs of that fact in writing. Upon application of the United States, the Court will appoint a divestiture trustee selected by the United States and approved by the Court to effect the divestiture of the Divestiture Assets.

B. After the appointment of a divestiture trustee by the Court, only the divestiture trustee will have the right to sell the Divestiture Assets. The divestiture trustee will have the power and authority to accomplish the divestiture to an Acquirer acceptable to the United States, in its sole discretion, after consultation with the State of New Hampshire, at a price and on terms as are then obtainable upon reasonable effort by the divestiture trustee, subject to the provisions of Sections IV, V, and VI of this Final Judgment, and will have other powers as the Court deems appropriate. The divestiture trustee must sell the Divestiture Assets as quickly as possible.

C. Defendants may not object to a sale by the divestiture trustee on any ground other than malfeasance by the divestiture trustee. Objections by Defendants must be conveyed in writing to Plaintiffs and the divestiture trustee within ten calendar days after the divestiture trustee has provided the notice of proposed divestiture required under Section VI.

D. The divestiture trustee will serve at the cost and expense of Defendants pursuant to a written agreement, on terms and conditions, including confidentiality requirements and conflict of interest certifications, that are approved by the United States.

E. The divestiture trustee may hire at the cost and expense of Defendants any agents or consultants, including, but not limited to, investment bankers, attorneys, and accountants, that are reasonably necessary in the divestiture trustee's judgment to assist with the divestiture trustee's duties. These agents or consultants will be accountable solely to the divestiture trustee and will serve on terms and conditions, including terms and conditions governing confidentiality requirements and conflict-of-interest certifications, that are approved by the United States.

F. The compensation of the divestiture trustee and agents or consultants hired by the divestiture trustee must be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement that provides the divestiture trustee with incentives based on the price and terms of the divestiture and the speed with which it is accomplished. If the divestiture trustee and Defendants are unable to reach agreement on the divestiture trustee's compensation or other terms and conditions of engagement within 14 calendar days of the appointment of the divestiture trustee by the Court, the United States may, in its sole discretion, take appropriate action, including by making a recommendation to the Court. Within three business days of hiring an agent or consultant, the divestiture trustee must provide written notice of the hiring and rate of compensation to Defendants and the United States.

G. The divestiture trustee must account for all monies derived from the sale of the Divestiture Assets sold by the divestiture trustee and all costs and expenses incurred. Within 30 calendar days of the date of the sale of the Divestiture Assets, the divestiture trustee must submit that accounting to the Court for approval. After approval by the Court of the divestiture trustee's accounting, including fees for unpaid services and those of agents or consultants hired by the divestiture trustee, all remaining money must be paid to Defendants and the trust will then be terminated.

H. Defendants must use their best efforts to assist the divestiture trustee to accomplish the required divestiture. Subject to reasonable protection for trade secrets, other confidential research, development, or commercial information, or any applicable privileges, Defendants must provide the divestiture trustee and agents or consultants retained by the divestiture trustee with full and complete access to all personnel, books, records, and facilities of the Divestiture Assets. Defendants also must provide or develop financial and other information relevant to the Divestiture Assets that the divestiture trustee may reasonably request. Defendants may not take any action to interfere with or to impede the divestiture trustee's accomplishment of the divestiture.

I. The divestiture trustee must maintain complete records of all efforts made to sell the Divestiture Assets, including by filing monthly reports with Plaintiffs setting forth the divestiture trustee's efforts to accomplish the divestiture ordered by this Final Judgment. The reports must include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring any interest in the Divestiture Assets and must describe in detail each contact with any such person.

J. If the divestiture trustee has not accomplished the divestiture ordered by

this Final Judgment within six months of appointment, the divestiture trustee must promptly provide Plaintiffs with a report setting forth: (1) The divestiture trustee's efforts to accomplish the required divestiture; (2) the reasons, in the divestiture trustee's judgment, why the required divestiture has not been accomplished; and (3) the divestiture trustee's recommendations for completing the divestiture. Following receipt of that report, the United States may make additional recommendations consistent with the purpose of the trust to the Court. The Court thereafter may enter such orders as it deems appropriate to carry out the purpose of this Final Judgment, which may include extending the trust and the term of the divestiture trustee's appointment by a period requested by the United States.

K. The divestiture trustee will serve until divestiture of all Divestiture Assets is completed or for a term otherwise ordered by the Court.

L. If the United States determines that the divestiture trustee is not acting diligently or in a reasonably cost-effective manner, the United States may recommend that the Court appoint a substitute divestiture trustee.

VI. Notice of Proposed Divestiture

A. Within two business days following execution of a definitive divestiture agreement with a proposed Acquirer other than United, Defendants or the divestiture trustee, whichever is then responsible for effecting the divestiture, must notify Plaintiffs of a proposed divestiture required by this Final Judgment. If the divestiture trustee is responsible for completing the divestiture, the divestiture trustee also must notify Defendants. The notice must set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the Divestiture Assets.

B. Within 15 calendar days of receipt by the United States of this notice, the United States, in its sole discretion, may request from Defendants, the proposed Acquirer, other third parties, or the divestiture trustee additional information concerning the proposed divestiture, the proposed Acquirer, and other prospective Acquirers. Defendants and the divestiture trustee must furnish the additional information requested within 15 calendar days of the receipt of the request unless the United States provides written agreement to a different period.

C. Within 45 calendar days after receipt of the notice required by Paragraph VI.A. or within 20 calendar days after the United States has been provided the additional information requested pursuant to Paragraph VI.B., whichever is later, the United States will provide written notice to Defendants and any divestiture trustee that states whether or not the United States, in its sole discretion, after consultation with the State of New Hampshire, objects to Acquirer or any other aspect of the proposed divestiture. Without written notice that the United States does not object, a divestiture may not be consummated. If the United States provides written notice that it does not object, the divestiture may be consummated, subject only to Defendants' limited right to object to the sale under Paragraph V.C. of this Final Judgment. Upon objection by Defendants pursuant to Paragraph V.C., a divestiture by the divestiture trustee may not be consummated unless approved by the Court.

D. No information or documents obtained pursuant to this Section VI may be divulged by Plaintiffs to any person other than an authorized representative of the executive branch of the United States or an authorized representative of the State of New Hampshire, except in the course of legal proceedings to which the United States is a party, including grand-jury proceedings, for the purpose of evaluating a proposed Acquirer or securing compliance with this Final Judgment, or as otherwise required by law.

E. In the event of a request by a third party for disclosure of information under the Freedom of Information Act, 5 U.S.C. 552, the Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Persons submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire ten years after submission, ''unless the submitter requests and provides justification for a longer designation period.'' *See* 28 CFR 16.7(b).

F. If at the time that a person furnishes information or documents to the United States or the State of New Hampshire pursuant to this Section VI, that person represents and identifies in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and marks each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' the United States and the State of New Hampshire must give that person ten calendar days' notice before divulging the material in any legal proceeding (other than a grand-jury proceeding).

VII. Financing

Defendants may not finance all or any part of Acquirer's purchase of all or part of the Divestiture Assets made pursuant this Final Judgment.

VIII. Asset Preservation Obligations

Until the divestiture required by this Final Judgment has been accomplished, Defendants must take all steps necessary to comply with the Stipulation and Order entered by the Court. Defendants must take no action that would jeopardize the divestiture ordered by the Court.

IX. Affidavits

A. Within 20 calendar days of the filing of the Complaint in this matter, and every 30 calendar days thereafter until the divestiture required by this Final Judgment has been completed, Defendant Health Plan Holdings must deliver to Plaintiffs an affidavit, signed by its Chief Financial Officer and Chief Legal Officer, describing the fact and manner of Defendants' compliance with this Final Judgment. The United States, in its sole discretion, may approve different signatories for the affidavits.

B. Each affidavit must include: (1) The name, address, and telephone number of each person who, during the preceding 30 calendar days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, an interest in the Divestiture Assets and describe in detail each contact with such persons during that period; (2) a description of the efforts Defendants have taken to solicit buyers for and complete the sale of the Divestiture Assets and to provide required information to prospective Acquirers; and (3) a description of any limitations placed by Defendants on information provided to prospective Acquirers. Objection by the United States to information provided by Defendants to prospective Acquirers must be made within 14 calendar days of receipt of the affidavit.

C. Defendants must keep all records of any efforts made to divest the Divestiture Assets until one year after the divestiture has been completed.

D. Within 20 calendar days of the filing of the Complaint in this matter, Defendant Health Plan Holdings also

must deliver to Plaintiffs an affidavit that describes in reasonable detail all actions Defendants have taken and all steps Defendants have implemented on an ongoing basis to comply with Section VIII of this Final Judgment. The United States, in its sole discretion, may approve different signatories for the affidavits.

E. If Defendants make any changes to the efforts and actions outlined in any earlier affidavits provided pursuant to Paragraph IX.D., Defendants must, within 15 calendar days after any change is implemented, deliver to Plaintiffs an affidavit describing those changes.

F. Defendants must keep all records of any efforts made to preserve the Divestiture Assets until one year after the divestiture has been completed.

X. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment or of related orders such as the Stipulation and Order or of determining whether this Final Judgment should be modified or vacated, upon written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, and reasonable notice to Defendants, Defendants must permit, from time to time and subject to legally recognized privileges, authorized representatives, including agents retained by the United States:

1. To have access during Defendants' office hours to inspect and copy, or at the option of the United States, to require Defendants to provide electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendants relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews must be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, Defendants must submit written reports or respond to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment.

C. No information or documents obtained by the United States pursuant to this Section X may be divulged by Plaintiffs to any person other than an authorized representative of the executive branch of the United States or an authorized representative of the State of New Hampshire, except in the course of legal proceedings to which the United States is a party, including grand jury proceedings, for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. In the event of a request by a third party for disclosure of information under the Freedom of Information Act, 5 U.S.C. 552, the Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Defendants submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire ten years after submission, ''unless the submitter requests and provides justification for a longer designation period.'' See 28 CFR 16.7(b).

E. If at the time that Defendants furnish information or documents to the United States pursuant to this Section X, Defendants represent and identify in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' the United States must give Defendants ten calendar days' notice before divulging the material in any legal proceeding (other than a grand jury proceeding).

XI. No Reacquisition

Defendants may not reacquire any part of or any interest in the Divestiture Assets during the term of this Final Judgment.

XII. Retention of Jurisdiction

The Court retains jurisdiction to enable any party to this Final Judgment to apply to the Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIII. Enforcement of Final Judgment

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendants agree that in a civil contempt action, a motion to show cause, or a similar action brought by the United States regarding an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of a remedy therefor by a preponderance of the evidence, and Defendants waive any argument that a different standard of proof should apply.

B. This Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore the competition Plaintiffs alleged was harmed by the challenged conduct. Defendants agree that they may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

C. In an enforcement proceeding in which the Court finds that Defendants have violated this Final Judgment, the United States may apply to the Court for a one-time extension of this Final Judgment, together with other relief that may be appropriate. In connection with a successful effort by the United States to enforce this Final Judgment against a Defendant, whether litigated or resolved before litigation, that Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as all other costs including experts' fees, incurred in connection with that enforcement effort, including in the investigation of the potential violation.

D. For a period of four years following the expiration of this Final Judgment, if the United States has evidence that a Defendant violated this Final Judgment before it expired, the United States may file an action against that Defendant in this Court requesting that the Court order: (1) Defendant to comply with the terms of this Final Judgment for an additional term of at least four years following the filing of the enforcement action; (2) all appropriate contempt remedies; (3) additional relief needed to ensure the Defendant complies with the terms of this Final Judgment; and (4) fees or expenses as called for by this Section XIII.

XIV. Expiration of Final Judgment

Unless the Court grants an extension, this Final Judgment will expire ten years from the date of its entry, except that after five years from the date of its entry, this Final Judgment may be terminated upon notice by the United

States to the Court and Defendants the divestiture has been completed and that the continuation of this Final Judgment is no longer necessary or in the public interest.

XV. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including by making available to the public copies of this Final Judgment and the Competitive Impact Statement, public comments thereon, and the United States' response to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date: _____

[Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16]

_____

United States District Judge

United States District Court for the District of New Hampshire

United States of Americaand State of New Hampshire, Plaintiffs, vs. Harvard Pilgrim Health Care, INC. and Health Plan Holdings, INC., Defendants.

Civil Action No.:1:20–cv–01183–JL
Judge Joseph N. Laplante

Competitive Impact Statement

The United States of America, under Section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h) (the ''APPA'' or ''Tunney Act''), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On August 9, 2019, Defendants Harvard Pilgrim and Health Plan Holdings (f/k/a Tufts Health Plan) agreed to a ''merger of equals'' (the ''Transaction''). The United States, along with the State of New Hampshire, filed a civil antitrust complaint on December 14, 2020, seeking to enjoin the proposed Transaction. The Complaint alleges that the likely effect of the Transaction would be to substantially lessen competition in (1) the sale of commercial group health insurance to private employers with up to 50 full-time eligible employees (''small groups'') in all seven New Hampshire Core Based Statistical Areas (''CBSAs''), and (2) the sale of commercial group health insurance to private employers with between 51 and 99 full-time eligible employees (''CRC groups'') in six New Hampshire CBSAs, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

At the same time the Complaint was filed, the United States filed an Asset Preservation Stipulation and Order (''Stipulation and Order'') and proposed Final Judgment, which are designed to remedy the loss of competition alleged in the Complaint. Under the proposed Final Judgment, which is explained more fully below, Defendants are required to divest Health Plan Holdings' New Hampshire subsidiary, Tufts Health Freedom Plans, Inc. (''Tufts Freedom''). The United States has approved UnitedHealth Group, Inc. (''United'') as the acquirer of Tufts Freedom. Under the terms of the Stipulation and Order, Defendants will take certain steps to ensure that Tufts Freedom is operated as a competitively independent, economically viable, and ongoing business concern, which will remain independent and uninfluenced by Defendants, and that competition is maintained during the pendency of the required divestiture.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment will terminate this action, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

II. Decription of the Events Giving Rise to the Alleged Violation

A. Defendants and the Proposed Transaction

Harvard Pilgrim is a nonprofit corporation organized and existing under the laws of the Commonwealth of Massachusetts with its headquarters in Wellesley, Massachusetts. Harvard Pilgrim sells commercial group health insurance plans to small and large employer groups in New Hampshire, Massachusetts, Connecticut, and Maine. Harvard Pilgrim's annual revenue in 2019 was approximately $3 billion, with the vast majority of this revenue coming from commercial insurance products, and it has over one million members across all its insurance products.

Health Plan Holdings is a nonprofit corporation organized and existing under the laws of the Commonwealth of Massachusetts with its headquarters in Watertown, Massachusetts. Prior to October 7, 2020, Health Plan Holdings was known as Tufts Health Plan, Inc. Health Plan Holdings sells commercial group health insurance plans to small and large employer groups in New Hampshire, Massachusetts, and Rhode Island. In New Hampshire, Health Plan Holdings sells health insurance through Tufts Freedom. Tufts Freedom was a joint venture with Granite Healthcare, a consortium of New Hampshire hospitals, until September 2020, when Health Plan Holdings purchased the hospitals' interests and became the sole owner. Health Plan Holdings' annual revenue in 2019 was over $5.5 billion, with roughly one-third of this revenue coming from commercial insurance products, and it has over one million members across all its insurance products.

On August 9, 2019, Defendants entered into an agreement entitled ''Combination Agreement'' pursuant to which Health Plan Holdings will acquire Harvard Pilgrim. No money is exchanging hands and Defendants have described the transaction as a ''merger of equals.''

B. The Competitive Effects of the Transaction

Health insurance companies sell commercial group health insurance to employers so employers can provide their employees and their employees' families with health insurance coverage. Harvard Pilgrim and Health Plan Holdings are two of the largest suppliers of commercial health insurance in New Hampshire to employers with less than 100 employees. Harvard Pilgrim and Health Plan Holdings compete vigorously with one another in the sale of commercial health insurance to these employers. As alleged in the Complaint, combining Harvard Pilgrim and Health Plan Holdings into one firm would likely lead to higher prices, lower quality, and reduced choice in New Hampshire.

1. The Relevant Markets

(a) Commercial Health Insurance Sold to Small Groups

As alleged in the Complaint, the sale of commercial health insurance to small groups is a relevant antitrust product market in which to analyze the effects of the Transaction. New Hampshire Insurance Department regulations define a ''small group'' as an employer with 50 or fewer full-time eligible employees. *See* N.H. Rev. Stat. Ann. § 420–G:2, XVI. For small groups, health plans are typically fully insured, which means that the employer pays a premium to the insurance company and in return the company covers the employees' healthcare costs. Small groups tend to be local in nature, requiring a strong local provider

network of doctors and hospitals that are contracted to provide medical care to the group's employees. The relevant market for small groups alleged in the Complaint does not include governmental employers (*e.g.,* municipalities, school districts) in New Hampshire with 50 or fewer employees, as historically almost all of these employers have purchased health insurance through a multi-employer trust instead of directly from an insurer.

The commercial health insurance plans offered to small groups are governed by the New Hampshire Insurance Department. The small group plans cannot be substituted with plans offered to New Hampshire employers with 51 or more full-time eligible employees, defined by statute in New Hampshire as ''large group.'' Harvard Pilgrim and Health Plan Holdings also differentiate small group accounts separately from large group accounts internally and offer different pricing for small group products compared to large group products.

New Hampshire law does not require that an insurer offer a small group product statewide and instead permits an insurer to offer small group plans only in certain counties. Accordingly, despite the fact that state law does not allow insurers to charge different prices for the same small group plans based on location, insurers can offer a more expensive set of small group plans in one part of the state, and a less expensive set of different small group plans in another part of the state. This allows insurers to charge different prices for different products to small groups based on where employees live and work.

There are seven Core Based Statistical Areas (CBSA) in New Hampshire: (1) The Manchester-Nashua CBSA, (2) the Concord CBSA, (3) the Laconia CBSA, (4) the Keene CBSA, (5) the Berlin CBSA, (6) the New Hampshire counties (Grafton and Sullivan) of the Lebanon NH–VT CBSA, and (7) the New Hampshire counties (Rockingham and Strafford) of the Boston-Cambridge-Newton MA–NH CBSA. As alleged in the Complaint, the Transaction is likely to substantially lessen competition for the sale of commercial health insurance to small groups in all seven of New Hampshire's CBSAs.

Each of these seven CBSAs is a relevant geographic market. A hypothetical monopolist over the sale of commercial health insurance to small groups in each of these markets would impose a small but significant and non-transitory increase in price (*e.g.* five percent). A small group employer, faced with a significant price increase, cannot defeat the price increase by purchasing a large group product for which it is ineligible. This price increase also would not be defeated by substitution outside the relevant market or by a small group employer trying to repurchase insurance through another employer group (*i.e.* arbitrage).

(b) Commercial Health Insurance Sold to CRC Groups

As alleged in the Complaint, the sale of commercial health insurance to CRC groups is a relevant antitrust product market. In New Hampshire, employers with between 51 and 99 full-time eligible employees represent a distinct segment of large group and are referred to as CRC employers (or CRC groups). CRC groups have different needs and make different buying decisions than small groups or even larger employers. Harvard Pilgrim and Tufts Freedom employ different sales strategies for this segment than they do for other types of employers.

Similar to small groups, CRC group health plans are typically fully insured, which means that the employer pays a premium to the insurance company and in return the company covers the employees' healthcare costs. Insurers offering commercial health insurance in New Hampshire, including Harvard Pilgrim and Tufts Freedom, differentiate employers with 51 to 99 full-time eligible employees from other large group employers, and refer to these employers as the CRC segment. As with small groups, CRC groups also tend to be more local in nature than other large group employers, requiring a strong local provider network, as opposed to large group employers with 100 or more full-time eligible employees, which, due to a more geographically dispersed employee base, are more likely to require strong national provider networks. As with small groups, the relevant market for CRC groups alleged in the Complaint does not include governmental employers (*e.g.,* municipalities, school districts) in New Hampshire with 51–99 employees, as historically almost all of these employers have purchased health insurance through a multi-employer trust instead of directly from an insurer.

Group health plans for CRC groups, in contrast to larger group employers, are typically (although not exclusively) community rated by class, meaning that, when setting rates for CRC groups, the insurer first establishes a base rate determined by the medical costs of a class of similar groups, rather than upon the medical costs of the individual group seeking the plan. The insurer then uses this base rate, along with the individual employer's medical costs, to negotiate rates with the specific CRC group.

Defendants target CRC groups directly through their sales efforts. For example, Tufts Freedom has focused its large group sales efforts on CRC groups since it began selling commercial health insurance in New Hampshire, while Harvard Pilgrim tracks CRC groups separately from other large group accounts. In addition, both Harvard Pilgrim and Tufts Freedom utilize specific pricing strategies for CRC groups. Defendants have formulated these specific pricing strategies because CRC groups in New Hampshire are generally more price sensitive than large group employers with 100 or more full-time eligible employees.

Unlike commercial health insurance sold to small groups, insurers offering commercial health insurance to CRC groups in New Hampshire can charge different prices to different employers. Thus, insurers may charge different prices to CRC groups based on where employees live and work. The Transaction is likely to substantially lessen competition for the sale of commercial health insurance to CRC groups in six separate CBSAs in New Hampshire: (1) the Manchester-Nashua CBSA, (2) the Concord CBSA, (3) the Laconia CBSA, (4) the Keene CBSA, (5) the New Hampshire counties (Grafton and Sullivan) of the Lebanon NH–VT CBSA, and (6) the New Hampshire counties (Rockingham and Strafford) of the Boston-Cambridge-Newton MA–NH CBSA.

As alleged in the Complaint, each of these six CBSAs is a relevant geographic market. A hypothetical monopolist over the sale of commercial health insurance to CRC groups in each of these markets would impose a small but significant (*e.g.,* five percent) and non-transitory increase in price. This price increase would not be defeated by substitution outside the relevant market or by arbitrage.

2. The Transaction Would Result in Large Combined Market Shares

Harvard Pilgrim and Tufts Freedom are two of the largest providers of small group and CRC group insurance in New Hampshire. The Transaction would result in a substantial increase in concentration of insurers that compete to offer commercial health insurance to small groups and CRC groups in New Hampshire.

The Supreme Court has held that mergers that significantly increase concentration in already concentrated markets are presumptively anticompetitive and therefore

presumptively unlawful. To measure market concentration, courts often use the Herfindahl-Hirschman Index (''HHI'') as described in the *Horizontal Merger Guidelines.* HHIs range from 0 in markets with no concentration to 10,000 in markets where one firm has a 100% market share. According to the *Horizontal Merger Guidelines,* mergers that increase the HHI by more than 200 and result in an HHI above 2,500 in any market are presumed to be anticompetitive and, therefore, unlawful.

The Complaint alleges that the Transaction is presumptively unlawful in the small group market. Based upon 2018 data, the combined market shares for Harvard Pilgrim and Tufts Freedom range from over 45% to over 60% in each of the seven CBSAs. As alleged in the Complaint, the Transaction would reduce the number of small group health insurers from four to three, with the two largest insurers—Anthem Blue Cross and Blue Shield (''Anthem'') and the merged Harvard Pilgrim/Tufts Freedom—possessing over 95% share in each of the seven CBSAs. The result is highly concentrated markets with HHIs of between 4,500 and 7,500 and increases in HHIs from over 350 to over 1,600.

As alleged in the Complaint, the Transaction is also presumptively unlawful in the CRC group market. Based upon 2018 data, the combined market shares for Harvard Pilgrim and Tufts Freedom range from more than 40% to over 65% in each of the six CBSAs. Similar to the small group market, the Transaction would reduce the number of CRC group health insurers from four to three, with the two largest insurers—Anthem and the merged Harvard Pilgrim/Tufts Freedom—possessing over 95% share in each of the six CBSAs. The result is highly concentrated markets with HHIs of between just under 5,000 to almost 7,000 and increases in HHIs from over 200 to over 2,000.

3. The Transaction Would Eliminate Head-to-Head Competition Between Two Close Competitors

As alleged in the Complaint, Harvard Pilgrim and Tufts Freedom are particularly close competitors for commercial health insurance sold to small groups and CRC groups in New Hampshire. The competition between the two insurers is more robust for certain types of groups than the market shares would predict. This is in part because Harvard Pilgrim and Tufts Freedom—two strong local health insurers that have not built national provider networks—are more attractive to small groups and CRC groups with higher percentages of employees residing in New Hampshire. Similarly, because Harvard Pilgrim and Tufts Freedom have priced aggressively, the two appeal to small groups and CRC groups that have greater price sensitivity.

Harvard Pilgrim and Tufts Freedom have engaged in head-to-head competition on price, plan features, and quality of service in the sale of commercial health insurance to small groups and to CRC groups in New Hampshire. For example, as the Complaint alleges, upon entering the New Hampshire market in 2016, Tufts Freedom priced aggressively, and gained significant market share, largely at the expense of Harvard Pilgrim. Additionally, in 2019, Harvard Pilgrim developed four new no-coinsurance plans, which limited out-of-pocket expenses to members and offered different features, with the express purpose of making them more attractive to members. Just this year, Tufts Freedom offered consumers a novel telehealth option that included zero copayment in fully insured plans in order to drive innovation around this emerging platform. Eliminating competition between Harvard Pilgrim and Tufts Freedom would likely result in higher prices, lower quality, less innovation, and less customer choice in the sale of commercial health insurance to small groups and to CRC groups in New Hampshire.

4. Difficulty of Entry or Expansion

As alleged in the Complaint, new entry and expansion by competitors will likely neither be timely nor sufficient in scope to prevent the likely anticompetitive effects of the proposed Transaction. Barriers to entry and expansion include state licensing and regulatory requirements, the cost of developing a comprehensive provider network where employees live and work, the inability of insurers without significant membership to obtain competitive discounts from providers, and the development of sufficient business to permit the spreading of risk.

The Complaint also alleges that the anticompetitive effects of the proposed Transaction are not likely to be eliminated by any efficiencies the proposed Transaction may achieve.

III. Explanation of the Proposed Final Judgment

The relief required by the proposed Final Judgment will remedy the loss of competition alleged in the Complaint by establishing an independent and economically viable competitor in the markets for the sale of commercial group health insurance to small groups and CRC groups in New Hampshire. Paragraph IV.A of the Proposed Final Judgment requires Defendants, within 30 days after entry of the Stipulation and Order by the Court, to divest Tufts Freedom, Health Plan Holdings' New Hampshire subsidiary, to United, or an alternative acquirer, acceptable to the United States, in its sole discretion, after consultation with the State of New Hampshire (''Acquirer''). Paragraph IV.B allows for this 30-day period to be extended until 5 calendar days after Harvard Pilgrim and Health Plan Holdings receive the required regulatory approvals from the Massachusetts Division of Insurance. Any extension for securing regulatory approvals shall be no longer than 60 calendar days after the 30-day time period provided in Paragraph IV.A, unless the United States, in its sole discretion, consents to an additional extension. Defendants must take all reasonable steps necessary to accomplish the divestiture quickly and must cooperate with Acquirer.

A. Divestiture Assets

The proposed Final Judgment requires Defendants to divest all assets and rights that an Acquirer needs to compete against Defendants and other commercial health insurers in New Hampshire for the sale of commercial group health insurance to small groups and CRC groups. The Divestiture Assets, which are defined in Paragraph II.F of the proposed Final Judgment, include all tangible and intangible assets of Tufts Freedom, including insurance licenses and real property interests, such as leases, membership, and customer contracts; all contracts with healthcare providers to which Tufts Freedom is a signatory; all current and historical member records for the health plans that Tufts Freedom offers or has offered, all underlying electronic data, and all files that contain any current or historical member records for those health plans; and all provider-furnished data related to members of health plans that Tufts Freedom offers or has offered and all files that contain any provider-furnished data related to those health plans.

The Divestiture Assets also include an exclusive license for Acquirer to use the ''Tufts Health Freedom,'' ''Tufts Health Freedom Insurance Company,'' and ''Tufts Health Freedom Plan(s)'' brand names, and all associated trademarks, service marks, and service names, in New Hampshire from the date on which the Divestiture Assets are divested to Acquirer through December 31, 2021. This license will assist Acquirer in

maintaining plan membership during the period immediately after the divestiture. Related to the license included in the Divestiture Assets, Paragraphs IV.R and IV.S of the proposed Final Judgment prohibit Defendants from selling commercial health insurance products in New Hampshire that use the ''Tufts Health'' or ''Tufts Health Plan'' brand(s) through December 31, 2021, and prohibit Defendants from using the terms ''Health Freedom Plan(s),'' ''Freedom,'' or ''Freedom Plan(s)'' for any business name or to identify, market, or promote any products or services in New Hampshire. This prohibition will protect against consumer confusion between Defendants' commercial health insurance plans and Tufts Freedom's commercial health insurance plans.

B. Hiring of Personnel

The proposed Final Judgment contains provisions intended to facilitate Acquirer's efforts to hire certain employees of Health Plan Holdings who have responsibilities for the Tufts Freedom business. These provisions will help ensure that Acquirer will be able to retain qualified employees to operate Tufts Freedom. Paragraph IV.I of the proposed Final Judgment requires Defendants to assist Acquirer in identifying and hiring employees based in New Hampshire or assigned to New Hampshire business and to make them available for interviews. It also provides that Defendants must not interfere with any negotiations by Acquirer to hire these employees. In addition, for employees who elect employment with Acquirer, Defendants must waive all non-compete and non-disclosure agreements; vest and pay (or provide to Acquirer for payment to the employee) on a prorated basis any bonuses, incentives, other salary, benefits, or other compensation fully or partially accrued at the time of the transfer of the employee to Acquirer; vest any unvested pension and other equity rights; and provide all other benefits that those employees otherwise would have been provided had they continued employment with Defendants, including any retention bonuses or payments. Paragraph IV.I further provides that Defendants may not solicit to rehire any employees who elect employment with Acquirer, unless an employee is terminated or laid off by Acquirer or Acquirer agrees in writing that Defendants may solicit to rehire that individual. The non-solicitation period runs for 12 months from the date of the divestiture.

C. Transition and Run-Out Services

The proposed Final Judgment also contains several provisions to facilitate the transition of the Divestiture Assets to Acquirer. These provisions will facilitate a smooth transition for Tufts Freedom members from Health Plan Holdings to Acquirer so that Acquirer can compete effectively in the markets for health insurance sold to small groups and CRC groups in New Hampshire. For example, Paragraph IV.L of the proposed Final Judgment requires Defendants to make best efforts to transition customers from the Health Plan Holdings operating platform to Acquirer's operating platform beginning July 1, 2021, and ending by December 31, 2021. This transition will not begin until July 2021 in order to give Acquirer enough time to prepare its own operating platform for the Tufts Freedom business. In addition, Paragraph IV.M requires Defendants, at Acquirer's option, to enter into one or more agreements to provide transition services to Acquirer for a period running until December 31, 2021, or if Acquirer is not United, one year from the date of the divestiture. Transition services must encompass all services necessary for Acquirer to operate the Divestiture Assets. Among other things, the proposed Final Judgment allows Health Plan Holdings to provide the operational platform and systems infrastructure to run the Divestiture Assets, prepare regulatory filings, and handle member services for Acquirer for a time-limited period. Acquirer may terminate a transition services agreement, or any portion of it, without cost or penalty at any time upon commercially reasonable notice. Paragraph IV.M also provides that employees of Defendants tasked with supporting this agreement must not share any competitively sensitive information of Acquirer with any other employee of Defendants, unless such sharing is for the sole purpose of providing transition services to Acquirer.

Paragraph IV.N of the proposed Final Judgment further requires Defendants, at Acquirer's option, to provide Run-out Services to Acquirer to cover the period from the date of a customer's transition to Acquirer's operating platform, until June 30, 2022, and at Acquirer's option, for up to an additional 90 days. Run-out Services are services that are customarily provided to an acquirer by a seller following an operational transfer of a health insurance plan. Run-out services include, among other things, claims processing, claims reporting, administrative support, and routine investigations necessary for claims processing. These services are provided by a seller of an insurance plan for a period of time after an operational transfer because the services relate to claims that were incurred prior to the transfer but have not been resolved. For example, a claim that occurred during the transition period might not be processed or investigated until after the transition period has ended. Requiring Defendants to provide these Run-out Services will help to smooth the transfer of the Divestiture Assets to Acquirer and ensure that Acquirer can immediately and successfully operate Tufts Freedom. The United States, in its sole discretion, may approve one or more extensions of Run-out Services. Acquirer may terminate a Run-out Services agreement, or any portion of it, without cost or penalty at any time upon commercially reasonable notice. Paragraph IV.N also provides that employees of Defendants tasked with supporting this agreement must not share any competitively sensitive information of Acquirer with any other employee of Defendants, unless such sharing is for the sole purpose of providing Run-out Services to Acquirer.

D. Healthcare Provider Contracts

An insurer's ability to compete on price depends largely on medical costs, which are impacted significantly by the discounts the insurer obtains from healthcare providers through its contracts with those providers. The proposed Final Judgment contains several provisions to help ensure that Tufts Freedom will maintain contracts with New Hampshire healthcare providers at competitive rates following the divestiture. Keeping contracts with local providers at competitive rates will better position Tufts Freedom to be competitive in the small group and CRC group markets in New Hampshire.

1. Contracts With Granite Healthcare Providers

Paragraph IV.P of the proposed Final Judgment requires that Defendants warrant that as of the date of divestiture, Tufts Freedom's contracts with Catholic Medical Center, Concord Hospital, Southern New Hampshire Health System, and Wentworth-Douglass Hospital, and any other hospitals that had an ownership interest in Granite Healthcare as of July 1, 2020, have not expired or terminated, will run through at least December 31, 2021, and will be on the same rates and terms that were in effect as of October 1, 2020, subject to certain permitted rate increases.

2. Contracts With Other Healthcare Providers

Paragraph IV.Q of the proposed Final Judgment requires that Defendants make best efforts and cooperate with and assist Acquirer to ensure that, following the divestiture, Acquirer will retain Tufts Freedom's current contracts with healthcare providers in New Hampshire. Defendants' obligations under Paragraphs IV.Q.1–5 of the proposed Final Judgment vary depending upon whether a Healthcare Provider Contract includes change in control provisions, terminates, or expires.

(a) Healthcare Provider Contracts Without Change in Control Provisions

Some Healthcare Provider Contracts have no requirement that Tufts Freedom notify the provider of a change in ownership or control of Tufts Freedom and do not include provisions allowing the provider to terminate the contract in the event of a change in ownership or control. Under Paragraph IV.Q.1, Defendants must make best efforts to ensure that contracts with Tufts Freedom's fifteen largest providers in New Hampshire (as measured by 2019 claims volume) that do not require a notice of change in ownership or control (1) have not expired or terminated and (2) include the same rates and terms that were in effect as of October 1, 2020, subject to certain permitted rate increases.

(b) Healthcare Provider Contracts With Change in Control Provisions

Other Healthcare Provider Contracts require the provider's consent to a change in Tufts Freedom's ownership or control, or allow the provider to terminate the contract upon notice of a change in ownership or control. Paragraph IV.Q.2 of the proposed Final Judgment requires Defendants to notify those providers of the change in ownership or control within 30 calendar days of entering into an agreement to divest the Divestiture Assets to Acquirer. Paragraph IV.Q.2 further requires Defendants to use best efforts to obtain consent to the change in ownership or control from these providers or written acknowledgement that the provider will not terminate its contract with Tufts Freedom because of the change in ownership or control. The preceding requirement does not apply in the event that a provider's deadline to exercise any termination rights has already expired without the provider terminating the contract or giving Defendants written notice of an intent to terminate.

(c) Healthcare Provider Contracts That Terminate

The proposed Final Judgment places additional obligations on Defendants if a healthcare provider terminates or gives notice of an intent to terminate within 90 days from the date of the divestiture. Paragraph IV.Q.3 requires Defendants to assist Acquirer, at Acquirer's request, to secure new contracts with those terminating healthcare providers. The assistance required includes sharing information with Acquirer concerning the history of the provider's participation in Tufts Freedom and aiding Acquirer in developing strategies to retain or bring the provider in-network, on the same rates and terms that were in effect as of October 1, 2020, subject to certain permitted increases. Paragraph IV.Q.4 further requires that if the terminating provider is one of Tufts Freedom's fifteen largest healthcare providers in New Hampshire (as measured by 2019 claims volume), or the termination would result in Tufts Freedom not meeting provider network adequacy standards required by applicable law or regulation, at Acquirer's request, Defendants must enter into a rental, lease, or similar contract to provide Acquirer with in-network access to the relevant healthcare provider(s) for a period of 12 months from the date of the divestiture.

(d) Expiring Healthcare Provider Contracts

Finally, Paragraph IV.Q.5 of the proposed Final Judgment requires Defendants to use best efforts to renew all Healthcare Provider Contracts that will expire between the filing of the Complaint in this matter and 90 days after the date of the divestiture, on the same rates and terms that were in effect as of October 1, 2020, subject to certain permitted rate increases.

E. Divestiture Trustee

If Defendants do not accomplish the divestiture within the period prescribed in Paragraphs IV.A and IV.B of the proposed Final Judgment, Section V of the proposed Final Judgment provides that the Court will appoint a divestiture trustee selected by the United States to effect the divestiture. If a divestiture trustee is appointed, the proposed Final Judgment provides that Defendants will pay all costs and expenses of the trustee. The divestiture trustee's commission will be structured so as to provide an incentive for the trustee based on the price obtained and the speed with which the divestiture is accomplished. After the divestiture trustee's appointment becomes effective, the trustee will provide monthly reports to the United States and the state of New Hampshire setting forth his or her efforts to accomplish the divestiture. If the divestiture has not been accomplished within six months of the divestiture trustee's appointment, the United States may make recommendations to the Court, which will enter such orders as appropriate, in order to carry out the purpose of the Final Judgment, including by extending the trust or the term of the divestiture trustee's appointment.

F. Compliance

The proposed Final Judgment also contains provisions designed to promote compliance and make enforcement of the Final Judgment as effective as possible. Paragraph XIII.A provides that the United States retains and reserves all rights to enforce the Final Judgment, including the right to seek an order of contempt from the Court. Under the terms of this paragraph, Defendants have agreed that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of the Final Judgment, the United States may establish the violation and the appropriateness of any remedy by a preponderance of the evidence and that Defendants have waived any argument that a different standard of proof should apply. This provision aligns the standard for compliance with the Final Judgment with the standard of proof that applies to the underlying offense that the Final Judgment addresses.

Paragraph XIII.B of the proposed Final Judgment provides additional clarification regarding the interpretation of the provisions of the proposed Final Judgment. The proposed Final Judgment is intended to remedy the loss of competition the United States alleges would otherwise be harmed by the transaction. Defendants agree that they will abide by the proposed Final Judgment, and that they may be held in contempt of this Court for failing to comply with any provision of the proposed Final Judgment that is stated specifically and in reasonable detail, as interpreted in light of this procompetitive purpose.

Paragraph XIII.C of the proposed Final Judgment provides that if the Court finds in an enforcement proceeding that a Defendant has violated the Final Judgment, the United States may apply to the Court for a one-time extension of the Final Judgment, together with such other relief as may be appropriate. In addition, to compensate American taxpayers for any costs associated with

investigating and enforcing violations of the Final Judgment, Paragraph XIII.C provides that in any successful effort by the United States to enforce the Final Judgment against a Defendant, whether litigated or resolved before litigation, that Defendant will reimburse the United States for attorneys' fees, experts' fees, and other costs incurred in connection with any effort to enforce the Final Judgment, including the investigation of the potential violation.

Paragraph XIII.D of the proposed Final Judgment states that the United States may file an action against a Defendant for violating the Final Judgment for up to four years after the Final Judgment has expired or been terminated. This provision is meant to address circumstances such as when evidence that a violation of the Final Judgment occurred during the term of the Final Judgment is not discovered until after the Final Judgment has expired or been terminated or when there is not sufficient time for the United States to complete an investigation of an alleged violation until after the Final Judgment has expired or been terminated. This provision, therefore, makes clear that, for four years after the Final Judgment has expired or been terminated, the United States may still challenge a violation that occurred during the term of the Final Judgment.

Finally, Section XIV of the proposed Final Judgment provides that the Final Judgment will expire ten years from the date of its entry, except that after five years from the date of its entry, the Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestiture has been completed and that continuation of the Final Judgment is no longer necessary or in the public interest.

IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment neither impairs nor assists the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against Defendants.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the U.S. Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time before the Court's entry of the Final Judgment. The comments and the response of the United States will be filed with the Court. In addition, comments and the United States' response will be published in the **Federal Register** unless the Court agrees that the United States instead may publish them on the U.S. Department of Justice, Antitrust Division's internet website.

Written comments should be submitted to: Eric D. Welsh, Chief, Healthcare and Consumer Products Section, Antitrust Division, U.S. Department of Justice, 450 Fifth Street, NW, Suite 4100, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

As an alternative to the proposed Final Judgment, the United States considered a full trial on the merits against Defendants. The United States could have continued the litigation and sought preliminary and permanent injunctions against the combination of Harvard Pilgrim and Health Plan Holdings. The United States is satisfied, however, that the divestiture of assets described in the proposed Final Judgment will remedy the anticompetitive effects alleged in the Complaint, preserving competition for the sale of commercial health insurance to small groups and CRC groups in each of the geographic markets alleged in the Complaint. Thus, the proposed Final Judgment achieves all or substantially all of the relief the United States would have obtained through litigation, but avoids the time, expense, and uncertainty of a full trial on the merits of the Complaint.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

(A) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States* v. *U.S. Airways Grp., Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that a court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the

antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable'').

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the proposed Final Judgment, a court may not ''make de novo determination of facts and issues.'' *United States* v. *W. Elec. Co.,* 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead, ''[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General.'' *W. Elec. Co.,* 993 F.2d at 1577 (quotation marks omitted). ''The court should bear in mind the *flexibility* of the public interest inquiry: the court's function is not to determine whether the resulting array of rights and liabilities is one that will *best* serve society, but only to confirm that the resulting settlement is within the *reaches* of the public interest.'' *Microsoft,* 56 F.3d at 1460 (quotation marks omitted); *see also United States* v. *Deutsche Telekom AG,* No. 19–2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would ''have enormous practical consequences for the government's ability to negotiate future settlements,'' contrary to congressional intent. *Id.* at 1456. ''The Tunney Act was not intended to create a disincentive to the use of the consent decree.'' *Id.*

The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft,* 56 F.3d at 1461 (recognizing courts should give ''due respect to the Justice Department's . . . view of the nature of its case''); *United States* v. *Iron Mountain, Inc.,* 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) (''In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'') (internal citations omitted); *United States* v. *Republic Servs., Inc.,* 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting ''the deferential review to which the government's proposed remedy is accorded''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (''A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case.''). The ultimate question is whether ''the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.''' *Microsoft,* 56 F.3d at 1461 (*quoting W. Elec. Co.,* 900 F.2d at 309).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''[T]he 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60.

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using consent judgments proposed by the United States in antitrust enforcement, Public Law 108–237 § 221, and added the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). ''A court can make its public interest determination based on the competitive impact statement and response to public comments alone.'' *U.S. Airways,* 38 F. Supp. 3d at 76 (citing *Enova Corp.,* 107 F. Supp. 2d at 17).

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: December 23, 2020.

Respectfully submitted,

Catherine R. Reilly,

U.S. Department of Justice, Antitrust Division, Healthcare and Consumer Products Section, 450 Fifth Street, NW, Suite 4100, Washington, DC 20530, catherine.reilly@usdoj.gov.

[FR Doc. 2020–28905 Filed 12–30–20; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On December 23, 2020, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Central District of Illinois in the lawsuit entitled *United States and Illinois* v. *Peoria City of Illinois and the Greater Peoria Sanitary and Sewage Disposal District,* Civil Action No. 20–1444.

The United States and State of Illinois filed this lawsuit under the Clean Water Act. The complaint seeks civil penalties and injunctive relief for violations of the Act and related permits addressing the sewer system that serves the City of Peoria and is operated by the Defendants. Among other things, the consent decree requires Peoria to significantly reduce sewage overflows from the system by performing a series of improvement projects over 18 years that meet final criteria and satisfy interim milestones. The Greater Peoria Sanitary and Sewage Disposal District (''GPSD'') is required to perform additional system improvements that

will result in reduced sewage overflows. In addition, Peoria will pay a penalty of $75,000 to the United States, $25,000 to the State, and perform a $200,000 State-only supplemental environmental project. The District will pay a $150,000 penalty, split evenly between the United States and the State.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and Illinois* v. *Peoria City of Illinois and the Greater Peoria Sanitary and Sewage Disposal District,* D.J. Ref. No. 90–5–1–1–08724. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $29 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $22.25.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–28923 Filed 12–30–20; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; American Time Use Survey

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Bureau of Labor Statistics (BLS)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before February 1, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Anthony May by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The American Time Use Survey (ATUS) is the Nation's first federally administered, continuous survey on time use in the United States. It measures, for example, time spent with children, working, sleeping, or doing leisure activities. In the United States, several existing Federal surveys collect income and wage data for individuals and families, and analysts often use such measures of material prosperity as proxies for quality of life. Time-use data substantially augment these quality-of-life measures. The data also can be used in conjunction with wage data to evaluate the contribution of non-market work to national economies. This enables comparisons of production between nations that have different mixes of market and non-market activities. The ATUS is used to develop nationally representative estimates of how people spend their time. This is accomplished by collecting a time diary about the activities survey respondents did over a 24-hour period ''yesterday,'' from 4 a.m. on the day before the interview until 4 a.m. on the day of the interview. In the one-time interview, respondents also report who was with them during the activities, where they were, how long each activity lasted, and if they were paid. All of this information has numerous practical applications for sociologists, economists, educators, government policymakers, businesspersons, health researchers, and others. The Well-being Module, a supplement to the ATUS, provides an additional dimension to data on time use by providing information about how Americans experience their time. Specifically, the Module collects information about how happy, tired, sad, and stressed individuals were yesterday, and the degree to which they felt pain, for three activities randomly selected from the time diary. The Wellbeing Module also collects data on whether people were interacting with anyone while doing the selected activities and how meaningful the activities were to them. Some general health questions, a question about overall life satisfaction, and a question about respondents' overall affective experience yesterday also are asked. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 5, 2020 (85 FR 26716).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization to reinstate this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes

that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–BLS.

Title of Collection: American Time Use Survey.

OMB Control Number: 1220–0185.

Affected Public: Individuals and households.

Total Estimated Number of Respondents: 7,860.

Total Estimated Number of Responses: 7,860.

Total Estimated Annual Time Burden: 734 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: December 23, 2020.

Anthony May,

Management and Program Analyst.

[FR Doc. 2020–28955 Filed 12–30–20; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Cognitive and Psychological Research

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Bureau of Labor Statistics (BLS)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before February 1, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Anthony May by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The BLS Behavioral Science Research Center (BSRC) conducts theoretical, applied, and evaluative research aimed at improving the quality of data collected and published by the Bureau. Since its creation in 1988, the BSRC has advanced the study of survey methods research, approaching issues of non-sampling error within a framework that draws heavily on the theories and methods of the cognitive, statistical, and social sciences. The BSRC research focuses primarily on the assessment of survey instrument design and survey administration, as well as on issues related to interviewer training, the interaction between interviewer and respondent in the interview process, and the usability of data-collection instruments by both interviewers and respondents. Improvements in these areas result in greater accuracy and response rates of BLS surveys, frequently reduce costs in training and survey administration, and further ensure the effectiveness of the Bureau's overall mission. clearance by the BSRC is to conduct cognitive and psychological research designed to enhance the quality of the Bureau's data collection procedures and overall data management.

The BLS is committed to producing the most accurate and complete data within the highest quality assurance guidelines. The BSRC was created to aid in this effort and it has demonstrated the effectiveness and value of its approach. As the use of web-based surveys continues to grow, so too will the need for careful tests of instrument design and usability, human-computer interactions, and the impact of multiple modes on data quality. The BSRC is uniquely equipped with both the skills and facilities to accommodate these demands.

The extension of this information collection reflects an attempt to accommodate the increasing interest by BLS program offices and other agencies in the methods used and the results obtained by the BSRC. This extension also reflects planned research and development activities for FY2021 through FY2023. The collection's approval will enable the continued productivity of a state-of-the-art, multi-disciplinary program of behavioral science research to improve BLS survey methodology.

For additional substantive information about this ICR, see the related notice published in the **Federal Register** on October 9, 2020 (85 FR 64168).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–BLS.

Title of Collection: Cognitive and Psychological Research.

OMB Control Number: 1220–0141.

Affected Public: Individuals and households; Private sector: businesses or other not-for-profits.

Total Estimated Number of Respondents: 24,400.

Total Estimated Number of Responses: 24,400.

Total Estimated Annual Time Burden: 8,400 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: December 23, 2020.

Anthony May,

Management and Program Analyst.

[FR Doc. 2020–28954 Filed 12–30–20; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL SCIENCE FOUNDATION

Alan T. Waterman Award Committee; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science

Foundation (NSF) announces the following meeting:

Name and Committee Code: Alan T. Waterman Award Committee (1172).

Date and Time: January 21, 2021; 11:00 a.m. to 2:00 p.m.

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual).

Type of Meeting: Closed.

Contact Person: Keith Sverdrup, Program Manager, (703) 292–4671. National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

Purpose of Meeting: To provide advice and recommendations in the selection of the Alan T. Waterman Award recipient.

Agenda: To review and evaluate nominations as part of the selection process for awards.

Reason for Closing: The nominations being reviewed include information of a personal nature where disclosure would constitute unwarranted invasions of personal privacy. These matters are exempt under 5 U.S.C. 552b(c), (6) of the Government in the Sunshine Act.

Dated: December 26, 2020.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2020–28949 Filed 12–30–20; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

RIN 3145–AA58

Notice on Penalty Inflation Adjustments for Civil Monetary Penalties

AGENCY: National Science Foundation.

ACTION: Notice announcing updated penalty inflation adjustments for civil monetary penalties for 2021.

SUMMARY: The National Science Foundation (NSF or Foundation) is providing notice of its adjusted maximum civil monetary penalties, effective January 15, 2021. These adjustments are required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act).

FOR FURTHER INFORMATION CONTACT: Bijan Gilanshah, Assistant General Counsel, Office of the General Counsel, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314. Telephone: 703.292.5055.

SUPPLEMENTARY INFORMATION: On June 27, 2016, NSF published an interim final rule amending its regulations to adjust, for inflation, the maximum civil monetary penalties that may be imposed for violations of the Antarctic Conservation Act of 1978 (ACA), as amended, 16 U.S.C. 2401 *et seq.,* and the Program Fraud Civil Remedies Act of 1986 (PFCRA), 31 U.S.C. 3801, *et seq.* These adjustments are required by the 2015 Act. The 2015 Act also requires agencies to make subsequent annual adjustments for inflation. Pursuant to OMB guidance dated December 23, 2020, the cost-of-living adjustment multiplier for 2020 is 1.01182. Accordingly, the 2021 annual inflation adjustments for the maximum penalties under the ACA are $17,791 ($17,583 × 1.01182) for violations and $30,107($29,755 × 1.01182) for knowing violations of the ACA. Finally, the 2021 annual inflation adjustment for the maximum penalty for violations under PFCRA is $11,803 ($11,665 × 1.01182).

Dated: December 28, 2020.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2020–28997 Filed 12–30–20; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0119]

Information Collection: NRC Form 149, "OCFO Invitational Traveler Request Form"

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a proposed collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, NRC Form 149, ''OCFO Invitational Traveler Request Form.''

DATES: Submit comments by February 1, 2021. 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: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance 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–2020–0119 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–2020–0119. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2020–0119 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.* The supporting statement and NRC Form 149 are available in ADAMS under Accession Nos. ML20338A229 and ML20338A228, respectively.
- *Attention:* The PDR, where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.
- *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 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–2020–0119 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 OMB, 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

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a proposed collection of information to OMB for review entitled, NRC Form 149, ''OCFO Invitational Traveler Request Form.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on September 3, 2020, 85 FR 55033.

1. *The title of the information collection:* NRC Form 149, ''OCFO Invitational Traveler Request Form.''
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:* NRC Form 149.
5. *How often the collection is required or requested:* The collection is required when there is an invitational traveler that will be reimbursed by the NRC. This occurs on an as needed basis and does not have a regular schedule for submission.
6. *Who will be required or asked to respond:* The invitational traveler will be asked to respond and NRC staff that are associated with the purpose of the invitational traveler may also be asked to respond on an as needed basis.
7. *The estimated number of annual responses:* 250.
8. *The estimated number of annual respondents:* 250.
9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 50 hours.
10. *Abstract:* The NRC provides reimbursement for people on invitational travel for the NRC. As such, the NRC would reimburse them through our Financial Accounting and Integrated Management Information System (FAIMIS). Additionally, the travel itself would be processed in our electronic travel systems (ETS2). Both the financial and travel systems must be set up appropriately for the invitational traveler to travel and receive reimbursement from the NRC. The information collected on Form 149 meets the requirements for the invitational traveler to have a profile created in FAIMIS and in ETS2. The information collected is necessary to meet the criteria for both systems.

Dated: December 28, 2020.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2020–28957 Filed 12–30–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–316; NRC–2020–0280]

Indiana Michigan Power Company; Donald C. Cook Nuclear Plant, Unit No. 2

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to provide comment, request a hearing, and petition for leave to intervene.

SUMMARY: The Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Renewed Facility Operating License No. DPR–74, issued to Indiana Michigan Power Company, for operation of the Donald C. Cook Nuclear Plant, Unit No. 2. (CNP–2). The proposed amendment would revise the CNP–2 technical specifications (TSs) to allow a one-time deferral of the requirement to inspect each steam generator (SG) from the spring of 2021 to the fall of 2022 refueling outage.

DATES: Submit comments by February 1, 2021. Requests for a hearing or petition for leave to intervene must be filed by March 1, 2021.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2020–0280. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Scott P. Wall, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2855; email: *Scott.Wall@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0280 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–2020–0280.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The application for amendment dated December 14, 2020, is available in ADAMS under Accession No. ML20352A221.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the

Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0280 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

The NRC is considering issuance of an amendment to Renewed Facility Operating License No. DPR–74, issued to Indiana Michigan Power Company, for operation of the CNP–2, located in Berrien County, Michigan.

The proposed amendment would revise the CNP–2 TSs to allow a one-time deferral of the requirement to inspect each SG from the spring of 2021 to the fall of 2022 refueling outage.

Before any issuance of the proposed license amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC's regulations.

The NRC has made a proposed determination that the license amendment request involves no significant hazards consideration. Under the NRC's regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed TS change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed license amendment modifies the [CNP–2] TS by deferring, on a one-time basis, the Unit 2 Steam Generator inspection by one cycle until the Unit 2 refueling outage scheduled for Fall of 2022. The SG tubes continue to meet the SG Program performance criteria and remain bounded by the plant's accident analyses. The operational assessment reanalysis demonstrates that the SG tubes meet the SG Program performance criteria throughout the 18-month one-time extension of the SG inspection.

Therefore, it is concluded that the proposed amendment does not involve a significant increase in the probability or the consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed license amendment modifies the [CNP–2] TS by deferring, on a one-time basis, the Unit 2 Steam Generator inspection by one cycle until the Unit 2 refueling outage scheduled for fall of 2022. The proposed change does not alter the design function or operation of the SGs or the ability of an SG to perform its design function. The SG tubes continue to meet the SG Program performance criteria. The proposed change does not create the possibility of a new or different kind of accident due to credible new failure mechanisms, malfunctions, or accident initiators that are not considered in the design and licensing bases.

Therefore, the proposed change does not create the possibility of a new or different kind of accident, from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed amendment does not involve a significant reduction in a margin of safety.

The proposed TS changes do not involve a significant reduction in the margin of safety. The proposed license amendment modifies the [CNP–2] TS by deferring, on a one-time basis, the Unit 2 Steam Generator inspection by one cycle until the Unit 2 refueling outage scheduled for Fall of 2022. Deferring the inspection schedule does not involve changes to any limit on accident consequences specified in the [CNP–2] licensing bases or applicable regulations, does not modify how accidents are mitigated and does not involve a change in a methodology.

Therefore, the proposed amendment does not involve a significant reduction in margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the license amendment request involves a no significant hazards consideration.

The NRC is seeking public comments on this proposed determination that the license amendment request involves no significant hazards consideration. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day notice period if the Commission concludes the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *https://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and

telephone number of the petitioner; (2) the nature of the petitioner's right to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions that the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion that support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one that, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a petition is submitted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *https://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time

the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this action, see the application for license amendment dated December 14, 2020 (ADAMS Accession No. ML20352A221).

Attorney for licensee: Robert B. Haemer, Senior Nuclear Counsel, Indiana Michigan Power Company, One Cook Place, Bridgman, MI 49106.

NRC Branch Chief: Nancy L. Salgado.

Dated: December 28, 2020.

For the Nuclear Regulatory Commission.

Scott P. Wall,

Senior Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–28988 Filed 12–30–20; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0143, Request to Disability Annuitant for Information on Physical Condition and Employment, RI 30–1

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on a revised information collection request (ICR), RI 30–1—Request to Disability Annuitant for Information on Physical Condition and Employment.

DATES: Comments are encouraged and will be accepted until February 1, 2021.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to: *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0143) was previously published in the **Federal Register** on April 7, 2020 at 85 FR 19517, allowing for a 60-day public comment period. One comment was received: ''*so off to work we go*''. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or

other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Form RI 30–1, Request to Disability Annuitant for Information on Physical Condition and Employment, is used by persons who are not yet age 60 and who are receiving a disability annuity and are subject to inquiry regarding their medical condition as OPM deems reasonably necessary.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Request to Disability Annuitant for Information on Physical Condition and Employment.

OMB Number: 3206–0143.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 8,000.

Estimated Time per Respondent: 60 minutes.

Total Burden Hours: 8,000.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2020–28959 Filed 12–30–20; 8:45 am]

BILLING CODE 6325–38–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2020–177; CP2020–186; CP2020–195; CP2020–199; CP2020–277; CP2020–228]

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:* January 5, 2021.

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:

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I. Introduction
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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.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2020–177; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 1 Negotiated Service Agreement; *Filing Acceptance Date:* December 23, 2020; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Curtis E. Kidd; *Comments Due:* January 5, 2021.

2. *Docket No(s).:* CP2020–186; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 4 Negotiated Service Agreement; *Filing Acceptance Date:* December 23, 2020; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Curtis E. Kidd; *Comments Due:* January 5, 2021.

3. *Docket No(s).:* CP2020–195; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to International Priority Airmail, International Surface Air Lift, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 1 Negotiated Service Agreement; *Filing Acceptance Date:* December 23, 2020; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* January 5, 2021.

4. *Docket No(s).:* CP2020–199; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to International Priority Airmail, International Surface Air Lift, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 2 Negotiated Service Agreement; *Filing Acceptance Date:* December 23, 2020; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* January 5, 2021.

5. *Docket No(s).:* CP2020–227; *Filing Title:* Notice of United States Postal Service of Filing Modification One to Global Reseller Expedited Package 2 Negotiated Service Agreement; *Filing Acceptance Date:* December 23, 2020; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* January 5, 2021.

6. *Docket No(s).:* CP2020–228; *Filing Title:* Notice of United States Postal Service of Filing Modification One to Global Reseller Expedited Package 2 Negotiated Service Agreement; *Filing Acceptance Date:* December 23, 2020; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Kenneth R.

[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).

Moeller; *Comments Due:* January 5, 2021.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–28990 Filed 12–30–20; 8:45 am]

BILLING CODE 7710–FW–P

SMALL BUSINESS ADMINISTRATION

Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration

under the Small Business Investment Act of 1958, as amended, under Section 309 of the Act and Section 107.1900 of the Small Business Administration Rules and Regulations (13 CFR 107.1900) to function as a small business investment company under the Small Business Investment Company License No. 01/71–0385 issued to MSR I SBIC, L.P. said license is hereby declared null and void.

United States Small Business Administration.

Thomas Morris,

Acting Associate Administrator,Office of Investment and Innovation.

[FR Doc. 2020–28932 Filed 12–30–20; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under the Small Business Investment Act of 1958, as amended, Section 309 and the Small Business Administration Rules and Regulations, Section 107.1900 (13 CFR 107.1900) to function as a small business investment company under the Small Business Investment Company License No. 03/03–0242 issued to NewSpring Mezzanine Capital, L.P., said license is hereby declared null and void.

United States Small Business Administration.

Thomas Morris,

Acting Associate Administrator, Office of Investment and Innovation.

[FR Doc. 2020–28938 Filed 12–30–20; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[License No. 03/03–0251]

Merion Investment Partners II, L.P.; Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under the Small Business Investment Act of 1958, as amended, under Section 309 of the Act and Section 107.1900 of the Small Business Administration Rules and Regulations (13 CFR 107.1900) to function as a small business investment company under the Small Business Investment Company License No. 03/03–0251 issued to Merion Investment Partners II, L.P. said license is hereby declared null and void.

U.S. Small Business Administration.

Thomas Morris,

Acting Associate Administrator, Office of Investment and Innovation.

[FR Doc. 2020–28933 Filed 12–30–20; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under the Small Business Investment Act of 1958, as amended, under Section 309 of the Act and Section 107.1900 of the Small Business Administration Rules and Regulations (13 CFR 107.1900) to function as a small business investment company under the Small Business Investment Company License No. 03/03–0260 issued to F.N.B. Capital Partners, L.P., said license is hereby declared null and void.

United States Small Business Administration.

Thomas G. Morris,

Acting Associate Administrator for Investment and Innovation.

[FR Doc. 2020–28939 Filed 12–30–20; 8:45 am]

BILLING CODE P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 286 (Sub-No. 8X)]

The New York, Susquehanna and Western Railway Corporation—Abandonment Exemption—in Bergen County, N.J.

The New York, Susquehanna and Western Railway Corporation (NYSW) has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon a segment of rail line between milepost 15.80 in Lodi, N.J., and milepost 14.50 in Hackensack, N.J., (the Lodi Branch), and a segment of rail line between milepost 17.30 in Elmwood Park, N.J., and milepost 18.40 in Garfield, N.J. (the Passaic Branch) (collectively, the Lines). The Lodi Branch traverses U.S Postal Service Zip Codes 07644 and 07601 and the Passaic Branch traverses U.S. Postal Service Zip Codes 07407 and 07026.

NYSW has certified that: (1) No local traffic has moved over the Lines for over 10 years; (2) no overhead traffic has moved over the Lines for over 10 years; (3) no formal complaint filed by a user of rail service (or by a state or local government entity acting on behalf of such user) regarding NYSW's cessation of service over the Lines is either pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the past two years; and (4) the requirements at 49 CFR 1105.7 and 1105.8 (notice of environmental and historic report), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

Any employee of NYSW adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,[1] this exemption will be effective on January 30, 2021, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues[2] must be filed by January 8, 2021. Formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2), and interim trail use/rail banking requests under 49

[1] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

CFR 1152.29 must be filed by January 11, 2021.[3] Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by January 21, 2021, with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to NYSW's representative, Eric M. Hocky, Clark Hill, PLC, Two Commerce Square, 2001 Market St., Suite 2620, Philadelphia, PA 19103.

If the verified notice contains false or misleading information, the exemption is void ab initio.

NYS&W has filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by January 8, 2021. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or interim trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), NYSW shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by NYSW's filing of a notice of consummation by December 31, 2021, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov.*

Decided: December 23, 2020.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2020–28845 Filed 12–30–20; 8:45 am]

BILLING CODE 4915–01–P

[3] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0999]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Protection of Voluntarily Submitted Information

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on October 22, 2020. The collection involves protection of voluntarily submitted information. Part 193 of the Federal Aviation Administration (FAA) regulations provides that certain information submitted to the FAA on a voluntary basis is not to be disclosed. This part implements a statutory provision. The purpose of Part 193 is to encourage the aviation community to voluntarily share information with the FAA so that the agency may work cooperatively with industry to identify modifications to rules, policies, and procedures needed to improve safety, security, and efficiency of the National Airspace System (NAS). The information collection associated with Part 193 also supports the Department of Transportation's Strategic Goal of Safety and Security.

DATES: Written comments should be submitted by February 1, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Lee Magnuson by email at: *lee.magnuson@faa.gov;* phone: 816–329–3275

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0646.

Title: Protection of Voluntarily Submitted Information.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on October 22, 2020 (85 FR 67419). Part 193 of the FAA regulations provides that certain information submitted to the FAA on a voluntary basis is not to be disclosed. Part 193 implements a statutory provision. Section 40123 was added to Title 49, United States Code, in the Federal Aviation Reauthorization Act of 1996 to encourage people to voluntarily submit desired information. Section 40123 allows the Administrator, through FAA regulations, to protect from disclosure voluntarily provided information relating to safety and security issues.

The purpose of part 193 is to encourage the aviation community to voluntarily share information with the FAA so that the agency may work cooperatively with industry to identify modifications to rules, policies, and procedures needed to improve safety, security, and efficiency of the National Airspace System. FAA programs that are covered under part 193 are Voluntary Safety Reporting Programs, Air Traffic and Technical Operations Safety Action programs, the Flight Operational Quality Assurance program, the Aviation Safety Action Program, and the Voluntary Disclosure Reporting Program. This rule imposes a negligible paperwork burden for certificate holders and fractional ownership programs that choose to submit a letter notifying the Administrator that they wish to participate in a current program.

The number of respondents has greatly increased since the initial approval of this information collection. In order to accurately reflect the burden of this information collection going forward, the FAA has included total current participants in the programs.

Respondents: 1,336.

Frequency: Varies per response time.

Estimated Average Burden per Response: Varies per response time.

Estimated Total Annual Burden: 1,346 Hours.

Issued in Washington, DC, on December 28, 2020.

Sandra Ray,

Aviation Safety Inspector, FAA, Policy Integration Brach, AFS–270.

[FR Doc. 2020–28953 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2021–2040]

Petition for Exemption; Summary of Petition Received; Critical Care Services, Inc. dba Life Link III

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 7, 2021.

ADDRESSES: Send comments identified by docket number FAA–2020–1101 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

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 *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Brittany Newton, (202) 267–6691, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Timothy R Adams,

Deputy Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–1101.

Petitioner: Critical Care Services, Inc. dba Life Link III.

Section(s) of 14 CFR Affected: § 135.619(g)(2)(i)(ii).

Description of Relief Sought: Petitioner requests an exemption for Helicopter Air Ambulance Operations (HAA) with established Operations Control Centers (OCC) to modify current staffing requirements. Due to the impact of the COVID–19 pandemic, the petitioner is asking to extend the authorized work-shift duty-day from 10 to 12 hours.

[FR Doc. 2020–28922 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–77]

Petition for Exemption; Summary of Petition Received; General Atomics Aeronautical Systems, Incorporated

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 21, 2021.

ADDRESSES: Send comments identified by docket number FAA–2020–0984 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

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 *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267–7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on December 21, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0984.

Petitioner: General Atomics Aeronautical Systems, Incorporated.

Section(s) of 14 CFR Affected: § 91.109(a).

Description of Relief Sought: General Atomics Aeronautical Systems, Incorporated seeks relief from Title 14 Code of Federal Regulations (14 CFR) § 91.109(a), which requires civil aircraft used for flight instruction to have dual fight controls. The petitioner requests to conduct customer crew training of individuals that have not been issued an FAA pilot certificate under part 61, when operating, at or above 2,500 feet above ground level (AGL), a company-owned unmanned aircraft systems (UAS) issued a Special Airworthiness Certificate—Experimental Category (SAC–EC).

[FR Doc. 2020–28915 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Industry Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: The FAA is hosting a virtual industry day to introduce the Small Airport Surveillance Sensor (SASS) Project to the aviation community. The FAA will present and discuss the SASS Project vision, objectives, and project timelines. The SASS Industry Day will provide a platform for interested organizations to learn about the technical details of the SASS system, and to potentially collaborate on projects with the FAA on SASS.

DATES: The virtual meeting will be held on February 4, 2021, from 10:00 a.m. to 12:00 p.m. Eastern Time.

Registrations to attend the SASS Industry Day must be completed by January 29, 2021.

Requests for accommodations to a disability must be received by January 15, 2021.

Letters of Interest from industry to work with the FAA on SASS must be received no later than March 12, 2021. Further details regarding submission of the Letters of Interest will be provided during the SASS Industry Day event.

ADDRESSES: This will be a virtual meeting. Those who wish to attend must register via the following Eventbrite link: *https://www.eventbrite.com,* search for ''SASS Industry Day'' under the Events, and click on Register. Follow-on electronic invitations for the virtual meeting will be sent to the Eventbrite-registered attendees.

FOR FURTHER INFORMATION CONTACT: Todd Lewis, SASS Project Manager, Technology Development & Prototyping Division (ANG–C51), Federal Aviation Administration, 800 Independence Ave. SW, Washington, DC 20591; telephone (202) 267–0875; email: *Ronald.Lewis@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

There are over 500 airports in the U.S. with air traffic control towers. Tower controllers maintain situational awareness of surface and nearby airborne traffic primarily via visual surveillance, which can be impaired during times of low visibility or bad weather. Depending on the airport size, visual surveillance can be augmented with various means. Most of the large airports (surrounded by Class B airspace) have Airport Surveillance Detection Equipment—Model X (ASDE–X) which provides situational awareness to tower controllers of surface and nearby airborne traffic. The medium size airports (surrounded by Class C airspace) generally lack ASDE–X due to cost considerations. All aircraft entering Class B or C airspace are now required to have ADS–B Out capability.

There are also approximately 350 airports surrounded by Class D airspace only, which does not require the ADS–B Out capability. Since aircraft not equipped with ADS–B capability will continue to operate at these airports surrounded by Class D airspace, there is a need for a low-cost, all-weather surveillance capability to provide situational awareness in times of bad weather and/or low visibility.

The SASS system addresses this need by employing a novel phased-array antenna, state-of-the-art digital signal processing and commercial off-the-shelf (COTS) hardware. Unlike ASDE–X, the SASS system only requires two sensor arrays and a master unit, all of which are located on the airport grounds. An SASS testbed has been implemented and operated at Hanscom Field in Massachusetts by MIT Lincoln Laboratory with FAA funding.

The SASS testbed has been used to demonstrate active (interrogated) and passive (listen only) surveillance of Mode S and air traffic control radar beacon system (ATCRBS) transponders. The positional accuracy goals of 30 feet on the airport surface and 0.2 nautical miles (NM) out to 20 NM range have been achieved. Based on this demonstrated performance, the FAA wishes to begin technology transfer of the SASS design to industry. The SASS Industry Day is the first step in this process.

Each industry member that is interested in working with the FAA to engage in the potential further development of SASS after attending the SASS Industry Day event must provide a Letter of Interest to the FAA which states the organization's capability to undertake the development of the technology, past performance/history in developing other secondary surveillance systems, proposed schedule for developing the technology and anticipated commercial use for the technology.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Issued in Washington, DC, on December 21, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

[FR Doc. 2020–28916 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–53]

Petition for Exemption; Summary of Petition Received; BNSF Railway

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and

must be received on or before January 21, 2021.

ADDRESSES: Send comments identified by docket number FAA–2020–0620 using any of the following methods:

• *Federal eRulemaking Portal:* Go to *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Operations at (202) 493–2251.

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 *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on December 21, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0620.

Petitioner: BNSF Railway.

Section(s) of 14 CFR Affected: §§ 61.113(a) and (b); 91.7(a); 91.113(b), (d), (e), (f), and (g); 91.119(c); 91.121; 91.151(b); 91.405(a); 91.407(a)(1) and (2); 91.409(a)(1) and (2); and 91.417(a) and (b).

Description of Relief Sought: BNSF Railway seeks relief from 14 CFR 61.113(a) and (b); 91.7(a); 91.113(b), (d), (e), (f), and (g); 91.119(c); 91.121; 91.151(b); 91.405(a); 91.407(a)(1) and (2); 91.409(a)(1) and (2); and 91.417(a) and (b) to allow the petitioner to utilize a single remote pilot in command (RPIC) who is remotely located, to simultaneously operate up to 5 small unmanned aircraft system (sUAS), with a take-off weight below 55 pounds (lbs.), for beyond visual line of sight operations, conducted under 14 CFR part 91. Operations would occur during both day and night hours under visual meteorological conditions. The proposed operation would permit UAS operations for rail infrastructure inspection and patrolling on the petitioner's privately owned property.

[FR Doc. 2020–28917 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–72]

Petition for Exemption; Summary of Petition Received; Virgin Galactic, LLC and TSC, LLC

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 21, 2021.

ADDRESSES: Send comments identified by docket number FAA–2020–0827 using any of the following methods:

• *Federal eRulemaking Portal:* Go to *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Operations at (202) 493–2251.

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 *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267–7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on December 21, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0827.

Petitioners: Virgin Galactic, LLC and TSC, LLC.

Sections of 14 CFR Affected: 91.319(a).

Description of Relief Sought: Virgin Galactic, LLC (VG) and TSC, LLC jointly petition for relief from Title 14 Code of Federal Regulations § 91.319(a) to the extent necessary to allow either petitioner to carry persons or property for compensation for hire on the WhiteKnightTwo (WK2) aircraft for flights that are not deemed to be a space support vehicle flight.

[FR Doc. 2020–28912 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2021–2034]

Petition for Exemption; Summary of Petition Received; BlueSky Helicopters, Inc.

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 21, 2021.

ADDRESSES: Send comments identified by docket number FAA–2020–0486 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

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 *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tiffany Griffith, *Tiffany.N.Griffith@faa.gov,* Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on December 21, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0486.

Petitioner: BlueSky Helicopters, Inc.

Section(s) of 14 CFR Affected: § 133.43(a) and (b).

Description of Relief Sought: BlueSky Helicopters, Inc. seeks relief from 14 CFR 133.43(a) and (b) to the extent necessary to conduct Class B human external cargo (HEC) operations in support of power line construction, maintenance, and patrol, as well as in support of law enforcement and search-and-rescue (SAR) operations, as there are no part 27 approved hook systems available for the H–60 series helicopter.

[FR Doc. 2020–28913 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2020–49]

Petition for Exemption; Summary of Petition Received; Phoenix Air Unmanned, LLC

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 21, 2021.

ADDRESSES: Send comments identified by docket number FAA–2020–0596 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

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 *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on December 21, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–0596.

Petitioner: Phoenix Air Unmanned, LLC.

Section(s) of 14 CFR Affected: §§ 61.113(a); 91.7(a); 91.113(b), (d), (e), (f), (g); 91.119(c); 91.121; 91.151(b); 91.405(a); 91.407(a)(1) and (2); 91.409(a)(1) and (2); and 91.417(a) and (b).

Description of Relief Sought: Phoenix Air Unmanned, LLC seeks relief from 14 CFR 61.113(a); 91.7(a); 91.113(b), (d), (e), (f), (g); 91.119(c); 91.121; 91.151(b); 91.405(a); 91.407(a)(1) and (2); 91.409(a)(1) and (2); and 91.417(a) and (b) to allow the petitioner to operate the SwissDrones SD050V2 unmanned aircraft system with a take-off weight not to exceed 192 pounds to remotely conduct inspections and patrol critical electric system infrastructures.

[FR Doc. 2020–28918 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0008]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; National Survey of Speeding Attitudes and Behaviors

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a reinstatement with modification of a previously approved collection of information.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below will be submitted to the Office of Management and Budget (OMB) for review. The ICR describes the nature of the information collection and its expected burden. The ICR is for a reinstatement with modification of a previously approved collection of information for a one-time voluntary survey regarding knowledge, attitudes, and behaviors associated with speeding. A **Federal Register** notice with a 60-day comment period soliciting public comments on the following information collection was published on August 3, 2020. NHTSA received two comments, which we address below.

DATES: Comments must be submitted on or before February 1, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the Office of Management and Budget at *www.reginfo.gov/public/do/PRAMain.* To find this particular information collection, select ''Currently under Review—Open for Public Comment'' or use the search function. Comments may also be sent by mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for Department of Transportation, National Highway Traffic Safety Administration, or by email at *oira_submission@omb.eop.gov,* or fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Kristie Johnson, Ph.D., Office of Behavioral Safety Research (NPD–310), National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, W46–498, Washington, DC 20590. Dr. Johnson's phone number is 202–366–2755, and her email address is *kristie.johnson@dot.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). In compliance with these requirements, this notice announces that the following information collection request has been forwarded to OMB.

A **Federal Register** notice with a 60-day comment period soliciting public comments on the following information collection was published on August 3, 2020 (**Federal Register**/Vol. 85, No. 149/pp. 46782–46786). NHTSA received two comments. Sarah Smoak provided comments supportive of the proposed information collection. An anonymous commenter provided remarks about the COVID–19 pandemic with no mention of the proposed survey or traffic safety.

Comments on the proposed information collection are appreciated. Thank you to Ms. Smoak for providing thoughtful commentary as to the importance of conducting the National Survey of Speeding Attitudes and Behaviors. This included using the data to be able to formulate plans, procedures, and countermeasures to have positive impacts on the public by reducing speed-related deaths. Ms. Smoak also appreciates that the periodic surveys help track behavioral changes related to speeding.

Title: National Survey of Speeding Attitudes and Behaviors.

OMB Control Number: 2127–0613.

Form Numbers: NHTSA Form 1538, NHTSA Form 1539, NHTSA Form 1544, NHTSA Form 1545, NHTSA Form 1546.

Type of Information Collection Request: Reinstatement with modification of a previously approved information collection (OMB Control No. 2127–0613).

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Respondents: Random sample of U.S. adults (18 years old and older) who drive a motor vehicle.

Summary of the Collection of Information: NHTSA is seeking approval to conduct a National Survey of Speeding Attitudes and Behaviors by web and mail among a national probability sample of 7,013 adult drivers (and 152 adult drivers for a pilot survey), age 18 and older. Participation by respondents would be voluntary. Survey topics would include the extent to which drivers speed, drivers' attitudes and perceptions about speeding, reasons and motivations for speeding, and knowledge and attitudes towards countermeasure strategies to deter speeding.

In conducting the proposed research, the survey would use computer-assisted web interviewing (*i.e.,* a programmed, self-administered web survey) to minimize recording errors, as well as optical mark recognition and image scanning for the paper and pencil survey to facilitate ease of use and data accuracy. A Spanish-language survey option would be used to minimize language barriers to participation. Surveys would be conducted with respondents using an address-based sampling design that encourages respondents to complete the survey online. Although web would be the primary data collection mode, a paper questionnaire would be sent to households that do not respond to the web invitations. The proposed survey would be anonymous and the survey would not collect any personal information. This collection only requires respondents to report their answers; there are no record-keeping costs to the respondents.

Description of the Need for the Information and Proposed Use of the Information:

NHTSA was established to reduce deaths, injuries, and economic losses resulting from motor vehicle crashes on the nation's highways. As part of this statutory mandate, NHTSA is authorized to conduct research for the development of traffic safety programs. Title 23, United States Code, Section 403 gives the Secretary of Transportation (NHTSA by delegation) authorization to use funds appropriated to conduct research and development activities, including demonstration projects and the collection and analysis of highway and motor vehicle safety data and related information, with

respect to all aspects of highway and traffic safety systems and conditions relating to vehicle, highway, driver, passenger, motorcyclist, bicyclist, and pedestrian characteristics; accident causation and investigations; and human behavioral factors and their effect on highway and traffic safety.

Traffic crashes are complex. Often, they involve multiple contributing factors, with speeding as one of the primary factors leading to a crash. Speeding-related crashes—defined as racing, exceeding the speed limit, or driving too fast for conditions [1]—resulted in 26% of all crash fatalities in 2018,[2] a percentage that has largely remained the same over the last 20 years despite national, State, and local efforts to address the speeding problem. In 2010, speeding-related crashes were estimated to result in $52 billion in economic costs and $203 billion in comprehensive costs.[3] Speeding is especially dangerous because it reduces the driver's ability to maneuver around obstacles in a timely manner, increases the distance a vehicle requires to stop, and increases the severity of injuries.[4] This stalled progress suggests that new countermeasures that differ from typical enforcement and engineering efforts may be needed to reduce speeding deaths. An interdisciplinary approach involving engineering, enforcement, and education is needed to change drivers' speeding behavior, thereby reducing speeding-related crashes, fatalities and injuries. To design interventions and countermeasure strategies that are likely to lead to behavior change, NHTSA requires up-to-date information on which drivers are speeding, their attitudes, perceptions, and motivations, as well as what countermeasures are most likely to reduce their speeding behavior. It is important to focus studies on factors underlying behaviors such as attitudes or perceptions of norms that are changeable.

NHTSA has conducted the National Survey of Speeding Attitudes and Behaviors on three previous occasions—first in 1997, again in 2002, and most recently in 2011. In the 2021 survey, NHTSA intends to examine the extent to which drivers' speed, who the speeders are, when and why drivers speed, and what countermeasures are most acceptable and effective in reducing speeding. Furthermore, NHTSA plans to assess whether self-reported behaviors, attitudes, and perceptions regarding speeding and associated countermeasure strategies have changed over time since the administration of the prior three national surveys. The 2021 survey will also include new questions on emerging speed-related technologies. The findings from this proposed information collection will assist NHTSA in designing, targeting, and implementing programs intended to reduce speed on the roadways and to provide data to States, localities, and law enforcement agencies that will aid in their efforts to reduce speed-related crashes and injuries.

NHTSA will use the information to produce a technical report that presents the results of the study. The technical report will provide aggregate (summary) statistics and tables as well as the results of statistical analysis of the information, but it will not include any personally identifiable information (PII). The technical report will be shared with State highway offices, local governments, and those who develop traffic safety communications that aim to reduce speed-related crashes.

Frequency of Collection: The study will be conducted one time during the three-year period for which NHTSA is requesting approval. This study is part of a tracking and trending study to measure changes over time. The last study was administered in 2011.

Respondents: Participants will be U.S. adults (18 years old and older) who drive a motor vehicle. Businesses are ineligible for the sample and would not be interviewed.

Estimated Number of Respondents: 7,165.

Participation in this study will be voluntary, with 7,013 participants sampled from all 50 States and the District of Columbia using address data from the most recent U.S. Postal Service (USPS) computerized Delivery Sequence File (DSF) of residential addresses. An estimated 20,600 households will be contacted and have the study described to them. No more than one respondent will be selected per household.

Prior to the main survey, a pilot survey will be administered to test the survey and the mailing protocol and procedures. Participation in this study will be voluntary, with 152 participants sampled from all 50 States and the District of Columbia using address data from the most recent U.S. Postal Service (USPS) computerized Delivery Sequence File (DSF) of residential addresses. An estimated 444 households will be contacted and have the study described to them. No more than one respondent will be selected per household.

Estimated Total Annual Burden Hours: NHTSA estimates the total burden of this information collection by estimating the burden to those that NHTSA contacts who do not respond (non-responders), those that NHTSA contacts who respond but are ineligible (ineligible respondents), and those who respond and are eligible for participation (eligible respondents or actual participants). The estimated time to contact 20,600 potential participants (actual participants, ineligible respondents, and non-responders) for the survey and 444 potential participants (actual participants, ineligible respondents, and non-responders) for the pilot is one minute per person per contact attempt. Contact attempts will be made in five waves with fewer potential participants contacted each subsequent wave. NHTSA estimates that 7,221 people will respond to the survey request and 156 will respond to the pilot. Of those, NHTSA estimates that nearly 3% will be ineligible because they are not drivers or are under 18 years old, resulting in 208 respondents to the survey and 4 respondents to the pilot who are ineligible. The estimated time to contact and screen 208 ineligible survey participants and 4 ineligible pilot participants is three minutes per person. The estimated time to contact and complete the survey for 7,013 participants and 152 pilot participants is 21 minutes per person. Details of the burden hours for each wave in the pilot and full survey are included in Tables 1 and 2 below.

[1] National Center for Statistics and Analysis. (2007). *Speeding: 2006 data* (Traffic Safety Facts. DOT HS 810 814). Retrieved from the NHTSA website: *https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/810814*

[2] National Center for Statistics and Analysis. (2019, December). Fatality Analysis Reporting System (FARS): 2018 Annual Report File (ARF) custom query. Retrieved from the NHTSA website: *https://cdan.dot.gov/query*

[3] Blincoe, L.J., Miller, T.R. Zaloshnja, E., & Lawrence, B.A. (2015, May). *The economic and societal impact of motor vehicle crashes, 2010. (Revised.)* (Report No. DOT HS 812 013). Retrieved from the NHTSA website: *https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/812013*

[4] National Center for Statistics and Analysis. (2007). *Speeding: 2006 data* (Traffic Safety Facts. DOT HS 810 814).

TABLE 1—ESTIMATED TOTAL BURDEN FOR PILOT SURVEY

Wave	Contacts	Participant type	Estimated burden per sample unit (minutes)	Sample units	Burden (hours)	Total burden
Wave 1 (Initial Invitation—NHTSA Form 1544).	444	Contacted potential participant—Non-respondent.	1	391	7	26
		Screened out participant—Ineligible respondent.	3	2	1	
		Recruited participant—Eligible respondent.	21	51	18	
Wave 2 (Reminder Postcard #1—NHTSA Form 1546).	391	Contacted potential participant—Non-respondent.	1	356	6	19
		Screened out participant—Ineligible respondent.	3	0	0	
		Recruited participant—Eligible respondent.	21	35	13	
Wave 3 (1st Survey Mailing—NHTSA Forms 1538, 1545).	356	Contacted potential participant—Non-respondent.	1	313	6	22
		Screened out participant—Ineligible respondent.	3	2	1	
		Recruited participant—Eligible respondent.	21	41	15	
Wave 4 (Reminder Postcard #2—NHTSA Form 1546).	314	Contacted potential participant—Non-respondent.	1	298	5	11
		Screened out participant—Ineligible respondent.	3	0	0	
		Recruited participant—Eligible respondent.	21	16	6	
Wave 5 (2nd Survey Mailing—NHTSA Forms 1538, 1545).	298	Contacted potential participant—Non-respondent.	1	289	5	9
		Screened out participant—Ineligible respondent.	3	0	0	
		Recruited participant—Eligible respondent.	21	9	4	
Total						87

TABLE 2—ESTIMATED TOTAL BURDEN FOR FULL SURVEY

Wave	Contacts	Participant type	Estimated burden per sample unit (minutes)	Sample units	Burden (hours)	Total burden
Wave 1 (Initial Invitation—NHTSA Form 1544).	20,600	Contacted potential participant—Non-respondent.	1	18,130	303	1,147
		Screened out participant—Ineligible respondent.	3	72	4	
		Recruited participant—Eligible respondent.	21	2,398	840	
Wave 2 (Reminder Postcard #1—NHTSA Form 1546).	18,130	Contacted potential participant—Non-respondent.	1	16,498	275	833
		Screened out participant—Ineligible respondent.	3	47	3	
		Recruited participant—Eligible respondent.	21	1,585	555	
Wave 3 (1st Survey Mailing—NHTSA Forms 1538, 1545).	16,498	Contacted potential participant—Non-respondent.	1	14,518	242	919
		Screened out participant—Ineligible respondent.	3	57	3	
		Recruited participant—Eligible respondent.	21	1,923	674	
Wave 4 (Reminder Postcard #2—NHTSA Form 1546).	14,519	Contacted potential participant—Non-respondent.	1	13,793	230	479
		Screened out participant—Ineligible respondent.	3	21	2	
		Recruited participant—Eligible respondent.	21	705	247	
Wave 5 (2nd Survey Mailing—NHTSA Forms 1538, 1545).	13,793	Contacted potential participant—Non-respondent.	1	13,379	223	365
		Screened out participant—Ineligible respondent.	3	12	1	
		Recruited participant—Eligible respondent.	21	402	141	
Total						3,743

When rounded up to the nearest whole hour for each data collection effort, the total estimated annual burden is 3,830 hours for the project activities.

Estimated Total Annual Burden Cost: Participation in this study is voluntary,

and there are no costs to respondents beyond the time spent completing the questionnaires.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department of Transportation, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including 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.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Issued in Washington, DC.

Nanda Narayanan Srinivasan,

Associate Administrator, Research and Program Development.

[FR Doc. 2020–28904 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2016–0204]

Exploring Industry Practices on Distribution and Display of Airline Fare, Schedule, and Availability Information

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Notice of withdrawal of request for information.

SUMMARY: The Department of Transportation (''Department'' or ''DOT'') is withdrawing a Request for Information (''RFI'') that solicited information on whether airline restrictions on the distribution or display of airline flight information harm consumers and constitute an unfair and deceptive business practice and/or an unfair method of competition.

DATES: December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Kimberly Graber and Blane A. Workie, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, 202–366–9342, 202–366–7152 (fax), *kimberly.graber@dot.gov* or *blane.workie@dot.gov.*

Electronic Access: You can view and download related documents and public comments by going to the website *http://www.regulations.gov.* Enter the docket number DOT–OST–2016–0204 in the search field.

SUPPLEMENTARY INFORMATION: The Department issued the RFI on October 31, 2016 in response to concerns raised by certain online travel agencies (OTAs), metasearch entities that operate flight search tools, and other stakeholders involved in the distribution of flight information and sale of air transportation, as well as consumer advocates and some members of Congress regarding certain practices related to the distribution and display of airline fare, schedule, and availability information.[1] The Department has also heard from airlines and other members of Congress opposing Departmental action in this area. On December 22, 2016, DOT extended the response date of the RFI to March 31, 2017.[2] On March 10, 2017, the Department suspended the response period while it evaluated next steps.[3]

The issue of airline restrictions on the distribution or display of airline flight information on third-party travel websites is a complex issue with far-reaching implications for consumers, airlines, ticket agents, and the various participants in the distribution chain. The Department recognizes that transparency is not only good for consumers but also good for competition in the airline industry. However, the Department also believes that airlines should be able to choose how and where they sell their products so long as they do not engage in unfair or deceptive practices. These two goals are not mutually exclusive. The Department does not consider its involvement at this time to be necessary to prevent unfair, deceptive, or anticompetitive practices. As such, the Department has decided to withdraw the RFI.

Issued in Washington, DC, under authority delegated in 49 CFR 1.27(n).

Christina G. Aizcorbe,

Deputy General Counsel.

[FR Doc. 2020–28927 Filed 12–30–20; 8:45 am]

BILLING CODE P

[1] 81 FR 75481.

[2] 81 FR 94021.

[3] 82 FR 13375.

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Regional Infrastructure Accelerators Demonstration Program

AGENCY: Build America Bureau, U.S. Department of Transportation (DOT).

ACTION: Notice of funding opportunity (NOFO).

SUMMARY: The Fixing America's Surface Transportation (FAST) Act, enacted in December 2015, authorized the establishment of a Regional Infrastructure Accelerators Demonstration Program (the Program) to assist entities in developing improved infrastructure priorities and financing strategies for the accelerated development of a project that is eligible for funding under the Transportation Infrastructure Finance and Innovation Act (TIFIA) Program under Chapter 6 of Title 23, United States Code. The Further Consolidated Appropriations Act, 2020, enacted on December 20, 2019, appropriated $5 million for this Program.

SUPPLEMENTARY INFORMATION: The Build America Bureau (Bureau) is issuing this NOFO to implement the Program and solicit applications for designating and funding Regional Infrastructure Accelerators (RIA) that will: (1) Serve a defined geographic area; (2) act as a resource to qualified entities in the geographic area in accordance with Section 1441 of the FAST Act; and (3) demonstrate the effectiveness of an RIA to expedite the delivery of eligible projects through the TIFIA credit program and, to the extent applicable, the Railroad Rehabilitation and Improvement Financing (RRIF) credit program, Private Activity Bonds (PABs) and other innovative financing methods.

Each section of this notice contains information and instructions relevant to the application process for the RIA grants. All applicants should read this notice in its entirety so that they have the information they need to submit eligible and competitive applications.

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A. Program Description

1. Background: The Bureau is responsible for driving transportation

infrastructure development projects in the United States through innovative financing programs. Its mission is to provide access to the Bureau's credit programs in a streamlined, expedient, and transparent manner. In accomplishing its mission, the Bureau also provides technical assistance and encourages innovative best practices in project planning, financing, delivery, and monitoring. The Bureau draws upon the full resources of DOT to best utilize the expertise of DOT's Operating Administrations while promoting a culture of innovation and customer service. Section 1441 of the FAST Act [1] provided the authority to establish the Program, and the Consolidated Appropriations Act, 2020,[2] appropriated $5 million to fund the Program. The intent of this Program is to demonstrate and evaluate the viability and effectiveness of a small number of accelerators in expediting the development and delivery of specific transportation projects within the geographic area of each RIA designated by the Bureau. It is not the Bureau's intention to provide RIA coverage nationwide. However, the Bureau is keenly interested in testing several RIA models to address needs based on common transportation infrastructure make-up and challenges within regions, particularly those with less capacity or experience in innovative financing and project delivery methods, and those supporting eligible entities that are likely to be first time users of the Bureau's credit programs, such as the TIFIA credit program. Therefore, the Bureau plans to select approximately three, but not more than five, RIAs based on proposals submitted by eligible applicants in response to this notice. Ideally, at least one State/multi-State application, one urban application, and one rurally focused application will be selected. However, flexibility exists to consider other proposed geographic configurations if the regional make-up is sound. For example, the Bureau would consider an RIA that has a corridor focus that does not entirely fit within one of the categories outlined in Regional Designation as follows:

2. Regional Designation: For the purpose of this Program, the Bureau will consider regional designation as broadly defined in the following categories:

a. State or Multi-State: An RIA that serves one State or a group of State entities with common interest in transportation projects being delivered.

b. Urban or Metropolitan Planning Organization (MPO): An RIA that serves local government or group of local jurisdictions with transportation functions within a metropolitan area. For the purpose of this Program, if the RIA serves MPOs sharing State boundaries, it would be considered under this category.

c. Rural: An RIA that serves a region of rural communities as defined in this notice. An RIA serving multiple rural communities across state lines would be considered under this category. To be considered a rural RIA, most of the projects listed in the proposal must meet the definition of rural in Section C.5 of this notice.

d. Other: Any proposal that includes multiple jurisdictions with shared priorities and interest, such as a river basin, transportation corridor, etc.

3. Program Goals: The primary intent for the RIAs is to provide project-specific technical assistance for projects that are eligible for the TIFIA credit program. In addition, the Bureau is interested in identifying RIAs that can facilitate the acceleration of projects that are eligible for credit assistance through the RRIF credit program and PABs. This assistance can be in the form of any of the following, based on the needs of the project(s) that the applicant proposes to assist:

a. Project planning;

b. Studies and analysis, including feasibility, market analysis, project costs, cost-benefit analysis, value for money, public benefit, economic assessments, and environmental reviews;

c. Revenue forecasting, funding and financing options analyses, application of best practices, innovative financing/procurement, and public-private partnerships, where appropriate;

d. Preliminary engineering and design work;

e. Statutory and regulatory framework analyses;

f. Evaluation of opportunities for private financing, project bundling and/or phasing;

g. Enhancement of rural project sponsors' capacity to use the TIFIA credit program and to the extent applicable, the RRIF credit program, PABs, and other innovative financing methods, helping to bundle projects across multiple smaller jurisdictions to create a project at a scale that is more appropriate for the Bureau's credit assistance, and pool the jurisdictions' resources to apply for TIFIA credit assistance and, to the extent applicable, RRIF credit assistance and PABs, as well as leveraging DOT's Rural Opportunities to Use Transportation for Economic Success (ROUTES) Initiatives' [3] products and offerings; and

h. Other direct, project-specific support as appropriate.

Funding, in the form of and pursuant to a cooperative agreement, will be provided for a single year, with an option for a second year for RIA that meet or exceed agreed-upon performance targets. Competitive proposals that demonstrate long-term self-sustainability will be given greater consideration. The Bureau intends to work closely with grant recipients in developing and, as applicable, financing projects within the RIA's geographic area.

B. Federal Award Information

1. The Bureau hereby requests applications from all interested parties to result in the award of several cooperative agreements, each containing substantial involvement on the part of the Federal government in accordance with Section 6305 of title 31, United States Code. The Bureau anticipates substantial Federal involvement between it and the recipient during this project will include among others:

a. Technical assistance and guidance to the recipients;

b. Close monitoring of performance;

c. Involvement in technical decisions; and

d. Participation in status meetings including kick off meeting and annual technical and budget reviews.

2. Total amount of funding that the Bureau expects to award under this notice is $5 million.

3. The Bureau will conduct the RIA selection based on principles of full and open competition.

4. Program Funding and Awards:

a. Number of Awards: The Bureau intends to select at least three but no more than five RIAs, based on the number and viability of applications.

b. Size of Award: A total of $5 million is available for this demonstration program. The size of individual awards will be determined by the number of RIAs selected and the funding needed for each to meet the program objectives.

5. Funding Period: The Bureau intends to award funds on a yearly basis for a period of two years under a cooperative agreement with the second year as an option year. A third option year of funding may be provided if the RIA is achieving agreed-upon performance objectives, subject to the availability of funds.

C. Eligibility Information

1. Eligible Applicants: To be selected as an RIA, an applicant must be an

[1] Public Law 114–94, 129 Stat. 1312, 1435.

[2] Public Law 116–94, div. H, tit. I, H.R. 1865 at 413 (as enrolled December 20, 2019).

[3] *https://www.transportation.gov/rural.*

eligible applicant. An eligible applicant is: A U.S. public entity, including a state, multi-state or multi-jurisdictional group, municipality, county, a special purpose district or public authority with a transportation function including a port authority, a tribal government or consortium of tribal governments, MPO, regional transportation planning organization (RTPO), Regional Transportation Commission, or a political subdivision of a State or local government, or combination of two or more of the foregoing.

In the event that more than one public entity is applying in a single proposal, one of the entities must be designated as the lead applicant. Such applicant will be authorized to negotiate and enter into a cooperative agreement with the Government on behalf of the entities, will be responsible for performance, and will be accountable for Federal funds. Applications will be accepted from a partnership between one or more eligible applicants and another U.S. party, such as a private entity, consulting or engineering firms, etc., as long as one of the eligible public entities is designated as the lead applicant and that entity will enter into the cooperative agreement, with the shared goal of establishing and operating the RIA. The location of all RIA application parties, their entire jurisdictions and all proposed projects must be located solely in the United States and its territories. Proposed projects and project sponsors (prospective borrowers) must meet the eligibility requirements for TIFIA and RRIF credit assistance as further defined in Chapter 3 of the Bureau's Credit Program Guide (*https://www.transportation.gov/sites/buildamerica.dot.gov/files/2019-08/Bureau%20Credit%20Programs%20Guide_March_2017.pdf#page=29*). In addition, the Bureau will consider the extent to which an applicant demonstrates the capacity to accelerate projects eligible for the TIFIA credit program and, to the extent applicable, the (RRIF) credit program and (PABs).

2. Cost sharing or Matching: There is no requirement for cost sharing or matching the grant funds.

3. Other: For the purposes of this program, the following terms apply:

a. Rural Infrastructure Project: Consistent with the definition of ''rural infrastructure project'' for the TIFIA credit program, ''rural'' for the purposes of this notice is defined as a surface transportation infrastructure project located outside of an urbanized area with a population greater than 150,000 individuals, as determined by the Bureau of the Census.

b. A proposed region whose geographic authority is in both an urban and a rural area will be designated as urban if the majority of the projects listed in the proposal are located in urban areas. Conversely, a proposed region located in both an urban area and a rural area will be designated as rural if the majority of the projects listed in the proposal are in rural areas.

c. Urban/Rural Project determination: A project located in both an urban and a rural area will be designated as urban if less than ½ of the project's costs are spent in a rural area. If ⅔ or more of a project's costs are spent in a rural area, the project will be designated as rural. For projects where between ½ and ⅔ of their costs are in a rural area, the project will be designated as rural if the applicant demonstrates that ⅔ or more of the project's benefits accrue to users in rural areas; if the applicant does not make such demonstration, the project will be designated as urban.

D. Application and Submission Information

1. Address to Request Application Package: Applicants must submit all applications through *www.Grants.gov.* Instructions for submitting applications can be found at *https://www.transportation.gov/buildamerica/financing/tifia/regional-infrastructure-accelerators-program.*

2. Content and Form of Application: The application must include the Standard Form 424 (Application for Federal Assistance), cover page, and the application narrative.

A. Cover Page: Each application should include a cover page that contains, at minimum, name of the applicant and sponsor, if applicable, the location; the region of designation; category of designation for which the applicant is to be considered; and RIA budget amount.

B. Application Narrative: The application narrative should follow the basic outline below to address the program requirements and assist evaluators in locating relevant information.

Section	Section explained
I. Applicant	See D.2.I.
II. Description of Proposed Geographic/Jurisdictional Region.	See D.2.II.
III. Accelerator Proposal	See D.2.III.
IV. Budget, Sources and Uses for Full Accelerator Funds.	See D.2.IV.
V. Selection Criteria	See D.2.V.

The application narrative should include the information necessary for the Bureau to determine that the applicant(s) proposed regional focus, the overall accelerator proposal, list of intended projects, budget, and other information satisfy the eligibility requirements set forth in this notice as described in Section C and to assess the selection criteria specified in Section E.1. To the extent practicable, applicants should provide supporting data and documentation in a form that is directly verifiable by the Bureau. The Bureau may ask any applicant to supplement data in its application but expects applications to be complete upon submission.

In addition to the information requested elsewhere in this notice, the proposal should include a table of contents, maps, and graphics, as appropriate, to make the information easier to review. The Bureau recommends that the proposal be prepared with standard formatting preferences (a single-spaced document, using a standard 12-point font such as Times New Roman, with 1-inch margins). The proposal narrative may not exceed 30 pages in length, excluding cover pages and table of contents. The only substantive portions that may exceed the 30-page limit are documents supporting assertions or conclusions made in the 30-page project narrative. If possible, applicants should provide website links to supporting documentation rather than copies of these supporting materials. If supporting documents are submitted, applicants should clearly identify within the project narrative the relevant portion of the project narrative that each supporting document supports. The Bureau recommends using appropriately descriptive file names (*e.g.,* ''Project Narrative,'' ''Maps,'' ''Memoranda of Understanding'' and ''Letters of Support,'' etc.) for all attachments.

I. Applicant: This section of the narrative should include information describing the organizational structure and formal/informal relationships between parties associated with the RIA application. It should directly address the eligibility requirements discussed in section C.1 of this notice. The applicant should use this section to explain the organization's history, qualifications, and experience of key individuals who will be working in the proposed RIA. This section should also include descriptions of previous projects relevant to the RIA's activities envisioned in this notice that the organization or its individuals completed. The narrative should place the projects into a broader context of transportation infrastructure

investments being pursued by the proposed RIA and its sponsors, and how it will benefit communities within the region.

II. Description of Proposed Geographic/Jurisdictional Region: This portion of the narrative should precisely identify the geographic region, the jurisdictions, and the agencies the RIA would serve and identify which of the four categories of RIA identified in Section A.2 that this proposal falls under, and explain why. The narrative should explain the commonalities and shared interests of parties in the proposed region as the rationale for establishing a region of this construct, along with the affiliations within the proposed region. Consistent with the Department's ROUTES Initiative (*https://www.transportation.gov/rural*), the Department encourages applicants to describe how activities proposed in their application would address the unique challenges facing rural transportation networks, regardless of the geographic location of those activities.

III. Accelerator Proposal: This section of the narrative should explain how the applicant(s) propose to establish the RIA and the concept of how it would operate, and provide the project-specific services identified in Section A of this notice, along with a proposed timeline for establishing the RIA, with key milestones and suggested performance targets during its operational phase.

The applicant should describe, in sufficient detail, the applicant's approach to identifying and building the pipeline of projects to be undertaken and how they will develop such projects utilizing their experience and expertise, and identify an initial pipeline of projects that are eligible for TIFIA credit assistance and, to the extent applicable, RRIF credit assistance, PABs and other innovative financing methods. The narrative should also contain a list of projects that the applicant(s) propose to assist under the RIA. This list, to the extent possible, should include, at a minimum:

(a) Project name and location;

(b) Project sponsor;

(c) Description;

(d) Bureau program most likely to apply (TIFIA, RRIF, PABs);

(e) Support activities the applicant envisions the RIA would provide

(f) Project costs; and

(g) Project timeline.

The prospective applicant should describe in their proposal to the extent possible and, where applicable, if the project will (1) decrease transportation costs and improve access, especially for rural communities or communities in Opportunity Zones, through reliable and timely access to employment centers and job opportunities; (2) improve long-term efficiency, reliability or costs in the movement of workers or goods; (3) increase the economic productivity of land, capital, or labor, including assets in Opportunity Zones; (4) result in long-term job creation and other economic opportunities; or (5) help the United States compete in a global economy by facilitating efficient and reliable freight movement. Projects that bridge gaps in service in rural areas, and projects that attract private economic development, all support local or regional economic competitiveness. The Department intends to collect Opportunity Zones information to advance other Department activities related to Opportunity Zones, but the Department does not consider projects located in an Opportunity Zone to be more competitive for an RIA award than projects located outside an Opportunity Zone.

IV. Budget, Sources, and Uses for Full Accelerator Funds: The applicant should include a proposed financial plan and budget including the Federal grant amount requested, non-federal matching funds, in-kind contributions and other sources. The proposed plan should also include a list of activities and projects as well as all associated costs of the proposed RIA. For non-Federal matching funds, the application should identify the sources as well as supporting documentation indicating the degree to which those funds are committed and dates of their availability. If the applicant proposes that the RIA will reach a point of long-term self-sustainability, the narrative should include a description of how this would happen, and where the long-term funds would be generated.

V. Selection Criteria: This section of the application should demonstrate how the application aligns with the criteria described in Section E.1 of this notice. The Bureau intends to select and designate RIA that demonstrate in their proposal the ability to effectively assist entities in developing improved infrastructure priorities and financing strategies for the accelerated development of one or more projects eligible for funding under the TIFIA program. DOT will consider the extent to which an RIA is likely to effectively promote investment in eligible projects, develop a pipeline of regional transportation projects, and result in the implementation of projects with innovative financing methods.

The Bureau encourages applicants to either address each criterion or expressly state that the project does not address the criterion. Applicants are not required to follow a specific format, but the outline suggested addresses each criterion separately and promotes a clear discussion that assists project evaluators. To minimize redundant information in the application, the Bureau encourages applicants to cross-reference from this section of their application to relevant substantive information in other sections of the application. The guidance in this section is about how the applicant should organize their application. Guidance describing how the Bureau will evaluate projects against the Selection Criteria is in Section E.1 of this notice. Applicants also should review that section before considering how to organize their application.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant must: (1) Be registered in SAM before submitting its application; (2) provide a valid unique entity identifier in its application; and (3) continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency. The Department may not make an RIA grant to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time the Department is ready to make a grant, the Department may determine that the applicant is not qualified to receive a grant and use that determination as a basis for making a grant to another applicant.

4. Submission Dates and Timelines

a. Deadline: Applications in response to this NOFO must be submitted through *Grants.gov* by 11:59 p.m. EST 90 days after publication of this notice. The *Grants.gov* ''Apply'' function will open on the date of publication. The Bureau may hold NOFO information session(s) before the due date.

To submit an application through *Grants.gov*, applicants must:

(1) Obtain a Data Universal Numbering System (DUNS) number;

(2) Register with the System Award for Management (SAM) at *www.sam.gov;* and

(3) Create a *Grants.gov* username and password; and

(4) The E-business Point of Contact (POC) at the applicant's organization must also respond to the registration email from *Grants.gov* and login at *Grants.gov* to authorize the POC as an Authorized Organization Representative

(AOR). Please note that there can only be one AOR per organization.

Please note that the *Grants.gov* registration process usually takes 2–4 weeks to complete and that the Department will not consider late applications that are the result of failure to register or comply with *Grants.gov* applicant requirements in a timely manner. For information and instruction on each of these processes, please see instructions at *http://www.grants.gov/web/grants/applicants/applicant-faqs.html.* If interested parties experience difficulties at any point during the registration or application process, please call the *Grants.gov* Customer Service Support Hotline at 1(800) 518–4726, Monday-Friday from 7:00 a.m. to 9:00 p.m. EST.

b. Consideration of Application

Only applicants who comply with all submission deadlines described in this notice and submit applications through *Grants.gov* will be eligible for award. Applicants are strongly encouraged to make submissions in advance of the deadline.

c. Late Applications

Applications received after the deadline will not be considered except in the case of unforeseen technical difficulties outlined in Section D.4.d.

d. Late Application Policy

Applicants experiencing technical issues with *Grants.gov* that are beyond the applicant's control must contact *RIA@dot.gov* prior to the application deadline with the user name of the registrant and details of the technical issue experienced. The applicant must provide:

(1) Details of the technical issue experienced;

(2) Screen capture(s) of the technical issues experienced along with corresponding *Grants.gov* ''Grant tracking number'';

(3) The ''Legal Business Name'' for the applicant that was provided in the SF–424;

(4) The AOR name submitted in the SF–424;

(5) The DUNS number associated with the application; and

(6) The *Grants.gov* Help Desk Tracking Number.

To ensure a fair competition of limited discretionary funds, the following conditions are not valid reasons to permit late submissions: (1) Failure to complete the registration process before the deadline; (2) failure to follow *Grants.gov* instructions on how to register and apply as posted on its website; (3) failure to follow all the instructions in this notice of funding opportunity; and (4) technical issues experienced with the applicant's computer or information technology environment. After the Department reviews all information submitted and contacts the *Grants.gov* Help Desk to validate reported technical issues, USDOT staff will contact late applicants to approve or deny a request to submit a late application through *Grants.gov*. If the reported technical issues cannot be validated, late applications will be rejected as untimely.

5. Applications under this NOFO are not subject to the State review under E.O. 12372.

6. Funding Restrictions: The DOT will not reimburse any pre-award costs or application preparation costs under this proposed agreement. Construction of any project being contemplated or aided by the proposed RIA is not an allowable activity under this grant. All non-domestic travel must be approved in writing by the DOT designated agreement officer prior to incurring costs. Travel requirements under the cooperative agreement will be met using the most economical form of transportation available. If economy class transportation is not available, the request for payment vouchers must be submitted with justification for use of higher class travel indicating dates, times, and flight numbers.

E. Application Review Information

1. Criteria: This section specifies the criteria that the Bureau will use to evaluate and award applications for Program grants. The criteria incorporate statutory eligibility requirements. For each proposed RIA, the Bureau will review the application for the criteria described in this section. The Bureau does not consider any criterion more important than the others.

A. Experience/Qualifications: The Bureau will assess whether and to what extent the applicant(s):

(1) Possess the ability to evaluate and promote innovative financing methods for local projects including the use of TIFIA and RRIF and other Federal assistance programs where applicable;

(2) Possess the ability to provide technical assistance on best practices with respect to financing projects;

(3) Have experience in increasing transparency with respect to infrastructure project analysis and using innovative financing for public infrastructure projects;

(4) Have experience in deploying predevelopment capital programs designed to facilitate the creation of a pipeline of infrastructure projects available for investment;

(5) Have a history of successfully bundling smaller-scale and rural projects into larger proposals that may be more attractive for private investment;

(6) Have demonstrated success in reducing transaction costs for public project sponsors; and

(7) Demonstrate the capacity to accelerate projects eligible for the TIFIA credit program and, to the extent applicable, the Railroad Rehabilitation and Improvement Financing (RRIF) credit program and Private Activity Bonds (PABs).

B. Partnerships: The Bureau will consider the extent to which applicant(s) demonstrate strong collaboration among a broad range of stakeholders in the proposed geographic area of the RIA. Applications with strong partnerships typically involve multiple partners in project development, funding, and finance. The Bureau will consider applicants that partner with State, local, and private entities for the development, funding, financing, and delivery of transportation projects to have strong partnerships. Evaluators will also consider the relationship of the RIA with its constituencies and authorities granted by them. The Bureau will assess the ability of the proposed RIA to quickly and effectively develop projects by having the support of its members and working across jurisdictions.

C. Regional Viability: The Bureau will evaluate the proposed region, geographically, organizationally, and functionally, as well as its jurisdictional relevance. In evaluating this criterion, the Bureau will consider the geographic make-up of the proposed RIA and the transportation needs of the region.

D. Business Model: The Bureau will assess the thoroughness, viability, and efficiency that the applicant(s) can establish the RIA, commence operations, and deliver project-specific outcomes. In conducting this assessment, evaluators will consider:

(1) The effort, cost, and actions necessary to initially establish the proposed RIA, including workspaces, fixed and variable costs, staffing, and the development of relationships necessary to function effectively in the proposed region.

(2) How the proposed RIA will operate once established, including costs, organization, efficiency, availability of the technical expertise and resources needed to accelerate project delivery, work plan, and time required to achieve operational status.

E. Pipeline: The Bureau will consider the proposed pipeline of projects and assess whether and to what extent they

are likely to be eligible projects and appropriate for development activities as set forth in this notice. The proposed pipeline must include one or more projects likely to be eligible for TIFIA credit assistance. In evaluating this criterion, the Bureau will consider the number of eligible projects in the pipeline, the degree of local/regional support of the projects, and the project status and timeline as they relate to the likelihood the RIA can impact the project during the performance period of the cooperative agreement. Evaluators will also assess the degree to which the skills/experience of the applicant(s) are appropriate for the proposed projects. The Bureau will also evaluate the viability and proposed approach the applicant(s) have developed for attracting new projects into the RIA's pipeline of projects and how they propose to assist and monitor the development of those projects.

F. Readiness: The Bureau will consider the extent to which the proposed RIA is prepared to commence operations and begin achieving project-specific results. Evaluators will also assess the viability of the proposed budget as it relates to the establishment and successful operations of the RIA as proposed. In considering this criterion, evaluators will also determine the likelihood that proposed milestones will be subject to delay and/or cost overruns and the risk that key milestones might be missed due to internal or external factors. Evaluators will also consider the readiness of the proposed RIA to commence operations, including but not limited to:

(1) Availability of facilities and equipment necessary to function;

(2) Existing governance structure as compared to proposed future structure; and

(3) Ability of existing relationships to rapidly deliver results.

G. Value: The Bureau will evaluate the relative value of the proposal to individual projects and the taxpayer, including but not limited to: the number of projects likely to measurably be accelerated as a result of the proposed technical assistance of the RIA, the number of projects reasonably expected to receive Bureau financing, and the asset class(es) most prevalent in the proposed project portfolio. In considering this criterion, evaluators will also consider the applicant's proposed performance targets (Section III of the application) and how they compare to the overall proposed cost of the RIA (Section IV of the application).

H. Rural Assistance: Where applicable, the Bureau will evaluate the degree to which the proposal can support individual rural project sponsors. The Bureau will consider opportunities proposed to overcome common barriers to using TIFIA and RRIF credit assistance and other innovative financing methods for rural project sponsors, such as project size or type, financial or institutional capabilities, and other issues. Consistent with the Department's ROUTES Initiative (*https://www.transportation.gov/rural*), the Department recognizes that rural transportation networks face unique challenges. To the extent that those challenges are reflected in the merit criteria listed in this section, the Department will consider how the activities proposed in the application will address those challenges, regardless of the geographic location of those activities. This can include delivering innovative technical assistance and leveraging the DOT ROUTES Initiative to provide user-friendly information and other assistance to rural project sponsors.

I. Self-Sustainability: The Bureau will consider whether and to what extent the proposed RIA will achieve self-sustainability during the Program's effective period of receipt of Federal funding. In the event that a proposed RIA will not achieve self-sustainability, the Bureau will evaluate the extent to which the termination of the RIA might deliver long-term benefits as the result of projects delivered during the funding period.

J. Risk: The Bureau will assess the risks to successful implementation and operation of the proposed RIA, and the degree to which proposed mitigation activities might address/offset those risks. Evaluators will also assess the practicality of proposed mitigation activities in terms of cost, complexity, and time required to implement the actions.

2. Review and Selection Process: A Review Team will review all eligible applications received by the deadline. This Review Team will consist of Modal Liaisons from the Federal Highway Administration (FHWA), Federal Railroad Administration (FRA) and Federal Transit Administration (FTA) and two Bureau employees appointed by the Executive Director. The Program grants review and selection process consists of two steps: (1) The Review Team will evaluate each proposal and make a determination of eligibility based on criteria outlined in Section C.1 of this notice and, if deemed eligible; (2) the Review Team will evaluate the proposal based on the Selection Criteria in Section E.1 of this notice. The Review Team will make recommendations to the Executive Director. The Executive Director will finalize those recommendations and present the recommendations to the Secretary. The final decisions as to recipients will be made by the Secretary of Transportation.

3. Additional Information

Prior to award, each selected applicant will be subject to a risk assessment as required by 2 CFR 200.205. The Department must review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). An applicant may review information in FAPIIS and comment on any information about itself. The Department will consider comments by the applicant, in addition to the other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants.

F. Federal Award Administration Information

1. Federal Award Notice

Following the evaluation process outlined in Section E.2, the Secretary will announce awarded projects by posting a list of selected RIA at *https://www.transportation.gov/buildamerica/financing/tifia/regional-infrastructure-accelerators-program.* Notice of selection is not authorization to begin performance or to incur costs for the proposed RIA. Following that announcement, the Bureau will contact the point of contact listed in the SF 424 to initiate negotiation of the cooperative agreement.

2. Administration and National Policy Requirements

Performance under the cooperative agreement will be governed by and in compliance with the following requirements as applicable to the type of organization of the recipient and any applicable sub-recipients:

All awards will be administered pursuant to the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards found in 2 CFR part 200, as adopted by DOT at 2 CFR part 1201.

Other terms and condition as well as performance requirements will be addressed in the cooperative agreement with the recipient. The full terms and conditions of the resulting cooperative

agreements may vary and are subject to discussions and negotiations.

In connection with any program or activity conducted with or benefiting from funds awarded under this notice, recipients of funds must comply with all applicable requirements of Federal law, including, without limitation, the Constitution of the United States statutory, regulatory, and public policy requirements, including without limitation, those protecting free speech, religious liberty, public welfare, the environment, and prohibiting discrimination; the conditions of performance, non-discrimination requirements, and other assurances made applicable to the award of funds in accordance with regulations of the Department of Transportation; and applicable Federal financial assistance and contracting principles promulgated by the Office of Management and Budget. In complying with these requirements, recipients must ensure that no concession agreements are denied or other contracting decisions made on the basis of speech or other activities protected by the First Amendment. If the Bureau determines that a recipient has failed to comply with applicable Federal requirements, the Bureau may terminate the award of funds and disallow previously incurred costs, requiring the recipient to reimburse any expended award funds.

Additionally, Executive Order 13858 directs the Executive Branch Departments and agencies to maximize the use of goods, products, and materials produced in the United States through the terms and conditions of Federal financial assistance awards. If selected for an award, grant recipients must be prepared to demonstrate how they will maximize the use of domestic goods, products, and materials, as applicable, in establishing and operating the RIA.

3. Reporting

A. Progress Reporting on Grant Activities

Each applicant selected for RIA grant funding must submit semi-annual progress reports as agreed to in the cooperative agreement to monitor RIA progress and ensure accountability and financial transparency in the RIA grant program.

B. Performance Reporting

Each applicant selected for RIA grant funding must collect and report to the Bureau information on the RIA's performance. The specific performance information and reporting period will be determined on an individual basis. It is anticipated that the Bureau and the grant recipient will hold monthly progress meetings or calls during which the Bureau will review project activities, schedule, and progress toward mutually agreed upon performance targets in the cooperative agreement. If the award is greater than $500,000 over the period of performance, applicants must adhere to the post award reporting requirements reflected in 2 CFR part 200 Appendix XII—Award Term and Condition for Recipient Integrity and Performance Matters.

C. Reporting of Matters Related to Recipient Integrity and Performance

If the total value of a selected applicant's currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this Federal award, then the applicant during that period of time must maintain the currency of information reported to the SAM that is made available in the designated integrity and performance system (currently FAPIIS) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110–417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111–212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

G. Federal Awarding Agency Contacts

For further information concerning this notice please contact the Bureau via email at *RIA@dot.gov,* or call Sam Beydoun at 202–366–0198. A TDD is available for individuals who are deaf or hard of hearing at 202–366–3993. In addition, the Bureau will post answers to questions and requests for clarifications on the Bureau's website at *https://www.transportation.gov/buildamerica/financing/tifia/regional-infrastructure-accelerators-program.* To ensure applicants receive accurate information about eligibility or the program, the applicant is encouraged to contact the Bureau directly, rather than through intermediaries or third parties, with questions. Bureau staff may also conduct briefings on the Program grant selection and award process upon request.

H. Other Information

1. Protection of Confidential Business Information

All information submitted as part of or in support of any application shall use publicly available data or data that can be made public and methodologies that are accepted by industry practice and standards, to the extent possible. If the applicant submits information that the applicant considers to be a trade secret or confidential commercial or financial information, the applicant must provide that information in a separate document, which the applicant may cross-reference from the application narrative or other portions of the application. For the separate document containing confidential information, the applicant must do the following: (1) State on the cover of that document that it ''Contains Confidential Business Information (CBI)''; (2) mark each page that contains confidential information with ''CBI''; (3) highlight or otherwise denote the confidential content on each page; and (4) at the end of the document, indicate whether the CBI is information the applicant keeps private and is of the type of information the applicant regularly keeps private. The Bureau/DOT will protect confidential information complying with these requirements to the extent required under applicable law. If the Bureau receives a Freedom of Information Act (FOIA) request for the information that the applicant has marked in accordance with this section, the Bureau will follow the procedures described in its FOIA regulations at 49 CFR 7. 29.

2. Publication/Sharing of Application Information

Following the completion of the selection process and announcement of awards, the Bureau intends to publish a list of all applications received along with the names of the applicant organizations and funding amounts requested. Except for the information properly marked as described in Section H.1, the Bureau may make application narratives publicly available or share application information within DOT or with other Federal agencies if DOT determines that sharing is relevant to the respective program's objectives.

3. Department Feedback on Application

The Bureau strives to provide as much information as possible to assist applicants with the application process. The Bureau will not review applications in advance, but Bureau staff are available for technical questions and assistance.

Issued in Washington, DC, on December 17, 2020.

Elaine L. Chao,

Secretary of Transportation.

[FR Doc. 2020–28284 Filed 12–30–20; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[OST Docket No. DOT–OST–2011–0170]

Notice of Submission of Proposed Information Collection to OMB; Agency Request for Revision of BTS Form 251 and Renewal of OMB Control Number 2138–0018: Part 250 of the Department's Economic Regulations—Oversales

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), this Notice confirms the Department of Transportation's (Department) intention to renew and revise an Office of Management and Budget (OMB) control number as related to the Department's Bureau of Transportation Statistics (BTS) Form 251, *Report of Passengers Denied Confirmed Space.* A 60-day comment period soliciting comments on the information collection was published on March 3, 2020. Three comments were received. The Department addresses those comments in this Notice and is seeking to renew the current OMB control number by forwarding the Information Collection Request (ICR) abstracted below to OMB. The ICR renames Form 251 to Form 250 and revises the form to reduce the burden on airlines, better clarify the instructions for completing the form, and provide more relevant information to consumers.

DATES: Comments on this Notice must be received by February 1, 2021.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW, Washington, DC 20503. Comments may also be sent via email to OMB at the following address: *oira_submissions@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Stuart Hindman, (202) 366–9342, *Stuart.Hindman@dot.gov,* Office of Aviation Consumer Protection (C–70), U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2138–0018.

Title: Report of Passengers Denied Confirmed Space Due to an Oversale Situation.

Type of Request: Request to Revise and Rename Form 251 and Renew OMB Control Number.

Abstract/Background: BTS Form 251 is a one-page report that U.S. reporting carriers submit to the Department on a quarterly basis. Among other things, the form contains the following information: (1) The number of passengers denied seats on flights that they hold confirmed spaces, either voluntarily or involuntarily, (2) the numbers of passengers involuntarily denied boarding (bumped passengers) who qualified for compensation and were or were not provided alternate transportation, (3) the number of passengers voluntarily or involuntarily denied boarding who received compensation and the amounts of the compensation paid to them, and (4) the total number of enplanements at a U.S. airport relating to flights that are subject to the oversales rule. For the purpose of Form 251, reporting carriers are U.S. air carriers that account for at least 0.5 percent of domestic scheduled-service passenger revenues. These reporting carriers must submit Form 251 for all flights operated on aircraft with a designed passenger capacity of 30 or more seats which depart a U.S. airport. Carriers do not report data from inbound international flights to the United States because the protections of 14 CFR part 250 *Oversales* do not apply to these flights. In addition, reporting carriers must file a separate form for all scheduled flight segments originating in the United States that are operated by a codeshare partner of the reporting carrier that is a certificated air carrier or commuter air carrier using aircraft that have a designed passenger capacity of 30 or more seats, and marketed only under one U.S. carrier's code. As of January 1, 2020, there are 5 such reporting carriers.

The Department uses Form 251 to monitor the level of oversales activity by each reporting carrier, the impact on passengers, and the effectiveness of the Department's oversales rule. Certain information collected from Form 251 is made available to the public in the Department's monthly publication, the *Air Travel Consumer Report (ATCR),* at: *https://www.transportation.gov/individuals/aviation-consumer-protection/air-travel-consumer-reports.* The *ATCR* is a widely cited source of information for newspapers, magazines and trade journals. A review of the Form 251 data reveals that the overall involuntarily denied-boarding rate has consistently decreased in recent years, while passenger enplanements are increasing. For example, compared to the annual involuntary denied boarding rate of 4.38 per 10,000 passengers in 1980, this rate has been reduced to 0.24 per 10,000 passengers in 2019. Publishing individual carrier's denied boarding rates publicly serves to diminish the need for more intrusive regulations by disincentivizing carriers from setting unreasonable overbooking rates—resulting in a market based mechanism that is more efficient than direct regulation. In addition, a carrier's denied boarding rate provides an insight into that carrier's operational principles and customer service practices. For instance, a rapid sustained increase in the rate of denied boarding may indicate operational difficulties. Because the rate of denied boarding is released quarterly, travelers and travel agents concerned about being bumped can select carriers with lower incidences of denied boardings.

In 2016, the Department issued a final rule that, in part, revised the oversales reporting requirements. In conjunction with that rulemaking, on May 23, 2014 the Department published a 60-day FR Notice (79 FR 29970), and, on November 3, 2016, a 30-day FR Notice (81 FR 76800) to renew and revise the OMB control number regarding oversales information collection (2138–0018). On October 12, 2017, OMB approved the control number authorizing these new collections of information until October 31, 2020. The Department received an emergency extension of the current OMB control number until December 31, 2020.

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), 1320.12. On March 3, 2020, the Department published a 60-day Notice in the **Federal Register** soliciting comment on ICRs for which the agency was seeking OMB approval (85 FR 12664). A line-by-line summary of the proposed changes to the form with an explanation for each change was published in the 60-day Notice. The Department received three comments, one from an industry trade organization, one from a U.S. airline, and one from a member of the public. The Department's

response to the comments on each change is below:

Form 250

• Title

A. *Change:* The current title of the form—''Report of Passengers Denied Confirmed Space''—is revised to ''Report of Passengers Denied Confirmed Space Due to an Oversale Situation'' and renamed to be ''Form 250.'' This revision is intended to clarify that the form is meant to capture data relating to passengers denied boarding due to an oversale situation and not for other reasons such as safety, security, or health related reasons. Renaming the form to ''Form 250'' is intended to clarify further the applicability of the data to oversale situations and correspond to the appropriate part of Title 14 of the Code of Federal Regulations which addresses oversales, Part 250.

Comments: No comments were received on the title change.

• Line 1

A. *Change:* Added ''from flights that were oversold'' to the leading sentence to reinforce that the form is intended to capture data from oversold flights.

Comments: No comments were received on this change

B. *Change:* In order to provide more complete and accurate regulation citations, changed the regulation citation in line 1(a) to ''§ 250.5(a)(2) or (b)(2)'' and added a regulation citation in lines 1(b) of ''§ 250.5(a)(3) or (b)(3).''

Comment: Revert to previous language to match regulatory text and add definition of ''oversold'' to form's instructions.

Response: The Department accepts this comment. The Department has reworded the language in lines 1(a) and 1(b), added a clarifying language in Instruction (B), and added the definition of ''oversold flight'' which is found in 14 CFR 250.9 to Instruction (A).

C. *Comment:* Combine the data in lines 1(a) and 1(b).

Response: The Department rejects this comment. The data contained in lines 1(a) and 1(b) are distinct from each other, thus combining the lines would result in the publication of misleading information. Moreover, keeping the data separate allows the Department to more accurately monitor airline oversales and accommodation practices.

• Line 2

A. *Change:* Added ''from flights that were oversold'' in the leading sentence to reinforce that the form is intended to capture data from oversold flights.

Comment: No comments were received on this change.

B. *Change:* Reworded the contents in lines 2(a), 2(b), and 2(c) to ensure that the language on the form matches the regulatory text, listed order of exceptions to the denied boarding compensation rule found in 14 CFR 250.6, and included the applicable citation to section 250.6.

Comment: Add clarifying language to line 2(a) to ensure consistency in reporting by carriers.

Response: The Department concurs with this suggestion and has added clarifying language to Instruction (C).

C. *Change:* Moved the content of line 6 to line 2; reordered lines 2(a), 2(b), 2(c), and 2(d).

Two Comments: (1) Remove all data in line 2 because the data is not published by the Department and the reported data is not related to denied boardings in an oversales situation. (2) In the alternative, the Department should remove data collection related to upgrades and downgrades (line 2(c)).

Response: The Department rejects the comment to remove all collection in line 2. Keeping data collection related to the exceptions for denied boarding compensation allows the Department to monitor and track overall compliance with the denied boarding compensation rules. However, the Department accepts the suggestion to remove data related to upgrades and downgrades. If a passenger is ultimately accommodated on the flight but in a different section of the aircraft, the passenger was not denied boarding due to the entire flight being ''oversold.''

• Line 3—no change was proposed

A. *Comment:* Remove line 3 as data contained in this line is duplicative of line 1 if line 2 is deleted.

Response: The Department rejects the deletion of all of the information in line 2; therefore, the data contained in line 3 is not duplicative of other collected data.

• Line 4

A. *Changes:* Added ''from an oversold flight'' to reinforce that the form is intended to capture data from oversold flights. Added ''regardless of the type of compensation (*e.g.,* voucher, cash)'' to clarify that reporting carriers must report the actual number of all passengers who receive any type of compensation as a result of being denied boarding involuntarily.

Comment: Remove line 4 as the data collected is duplicative of Line 1.

Response: The Department rejects this comment. The data collected in lines 1 and 4 are distinct. Line 1 collects the number of passengers entitled to denied boarding compensation, while line 4 collects the number of passengers that actually received denied boarding compensation. The collection of the data in line 4 enables the Department to monitor carriers' compliance with the denied boarding compensation requirements, especially with regard to the proper payment of owed denied boarding compensation. A discrepancy in the data contained in lines 1 and 4 is an indication that a carrier may not be properly compensating all passengers who are entitled to denied boarding compensation.

• Line 5

A. *Change:* Added ''due to a potential oversale situation'' to reinforce that the form is intended to capture data from oversold flights.

Comment: Remove the word ''potential'' as it could place an excessive burden on reporting carriers and could result in overreporting of data.

Response: The Department accepts the comment in part and has substituted new language in line 5 to now read: Number of passengers who voluntarily accepted a carrier's offer to give up reserved space due to a potential oversale situation and did not travel on their original flight in exchange for a payment of the carrier's choosing. In the 60-day notice, line 5 stated: Number of passengers who volunteered to give up reserved space due to a potential oversale situation in exchange for a payment of the carrier's choosing. The Department believes that adding the phrase ''and did not travel on their original flight'' will prevent overreporting of potential oversale situation and any undue burden for reporting carriers as the carrier would only report the number of passengers who volunteer to be denied boarding after solicitation by the carrier and ultimately give up a reserved space.

• Line 6

A. *Changes:* Moved the text in line 6 regarding upgrades and downgrades to line 2 so that all data relating to exceptions to the denied boarding compensation rule is on one line. Moved the text from line 7 regarding total boardings to line 6 without any change.

Comments: No comments were received on this change.

• Line 7

A. *Change:* Moved the text from line 8 up to line 7 and added the regulation citation to ''§ 250.5(a)(2) or (b)(2)'' to line 7(a) and ''§ 250.5(a)(3) or (b)(3)'' to line 7(b) to complete the applicable regulatory citation.

Comment: Remove lines 7(a) and 7(b) as requiring the reporting of aggregate

data does not provide the Department or the public with usable information.

Response: The Department accepts the suggestion to remove lines 7(a) and 7(b). Instead, the Department will rename and reword proposed line 7 to read: Amount of compensation paid to passengers who voluntarily accepted a carrier's offer to give up reserved space on an oversold flight that received cash or cash equivalent payment. This change allows the Department to monitor industry practice regarding payment of voluntary denied boarding compensation for potential regulatory changes in the future.

Instructions to Form 250

No Comments were received on the changes proposed in the Instructions.

- Instruction (A)
  - Added clarifying language to ensure reporting carriers are only reporting data relating to oversold flights operated by covered aircraft (*i.e.,* aircraft with 30 or more seats).
  - Added language related to the requirement for reporting carriers to submit a separate Form 250 for flights operated by a reporting marketing carrier's code-share partner if the code-share partner is also a reporting carrier.
- Instruction (B)
  - Added clarifying language to include the full citation to the applicable regulation to ensure that reporting carriers are properly reporting data on lines 1(a) and 1(b).
- Instruction (C)—no change.
- Instruction (D)
  - Added a new Instruction D to clarify that reporting carriers must include on line 4 passengers who receive any type of compensation as a result of being denied boarding involuntarily from an oversold flight.
- Instruction (E)
  - Moved text from previous Instruction (D) to Instruction (E) without additional change.
- Instruction (F)
  - Moved text from previous Instruction (E) to Instruction (F) without additional change.
- Instruction (G)
  - Moved text from previous Instruction (F) to Instruction (G) and added clarifying language to ensure reporting carriers properly report only the amount of cash or cash-equivalent compensation provided to passengers denied boarding either voluntarily or involuntarily.
- Instruction (H)
  - Moved text from previous Instruction (G) to Instruction (H) without additional change.
- Instruction (I)
  - Moved text from previous Instruction (H) to Instruction (I) and include a new submission email address.

Copies of the revised form and accompanying instructions reflecting the changes are included in this Notice.

Accordingly, the Department announces that these information collection activities have been re-evaluated and certified under 5 CFR. 1320.5(a) and forwarded to OMB for review and approval pursuant to 5 CFR 1320.12(c). Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment., *see* 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day Notice is published, *see* 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983 (Aug. 29, 1995). The 30-day Notice informs the regulated community to file relevant comments to OMB and affords the Agency adequate time to review and respond to public comments before rendering a decision. *See* 60 FR 44983 (Aug. 29, 1995). Therefore, respondents should submit any comments to OMB within 30 days of publication to best ensure their full consideration. 5 CFR 1320.12(c); *see also* 60 FR 44983 (Aug. 29, 1995).

This Notice addresses the information collection requirements set forth in the Department's regulation mandating reporting of oversales data, 14 CFR 250.10. The renewed OMB control number will be applicable to all the provisions set forth in this Notice.

The PRA and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 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 the OMB under the PRA and displays a currently valid OMB Control Number. In addition, as a general matter, notwithstanding any other provisions of law, no person shall be subject to monetary penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

For each of these information collections, the title, a description of the respondents, and an estimate of the annual recordkeeping and periodic reporting burden are set forth below:

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501) requires a statistical agency to clearly identify information it collects for non-statistical purposes. The Departments hereby notifies the respondents and the public that it uses the information it collects under this OMB approval for non-statistical purposes including, but not limited to, publication of the data in the Department's Air Travel Consumer Report and submission of the information to DOT agencies outside BTS for review, analysis, and possible use in regulatory, enforcement, and other administrative matters.

Requirement to Submit BTS Form 250 as related to oversold flights.

Respondents: U.S. air carriers that account for 0.5 percent of domestic scheduled-service passenger revenues for all flights operated on aircraft with a designed passenger capacity of 30 or more seats which depart a U.S. airport. We have identified 16 carriers meeting this threshold in 2020. Additionally, out of the 16 carriers, five reporting carriers must file a separate form for all scheduled flight segments originating in the United States which are operated by a codeshare partner of the reporting carrier that is a certificated air carrier or commuter air carrier using aircraft that have a designed passenger capacity of 30 or more seats, and marketed only under one U.S. carrier's code.

Number of Respondents: 16 (effective January 1, 2020).

Frequency: Four times a year.

Estimated Total Burden on Respondents: 1,144 hours.

This estimate is based on the following information: [1]

FLIGHTS OPERATED BY REPORTING CARRIERS

[Form 250 for flights they operate]

Respondents	16
Quarterly Reports	4
Total Reports	*64*
Hours per Reports	16
Burden Hours	1,024

[1] The burden estimate was based on a cost/benefits analysis conducted in 2016 as part of the Department's Final Rule on Enhancing Airline Passenger Protections III. *See, Regulatory Impact Analysis for Final Rule Enhancing Airline Passenger Protection III, October 18, 2016. https://www.regulations.gov/document?D=DOT-OST-2014-0056-0792.*

CODESHARE FLIGHTS MARKETED BY REPORTING CARRIER

[Form 250 for codeshare flights they market]

Respondents	5
Quarterly Reports	4
Total Reports	*20*
Hours per Reports	6
Burden Hours	120

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

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

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.

Blane A. Workie,

Assistant General Counsel for Aviation Consumer Protection.

BILLING CODE 4910–9X–P

OMB No. 2138-0018
Expires 10-31-2020

U.S. Department of Transportation Bureau of Transportation Statistics

Report of Passengers Denied Confirmed Space Due to an Oversale Situation

Name of Air Carrier: _____

OAG Carrier Code: _____

Quarter ended: _____

This form should be mailed within 30 days after the calendar quarter to:
Office of Airline Information, BTS, U.S. Department of Transportation,
1200 New Jersey Ave., S.E., Washington, D.C. 20590-0001
Or emailed to: Form250.support@dot.gov

(See Instructions Below)

1.	Number of passengers who were denied boarding involuntarily from flights that were oversold, and: (a) who qualified for denied boarding compensation within the meaning of § 250.5(a)(2) and 250.5(b)(2)	
	(b) who qualified for denied boarding compensation within the meaning of § 250.5(a)(3) and 250.5(b)(3)	
2.	Number of passengers denied boarding involuntarily from flights that were oversold, who did not qualify for denied boarding compensation due to: (a) The passenger does not comply fully with the carrier's contract of carriage or tariff provisions regarding ticketing, reconfirmation, check-in, and acceptability for transportation (*see* § 250.6(a))	
	(b) substitution of aircraft of lesser capacity or due to weight/balance restrictions on an aircraft with a designed passenger capacity of 60 or fewer seats (*see* § 250.6(b))	
	(c) The carrier arranges comparable air transportation or other transportation that is planned to arrive not later than 1 hour after the planned arrival time of the passenger's original flight or flights (*see* § 250.6(d))	
3.	TOTAL NUMBER DENIED BOARDING INVOLUNTARILY	
4.	Number of passengers denied boarding involuntarily from an oversold flight who actually received compensation, regardless of the type of compensation (e.g., voucher, cash).	
5.	Number of passengers who voluntarily accepted a carrier's offer to give up reserved space due to a potential oversale situation and did not travel on their original flight in exchange for a payment of the carrier's choosing.	
6.	Total Boardings	
7.	Amount of compensation paid to passengers who voluntarily accepted a carrier's offer to give up reserved space on an oversold flight that received cash or cash equivalent payment.	

I, _____, (Name and Title) of the above-named carrier, certify that the above report has been examined by me and to the best of my knowledge and belief is a true, correct, and complete report for the period stated.

_____ (Signature) _____ (Date)

BTS Form 250 **Formerly CAB, RSPA, and BTS Form 251**	Estimated burden — 1 to 16 hours with the average being 6 hours. Comments regarding reporting burden or any aspect of this data collection should be sent to this office.

FORM 250

REPORT OF PASSENGERS DENIED CONFIRMED SPACE DUE TO AN OVERSALE SITUATION

INSTRUCTIONS

(A) Air carriers that are submitting Airline Service Quality Performance Reports must submit Form 250, as it relates to flights which are oversold, on a quarterly basis for scheduled passenger flights operated by the reporting carriers with 30 or more seat aircraft, departing from a point within the United States. "Oversold flights" mean those flights where more passengers hold confirmed reservations than there are seats available on the aircraft.

For air transportation taking place on or after January 1, 2018, air carriers that are submitting Airline Service Quality Performance Reports must submit a separate Form 250 for flights marketed under only their carrier's code and operated by a code-share partner that is a certificated air carrier or commuter air carrier using aircraft that have a designed passenger capacity of 30 or more seats. Reports are due 30 days after the end of the quarter. No data are to be reported for inbound international flights that departed from a foreign point. (Data for a nonstop flight segment that departed from a U.S. point are to be reported even if that flight segment is part of a flight that originated outside the United States). The reporting regulations are contained in 14 CFR Part 250, *Oversales.*

(B) Line (1)(a), *passengers who qualified for denied boarding compensation within the meaning of 250.5(a)(2) and 250.5(b)(2),* means any passenger who was offered alternate transportation which, at the time the arrangement is made, is planned to arrive at the passenger's destination or first stopover more than one hour but less than 2 hours for domestic flight and more than one hour but less than 4 hours for international flights after the planned arrival time of the flight from which the passenger was denied boarding and is therefore entitled to compensation equal to 200% of the passenger's one-way fare.

Line (1)(b), *passengers who qualified for denied boarding compensation within the meaning of 250.5(a)(3) and 250.5 (b)(3)*, means any passenger who (1) was offered alternate transportation which, at the time the arrangement is made, is planned to arrive at the passenger's destination or first stopover two hours or more for domestic flights and 4 hours or more for international flights after the planned arrival time of the flight from which the passenger was denied boarding; or (2) were not offered alternate transportation and is therefore entitled to compensation equal to 400% of the passenger's one-way fare.

(C) Line (2)(a) should include the number of passengers who were denied boarding on flights which were oversold and would otherwise be entitled to denied boarding compensation, but were refused transportation due for reasons other than selection by the carrier according to its established denied boarding priority rules. For example, if a flight is oversold but a passenger is refused transportation because they did not comply with the carrier's check-in requirements, the passenger would not be entitled to denied boarding compensation and would be recorded in line 2(a). If a passenger is refused transportation on a flight which is NOT oversold, the passenger would not be recorded in line 2(a).

(D) *Total number denied boarding involuntarily* should equal the sum of lines 1 and 2. If not, attach notes explaining any discrepancy.

(E) Any passenger who receives any type of compensation as a result of being involuntarily denied boarding from an oversold flight, including cash, check, or travel voucher, should be included on Line 4.

(F) On line 5, a passenger who **volunteers** is a person who responds to the carrier's request for volunteers pursuant to 14 CFR § 250.2b and willingly consents to exchange his or her confirmed reserved space for compensation of the carrier's choosing. Any passenger selected by the carrier for denied boarding in accordance with boarding priority other than a request for volunteers is considered to have been denied boarding **involuntarily**, whether or not the passenger accepts denied boarding compensation. In order to be classified as a volunteer, a passenger must have been given the option of taking the oversold flight for which he or she held a reservation.

(A) boarding **involuntarily**, whether or not the passenger accepts denied boarding compensation. In order to be classified as a volunteer, a passenger must have been given the option of taking the oversold flight for which he or she held a reservation.

(B) *Total Boardings* on line 6 includes only revenue passengers on flights for which confirmed reservations are offered. For international flights, *Total Boardings* include only revenue passengers on flight segments departing from a U.S. point that are subject to Part 250 and for which confirmed reservations are offered.

(C) Line 7 should include the amount of compensation paid to passengers denied boarding voluntarily who actually received compensation in the form of cash or cash equivalent payments made to those passengers, i.e., payments actually accepted by passengers, plus payments that are offered or mailed and not rejected. If a carrier does not provide cash or cash equivalent as voluntary denied boarding compensation, line 7 should be zero.

(D) Note on the report any abnormal conditions, such as strikes, having an impact on the results.

(E) Send reports to either: e-mail Form250.support@dot.gov , fax 202 366-3383 or mail:

U.S. Department of Transportation
BTS/OAI, RTS-42
1200 New Jersey Avenue, SE
Washington, D.C. 20590-0001

OMB NO: 2138-0018
EXPIRATION DATE: 10/31/2020

Paperwork Reduction Act Burden Statement

- A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2138-0018. Public reporting for Form 250, Report of Passengers Denied Confirmed Space Due to an Oversale Situation, is estimated to be approximately 10-16 hours per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. This is a consumer report which is released to the public. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OAI.ICCO@dot.gov

[FR Doc. 2020–28798 Filed 12–30–20; 8:45 am]
BILLING CODE 4910–9X–C

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Internal Revenue Service Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests 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. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before February 1, 2021 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Molly Stasko by emailing *PRA@treasury.gov,* calling (202) 622–8922, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

Title: Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act.

OMB Control Number: 1545–2178.

Type of Review: Extension of a currently approved collection.

Description: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding status as a grandfathered health plan.

Regulation Number: REG–118412–10.

Affected Public: Businesses or other for-profit organization.

Estimated Number of Respondents: 133,200.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 66,600.

Estimated Time per Response: 18 minutes.

Estimated Total Annual Burden Hours: 2,220 hours.

Authority: 44 U.S.C. 3501 et seq.

Dated: December 28, 2020.

Molly Stasko,

Treasury PRA Clearance Officer.

[FR Doc. 2020–28960 Filed 12–30–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

United States Mint

Establish Price Increases for United States Mint Numismatic Products

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

The United States Mint is announcing new pricing for the United States Mint numismatic products in accordance with the table below:

Product	2021 Retail price
United States Mint Birth Set (2018, 2020, and 2021)	$25.00
United States Mint Happy Birthday Coin Set (2019, 2020, 2021)	25.00
2019 United States Mint Uncirculated Coin Set®	25.25
2019 United States Mint Native American $1 25-Coin Roll (P & D)	34.50
2019 United States Mint Kennedy Half-Dollar Two-Roll Set (P & D)	34.50
2019 United States Mint Kennedy Half-Dollar 200-Coin Bag (P & D)	147.00
2019 United States Mint American Innovation™ $1 25-Coin Roll, Georgia, New Jersey, Pennsylvania, and Delaware (P & D)	34.50
2019 United States Mint Proof Set®	32.00
2019 United States Mint American Innovation™ $1 Coin-Bag, Georgia, New Jersey, Pennsylvania, and Delaware (P & D)	117.50
2019 United States Mint American Innovation™ $1 Reverse Proof Coin, Georgia, New Jersey, Pennsylvania, and Delaware	11.50
2019 United States Mint American Innovation™ $1 Coin Proof Set	24.00
2019 United States Mint America the Beautiful Quarters 3-Roll Set-River of No Return Wilderness (P, D, & S)	49.25
2019 United States Mint America the Beautiful Quarters 40-Coin Roll Set-River of No Return Wilderness (S)	19.75
2019 United States Mint America the Beautiful Quarters Two-Roll Set-River of No Return Wilderness (P & D)	34.50
2019 United States Mint America the Beautiful Quarters Proof Set™	18.50
United States Mint America the Beautiful Quarters Three-Coin S™-Frank Church River of No Return Wilderness, San Antonio Missions National Historical Park, American Memorial Park, Lowell National Park, Block Island National Wildlife Refuge, Cumberland Island National Seashore, Voyageurs National Park, and Apostles Islands National Lakeshore (2018 and 2019)	11.50
2019 United States Mint America the Beautiful Quarters Circulating Coin™ Set	10.00
2019 United States Mint America the Beautiful Quarters 100-Coin Bag, Frank Church River of No Return Wilderness, (P, D, and S)	36.75
2018 United States Mint American Innovation™ $1 25-Coin Roll (P & D)	34.50
2018 United States Mint American Innovation™ $1 100 Coin Bag (P & D)	117.50
2018 United States Mint American Innovation™ $1 Proof Coin	11.50

FOR FURTHER INFORMATION CONTACT: Angela Hicks, Marketing Specialist, Sales and Marketing; United States Mint; 801 9th Street NW, Washington, DC 20220; or call 202–354–7750.

(Authority: 31 U.S.C. 5111, 5112, 5132 and 9701)

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2020–28961 Filed 12–30–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0212]

Agency Information Collection Activity Under OMB Review: Veterans Mortgage Life Insurance Statement

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of the publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting

''Currently Under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0212''.

FOR FURTHER INFORMATION CONTACT: Danny S. Green, Enterprise Records Service (005R1B), Department of Veterans Affairs, 811 Vermont Avenue NW, Washington, DC 20420, (202) 421–1354 or email *danny.green2@va.gov.* Please refer to ''OMB Control No. 2900–0212'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Veterans Mortgage Life Insurance Statement, VA Form 29–8636.

OMB Control Number: 2900–0212.

Type of Review: Reinstatement of a previously approved collection.

Abstract: This form is used by veterans who have Specially Adapted Housing Grants to decline VMLI. The information on the form is required by law, 38 U.S.C. Section 806. **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 85 FR 206 on October 23, 2020, page 67609.

Affected Public: Individuals and Households.

Estimated Annual Burden: 250 hrs.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 1,000.

By direction of the Secretary.

Danny S. Green,

VA PRA Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2020–28989 Filed 12–30–20; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 85 Thursday,

No. 251 December 31, 2020

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 438, 447, Et al.

Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 438, 447, and 456

[CMS–2482–F]

RIN 0938–AT82

Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will advance CMS' efforts to support state flexibility to enter into innovative value-based purchasing arrangements (VBPs) with manufacturers, and to provide manufacturers with regulatory support to enter into VBPs with payers, including Medicaid. To ensure that the regulatory framework is sufficient to support such arrangements and to promote transparency, flexibility, and innovation in drug pricing without undue administrative burden, we are finalizing new regulatory policies and clarifying certain already established policies to assist manufacturers and states in participating in VBPs in a manner that is consistent with the law and maintains the integrity of the Medicaid Drug Rebate Program (MDRP). This final rule also revises regulations regarding: Authorized generic sales when manufacturers calculate average manufacturer price (AMP) for the brand name drug; pharmacy benefit managers (PBM) accumulator programs and their impact on AMP and best price when manufacturer-sponsored assistance is not passed through to the patient; state and manufacturer reporting requirements to the MDRP; new Medicaid Drug Utilization Review (DUR) provisions designed to reduce opioid related fraud, misuse and abuse; the definitions of CMS-authorized supplemental rebate agreement, line extension, new formulation, oral solid dosage form, single source drug, multiple source drug, innovator multiple source drug for purposes of the MDRP; payments for prescription drugs under the Medicaid program; and coordination of benefits (COB) and third party liability (TPL) rules related to the special treatment of certain types of care and payment in Medicaid and Children's Health Insurance Program (CHIP).

DATES: These regulations are effective on March 1, 2021, except for amendatory instructions 7, 10.a., 14, 16, and 17, which are effective on January 1, 2022, and amendatory instructions 9 and 11, which are effective on January 1, 2023.

FOR FURTHER INFORMATION CONTACT: Ruth Blatt, (410) 786–1767, for issues related to the definition of line extension, new formulation, oral solid dosage form, single source drug, multiple source drug, and innovator multiple source drug.

Cathy Sturgill, (410) 786–3345, for issues related to third party liability.

Michael Forman, (410) 786–2666, and Whitney Swears, (410) 786–6543 for issues related to drug utilization review.

Christine Hinds, (410) 786–4578, for issues related to value-based purchasing.

Joanne Meneeley, (410) 786–1361, for issues related to State Drug Utilization Data (SDUD) certification.

Christine Hinds, (410) 786–4578, for issues related to authorized generics and inflation rebates.

Charlotte Amponsah, (410) 786–1092, for issues related to manufacturer-sponsored patient assistance programs.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicaid program, states may provide coverage of prescribed drugs as an optional benefit under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for federal financial participation (FFP) in state expenditures for these drugs. In the case of a state that provides for medical assistance for covered outpatient drugs (CODs), as provided under section 1902(a)(54) of the Act, the state must comply with the requirements of section 1927 of the Act. Section 1927 of the Act governs the MDRP and payment for CODs, which are defined in section 1927(k)(2) of the Act. In general, for payment to be made available for CODs under section 1903(a) of the Act, manufacturers must enter into a National Drug Rebate Agreement (NDRA) as set forth in section 1927(a) of the Act. See also section 1903(i)(10) of the Act. The MDRP is authorized under section 1927 of the Act, and is a program that includes CMS, state Medicaid agencies, and participating drug manufacturers that helps to partially offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid beneficiaries. The MDRP provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, drug utilization reviews (DUR), and requirements for states for CODs.

The Covered Outpatient Drugs final rule with comment period (COD final rule) was published in the February 1, 2016 **Federal Register** (81 FR 5170) and became effective on April 1, 2016. The COD final rule implemented provisions of section 1927 of the Act that were added by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for CODs. It also revised other requirements related to CODs, including key aspects of Medicaid coverage and payment and the MDRP under section 1927 of the Act. The regulations implemented through the COD final rule, and those proposed in the ''Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'' proposed rule that appeared in the June 19, 2020 **Federal Register** (85 FR 37256) (hereinafter referred to as the June 2020 proposed rule) are consistent with the Secretary's authority set forth in section 1102 of the Act to publish regulations that are necessary to the efficient administration of the Medicaid program.

A. Changes to Coordination of Benefits/Third Party Liability Regulation Due to Bipartisan Budget Act (BBA) 2018

Medicaid is the payer of last resort, which means that other available resources—known as third party liability, or TPL—must be used before Medicaid pays for services received by a Medicaid-eligible individual. Title XIX of the Act requires state Medicaid programs to identify and seek payment from liable third parties, before billing Medicaid. Section 53102 of the Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted February 9, 2018) amended the TPL provision at section 1902(a)(25) of the Act. Specifically, section 1902(a)(25)(A) of the Act requires that states take all reasonable measures to ascertain legal liability of third parties to pay for care and services available under the plan. That provision further specifies that a third party is any individual, entity, or

program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a state plan. Section 1902(a)(25)(A)(i) of the Act specifies that the state plan must provide for the collection of sufficient information to enable the state to pursue claims against third parties. Examples of liable third parties include: Private insurance companies through employment-related or privately purchased health insurance; casualty coverage resulting from an accidental injury; payment received directly from an individual who has voluntarily accepted or been assigned legal responsibility for the health care of one or more Medicaid recipients; fraternal groups, unions, or state workers' compensation commissions; and medical support provided by a parent under a court or administrative order.

Effective February 9, 2018, section 53102(a)(1) of the BBA 2018 amended section 1902(a)(25)(E) of the Act to require a state to use standard COBs cost avoidance when processing claims for prenatal services which now included labor and delivery and postpartum care claims. Additionally, effective October 1, 2019, section 53102(a)(1) of the BBA 2018 amended section 1902(a)(25)(E) of the Act, to require a state to make payments without regard to third party liability (TPL) for pediatric preventive services unless the state has made a determination related to cost-effectiveness and access to care that warrants cost avoidance for 90 days.

Section 53102(b)(2) of the BBA 2018 delays the implementation date from October 1, 2017 to October 1, 2019 of the provision from the Bipartisan Budget Act of 2013 (Pub. L. 113–67, enacted December 26, 2013) (BBA 2013), which allowed for payment up to 90 days after a claim is submitted that is associated with medical support enforcement instead of 30 days under previous law. Medical support is a form of child support that is often provided through an absent parent's employers health insurance plan.

Effective April 18, 2019, section 7 of the Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116–16, enacted April 18, 2019) (MSIAA) amended section 202(a)(2) of the BBA 2013 to allow 100 days instead of 90 days to pay claims related to medical support enforcement under section 1902(a)(25)(F)(i) of the Act.

B. Changes to the Calculation of Average Manufacturer Price (AMP) Regarding Authorized Generic Drugs Due to the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019

On September 27, 2019, the President signed into law the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Health Extenders Act) (Pub. L. 116–59), which made changes to sections 1927(k)(1) and 1927(k)(11) of the Act, revising how manufacturers calculate the AMP for a COD, for which the manufacturer permits an authorized generic to be sold and redefines the definition of wholesaler. Manufacturers that approve, allow, or otherwise permit any drug to be sold under the manufacturer's own new drug application (NDA) approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (Pub. L. 75–717, enacted June 25, 1938) (FFDCA), shall no longer include sales of these authorized generics in the calculation of AMP of the brand name drug, regardless of the relationship between the brand name manufacturer and the manufacturer of the authorized generic. That is, a separate AMP would be calculated for the sales of the brand name drug and the authorized generic.

Specifically, section 1603 of the Health Extenders Act of 2019 (Pub. L. 116–59, enacted September 27, 2019), which is titled ''Excluding Authorized Generic Drugs from Calculation of Average Manufacturer Price for Purposes of the Medicaid Drug Rebate Program; Excluding Manufacturers from Definition Of Wholesaler,'' amended the statute as follows:

- Section 1927(k)(1)(C) of the Act to replace the term ''Inclusion'' with ''Exclusion'' in the title and further amended paragraph (C) to state that, in the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under the manufacturer's NDA approved under section 505(c) of the FFDCA, such term shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.
- The definition of wholesaler at section 1927(k)(11) of the Act to remove references to manufacturers from the definition of wholesaler.

Typically, an authorized generic is a product that a manufacturer (primary manufacturer) allows another manufacturer (secondary manufacturer) to sell under the primary manufacturer's Food and Drug Administration (FDA) approved NDA but under a different National Drug Code (NDC) number. The authorized generic is typically the primary manufacturer's brand product offered at a lower price point. Primary manufacturers may sell the authorized generic product to the secondary manufacturer they are allowing to sell an authorized generic of their brand product, and such sales are commonly referred to as transfer sales, or they may allow a subsidiary manufacturer to sell the authorized generic.

Under the amendments made to section 1927 of the Act, a primary manufacturer that sells the authorized generic version of the brand drug to the secondary manufacturer can no longer include the price of the transfer sale of the authorized generic to the secondary manufacturer in its calculation of AMP for the brand product. The exclusion of these transfer sales from the primary manufacturer's brand drug AMP will likely result in higher AMPs for the brand drugs and a potential increase to a manufacturer's Medicaid drug rebates to states.

The amendments to section 1927 of the Act authorized under section 1603 of the Health Extenders Act are effective October 1, 2019. Therefore, manufacturers must reflect the changes to the calculation of their AMPs for rebate periods beginning October 1, 2019 (reported to CMS no later than 30 days after the end of the rebate period). To assist manufacturers, CMS provided guidance in Manufacturer Release #111 [1] and Manufacturer Release #112.[2] Furthermore, in accordance with 42 CFR 447.510(b), manufacturers have 12 quarters from the quarter in which the data were due to revise AMP, if necessary. The amendments to section 1927 of the Act have not changed the inclusion of authorized generic drugs in best price; therefore, we did not propose any amendments to the regulatory requirements at § 447.506(c) and (d).

C. Changes as Result of the Bipartisan Budget Act of 2015

Under the Medicaid program, states may provide coverage of prescribed drugs as an optional service under section 1905(a)(12) of the Act. Section 1903(a) of the Act provides for FFP in state expenditures for these drugs. Section 1927 of the Act governs the MDRP and payment for CODs, which are defined in section 1927(k)(2) of the Act. In general, for payment to be made available under section 1903(a) of the Act for CODs, manufacturers must enter into an NDRA as set forth in section

[1] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-111.pdf.*

[2] *https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-112.pdf.*

1927(a) and (b) of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, and requirements for states for CODs. Section 602 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74, enacted November 2, 2015) (BBA 2015) amended section 1927(c)(3) of the Act to require that manufacturers pay additional rebates on their non-innovator multiple source (N) drugs if the AMPs of an N drug increase at a rate that exceeds the rate of inflation. This provision of BBA 2015 was effective beginning with the January 1, 2017 quarter, or in other words, beginning with the unit rebate amounts (URAs) that are calculated for the January 1, 2017 quarter. This additional inflation adjusted rebate requirement for N drugs was discussed in Manufacturer Release Nos. 97 (Manufacturer Release 97) and 101 (Manufacturer Release 101).

D. Current MDRP and Value-Based Purchasing (VBP) Arrangements

In the preamble of the COD final rule, in response to a comment (81 FR 5253), we recognized the importance of VBPs, especially when such arrangements benefit patient health care outcomes. We acknowledged that, given the uniqueness of each VBP arrangement, we had to consider how to provide more specific guidance on the matter, including how such arrangements affect a manufacturer's calculation of a drug's best price and Medicaid drug rebate obligations. Thereafter, we released a state and manufacturer notice on July 14, 2016 (available at State Release 176 [3] and Manufacturer Release 99 [4]) to inform states and manufacturers on how to seek guidance from us on their specific VBP, as well as to encourage states to consider entering into VBP as a means to address high cost drug treatments.

Since the release, manufacturers and states have shown an increased interest in VBP as a possible option for better managing and predicting drug spending, which helps to assure that manufacturers have some vested interest in assuring positive patient outcomes from the use of their drugs. To this end, we have approved nine state plan amendments (SPAs) submitted by states that allow states to negotiate supplemental rebates under CMS-authorized rebate agreements with drug manufacturers based on evidence-based measures or outcomes-based measures for a patient or beneficiary based on use of the drug.

In addition, manufacturers have approached us with their issues and questions regarding the impact of various types of VBP proposals on their MDRP price reporting obligations (that is, AMP and best price), as well as the regulatory challenges they encounter when structuring and implementing VBP. Finally, manufacturers have noted MDRP reporting challenges with VBP programs, whose evidence or outcomes-based measures extend beyond 3 years, particularly given that manufacturers have limited ability to make changes to reporting metrics outside the 12-quarter MDRP reporting period. In the June 2020 proposed rule, we addressed some of the manufacturer concerns with regards to these MDRP requirements.

E. Definition of Line Extension, New Formulation, and Oral Solid Dosage Form for Alternative URA

Section 2501(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), as amended by section 1206 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010) (collectively referred to as the Affordable Care Act) added section 1927(c)(2)(C) of the Act effective for drugs paid for by a state on or after January 1, 2010. This provision establishes an alternative formula for calculating the URA for a line extension of a single source drug or innovator multiple source drug that is an oral solid dosage form. We refer to the URA calculated under the alternative formula as the ''alternative URA.'' Additionally, the Affordable Care Act defined ''line extension'' to mean, for a drug, a new formulation of the drug, such as an extended release formulation. Section 1927(c)(2)(C) of the Act was further amended by section 705 of the Comprehensive Addiction and Recovery Act of 2016 (Pub. L. 114–198, enacted July 22, 2016) (CARA) to exclude from that definition an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation. The determination of whether a drug is excluded because it is an abuse deterrent formulation is explained in at Manufacturer Release 102.[5] The CARA amendment applies to drugs paid for by a state in calendar quarters beginning on or after the July 22, 2016 date of enactment of CARA (that is, beginning with 4Q 2016). Finally, section 1927(c)(2)(C) of the Act was further amended by section 53104 of the BBA of 2018, which provided a technical correction such that the rebate for a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form shall be the greater of either (1) the standard rebate (calculated as a base rebate amount plus an additional inflation-based rebate) or (2) the base rebate amount increased by the alternative formula described in section 1927(c)(2)(C)(iii)(I) through (III) of the Act. We refer to the additional inflation-based rebate as the ''additional rebate.'' Additionally, as we have used the term ''initial brand name listed drug'' in the ''Medicaid Program; Covered Outpatient Drugs'' proposed rule published in the February 2, 2012 **Federal Register** (77 FR 5318, 5323 through 5324) (hereinafter referred to as the February 2, 2012 proposed rule), the Covered Outpatient Drugs final rule with comment published on February 1, 2016 (81 FR 5197), and § 447.509(a)(4)(iii) to refer to the initial single source drug or innovator multiple source drug, we continued to do so in the June 2020 proposed rule. The BBA of 2018 amendment applies to rebate periods beginning on or after October 1, 2018.

We proposed a definition of ''line extension'' in the February 2, 2012 proposed rule (77 FR 5323 through 5324) and received numerous comments. In the COD final rule, we did not finalize the proposed definition and requested additional comments with a 60-day comment period that closed on April 1, 2016. The additional comments received, although instructive of the public's thoughts at the time, were not informed by the then-current statutory framework. Therefore, we did not finalize a definition of ''line extension'' in the April 1, 2019 final rule (84 FR 12132). We reiterated in the April 1, 2019 final rule that manufacturers are to rely on the statutory definition of ''line extension'' at section 1927(c)(2)(C) of the Act, and where appropriate are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension. We also stated that if we later decide to develop a regulatory definition of ''line extension,'' we

[3] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-176.pdf.*

[4] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-099.pdf.*

[5] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-102.pdf.*

would do so through our established Administrative Procedures Act (APA) compliant rulemaking process and issue a proposed rule. In the June 2020 proposed rule (85 FR 37294 through 37296), we proposed definitions of ''line extension'', ''new formulation'', and ''oral solid dosage form''.

The line extension provision has been in effect since January 1, 2010, and the Drug Data Reporting (DDR) for Medicaid system was modified in 2016 to implement the data reporting requirements for line extensions. However, we have found that some manufacturers are unclear about their line extension reporting obligations, for example, whether a particular drug satisfies the statutory definition of line extension and the identification of the initial brand name listed drug. Therefore, in addition to proposing definitions of ''line extension'', ''new formulation'', and ''oral solid dosage form'', we provided the clarification below regarding manufacturers' reporting obligations in the June 2020 proposed rule (85 FR 37289).

Details regarding how to calculate the additional rebate (calculated as a percentage of AMP) and the alternative URA can be found in the ''Medicaid Program; Covered Outpatient Drug; Line Extension Definition; and Change to the Rebate Calculation for Line Extension Drugs'' final rule and interim final rule with comment period that was published in the April 1, 2019 **Federal Register** (84 FR 12133) (hereinafter referred to as the April 1, 2019 final rule). We note that under § 447.509(a)(4)(iii), manufacturers are required to calculate the alternative URA if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug. As noted in the June 2020 proposed rule (85 FR 37295), although a drug that meets the definition of a line extension should be identified as such in DDR, a manufacturer is not required to calculate the alternative URA unless the manufacturer of the line extension also manufactures, or has a corporate relationship with the manufacturer of, the initial brand name listed drug.

To apply the alternative formula described in section 1927(c)(2)(C)(iii)(I) through (III) of the Act for each line extension and rebate period, the manufacturer must determine which NDC represents the initial brand name listed drug that will be used to calculate the alternative URA. First, the manufacturer must identify all potential initial brand name listed drugs by their respective NDCs by considering all strengths and dosage forms of the initial brand name listed drug in accordance with section 1927(c)(2)(C)(iii)(II) of the Act. Additionally, only those potential initial brand name listed drugs that are manufactured by the manufacturer of the line extension or by a manufacturer with which the line extension manufacturer has a corporate relationship should be considered. Then, the manufacturer must evaluate the additional rebate (calculated as a percentage of AMP) for each potential initial brand name listed drug. The potential initial brand name listed drug that has the highest additional rebate (calculated as a percentage of AMP) is the initial brand name listed drug that must be identified in DDR and used to calculate the alternative URA for the rebate period.

Section 1927(c)(2)(C)(i) of the Act requires the manufacturer to calculate the alternative formula for each quarter to determine the initial drug for each quarter that has the highest additional rebate (calculated as a percentage of AMP). Therefore, the manufacturer must re-evaluate the additional rebate (calculated as a percentage of AMP) for each potential initial brand name listed drug each quarter. Because the additional rebate (calculated as a percentage of AMP) for any potential initial brand name listed drug may change from one quarter to the next, the initial brand name listed drug used for the alternative URA calculation may also change from one quarter to the next. Additionally, the NDC for the initial brand name listed drug must be active in MDRP for the quarter, that is, an NDC that is produced or distributed by a manufacturer with an active NDRA and the NDC does not have a termination date that occurred in a rebate period earlier than the rebate period for which the calculation is being performed. Because drugs may come on and off the market, an initial brand name listed drug that was used to calculate the alternative URA for one quarter may not be active in MDRP for the next quarter. However, a different initial brand name listed drug may be active in MDRP and available to use to calculate the alternative URA for the next quarter.

F. Impact of Certain Manufacturer Sponsored Patient Assistance Programs (''PBM Accumulator Programs'') on Best Price and AMP

Manufacturer-sponsored patient assistance programs can be helpful to patients in obtaining necessary medications. However, PBMs contend that manufacturer-sponsored assistance programs steer consumers towards more expensive medications when there may be more cost saving options available to health plans. Therefore, as a cost saving measure, PBMs have encouraged health plans in some cases to not allow the manufacturer-sponsored assistance provided under such programs to be applied towards a patient's health plan deductible for a brand name drug not on a plan's formulary. In the June 2020 proposed rule, we provided proposed instruction to manufacturers on how to consider the implementation of such programs when determining best price and AMP for purposes of the MDRP.

G. State Drug Utilization Data (SDUD) Reported to MDRP

Section 1927(b)(2)(A) of the Act requires each state agency to report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each COD dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each Medicaid managed care organization (MCO), and shall promptly transmit a copy of such report to the Secretary. In accordance with this requirement, states are required to send state drug utilization data (SDUD) using OMB-approved Rebate Invoice Form, the CMS–R–144 (the data fields and descriptions are included as Exhibit X in the June 2020 proposed rule) to manufacturers and transmit a copy of this report to CMS.

While many states subject their SDUD on the CMS–R–144 to edits to uncover outliers/inaccuracies in the invoices to manufacturers before sending copies to CMS, some states send unedited copies of the SDUD to CMS, resulting in discrepancies that do not conform with the statutory requirement at section 1927(b)(2)(A) of the Act. The statute requires such reporting to be in a form consistent with a standard reporting format established by the Secretary, and we believe that such a copy means that the data submitted on the invoice (CMS–R–144) to the manufacturer must be accurate and identical to the report (copy) states send to CMS. Further, we expect that when states send SDUD updates or changes to manufacturers, they transmit those changes to us concurrently in a copy to CMS. However, in some cases, states fail to submit these updates causing the data to be mismatched. This results in states not complying with section 1927(b)(2)(A) of the Act and CMS not

having an accurate account of rebates billed in the MDRP.

H. Changes Related to the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

The epidemic of opioid overdose, misuse, and opioid use disorders is a critical public health issue that affects the lives of millions of Americans. Research shows the opioid overdose epidemic has a disproportionate impact on Medicaid beneficiaries and the consequences have been tragic. In 2017, 47,600 people in America died of an opioid overdose per the Centers for Disease Control and Prevention (CDC).[6] Inappropriate opioid prescribing can result in costly medical complications such as abuse, misuse, overdoses, falls and fractures, drug to drug interactions and neonatal conditions. The use of multiple opioids is associated with a higher risk of mortality, with mortality risk increasing in direct relation to the number of opioids prescribed concurrently.[7] [8] Beneficiaries who receive multiple opioids may lack coordinated care and are at higher risk for opioid overdose.[9] These complications are costly, preventable, and result in avoidable healthcare expenditures.[10] Moreover, according to the National Institute on Drug Abuse (NIDA), research suggests that misuse of prescription pain relievers may actually open the door to heroin use, as four in five new heroin users started out misusing prescription pain reliever.[11] More than half of the individuals misusing prescription opioids obtained the medication they used from a friend or relative; [12] this emphasizes the need for safe disposal [13] of unused medications, including opioids.

Since 1993, section 1927(g) of the Act has required each state to develop a DUR program targeted, in part, at reducing abuse and misuse of outpatient prescription drugs covered under the state's Medicaid Program. The DUR program operates to help ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical events. Each state DUR program consists of prospective drug use review, retrospective drug use review, data assessment of drug use against predetermined standards, and ongoing educational outreach activities.

Consistent with section 1927(g)(3)(D) of the Act, we require each state Medicaid program to submit to us an annual report on the operation of its Medicaid DUR program for the fee-for-service (FFS) delivery system, including information on prescribing patterns, cost savings generated by the state's DUR program, and the state's DUR program's overall operations, including any new or innovative practices. Additionally, § 438.3(s)(4) and (5) require state contracts with any MCO, prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP) that covers CODs to require the MCO, PIHP, or PAHP to operate a DUR program that complies with section 1927(g) of the Act and 42 CFR part 456, subpart K, and to submit detailed information about its DUR program activities annually. For the purposes of this final rule, managed care program (MCP) references MCOs, managed care entities (MCEs), PAHPs and PIHPs.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271, enacted October 24, 2018) (the SUPPORT Act) includes measures to combat the opioid crisis in part by reducing opioid related abuse and misuse by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly illicit synthetic drugs. There are several Medicaid-related DUR provisions for FFS and MCP pharmacy programs contained within section 1004 of the SUPPORT Act. These provisions establish drug review and utilization standards in section 1902(a)(85) and (oo) of the Act to supplement existing requirements under section 1927(g) of the Act, in an effort to reduce opioid-related fraud, misuse and abuse. State implementation of these strategies was required by October 1, 2019, and states must include information about their implementation in their annual reports under section 1927(g)(3)(D) of the Act. In turn, the Secretary is required to report to Congress on the information submitted by the states, starting with information from states' FY 2020 reports.

Consistent with section 1927(g) of the Act, the SUPPORT Act has the goal of improving the quality of care received by Medicaid recipients by reducing their exposure to hazards resulting from the inappropriate prescribing, gross overuse, or inappropriate or medically unnecessary care. In this context, strategies to assure the appropriate use of opioids are now being implemented in clinical settings, health care systems and public health agencies. Efforts to prevent harms associated with overuse and misuse of opioids must be integrated to ensure patients are receiving appropriate pain care. Pain is a common condition; estimates of chronic pain and high impact chronic pain in adults 65–84 years of age were 28 percent and 11 percent respectively, based on 2016 National Health Interview Survey Data.[14] Estimates of acute pain in people under 65 years range from 7 to 52 percent, with headache, joint, and neuropathic pain commonly cited.[15] We recognize efforts involving multiple stakeholders including the pain management community are needed to address the opioid crisis, to assure the health and well-being of Medicaid beneficiaries, and decrease any related health care expenditures. We are committed to ensuring there are basic minimum standards implemented through Medicaid DUR programs nationwide to help ensure that prescriptions are appropriate, medically necessary and align with current standards of care, under our authority to implement section 1927(g) of the Act and section 1004 of the SUPPORT Act.

I. Single Source Drug, Multiple Source Drug, Innovator Multiple Source Drug

Section 6(c) of the MSIAA modified the definitions in section 1927(k) of the Act for single source drug, multiple source drug, and innovator multiple source drug. In the June 2020 proposed rule, we proposed to revise the definitions of these terms at § 447.502 to reflect these statutory changes.

[6] *https://www.cdc.gov/drugoverdose/data/statedeaths.html.*

[7] Ray WA, Chung CP, Murray KT, Hall K, Stein CM. Prescription of Long-Acting Opioids and Mortality in Patients with Chronic Noncancer Pain. JAMA. 2016 Jun 14; 315(22):2415–23.

[8] Baumblatt JA, Wiedeman C, Dunn JR, Schaffner W, et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. JAMA Intern Med. 2014 May; 174(5):796–801.

[9] Bonnie, Richard J., et al. Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use. The National Academies Press, 2017.

[10] Davis, Cory. ''Naloxone for Community Opioid Overdose Reversal.'' Naloxone for Community Opioid Overdose Reversal|Public Health Law Research, Public Health Law Research (PHLR), 22 June 2015, *http://phlr.org/product/naloxone-community-opioid-overdose-reversal.*

[11] ''Opioid Addiction 2016 Facts & Figures—ASAM Home Page.'' American Society of Addition Medicine, *www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.*

[12] *https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHFFR2017/NSDUHFFR2017.pdf.*

[13] *https://www.fda.gov/consumers/consumer-updates/where-and-how-dispose-unused-medicines.*

[14] *https://www.cdc.gov/nchs/nhis/nhis_nhsr.htm.*

[15] Ibid.

II. Summary of the Provisions of the Proposed Regulations, Analysis of and Response to Public Comments, and Provisions of the Final Rule

The following summarizes comments received in response to the June 2020 proposed rule (*https://www.regulations.gov/docket?D=CMS-2020-0072*) in general, or about issues not addressed in the proposed regulations.

Comment: A few commenters expressed concern that the proposed rule will jeopardize future drug development or enable drug manufacturers to rush drugs to market.

Response: We understand the concern about the possible impact of a new regulation on drug development; however, we do not believe the rule will jeopardize future drug development or enable drug manufacturers to rush drugs to the market. The rule, as it relates to VBP, is meant to help improve patient access to new medications, particularly new high cost therapies such as gene or cell therapies, by facilitating the use of VBP arrangements when purchasing such medications. We believe this rule helps create incentives for manufacturers to bring new drugs to market, and depending on the nature of the VBP arrangements could also create incentives for manufacturers to complete their clinical trials post marketing.

We note that this rule has no impact on the processes manufacturers must follow to bring new drugs to the market. Processes for review, approval, and marketing of drug products are the responsibility of FDA.

Comment: A few commenters expressed concern that the proposed changes to regulations will place additional burden on healthcare providers and the Medicaid program which are already overburdened by the novel coronavirus pandemic, both financially and administratively. A few commenters specifically expressed concern that the proposed changes will exacerbate access barriers and financial hardships for patients who are already experiencing increased barriers to care and financial hardship due to the coronavirus disease 2019 (COVID–19) pandemic and did not believe that the proposed changes were appropriate at the time of a public health emergency (PHE). The commenters suggested that the result of this rule on patients during this time will lead to increased healthcare costs that force patients to skip needed healthcare and lead to increased health issues and debilitating harms. One commenter also noted that the proposed rule was inconsistent with the President's Executive Order 13924, ''Regulatory Relief to Support Economic Recovery,'' that requires the heads of federal agencies to remove regulatory barriers to support the nation's economic recovery following the COVID–19 pandemic.

Response: We appreciate the concerns expressed by the commenters. As noted in the ''EFFECTIVE DATE'' section of this rule, these provisions will be effective March 1, 2021. However, we recognize that some final policies established in this final rule will require additional time to make necessary operational and administrative changes in order to ensure compliance, specifically those final policies related to the Definition of Line Extension, New Formulation, Oral Solid Dosage Form at § 447.502; Changes to Medicaid drug rebates (MDR) at § 447.509(a)(4); Changes to the Requirements for States at § 447.511 (SDUD and State Certification); Changes to State plan requirements, findings, and assurances at § 447.518(d) (CMS-Authorized Supplemental Rebate Reporting); and therefore these sections will not be effective until January 1, 2022. Similarly, changes to the Determination of AMP at § 447.504(c) and (e) and determination of Best price at § 447.505 (c) will not be effective until January 1, 2023. These final policies are discussed further in the applicable sections of this final rule.

Comment: Several commenters believed that the 30-day comment was not sufficient for the public and industry to analyze the impact of the policies being proposed. One commenter in particular did not agree that it was a not an economically significant rule, and that industry have only 30 days to comment.

Response: CMS provided a 30-day comment period, which is consistent with the Administrative Procedure Act. CMS believes that interested stakeholders had adequate opportunity to provide comment on the policies established in this final rule.

Comment: A few commenters suggested that proceeding to a final rule at this stage will raise APA issues because any final rule must be a ''logical outgrowth'' of its proposal.

Response: We disagree with the commenter that this rule raises logical outgrowth concerns. In the proposed rule, we described the substance and alternatives to the proposed rule and described the subjects and issues covered by the rule. Where this final rule is different from that discussed in the proposed rule, it does not deviate sharply from the proposed rule. We provided adequate notice in the proposed rule that those changes were possible. Accordingly, we provided interested parties sufficient notice that they should have anticipated that those changes were possible.

After consideration of public comments, we are issuing this final rule, as discussed in greater detail in the sections that follow.

Comment: A few commenters suggested that CMS specify a later effective date for the final rule, such as at least 4 quarters from final rule publication to allow CMS to issue additional guidance, manufacturers to evaluate each drug in their portfolio, and manufacturers and state Medicaid agencies to make necessary system changes to price and data reporting systems.

Response: We are issuing this rule with an effective date of March 1, 2021. However, certain sections of this final rule as noted above, will not be effective until January 1, 2022 or January 1, 2023.

Comment: Several commenters expressed concern that the proposed rule will increase outpatient prescription drug prices and out-of-pocket costs for patients, and therefore, decrease patient access to needed care and medications. Furthermore, commenters noted that the regulation may intrude into the provider and patient relationship. One commenter urged CMS to withdraw the proposed rule and reconsider the proposed changes or include express protections to ensure that Medicaid beneficiaries continue to have access to medically necessary outpatient prescription drugs.

Response: We appreciate the commenters concerns regarding patient protections, but we disagree that this rule negatively impacts access to needed care and medications. In particular, and as discussed in the preamble to the June 2020 proposed rule (85 FR 37288), CMS supports manufacturer and state's use of VBP arrangements because we believe it will assist states with providing Medicaid patients access to needed therapies while providing a payment arrangement that allows the state flexibility, including an option to only pay for a drug when an evidence-based or outcomes-measures are achieved. For such arrangements to work for Medicaid, we need to balance changes to MDRP regulations to address manufacturers' concerns with offering such innovative payment arrangements to Medicaid programs, while ensuring the required economies, efficiencies, and quality of care continue to be provided under the Medicaid program. If we do not address a number of potential regulatory hurdles, states may not be able to provide such methods and

procedures relating to the utilization of, and payment for care and services as may be necessary to safeguard against unnecessary utilization of such care and services and assure that consistent with section 1902(a)(30)(A) of the Act, Medicaid payments are consistent with efficiency, economy, and quality of care (85 FR 37291).

A. Third Party Liability: Payment of Claims (42 CFR 433.139)

In 1980, under the authority in section 1902(a)(25)(A) of the Act, we issued regulations at part 433, subpart D establishing requirements for state Medicaid agencies to support the coordination of benefits (COB) effort by identifying TPL. Effective February 9, 2018, section 53102(a)(1) of BBA 2018 amended section 1902(a)(25)(E) of the Act to require states to cost avoid claims (for example, when the state Medicaid agency has determined there is a legally liable third party responsible for paying the claim, it will reject (''cost avoid'') the claim) for prenatal care for pregnant women including labor and delivery and postpartum care, and to allow the state Medicaid agency 90 days instead of 30 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments. Effective April 18, 2019, section 7 of the MSIAA amended section 1902(a)(25)(E) of the Act to allow 100 days instead of 90 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments.

Section 433.139(b)(2), (b)(3)(i), and (b)(3)(ii)(B) detail the exception to standard COB cost avoidance by allowing pay and chase for certain types of care, as well as the timeframe allowed prior to Medicaid paying claims for certain types of care. Specifically, we proposed to delete § 433.139(b)(2). We also proposed to revise § 433.139(b)(3)(i) by removing ''prenatal care for pregnant women, or'' from pay and chase services, and § 433.139(b)(3)(ii)(B) by removing ''30 days'' and adding ''100 days.''

The following is a summary of the public comments we received on our proposal to revise § 433.139.

Comment: One commenter requested that CMS provide guidance to Medicaid MCOs on how they can more reliably and efficiently identify other payers through the state Medicaid agency. The commenter stated this will facilitate implementation of CMS' proposals to require states to reject claims for pregnancy-related services in cases where a third party is legally responsible for payment and to allow states a period of 100 days to pay claims related to medical support enforcement services.

Response: COB/TPL requirements apply in Medicaid MCOs, as well as Medicaid FFS programs. MCOs are required to pay certain types of claims and then seek recovery—''pay and chase''—in the same circumstances as the SMA Medicaid FFS program is required to do so. SMAs have options for ensuring that they meet the COB/TPL requirements in Medicaid MCOs. Regardless of how SMAs choose to allocate responsibility for COB/TPL activities, the contract between the SMA and the MCO must list any COB/TPL responsibilities of the SMA and the MCO must list any COB/TPL responsibilities of the plan see for example, 42 CFR 438.3(t). For more information on general COBs/TPL requirements under managed care, please see our guidance published on *Medicaid.gov* at *https://www.medicaid.gov/medicaid/eligibility/downloads/cob-tpl-handbook.pdf.*

Comment: One commenter recommended that CMS should ensure that providers bear the responsibility of ensuring all third parties are notified and payments are retrieved citing their belief that the burden should be removed from the state and federal government.

Response: If there is no established liable third party, the state Medicaid agency (SMA) may pay claims to the maximum Medicaid payment amount establish for the service in the state plan. If the SMA later establishes that a third party was liable for the claims, it must seek to recover the payment. The SMA should first seek recovery from the liable third party. If that is not feasible (for example, Medicare will not accept a claim directly from an SMA), it may be necessary to recoup the payment from the provider and ask the provider to rebill correctly. Section 433.139(d)(2) states that SMAs must seek reimbursement within sixty days from the end of the month in which it learns of the existence of the liable third party.

Comment: One commenter expressed concern that the proposed revisions to § 433.139 will not permit states to elect to cost avoid claims for pediatric services as allowed under the BBA 2018. The commenter stated the BBA allows states to pursue cost avoidance for pediatric services upon determination that cost-effectiveness and access to care ''warrants cost avoidance for 90 days.'' The commenter recommended that CMS revise the proposed provision to allow states to pursue cost avoidance for pediatric care.

Response: The BBA 2018 did not eliminate pay and chase for pediatric preventive services; The BBA 2018 amended the statute to eliminate pay and chase for prenatal services. Therefore, this request is outside of the scope of our regulation change authority under § 433.139(b)(3)(i) and the BBA of 2018 as identified within. For additional guidance on this change in law, please see our guidance published on *www.Medicaid.gov* at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib111419.pdf* and *https://www.medicaid.gov/medicaid/eligibility/downloads/cob-tpl-handbook.pdf.*

Comment: One commenter recommended that CMS provide states with an alternative option to the required cost avoidance determinations of cost-effectiveness and access to care. The commenter stated that current cost avoidance determination process is burdensome for states to perform and recommended that CMS allow an alternative option where state Medicaid agencies may attest that their program is compliant, has an ''exception, grievance, fairing hearing'' process, and does not have known access issues for beneficiaries seeking pediatric preventive services.

Response: This request is outside of the scope of our regulation change authority under § 433. 139(b)(3)(i) and the BBA 2018 as identified within.

Comment: One commenter requested clarification from CMS on the application of the 100-day waiting period application to preventive pediatric services. The commenter indicated that the provision's reference to § 433.139(b)(3)(ii)(B) appears to apply to child support enforcement services. The commenter requested CMS clarify whether the 100-day waiting period applies to both preventive pediatric services and child support enforcement services as it may impact implementation and cost-effectiveness.

Response: The 100-day waiting period only applies to medical support enforcement and not preventative pediatric services. Preventive pediatric service claims must be ''paid and chased'' without regard to a liable third party unless the state has made a determination related to cost-effectiveness and access to care that warrants cost avoidance for 90 days.

Section 53102(b)(2) of the Bipartisan Act of 2018 delayed the implementation date from October 1, 2017 to October 1, 2109 of the BBA 2013 provision, which allowed for payment up to 90 days after a claim is submitted that is associated with medical support enforcement instead of 30 days under previous law.

Medical support is a form of child support that is often provided through an absent parents employers health insurance plan. Effective April 18, 2019, section 7 of the MSIAA amended section 202(a)(2) of the BBA 2013 to allow 100 days instead of 90 days to pay claims related to medical support enforcement under section 1902(a)(25)(F)(i) of the Act.

Additionally, effective October 1, 2019, section 53102(a)(1) of the BBA 2018 amended section 1902 (a)(25)(E) of the Act, to require a state to make payments without regard to TPL for pediatric preventive services unless the state has made a determination related to cost-effectiveness and access to care that warrants cost avoidance for 90 days.

Comment: One commenter noted that the provisions as written will not allow a state Medicaid agency to implement a cost avoidance period of less than 90 days. The commenter noted that their state requires a 60-day timeframe after finding that a 90-day period was not cost-effective and that access to care issues may result from provider abrasion. The commenter requested clarification from CMS that state Medicaid agencies may continue to keep a shorter cost avoidance period based on cost-effectiveness and access to care evaluations.

Response: Our November 14, 2019 [16] guidance clarified that a state can allow up to 100 days to pay claims related to medical support enforcement. States are permitted the flexibility to pay and chase medical support enforcement claims within that 100-day time period if they have made a determination that the full waiting period creates a cost-effectiveness or access to care issue.

As background, section 53102(b)(2) of the BBA 2018 delays the implementation date from October 1, 2017 to October 1, 2019 of the BBA 2013 provision, which allowed for payment up to 90 days after a claim is submitted that is associated to medical support enforcement instead of 30 days under the previous law. Medical support is a form of child support that is often provided through an absent parents employers health insurance plan.

Effective April 18, 2019, section 7 of the MSIAA amended section 202(a)(2) of the BBA 2013 to allow 100 days instead of 90 days to pay claims related to medical support enforcement pursuant to section 1902(a)(25)(F)(i) of the Act. We are finalizing as proposed.

[16] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib111419.pdf.*

B. Changes To Address Medicaid Access to Drugs Using Value-Based Purchasing Arrangements (VBP)

In the preamble of the COD final rule, in response to a comment (81 FR 5253), we recognized the importance of VBP especially when such arrangements benefit Medicaid patients' access to drug treatments. We acknowledged that given the uniqueness of each VBP arrangement, we had to consider how to provide more specific guidance on the matter, including how such arrangements affect a manufacturer's best price and Medicaid drug rebate obligations. Thereafter, we released a state and manufacturer notice on July 14, 2016 (State Release 176 and Manufacturer Release 99) to inform states and manufacturers on how to seek guidance from us on their specific VBPs, as well as encourage states to consider entering into VBPs with manufacturers as a means to address high cost drug treatments.

Since those releases, manufacturers and states have shown an increased interest in VBP as a potential option for better managing and predicting drug spending, which helps to assure that manufacturers have some vested interest in assuring positive patient outcomes from the use of their drugs. However, some manufacturers hesitate to offer VBP arrangements to payers, including Medicaid, because of concerns that the existing Medicaid COD statute and applicable regulations do not specifically address, for price reporting, the rebating or discounting of drugs based on evidence or outcomes-based measures. Specifically, CMS had not addressed the possible impact of offering VBP arrangements on manufacturer compliance with applicable MDRP price reporting obligations, including best price and AMP reporting.

We support VBP because we believe it will assist states with providing Medicaid patients access to needed therapies while providing a payment arrangement that allows the state flexibility, including an option to only pay when a therapy actually works. For such arrangements to work for Medicaid, we need to consider changes to MDRP regulations to address manufacturers' concerns with offering Medicaid such innovative payment arrangements, while also ensuring the required economies, efficiencies, and quality of care provided under the Medicaid program. As discussed in the June 2020 proposed rule, if we do not consider addressing a number of potential regulatory hurdles in this regulation to increase patient access to new medications, manufacturers may not be willing to offer VBP arrangements in the marketplace to commercial payers or to states. As a result, states may not be able to take advantage of these arrangements to afford new high priced medications such as gene and cell therapies, among others, limiting their availability to Medicaid patients. Subsequently, states may not be able to provide such methods and procedures relating to the utilization of, and payment for care and services as may be necessary to safeguard against unnecessary utilization of such care and services, and assure that, consistent with section 1902(a)(30)(A) of the Act, Medicaid payments are consistent with efficiency, economy, and quality of care.

One potential regulatory hurdle manufacturers have raised with us is a manufacturer's quarterly best price reporting. Section 1927(c)(1)(C) of the Act defines best price in relevant part to mean for a single source drug or innovator multiple source drug of a manufacturer *the lowest price available* from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization (HMO), non-profit entity, or governmental entity within the United States, with certain exclusions enumerated at sections 1927(c)(1)(C)(i)(I) through (VI) of the Act. One of the issues manufacturers face in determining best price with the advent of VBP arrangements is that a manufacturer's best price can be reset based upon the outcome of a drug treatment for one patient or one unit of the drug because of the VBP. When this occurs, the price for that single use of the drug during a quarter that resulted in a negative outcome will reset the best price to a significantly lower amount, sometimes zero, prompting a significantly higher rebate (sometimes 100 percent of the drug's AMP) for all uses of the drug during that quarter.

This being the case, manufacturers have questioned how they should calculate best price and account for these units when an outcome of a VBP arrangement results in ''a lowest price available'' of zero or at a significant discount. Manufacturers have expressed concern to CMS that without further guidance from CMS in regulation regarding the determination of best price in this scenario, the manufacturer could be at risk of understating rebates and may potentially be subject to False Claims Act liability, a risk which further diminishes manufacturer interest in offering VBP payment arrangements in either the commercial or Medicaid market. In turn, this may hinder Medicaid access to the care and services

provided as part of these VBP arrangements (for example, to gene therapies and potentially curative orphan drug treatments) that are available in the general population.

In the June 2020 proposed rule, we proposed changes to the MDRP price reporting (in particular best price) to address the changing market atmosphere and regulatory challenges manufacturers encounter when structuring and implementing VBP, and therefore, to give manufacturers a greater ability to offer these programs to commercial payers or Medicaid without the negative impact on best price or the potential for manufacturers' non-compliance when calculating best price.

1. Overall VBP Comments

Comment: Several commenters supported CMS' efforts to increase adoption of, and foster more meaningful value-based payment arrangements for, prescription drugs as a step to ensuring affordable, high value healthcare and lowering drug prices. Commenters expressed appreciation for efforts to relieve the regulatory requirements that have prevented manufacturers and states from developing VBP arrangements. A few commenters noted that manufacturers, commercial payers, state Medicaid agencies and health plans, and other commenters are well-suited to negotiate VBP arrangements and associated measures.

Commenters also noted that VBP arrangements:

- Increase patient access to drug therapies, especially for breakthrough, gene, and other novel therapies including therapies for treatment of rare diseases.
- Accelerate research and new treatment development while also fostering greater patient safety.
- Support manufacturer accountability as a result of a shared-risk model.
- Promote transparency in manufacturers' production processes, costs, and the distribution of drug therapies.
- Improve healthcare system sustainability by decreasing overall treatment costs and incentivizing improved treatment modalities.
- Hold drug manufacturers liable for drug effectiveness.

Response: We appreciate these comments of support for value based purchasing (VBP) arrangements.

Comment: Several commenters did not support the proposed rule to accommodate VBP arrangements due to concerns of unintended consequences on patient access to prescription drugs and on drug prices. Commenters expressed concerns that evidence and outcomes-based contracts do not address the underlying price of a therapy and noted the proposal does little to ensure that the VBP arrangements incentivized by the proposed changes to best price actually meet the objectives to increase therapeutic value while reducing cost for consumers and insurers. A few commenters noted that the proposed changes may allow manufacturers to manipulate program rules to increase drug prices, and therefore, increase their profits. Other commenters noted that they did not see VBP arrangements as a comprehensive solution to high drug prices and suggested that CMS reconsider the provisions in the proposed rule and take additional actions to control drug prices. One commenter expressed concern that the proposed rule introduced major policy changes without articulating substantial policy justifications in the proposed preamble text.

A few commenters also expressed concern that the VBP arrangement proposals and the definition of such arrangements lack the requisite clarity for manufacturers to undertake the operational overhauls necessitated by these proposals. Commenters requested that CMS work with commenters to develop a more specific regulatory proposal and reissue a new proposed rule before moving forward with any changes. The commenter requested that CMS provide additional detailed guidance before implementing provisions of the rule.

Response: We believe that access to pharmaceutical manufacturer VBP arrangements by both state Medicaid programs and commercial payers is one of many negotiating tools that payers may take advantage of in today's pharmaceutical market. We are not requiring states or payers enter into VBP arrangements as part of this final rule. Instead, we are clarifying and amending the regulatory framework so it is sufficient to support such arrangements and to promote transparency, flexibility, and innovation in drug pricing without undue administrative burden. These rules clarify certain already established policies to assist manufacturers and states in participating in VBP arrangements in a manner that is consistent with the law and maintains the integrity of the MDRP.

Comment: Many commenters expressed concerns that CMS' proposals related to VBP arrangements may negatively impact state Medicaid programs in several ways including compromising the integrity of the MDRP and noting that states would likely experience smaller Medicaid drug rebates and increased Medicaid spending as a result of the rule if finalized. A few commenters recommended that CMS establish specific guardrails to ensure that state Medicaid programs benefit from the value of VBP arrangements. The commenters noted that manufacturers could reduce their Medicaid rebate obligations by shifting their commercial rebating strategy to VBP arrangements (sheltered from being included in best price) by refusing to negotiate VBP arrangements with state Medicaid programs at all.

Commenters also noted that they believe the cost savings generated under the VBP arrangement must exceed those currently available under the MDRP framework and be inclusive of administrative costs to implement the VBP arrangement. Another commenter requested that CMS provide additional guidance on how VBP arrangements might address barriers to treatment that are unique to the Medicaid population.

One commenter expressed concern that the proposed regulations will have serious consequences to state Medicaid programs and their ability to provide access to vital healthcare services to the state's Medicaid beneficiaries.

Response: The new VBP approach would build upon the approach that exists in current law regarding how manufacturers pay rebates to states for a dosage form and strength of a drug. Manufacturers are required to report a best price each quarter to CMS which is used by CMS to calculate the state's unit rebate amount (URA) for the drug, and that reporting will continue. Under this new approach, manufacturers that offer a value based purchasing arrangement (as defined at § 447.502) to all states, may report a best price that includes varying best price points for a single dosage form and strength as a result of that VBP arrangement.

Otherwise, manufacturers that do not offer VBP arrangements to states will be required to report a single best price (which would include all prices, including applicable discounts, rebates, or other transactions that adjust prices to the best price eligible entities, including such transactions from VBP arrangements not offered to states). This would address the commenters' concerns that this approach would compromise the integrity of the rebate program, shift manufacturer rebates to VBP programs, or allow manufacturers to not offer these VBP programs to states. States would not be required to participate in these arrangements, but can do so if they so choose. Manufacturers that choose to offer their

VBP arrangement to the states and report multiple best prices would continue to report a non-VBP best price for this dosage form and strength of this drug for the quarter. States that opt not to participate in a multiple best price arrangement that is being offered by manufacturers would receive rebates based on the manufacturer's non-VBP best price for this dosage form and strength of the drug.

Therefore, each state should consider the value of entering into VBP arrangements and potential consequences, be it impact on access to health care in their state or the administrative costs associated with operationalizing a VBP arrangement, and make the appropriate decision for their state.

Comment: One commenter requested that CMS maintain incentives for providers to choose the lower-cost therapeutic option that is clinically appropriate and for ongoing development of lower-cost therapies, including biosimilars in addition to permitting flexibilities around VBP arrangements.

Response: This rule does not require providers to participate in VBP arrangements or to discontinue offering lower-cost therapeutic options when clinically appropriate. Like states and commercial payers, providers have the option to participate in VBP arrangements and may choose to forgo these arrangements and avail their patients of lower cost therapies that the provider believes may be just as effective.

Comment: A few commenters requested CMS address the potential incentive for manufacturers to expedite market entry (VBP for accelerated approval pathway drugs) for drug therapies that may be the subject of a potential VBP arrangements.

Response: We believe that the commenter may be concerned that the use of VBP may create incentives for manufacturers to attempt to use FDA's accelerated approval pathway to bring a drug to market, and then use a VBP approach to market the drug as payers, including state Medicaid agencies, might not believe that the drug has a fully-determined clinical benefit. This rule does not address drug development and how drugs are approved for marketing in the United States by FDA. We do not believe that manufacturers make decisions about developing or marketing a drug based on the existence of VBP approaches. However, we do think that accelerated approval drugs might be good candidates for VBP, as these drugs can meet the definition of covered outpatient drug under the Medicaid Drug Rebate Program, and payers may want some additional evidence that they will be paying for a drug that will provide a clinical benefit to the patient, and thus seek a VBP arrangement from the manufacturer.

Comment: A few commenters commented on the timing of the final rule and encouraged CMS to finalize the proposed rule this calendar year and develop further subregulatory guidance based on their belief it will improve access to cell and gene therapies coming to market. Another commenter recommended that CMS work through CMS' Center for Medicare and Medicaid Innovation (CMMI) to test broader VBP arrangements and other payment innovations for drug therapies. A few commenters requested that CMS clarify that existing VBP arrangements established prior to the final rule will be grandfathered in if they are not found to be compliant with definitions articulated in the final rule.

Response: While this rule will be effective 60 days after its publication, we are delaying the effective date of certain amendments in this final rule until January 1, 2022, including the policy permitting manufacturers to report multiple best prices under a VBP arrangement. This will allow manufacturers, states and CMS to make the necessary system changes, and CMS to issue operational guidance regarding the final policy permitting multiple best price reporting, as necessary. The definition of VBP arrangement will be effective 60 days after the rule publication in order to apply the changes made to the bundled sales definition as discussed later in this rule.

While we appreciate the request to test these innovative payment arrangements, we do not believe VBP arrangements need to be tested under the CMMI authority in order to issue this final rule. Many state Medicaid programs (nine states via CMS-authorized supplemental rebates) and commercial payers already have VBP arrangements in place that have provided some initial evidence about the pros and cons of these programs. This final rule addresses potential regulatory hurdles manufacturers and states face when choosing to offer and participate in VBP arrangements.

Comment: A commenter was concerned that the proposals with regard to VBP arrangements and the definition of such arrangements lack the requisite clarity for manufacturers to undertake the operational overhauls necessitated by these proposals. For example, the commenter questioned whether outcomes-based measurement metrics create bundled sales under arrangements that do not meet the proposed definition of a VBP arrangement (including the as yet undefined requirement that the outcomes-based measure ''substantially'' link the cost of the drug to that of the drug's actual performance). The commenter indicated that without further detail regarding the operation of CMS' VBP arrangement proposals, manufacturers will lack the certainty needed to invest in operationally-complex innovative payment arrangements.

Some commenters raised concerns about how states will become aware that a manufacturer is in fact offering a multiple best price VBP arrangement to states for a drug, how such information will be reported to CMS and accessed by states, whether states and manufacturers would have to enter into side agreements regarding the VBP arrangement, and how such future price adjustments under the VBP program would be reported to and made by states and manufacturers, among others.

Response: We understand that there may be unresolved issues regarding some aspects of the VBP policies that are being implemented in this regulation, and if necessary and appropriate, expect to address any such issues that may arise in the future through operational guidance.

We note that some manufacturers have been using the bundled sales approach for VBP arrangements, under the reasonable assumption that a VBP arrangement represents a type of performance requirement. Regulations found at § 447.502 allow manufacturers to allocate discounts in a bundle across the entire bundle if tied to a performance requirement. After the regulation is finalized, any VBP arrangement would have to meet the new definition of VBP arrangement in order to avail itself of potential regulatory flexibilities, whether the manufacturer reports pricing using a bundled sale or multiple best prices approach (effective January 1, 2022). To be clear, with respect to the bundled sales approach, a manufacturer could only use the bundled sales approach, and thus allocate any VBP discounts across the products in the bundle, if the manufacturer's value-based payment arrangement met the new definition of VBP arrangement, as adopted in this final rule as discussed below.

We also believe that the commenter's reference to operational complexity is referencing the technology and systems that may have to be developed or modified to accommodate the necessary tracking of patients that are enrolled in VBP arrangements. We appreciate the

comment, and recognize that VBP arrangements can be complex to design and implement. However, this rule does not require manufacturers, states or payers to enter into VBP arrangements but rather makes changes to price reporting requirements to allow manufacturers to report multiple best prices associated with such arrangements. We know that some Medicaid programs are already implementing these VBP arrangements, as are some commercial payers, so there is some experience in the marketplace with implementation of these programs. We also understand that state Medicaid programs, commercial payers and manufacturers, as well as CMS, will have to make some operational changes to accommodate the reporting of multiple best prices associated with VBP arrangements being offered to the states.

We are also developing a new Medicaid Drug Program (MDP) system that will replace both the current Drug Data Reporting (DDR) and Medicaid Drug Reporting (MDR) systems, and this new system is expected to be fully functional in July 2021. We expect that this new system will help support the reporting by manufacturers of multiple best prices, as well as the reporting by CMS of VBP-related unit rebate amounts to the states, that would obviate the need for manual reporting of these prices by manufacturers to CMS and to the states. We will need to provide operational guidance on these and other related issues over the next year.

For these and other reasons, the final policy permitting multiple best prices reporting will not be effective until January 1, 2022 so that all affected stakeholders have sufficient time to address these operational technology and system challenges. We believe that delaying the effective date until January 1, 2022 after the new MDP system is expected to come on line will provide sufficient time to test the system and assure that it can support the new multiple best price reporting options.

2. Subpart I—Payment for Drugs (Definitions (§ 447.502)

a. Value-Based Purchasing (VBP) Arrangement

A VBP arrangement is not expressly defined or addressed in section 1927 of the Act or the MDRP implementing regulations. To address the issues, we proposed a definition of VBP to apply, as appropriate, in implementation of the MDRP. More specifically, we proposed to define VBP at § 447.502 to further clarify for manufacturers how discounts, rebates, pricing etc. as a result of VBP arrangements should be accounted for in a manufacturer's determination of AMP and best price for an applicable COD.

At this time, manufacturers are permitted to make reasonable assumptions in the absence of applicable statute, regulation or guidance regarding how to treat pricing as a result of VBP. However, because of the uncertainty or lack of assurances as to the propriety of those reasonable assurances, we understand manufacturers may be discouraged from offering VBP to payers including Medicaid. Therefore, we proposed to define VBP as an arrangement or agreement intended to align pricing or payments to an observed or expected therapeutic or clinical value in a population (that is, outcomes relative to costs) and includes (but is not limited to):

- Evidence-based measures, which substantially link the cost of a drug product to existing evidence of effectiveness and potential value for specific uses of that product;
- Outcomes-based measures, which substantially link payment for the drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses.

We have observed that some examples of evidence or outcomes-based measures used by manufacturers in their VBP proposals may be derived by observing and recording the absence of disease over a period of time, reducing a patient's medical spending, or improving a patient's activities of daily living thus resulting in reduced non-medical spending. In response to the proposed definition of VBP, we solicited suggestions for other measures and a rationale for the suggested measures that could be used to reflect value from a drug therapy and considered as we develop a final definition. We also solicited suggestions as to how to interpret ''substantially'' as used in the definition. That is, how much of the drug product's final cost should be associated with the evidence or outcomes based measure in order for the arrangement to be considered a VBP (for example, a drug product cost with less than 90 percent of the discounts/rebates tied to the drug's performance not be considered a VBP arrangement).

a. Definition of VBP Arrangement

Comment: Many commenters encouraged CMS to maintain a broad definition of VBP arrangements and expand the definition to ensure that all contracting parties have the flexibility needed to develop arrangements that best meet their priorities for a wide range of drug therapies, including cell and gene therapies, as well as oral small-molecule drugs dispensed in retail settings based on their belief that evidence and/or outcomes-based approaches can be used independent of whether a drug is or is not classified as specialty. A few commenters requested that CMS clarify that VBP arrangements are not limited to one-time, high-priced therapies to enable use of these arrangements for therapeutic areas that require recurring treatment, have a substantial prevalence and overall disease burden to patients, and/or drive substantial cost to Medicaid and payers (for example, chronic condition).

However, several commenters expressed concern with CMS' proposed definition of VBP arrangements because they noted it was not detailed enough to operationalize and had potential for fraud, waste, and abuse. One commenter further noted that the proposed definition does not include any guardrails or features to ensure that VBP arrangements meet reasonable thresholds for providing value for a drug.

A few commenters requested CMS to revise the definition to reflect the following: ''An arrangement or agreement intended to align pricing and/or payments to observed or expected therapeutic or clinical values in select populations (that is, outcomes relative to costs) and including (but not limited to): Evidence-based measures, which link the cost of drug products to existing evidence of effectiveness and potential value for specific uses of products included under the arrangement; Outcomes-based measures, which link drug costs to the actual performance (actual endpoints and direct or indirect surrogate markers, including duration of therapy or discontinuation) in a patient or a population, or a reduction in other medical expenses.'' One commenter recommended that CMS review current state VBP arrangements to refine the proposed definitions.

Several commenters emphasized the need to maintain the option for VBP arrangements to include evidence- or outcomes-based measures to provide maximum flexibility for payers and manufacturers when negotiating contracts. The commenters requested that CMS include an ''or'' between the two examples of measures to make clear that both are not required for VBP arrangements. A few commenters recommended that CMS only consider outcomes-based measures for VBP arrangements eligible for alternative best price calculations. One commenter noted that the parenthetical phrase,

''that is, outcomes relative to costs'' is confusing and should be removed from the definition.

One commenter recommended that CMS only allow outcomes-based VBP arrangements to be allowed to perform alternative best price calculations based on their belief that they are likely to have significant best price implications from a single sale. The commenter distinguished outcomes-based VBP arrangements from evidence-based ones further, expressing their opinion that evidence-based contracts are more likely to have a value-based price across multiple sales. One commenter suggested CMS should require manufacturers to demonstrate a drug's outcome effectiveness prior to market entry. The commenter noted that this change will enable payers to negotiate payments based on proven outcomes.

Response: We believe the definition of VBP arrangement is sufficiently broad to include most VBP structures currently on the market and would not exclude specific drugs on the market—be it highly utilized drugs that treat large populations for chronic conditions or one-time gene therapies that are used in small populations. Therefore, we are maintaining a broad definition to ensure such arrangements are recognized for purposes of determining and reporting best price and AMP; however, we agree with commenters that the evidence or outcomes-based measures used in a VBP arrangement should be evaluated in a select population and are therefore adding the term ''select'' before populations to clarify that VBP arrangements are arrangements that are specific to select population groups using the drug therapy (for example, gene therapy specific to a specific cancer type). We are also adding ''and/or'' between the two measures in the definition to further clarify that either evidence-based and/or outcomes-based measures could be used in a VBP arrangement. Furthermore, we agree that the parenthetical ''that is, outcomes relative to costs'' is confusing given outcomes measures is already part of the definition of VBP arrangement. Therefore, we are removing it to reduce redundancy. Also, in response to commenters concerns that the drug covered by the VBP arrangement has demonstrated effectiveness, we are clarifying that VBP arrangements apply to CODs as defined at section 1927(k)(2) of the Act.

Comment: One commenter requested CMS to clarify the definition of the terms ''effectiveness'' and ''performance'' within the definition of VBP arrangement.

Response: We do not agree that the definition of VBP arrangement should be revised to further define ''effectiveness'' or ''performance.'' Each VBP arrangement will be fact-specific to the drug, the diagnosis it is treating, and patient population being treated, and we expect such terms will be defined as part of the VBP agreement itself.

Comment: A few commenters recommended that CMS use an alternative term to ''value-based purchasing arrangements.'' Commenters recommended that CMS use ''value-based pricing'' arrangements to reflect that VBP arrangements can be entered into between manufacturers and customers that do not ''purchase'' a product (for example, payers). A few commenters recommended that CMS use ''value-based arrangements,'' or VBAs, to reflect common industry terminology. One commenter requested that CMS use ''value-based contracts,'' or VBCs, instead.

Response: For the purpose of this rule, we will continue to use the term value-based purchasing (VBP) arrangement as proposed. However, we recognize there may be arrangements already available on the market that manufacturers may label differently, yet still align with the definition of VBP arrangement as finalized in this rule.

Comment: One commenter recommended that CMS require VBP arrangements to include minimum, maximum, and expected percentage rebates that will be offered and limit permissible VBP arrangements to drugs meeting certain characteristics, such as a floor for average annual cost, course of treatment cost, and/or genetic therapies and other similarly specialized drugs.

Response: CMS will not be requiring manufacturers offer specific percentage rebates or limit VBP arrangements to only certain drugs as part of the definition of VBP arrangement. Instead we will be maintaining a broad definition of VBP arrangement so that manufacturers and payers (including states) have the flexibility to design the VBP arrangement, taking into consideration the specifics of the drug treatment and patient population served. The final definition will include the language that there be a substantial link between an outcomes-based measure and the payment for the drug; or, evidence-based measure and the cost of the drug as discussed later in this preamble.

b. Evidence-Based Measures

Comment: Several commenters either supported or did not support the inclusion of evidence-based measures in the definition of VBP.

Commenters that supported the inclusion of evidence-based measures noted it was sufficiently flexible to account for the breadth of potential measures that may be considered in VBP arrangements. A few commenters urged CMS to preserve a broad definition of evidence-based measures to allow manufacturers and payers to identify appropriate measures for each VBP arrangement, tailored to a particular drug therapy and patient population. Another commenter suggested that CMS ensure that the definition of evidence-based measures be sufficiently broad to allow clinical endpoints and direct or indirect surrogate endpoints to be used in VBP arrangements. Commenters also noted that use of evidence-based measures is already allowed under current best price reporting requirements and CMS-authorized supplemental rebate agreements (SRAs).

Some commenters did not support CMS' inclusion of ''evidence-based measures'' in the definition of VBP arrangements, claiming the inclusion of such measures leaves the VBP arrangement definition excessively broad. The commenters stated that the inclusion of evidence-based measures is unnecessary because these measures are currently used to negotiate regular discounts for formulary or preferred drug list (PDL) placement between manufacturers and commercial payers or states. Several commenters noted that including evidence-based measures in the definition of VBP arrangements will likely undermine best price reporting requirements and allow manufacturers to reduce their Medicaid rebate obligations.

A few commenters opposed inclusion of evidence-based measures in the definition of VBP arrangements because they noted that CMS did not provide sufficient details in the proposed rule. A few commenters expressed concern with the proposed inclusion of evidence-based measures in the definition of VBP arrangements citing their belief that the administrative burden associated with reporting will be significant. One commenter noted that the inclusion of evidence-based measures in the definition of VBP is redundant based on their belief that external entities like the Institute for Clinical and Economic Review (ICER) already account for evidence-based measures.

Some commenters requested that CMS clarify that evidence-based measures may be based on a limited clinical data set, health economics, outcomes research or other documented evidence. A few commenters also

encouraged CMS to clarify that clinical effectiveness is defined more broadly than required under FDA regulatory requirements and requested that CMS provide clarity on how clinical effectiveness will be determined, especially for new drugs.

Other commenters requested CMS to require evidence-based measures be developed through a patient-centered approach that requires patient input on measure selection and desired outcomes. Several commenters emphasized the importance of CMS' consideration of a patient-centered approach to measuring value because they noted that they believe in the need for patients to be involved throughout the design of VBP arrangements, including the selection of measures that are important and relevant to patients. A few commenters recommended that CMS include patient-reported measures that signal improvement in patient health or quality of life as an indicator of a drug's value. One commenter suggested that long-term benefits for patient health, or durability, also be considered to measure value.

One commenter encouraged CMS to provide guidance refining the definition of evidence-based measures in the context of therapies treating rare diseases with limited availability of data and small target populations that require highly personalized treatment. A few commenters noted that they believe there are often limited evidence-based measures for rare disease groups given limited natural history data, small patient populations and other challenges.

Response: We appreciate the comments regarding the use of evidence-based measures as part of the definition of a VBP arrangement, but we will not be revising the definition to provide additional refinement to what is meant by evidence-based measures. We believe further clarification to the term evidence-based measures will unnecessarily limit the potential for VBP arrangements using such measures. While we support VBP arrangements that establish evidence-based measures using patient-centered approaches such as quality of life indicators and believe that evidence-based measures must be based on clinical data sets and documented evidence, we believe determining the appropriate features of a VBP arrangement are more appropriately left to the manufacturer and further negotiated with the payer (be it a health plan, provider, or patient).

Comment: A few commenters noted that the proposed definition of evidence-based measures could result in inconsistent interpretations of requirements for best price calculations between manufacturers, which may result in a smaller rebate obligations under VBP arrangements as compared to current Medicaid supplemental rebate agreements (SRAs).

Response: There may be differences between rebates offered under a CMS-authorized SRA and the VBP arrangements under the multiple best price approach. States will be in the best position to determine which arrangement meets the financial and patient care needs of their state's Medicaid program. A state is not required to participate in a manufacturer's VBP arrangement as offered on the commercial market. They may negotiate their own arrangement under a CMS-authorized SRA, and those arrangements do not have to meet the definition of VBP arrangement. States may choose to negotiate participation in both types of arrangements as well. However, a manufacturer who wishes to utilize the multiple best price approach or the bundled sales approach must ensure that their VBP arrangements satisfies the definition of a VBP arrangement in this final rule, and with respect to using the best price reporting flexibilities, offer such VBP arrangements to all states, in order to avail themselves of such regulatory flexibilities.

Comment: One commenter requested CMS to clarify that VBP arrangements that rely solely on evidence-based measures are sufficient to meet the proposed definition of VBP arrangements. The commenter further noted that there may be circumstances in which the combination of evidence and outcome-based measures may not be feasible.

Response: VBP arrangements may be based on either evidence-based or outcomes-based measures or both, as provided in the final definition of a VBP arrangement.

Comment: One commenter recommended CMS clarify in the final rule that the list of evidence-based measures in the preamble to the proposed rule is not an exhaustive list of acceptable measures to meet the definition of VBP arrangements.

Response: The commenter is correct that the list of examples provided in the preamble to the proposed rule (85 FR 37292) is not an exhaustive list of evidence-based measures and CMS does not intend to further define or limit evidence-based measures based upon these examples as part of this final rule. Therefore, manufacturers may make reasonable assumptions, in the absence of any further guidance on such measures; as part of their determinations as to whether an arrangement satisfies the definition of a VBP arrangement and retain such documents in accordance with recordkeeping requirements at § 447.510(f).

Comment: One commenter suggested that CMS require VBP arrangements to be either cost-based or outcomes-based unless the state Medicaid agency finds an evidence-based VBP arrangement to be appropriate. It is the opinion of the commenter that evidence-based measures alone are not sufficient to ensure value.

Response: We will not be requiring the VBP arrangements be cost-based or outcomes-based as part of this final rule. Furthermore, states will not be required to enter into a VBP arrangement in instances when the state does not agree with entering into an evidence-based VBP arrangement.

c. Outcomes-Based Measures

Comment: Several commenters requested CMS provide additional clarification regarding what is meant by outcomes-based measures in VBP arrangements. Commenters indicated that outcomes measures should be easily measurable, clinically relevant, and associated with clinical and/or financial improvements and must rely on documented evidence. One commenter expressed concern that the proposed rule did not provide information around the process for developing performance (outcomes) measures and how those measures will be established for new treatments.

Other commenters supported maximum flexibility in CMS' proposed definition of outcomes-based measures to account for the breadth of potential measures, diseases, and populations that may be considered in VBP arrangements.

Response: We are not defining what is meant by outcomes-based measures as part of the definition of VBP arrangement, or a process to develop such measures. With this final rule, we intend to provide the greatest flexibility to manufacturers and states (and other payers) to develop and design VBP arrangements, as appropriate. We believe that a broad definition of VBP arrangement allows manufacturers and payers to develop, structure and implement VBP arrangements in the ever-evolving health care environment, as well as allow manufacturers and payers to consider future changes in the scope and nature of such arrangements. Providing overly prescriptive performance or outcomes-based measures to be used by manufacturers

and payers in these arrangements may impede this flexibility.

Comment: A few commenters recommended that CMS clarify the difference between evidence-based and outcomes-based measures included in the proposed definition of VBP arrangements. One commenter suggested that the proposed definition of both measures included confounding language based on their belief that performance measures in outcomes-based arrangements are based on effectiveness derived from evidence.

Response: We do not believe additional clarification is necessary to distinguish between evidence-based and outcomes-based measures within the definition, as doing so may impede manufacturer and payers ability to negotiate VBP arrangements. We believe that the final definition of VBP arrangement provides manufacturers and payers substantial flexibility to develop, structure and implement VBP arrangements in the evolving health care environment, and the capacity to adapt future changes in the scope and nature of these programs. An example of an evidence-based measure is a situation where a manufacturer may use documented evidence that its cancer drug results in complete remission for 80 percent in a population. The manufacturer may then negotiate with the payer that if 80 percent of the payer's patients do not enter complete remission as based on this evidence-based measure, the payers cost of the drug will be rebated for a portion of their patient's population. On the other hand, an example of an outcomes-based measure is that the manufacturer and payer agree to a payment based upon whether or not a patient reaches an agreed upon clinical outcome. The outcome may include a reliance upon documented evidence or not.

Comment: One commenter recommended that CMS remove from the outcomes-based part of the definition of VBP arrangement ''reduction in other medical expenses'' and replace it with ''an impact to other medical expenditures'' based on their belief that it will provide more flexibility to payers and manufacturers.

Response: We decline to make this change as the phrase ''an impact to other medical expenditures'' is overly broad and could be interpreted to mean something other than decreases to medical expenditures. For example, ''impact'' to other medical expenditures could mean that medical expenditures could increase under a VBP arrangement. This would seem to be counter intuitive to the use of VBP arrangements. For example, a manufacturer may offer a VBP arrangement for a drug that will keep the patient out of the hospital, or require fewer emergency room visits. If the use of the drug did not reduce these other health care expenditures, then payers may not be willing to enter into these arrangements or discontinue participation. We believe that the reduction in other medical expenses should be a primary outcome of the use of VBP arrangements.

Comment: Several commenters suggested various types and considerations for selecting outcomes-based measures, including disease-specific measures, patient or population total cost of care, healthcare utilization rate, clinical and direct or indirect surrogate endpoints, biomarkers, survival and recovery, cure rate, adverse event rates, laboratory values, quality of life, medication adherence, drug persistence, or tied to additional doses of therapy. A few commenters encouraged CMS to require alternative treatments to be considered when developing VBP arrangements, in particular comparing cost and outcomes of new treatments to existing therapies. One commenter recommended that outcomes-based measures adhere to the HHS OIG's October 2019 proposed rule (84 FR 55694; RIN: 0936–AA10) [17] requiring outcome measures grounded in legitimate, verifiable data or other information from a credible external source (such as a medical journal, social sciences journal, or scientific study), an established industry quality standards organization, or results of a payor or a CMS-sponsored model or quality program.

Response: We appreciate these recommendations but do not believe we need to revise the definition of a VBP arrangement to account for these considerations. The manufacturers will enter into these agreements with commercial payers and state Medicaid programs, and we encourage the manufacturers to work very closely with payers and patient groups when developing their VBP arrangements in a process that is transparent and free of financial conflict such that there is confidence in the outcomes-measures chosen.

Comment: A few commenters requested that CMS allow VBP arrangements to be evaluated with outcomes-based measures that were not included in clinical trials and provide guidance on how manufacturers should report initial prices under a VBP arrangement if those prices vary based on patient outcomes that were not documented during clinical trials. The commenter noted that narrowing VBP arrangements to evidence generated in a limited number of single trials will limit VBP arrangements and fail to meet desired patient outcomes.

Response: We appreciate the commenter's suggestions. We hope that manufacturers and payers will take note of them. However, we do not believe we need to revise the definition of a VBP arrangement to account for these considerations. Manufacturers and payers will determine the development and evaluation of these VBP arrangements, and determine whether such VBP arrangements satisfy the regulatory definition and avail themselves of the regulatory flexibilities being finalized in this final rule, as appropriate.

Comment: A few commenters expressed concern that the proposed outcomes-based measures included in the proposed definition of VBP arrangements may not align well with rare diseases, especially if the outcomes-based measure(s) is further restrictive. The commenter also claimed that rare disease products are developed through the Accelerated Approval Pathway, and thus limited clinical data is available at the time when an application is reviewed and approved. One commenter suggested that reliance solely on clinical outcome assessments for small patient populations may obscure a therapy's true value and patient feedback when evaluating VBP arrangements.

Response: We believe that drugs for rare diseases approved under FDA's accelerated approval authority could make good candidates for VBP arrangements for the very reason that the commenter mentions. FDA approval in these instances may be dependent upon further studies to confirm the clinical benefit of the drug. The VBP program could, for example, have some connection to the manufacturer completing these additional studies, or be based on the evidence from the additional trials that the manufacturer is conducting during the period of the VBP arrangement.

Comment: A few commenters recommended that CMS clarify in the final rule that outcomes-based measures based upon quality of life or age are discriminatory and devalue the lives of persons with disabilities and older adults. Another commenter encouraged CMS to require that VBP arrangements account for complex conditions experienced by Medicaid beneficiaries,

[17] *https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.*

including mental illness, and account for how those medical comorbidities may affect outcomes.

Response: We appreciate these comments regarding outcomes-based measures and how they should not discriminate against certain populations. In accordance with legal obligations under section 504 of the Rehabilitation Act, the Americans with Disabilities Act, the Age Discrimination Act, and section 1557 of the Affordable Care Act, manufacturers and payers, including state Medicaid agencies, may not make use of measures that would unlawfully discriminate on the basis of disability or age when designing or participating in VBP arrangements.

d. Defining Substantially Under VBP Arrangement Definition

Comment: A few commenters encouraged CMS to include input from patient groups and the National Health Council (NHC) when defining the term substantially. The commenters recommended CMS consider the NHC's patient-centered approach to establishing criteria for ''substantially'', including the six domains of patient partnership, transparency, representativeness, diversity, outcomes that patients care about, and patient-centered data sources and methods.

Response: While we appreciate the recommendation, we will not further define the term ''substantially'' as used in the definition of VBP arrangement in this final regulation. Instead, we expect information regarding the link between the evidence or outcomes-based measures will be included in the VBP arrangement itself and that manufacturers will retain records of how the measures link to the payment/cost of the drug consistent with the recordkeeping requirements at § 447.510(f). For example, a drug sale may be subject to two types of sales arrangements: A 5 percent discount based upon formulary placement and 50 percent rebate linked to an outcomes-based measure. The second arrangement would be a VBP arrangement because there is a substantial link between the cost of the drug and the outcome. CMS may consider providing additional examples in subregulatory guidance as more arrangements become available and we gain more experience on the various arrangements available or offered in the marketplace.

Comment: Several commenters recommended potential prescriptive or percentage thresholds to define substantially or that CMS further define the term substantially in regulation while some commenters noted they believe a prescribed percentage would be arbitrary.

Specifically, a few commenters recommended that CMS establish a minimum threshold at the current mandatory rebate percentages of AMP (that is, 23.1 percent of AMP for single source or innovator multiple source drugs or 17.1 percent of AMP for drugs for pediatric indications or eligible clotting factors) to define substantially. The commenters claimed this will ensure the Medicaid program is eligible to receive larger rebates and will ensure the amount of risk and discounts during VBP arrangement negotiations will be acceptable to payers and manufacturers.

A few commenters recommended that CMS define ''substantially'' as a maximum possible discount that is greater than the current minimum mandatory rebate percentages, where the maximum possible discount accounts for all VBP arrangement and all non-VBP arrangement best price-eligible discounts. They noted that under the scenario where the maximum possible discount is less than the applicable mandatory rebate percentage of AMP, Medicaid URA calculations will align with current statutory requirements, eliminating the need for regulatory relief to promote VBP arrangements under the proposed rule.

A few commenters requested that CMS define ''substantially'' by requiring a threshold average of at least 50 percent of AMP over the life of a VBP arrangement. The commenters noted this threshold will allow manufacturers and payers the flexibility to adjust the rebate percentage throughout the agreement. A few commenters recommended that CMS ensure a robust definition of substantially and apply a ''significantly high threshold.'' The commenters stated that a high threshold will disincentivize gaming on the part of manufacturers seeking to reduce rebate obligations.

One commenter suggested that CMS set the threshold for ''substantially'' at greater than 33–50 percent of the ingredient cost of a drug rather than the current minimum mandatory rebate percentages. The commenter noted this threshold will allow payers to hold manufacturers accountable for the value of drugs. One commenter noted that if CMS includes the term ''substantially'' in the final rule, CMS should set the threshold at a minimum of 25–30 percent of AMP based on their belief that it will incentivize broader uptake of VBP arrangements. One commenter suggested that CMS define substantially with a threshold of at least 80 percent. Another commenter requested that CMS consider the dictionary definition of the term ''substantially'' to leverage an ordinary meaning of the term for the final rule.

However, many commenters expressed concern with CMS' application of a prescriptive or percentage threshold to define the term ''substantially''. Several commenters suggested that a percentage threshold will be arbitrary and could stifle innovative contracting arrangements and if CMS were to define examples of a VBP arrangement narrowly, by reference to a specific or high percentage threshold, manufacturers could be led to believe they can no longer subject VBP arrangements that do not meet that threshold to bundled sale treatment.

A few commenters recommended that CMS delay defining ''substantially'' until after the final rule when commercial and Medicaid payers gain additional experience with VBP arrangements.

Response: We appreciate the recommendations from commenters on how CMS should define substantially when it comes to the manufacturer determining if it is offering a VBP arrangement.

First, we appreciate the commenters' concern that the manufacturer's VBP arrangement provide at least the minimum Federal Medicaid rebate as determined in accordance with § 447.509, and that any additional VBP rebates paid to the state by a manufacturer over time as a result of the VBP arrangement be additive to that rebate. We want to assure states that the minimum rebate that the states would receive in the quarter in which the drug is administered, whether under a VBP arrangement or non-VBP program, would be the minimum Medicaid rebate—that is, a rebate for single source/innovator multiple source drugs, equal to the greater of the minimum 23.1 percent of AMP or the difference between the AMP and ''best price'' in a quarter for a dosage form and strength of a drug.

Should the state participate in a VBP arrangement for which the manufacturer reports multiple best prices, the state will at least receive the Federal Medicaid rebate based upon the non-VBP best price in the quarter in which the drug is administered, and additional rebates based upon the multiple best prices reported as a result of the manufacturer VBP arrangement, if the state has opted to participate in the VBP arrangement and therefore, eligible to receive such additional rebates under the VBP arrangement.

If the state is participating in a VBP arrangement under a CMS authorized

supplemental rebate program, that state-negotiated supplemental rebate as a result of the VBP arrangement is supplemental to the Federal Medicaid rebate, as well as exempt from AMP and best price. A VBP arrangement offered pursuant to a CMS-authorized supplemental rebate agreement should not be confused with a VBP arrangement that satisfies the regulatory definition of such that is being finalized in this rule.

With respect to designating an actual rebate percentage that would represent a ''substantial'' link to satisfy the new VBP definition, this will likely be a function of several factors, including the number of patients that might be enrolled in the health plan as well as the evidence of the drug's effectiveness, among others. For a plan with a few number of patients, for a drug with limited clinical evidence, the threshold of a ''substantial'' link would likely be different than a plan with a significant number of patients, for a drug with significant clinical evidence. The amount could even be different for the same drug. Therefore, it would be difficult to designate an amount or range of rebates that might represent a substantial link.

After further consideration of the commenters' recommendations, we will not be defining substantially or requiring a specific percentage threshold to determine whether or not there is a substantial link between the cost/payment for the drug and either of the measures in the definition of VBP arrangement. We do not want the manufacturer and the payer (state or otherwise) to be held to a specific threshold when making the determination as to the link between the cost/payment for the covered outpatient drug and outcome within the agreement and believe the parties involved should have the flexibility to determine the link. As stated earlier, VBP arrangements are voluntary and payers, including states, will not be required to participate in them if they believe the arrangement does not result in a price they are willing to pay. Also, we provided an example in the proposed regulation that used a 90 percentage threshold as an example of a possible ''substantial'' financial link between the expected outcome of a therapy in a patient and the compensation that a manufacturer might be expected to provide to a payer if the drug didn't meet the expected outcomes. That is, the manufacturer would refund 90 percent of the initial purchase price to the payer if the therapy failed. The 90 percent example that was provided was an illustration of a substantial financial link for a VBP arrangement and was not meant to be a firm regulatory threshold for the establishment of a VBP arrangement. The example demonstrates further that the intent of a VBP arrangement is that the cost/payment for the covered outpatient drug is driven by the outcome in the arrangement and that the cost/payment for a drug that is driven by other factors beyond the outcomes or evidence-based measures would not qualify the VBP arrangement under our definition. Therefore, manufacturers should ensure that in order to satisfy the definition of a VBP arrangement under our rules, any arrangement they have as a VBP arrangement with payers, provides that the cost/payment is substantially linked to outcomes.

Since we are not further defining ''substantially'' as part of this final rule, manufacturers may make reasonable assumptions and should document how its arrangement substantially links the payment/cost of the drug to the outcome in the arrangement and therefore qualifies as a VBP arrangement under this final rule. Manufacturers should continue to maintain records of reasonable assumptions consistent with Federal recordkeeping requirements at § 447.510(f). We may also consider issuing further subregulatory guidance on policy and operational issues relating to the definition of VBP arrangement given the nature and scope of the various arrangements coming to the market. We note that VBP arrangements offered on the commercial market before this regulation that do not meet the new regulatory definition of VBP arrangement (which goes into effect within 60 days of the publication of this final rule) will have to be restructured to meet the new definition and requirements of this final regulation if a manufacturer wants to take advantage of the regulatory flexibilities included in this final rule. Since the revised definition of VBP arrangement does not apply to arrangements negotiated under a CMS-authorized supplemental rebate agreement, those arrangements will not need to be restructured.

e. Other Measures of Value

Comment: A few commenters recommended CMS consider certain measures of value such as work productivity, patient satisfaction with treatment, and medical spending to assess a drug's value. A few commenters suggested that CMS consider healthcare utilization like reduction in hospitalization rates and emergency department visits as a measure of a drug's value. One commenter noted further that a reduction of utilization of services should be controlled for maintenance of healthcare quality standards. A few commenters identified measures like laboratory tests or screenings or use of electronic health records (EHRs) as measures of a drug's value based on their belief that such measures incentivize providers to give high quality care. A few commenters recommended that CMS consider disease-specific measures to measure value for patients with rare disorders, including rare cancers, because they believe they are inherently disease-specific and highly variable across patients.

Some commenters recommend revising the VBP arrangement definition to include individual patient cost-limiting arrangements that reduce pricing for an individual patient for greater-than-expected usage based on available evidence, discounts based on the achievement of patient-testing benchmarks, patient-reported measures that signal improvement in patient health or quality of life as an indicator of a drug's value and expected therapeutic, clinical, or patient-centric value in a population.

Other commenters recommended that CMS measure the value of a particular drug by comparing its performance to a competing therapy or treatment option. One commenter noted that such a comparison will facilitate the cultivation of comparative effectiveness research available for drug therapies. One commenter recommended comparative effectiveness of target immunomodulatory treatments in particular for the psoriatic disease community.

Response: We appreciate the suggestions raised by the commenters and believe that all of these measures could be used by a manufacturer and payer as part of a VBP arrangement; however, we will not be amending the regulatory text to further define value. While we will not be specifically directing manufacturers to use specific measures as part of an arrangement in order to meet the definition of VBP arrangement, we believe these recommendations may be considered in the structuring of VBP arrangements as manufacturers and payers negotiate arrangements specific to a particular drug treatment. After reading all the comments, and reflecting on the best approach to help make these VBP arrangements succeed, we believe that the key is giving the most flexibility to payers and manufactures in structuring these arrangements. Each VBP arrangement is fact-specific; therefore, the recommended measures to assess a drug's value will be driven by a number

of factors including, but not limited to, the drug's indication, patient population treated, the availability of clinical evidence for the drug, and treatment setting. Therefore, we are not revising our proposed definition of a VBP arrangement to require specific measures beyond outcomes-based or evidence based measures.

Comment: Many commenters provided suggestions for other measures that could be used to reflect the value of a drug therapy. A few commenters recommended that CMS consider total cost of care as an additional measure of value tied to cost savings resulting from VBP arrangements and should involve a comparison of the total cost of care (inclusive of medical and pharmacy costs) to a payer for a patient (or cohort of patients) who is prescribed the contracted drug to another patient (or cohort) with equivalent disease type and severity that is not prescribed the drug. Another commenter further recommended that CMS require manufacturers to report cost savings for VBP arrangements prior to and after a VBP arrangement was implemented to promote transparency. One commenter also noted that a reduction in total cost of care should be controlled for maintenance of healthcare quality standards.

Several commenters encouraged CMS to provide flexibility and finalize broad categories of measures, especially when determining the value of drug therapies. Commenters noted that finalizing a broad definition with broad categories of measures will provide maximum flexibility between payers and manufacturers to specify more detailed medical and non-medical metrics, incentivize uptake of VBP arrangements, and avoid stifling innovation.

Response: We appreciate the commenters' suggestions for additional measures of drug value; however, we will not be amending the regulatory text to further define value, and we will not be requiring these measures as part of the final definition of VBP arrangement in order to ensure that the definition is sufficiently broad to permit flexibility by manufacturers and payers to negotiate the specific terms of each VBP arrangement. We encourage manufacturers and payers to consider these measures of value as recommended by the commenters, such as a comparison between the cost of the drug under the VBP versus other therapies, the impact of the VBP on total cost of care, such as a reduction in hospitalizations or other medical interventions, when evaluating a drug's value and designing and negotiating the specific terms of a VBP arrangement.

Comment: One commenter noted it is important that VBP arrangements facilitate access to high-value products by appropriately accounting for the actual clinical outcomes a specific product achieves. Appropriate measures include primary and secondary clinical trial endpoints, serious adverse effects avoided, total cost of care savings, episode-based reductions in spending below established benchmarks, and other clinically relevant measures that are substantially related to the underlying performance of the product and the overall improvement of the patient's health. Requiring that VBP arrangements be linked to actual clinical outcomes will help facilitate the types of arrangements CMS hopes to promote and limit the opportunities for gaming the flexibilities introduced by this rule.

Response: We appreciate the suggestion that actual clinically-relevant measures be used when measuring the performance of a drug product in a patient. We are not providing a specific definition of performance measure or giving specific examples of acceptable performance measures as part of the VBP definition and instead believe such measures may be addressed as part of the VBP agreement between the manufacturer and the payer.

Comment: A few commenters encouraged CMS to require that measures of value or effectiveness must be person-centered and based on individual assessments of patient needs, excluding measures that are discriminatory against individuals with disabilities or older adults based upon quality of life or age. A few commenters requested that CMS specify that VBP arrangements may not lock-in patients or prevent them from determining the best treatment(s) in consultation with their providers. One commenter recommended that CMS require patient management and support services be included in VBP arrangements to promote medication compliance and adherence. Several commenters suggested that the proposed rule does not ensure coverage or access to prescription drugs is preserved, especially for Medicaid enrollees, individuals with disabilities, and patients with rare or complex genetic disease. A few commenters suggested that CMS require VBP arrangements to have substantive input from patients on their needs, priorities, and desired outcomes. A few commenters requested that CMS require a simple, transparent appeals process and patient safety monitoring protocols that they believe could serve to inform patients and providers of the effectiveness of a particular drug therapy.

Response: With the exception of non-discrimination obligations required under federal civil rights law, patient protections provided under manufacturer and payer arrangements are not a subject of this final rule. Therefore, while we agree with the commenters that measures adopted under VBP arrangements should not endanger certain patients, providers, or impede access to other available medications and treatments, or interfere with the practice of medicine generally, we are not imposing patient protection requirements on manufacturers or payers embarking on VBP arrangements as part of this final rule beyond previously articulated non-discrimination obligations.

f. Transparency and CMS Oversight

Comment: Many commenters requested that CMS require certain transparency elements in the definition of VBP arrangements. Specifically, commenters recommend that CMS require manufacturers share details of VBP arrangements with states and payers, including cost-related and comparative effectiveness data and information available prior to FDA approval. In addition, they suggest that we report on measures included in VBP arrangements, including a description of the measure, justification for the measure selection, and the amount of the product's cost that is tied to the measure; and publicly release outcomes-based data associated with VBP arrangements.

Commenters also requested CMS issue guidance on the timing of negotiations for VBP arrangements with states, describe the process for maintaining confidentiality, identify information manufacturers are required to share with states and payers, establish a robust legal framework to allow all commenters to participate in VBP arrangements. They also requested that manufacturers be required to provide legal details in a timely manner to minimize gaps between VBP arrangements being implemented and a state beginning to participate in the arrangement.

Commenters also suggested that CMS mandate that states be allowed to participate in the VBP arrangement, that specific details of contract structures of VBP arrangements remain confidential and disallow direct marketing or outreach by manufacturers to patients using manufacturer gathered data from VBP arrangements.

Response: We believe the list of suggestions for CMS requirements on manufacturers, payers and states as they relate to transparency in VBP

arrangements are good suggestions and may be considered as part of the negotiation of a VBP arrangement between the manufacturer and payer. However, we are not establishing them as requirements on manufacturers and payers, including states, when participating in VBP arrangements in this final rule and we will not revise the definition of a VBP arrangement to specify such terms.

As further arrangements may emerge as a result of this final rule, CMS may consider engaging states and other industry experts regarding best practices when negotiating VBP agreements.

In order to clarify manufacturer obligations when reporting multiple best prices, we are revising the proposed regulation text at § 447.505(a) in this final rule to state that if a manufacturer offers a value based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value based purchasing arrangement. However, states will not be required to participate in these VBP arrangements. In addition, if a state does not participate in the VBP arrangement, the best price that sets the rebate for that state will be the non-VBP arrangement best price point that must also be offered by the manufacturer and reported to CMS along with the multiple best price points reported by the manufacturer.

Comment: Several commenters encouraged CMS to consider establishing oversight processes for VBP arrangements. Specifically, a few commenters suggested the Secretary of the Department of Health and Human Services (the Secretary) should establish a pre-certification process where outcomes-based VBP arrangements must be reviewed and approved before implementation and a process to validate performance measures used in VBP arrangements to ensure that measures are meaningful and rigorous. Another commenter requested that CMS establish a pre-certification process to ensure that manufacturers do not owe lesser Medicaid rebates under VBP arrangements.

Response: We did not propose that we would provide specific oversight of the nature of VBP arrangements as part of this final rule. The federal oversight of VBP arrangements in the context of this rule would be related to the accuracy of manufacturer government price reporting and certification (for example, calculation and reporting of AMP and best price as described in § 447.510) and the manufacturer payment of required Medicaid drug rebates. Therefore, manufacturers should maintain records of their VBP arrangements as part of their recordkeeping requirements at § 447.510(f). However, while we will not review or certify VBP arrangements offered under the multiple best price approach, we will continue to review and approve SPAs associated with CMS-authorized supplemental rebate agreement templates for state arrangements with manufacturers if a state chooses to use a VBP approach.

We also note that as discussed later in this regulation, we will require state Medicaid programs under § 447.518 that have VBP arrangements under CMS-approved SRAs to report on a quarterly basis certain information regarding the program, such as the drugs covered, costs to administer the program, and savings generated. This will help provide feedback to states and CMS on the value of these programs to Medicaid, and the operational and policy issues that states may face with implementation. This requirement will go into effect on January 1, 2022.

Otherwise, we will not be providing ongoing oversight or an approval process for VBP arrangements or the agreements between a manufacturer and payer.

g. Patient and Provider Engagement

Comment: Several commenters recommended that CMS require payers, including states, and manufacturers to engage patients and providers when determining outcomes-based measures and metrics for VBP arrangements. Several commenters emphasized the importance of including patient-reported outcomes in VBP arrangements and that there was concern that a therapy successful in achieving outlined outcomes may still leave a patient with significant medical needs and medical costs. A few commenters recommended that CMS consider the National Health Council's (NHC's) patient-centered approach when establishing criteria for outcomes-based measures, including the six domains of patient partnership, transparency, representativeness, diversity, outcomes that patients care about, and patient-centered data sources and methods. A few commenters encouraged CMS to mandate substantive input from patients on factors like disease mitigation and management, impact on patient out-of-pocket (OOP) costs, ease of adherence, and improved aspects of quality of life. Another commenter noted patients, patient advocates and physicians without financial interest in a drug therapy must be included in the process of reviewing VBP arrangements.

Response: We appreciate the comments summarized above and agree that patient and provider input in VBP arrangements are important, but we are not mandating patient or provider input with respect to VBP arrangement design or development in this final rule. We believe commercial payers and state Medicaid programs are in the best position to evaluate the benefits of a particular manufacturer's value-based arrangement for their particular enrolled patient population and may ask manufacturers to engage with patient and provider groups as part of the VBP arrangement. We note that commercial payers generally have a mechanism to evaluate the costs and benefits of such programs through pharmacy and therapeutics committees, which often include health professional participation. Furthermore, state Medicaid DUR Boards that make coverage and criteria decisions for states may also assist states with the evaluation of evidence-based or outcomes-based measures associated with particular drug therapies available under VBP arrangements, and these Boards often include providers and patients or consumers.

h. Burden of VBP Operations and Data Collection

Comment: Many commenters expressed concern that there are administrative burdens, operational requirements and significant costs borne by providers, payers, and/or manufacturers to monitor patients and collect data to evaluate VBP arrangements. A few commenters identified patient portability, especially as a result of patients that may move in and out of the Medicaid program, as a significant challenge to operationalizing VBP arrangements as it may disrupt the ability to monitor and evaluate patient outcomes over longer periods of time.

One commenter noted that manufacturers may further complicate data collection by requiring measures that labs might be incapable of testing and require involvement of third-party vendors and additional costs. Another commenter noted that manufacturers may increase data collection and monitoring burdens on providers and payers to gather data valuable for marketing, applications for FDA approval of supplemental indications, or post-marketing studies.

Several commenters recommended that CMS provide additional guidance to address these operational barriers and the additional costs associated with the adoption of VBP arrangements, including developing internal state capacity and cross-sector, multi-payer

databases, and best practices for data collection and sharing. One commenter recommended that CMS partner with FDA and the Office of the National Coordinator for Health Information Technology (ONC) to provide guidance addressing these challenges.

Response: We do not plan to issue guidance or best practices at this time as to how to operationalize, evaluate, or monitor VBP arrangements because each arrangement will have its own set of specific facts and circumstances associated with the VBP, such as the drug, the anticipated outcomes, and population included in the arrangement. In other words, a one-size fits all approach to operationalizing a VBP arrangement is not possible because of the many different arrangements on the marketplace.

We also note that we are not requiring any entity to enter into VBP arrangements. Therefore, any entity that wants to voluntarily participate in a VBP arrangement (be it a provider, payer, or state) should evaluate the complexity of entering into a specific arrangement by noting the obligations required, such as increased data collection responsibilities, monitoring burden, patient-specific portability challenges, and patient monitoring associated with the outcomes or evidence-based evaluation under the VBP arrangement. Payers, including states, should take into consideration whether participating in these VBP arrangements are of value to their beneficiaries and consider the additional costs that they will likely incur for provider or other third party services as they evaluate the final price that they may pay for the drug being purchased under the VBP arrangement.

Comment: A few commenters questioned whether VBP discounts (inclusive of administrative fees paid by manufacturers) are large enough to cover the additional operational costs (that is, staff, expertise, technical resources) to states to perform multiple and complex outcomes analyses.

Response: Participants in VBP arrangements will need to determine if the price for the drug, as discounted by the manufacturer, through the VBP arrangement, will be significant enough to cover administrative and operational costs. Both state Medicaid programs and commercial payers should be mindful of these costs before entering into VBP arrangements with manufacturers.

Comment: A few commenters recommended that CMS consider what state-level coordination is needed to track health outcomes for Medicaid beneficiaries involved in VBP arrangements. A few commenters noted that state Medicaid agencies may not have the capacity to perform data collection to validate performance of drug therapies under VBP arrangements and that Medicaid agencies will need to coordinate monitoring and data collection efforts across Medicaid managed care plans (MCPs), as well as states. Another commenter noted that states engaging in VBP arrangements should not impose additional data collection and reporting requirements on hospitals and providers as a condition of participation.

Response: As noted earlier, we are not requiring state Medicaid agencies or their providers to enter into VBP arrangements as part of this final rule. Therefore, states will need to determine, when entering into VBP arrangements, if they have the capacity to operationalize and administer the various data collection efforts that may be required of a VBP arrangement.

States should also consider the impact of a VBP arrangement's data collection and reporting on Medicaid MCOs and Medicaid providers participating in these arrangements and whether or not these parties are interested in participating. Since the provider costs associated with a manufacturer's VBP arrangement are not reimbursable under Medicaid (unless it is a Medicaid covered service paid for under the state plan), providers, manufacturers and states (including Medicaid MCOs) should evaluate the compensation offered (if available) for the provider tasks under the arrangement and whether or not such compensation is sufficient for the tasks to be performed.

Comment: A few commenters requested that CMS offer reimbursement to providers when data collection is required. One commenter suggested that CMS should not allow VBP arrangements to place burden on providers to track and report on outcomes. One commenter noted that providers administering drug therapies will be better suited to evaluate patient outcomes and encouraged CMS to reimburse for monitoring and reporting costs. One commenter expressed concern that any savings associated with successful VBP arrangements are not shared with hospitals and providers.

A few commenters recommended that CMS acknowledge the role of providers in patient monitoring and performance measure reporting in the final rule and noted that providers administering drug therapies will be better suited to evaluate patient outcomes and encouraged CMS to reimburse for monitoring and reporting costs. One commenter requested CMS to clarify if savings associated with VBP arrangements will be shared with providers through higher reimbursement rates furnished to Medicaid beneficiaries.

Response: We understand that depending upon the VBP arrangement, providers may have a significant role in providing or administering the drug, evaluating of patient outcomes, and monitoring patient and other clinical details associated with the VBP arrangement. Each VBP arrangement will have its own set of criteria that are needed to evaluate outcomes; therefore, it should be up to the parties participating in the VBP arrangement to negotiate terms regarding the source of payment or reimbursement relating to the performance of these activities. We did not propose and is not finalizing a new payment authority as part of this rule for Medicaid providers to perform these activities.

i. Patient Considerations

Comment: A few commenters expressed concern that VBP arrangements may compromise patient safety based on their belief that manufacturers might be encouraged to bring a drug to market with potential outcomes, not proven ones. The commenters also noted that if a drug proves to be more effective than initially demonstrated, the manufacturer should have the opportunity to demonstrate the increased benefit and re-apply for payment that reflects the new outcome effectiveness.

Response: We disagree with the commenter that this rule, which gives manufacturers and payers flexibility to enter into VBP arrangements will allow manufacturers to market suboptimal drugs or compromise patient safety. The safety and effectiveness of a drug is not the subject of this final rule. And we further add that the final definition of VBP arrangement at § 447.502 is limited to covered outpatient drugs as defined at section 1927(k)(2) of the Act which with very limited exceptions have already been approved by FDA.

Comment: A few commenters requested that CMS prohibit manufacturers from using data for direct marketing to patients or clinicians, applications for FDA approval of supplemental indications, or post-marketing studies.

Response: The proposed rule did not address the use of data by manufacturers as part of their VBP arrangement, therefore it is not a topic of this final rule. We believe any data use as a result of a VBP arrangement should be negotiated between the parties of the VBP agreement.

We also remind states that the use of a VBP arrangement in the Medicaid program does not modify the Section 1927 requirements regarding state coverage of the covered outpatient drugs of those manufacturers that have a rebate agreement in place with the Secretary of HHS. Moreover, we reiterate that CMS will not be overseeing the specific VBP arrangements or the specific pricing agreements entered into between states and manufacturers with respect to multiple best prices. Our role will be limited to receiving best price and other price information that manufacturers are required to send us under law and regulation, as well as making states aware that such multiple best prices have been reported to us for a specific drug.

Comment: A few commenters requested that CMS reject VBP arrangements and other alternative payment arrangements that unduly limit Medicaid enrollee access to medically necessary outpatient prescription drugs.

Response: This rule, and the development of a various VBP approaches under this regulation, including the multiple best price approach, does not change state Medicaid program drug coverage requirements under section 1927 of the Act, and therefore, we do not believe there will be an access issue to medically-necessary covered outpatient drugs as a result of this final rule or VBP arrangements offered by manufacturers.

States are still required to cover drugs that satisfy the definition of a covered outpatient drug subject to a manufacturer rebate agreement, whether that drug is subject to a VBP arrangement or not. If the drug is subject to a VBP arrangement and the state decides to participate in the manufacturer's VBP arrangement, the state would have to cover the drug under the VBP arrangement similar to how it would cover it if it chose not to participate in the VBP. The difference is the state would be able to collect additional rebates based upon the VBP arrangement design and presumably, the multiple best prices reported by the manufacturer under the VBP arrangement. Moreover, this rule does not establish any CMS review and approval process for VBP arrangements.

j. AMP/Best Price Reporting and MDRP

Comment: A few commenters expressed concern that manufacturers may be able to set artificially low initial prices to delay when they have to pay the full rebates they owe, and requested CMS clarify how manufacturers will report their initial prices.

Response: Manufacturers that offer VBP arrangements (as defined at § 447.502) would report AMP and best price to CMS as they currently do each quarter. They would report a best price that was not tied to a VBP arrangement, and then report the multiple best prices for any VBP arrangements that they are willing to offer to the states. We will provide additional guidance to manufacturers on how such reporting would be made, as well how we would report these non-VBP and VBP prices to states so they can evaluate their participation.

The establishment of drug launch prices is outside the scope of this rule. However, to the extent that manufacturers increase prices on their products faster than the CPI–U, manufacturers would pay additional rebates (that is, inflation penalties) as required under section 1927(c) of the Act.

Comment: Several commenters recommended that manufacturers be permitted to report AMP as the full price of the drug at the time the drug is administered, even if installment payments would extend to subsequent quarters. A few commenters recommended CMS clarify that any installment that is forgiven under a VBP arrangement will be treated as a lagged price concession for purposes of the AMP smoothing methodology.

Response: Manufacturers must include the full price of the drug in the quarter in which the drug is sold in the determination of AMP in accordance with the definition of AMP at section 1927(k)(1) of the Act regardless of the payment arrangements negotiated with payers. Both the statutory and regulatory definition of AMP at § 447.504(a) require that AMP reflect ''the average price paid'' to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. Installment payments do not represent the price of the drug, but rather a partial payment of the drug's price.

We also believe it is appropriate that an installment payment not made because of a VBP arrangement outcome which would result in a significant discount, be treated as a lagged price concession (as defined at § 447.502) for purposes of the determination of AMP in accordance with § 447.504(f)(3) and best price in accordance with § 447.505(d)(3).

Comment: One commenter recommended that until a manufacturer has VBP arrangements in place that cover 50 percent of the treated disease-state population, Medicaid should continue to exclude VBP arrangements from the manufacturer's calculation of best price. Another commenter recommended CMS implement standardized process for manufacturers to correct best price data generated under a VBP arrangement.

Response: The proposed regulation did not propose that VBP arrangements be excluded from the determination of best price. Moreover, best price, as defined at section 1927(c)(1)(C) of the Act, does not permit the exclusion of prices available under VBP arrangements. Instead, we expanded § 447.505(a) to revise best price to state that a lowest price available from a manufacturer may include varying price points for a single dosage form and strength as a result of a VBP arrangement defined at § 447.502. We further discuss this policy in the multiple best prices section in the preamble below.

Comment: A few commenters recommended that CMS require manufacturers to provide separate payments for data collection and monitoring services in VBP arrangements and to expressly characterize them in the contract as either discounts or bona fide service fees paid separately from the VBP contract. This separation will provide clarity for all parties for legal and regulatory price reporting obligations (for example, AMP and best price).

Other commenters noted that manufacturer payment to third parties to track patient outcomes and fees associated with the administrative services should be excluded from best price and AMP calculations and reporting and requested CMS to provide guidance on the appropriate fair market value reimbursement for pharmacy services provided under VBP arrangements.

Response: We made no proposals about how manufacturers or other parties pay for data collection and monitoring associated with VBP arrangements in this rule. We believe payments for data collection and monitoring services as part of a VBP arrangement should be addressed during negotiations with the parties involved in the VBP arrangement. Furthermore, if a manufacturer pays a fee to any entity for data collection, administration or evaluation of a patient in a VBP arrangement, the manufacturer should evaluate whether or not that fee represents a fair market value for the service in accordance with the definition of bona fide service fee at § 447.502, as such fees shall be excluded

from the determination of AMP and best price (see §§ 447.504(c)(14) and (e)(5) and 447.505(c)(16)). Further discussion regarding the definition of bona fide service fees and fair market value is provided in the preamble (81 FR 5176 through 5181) to the COD final rule.

Comment: One commenter requested that CMS clarify how a manufacturer should structure rebates under VBP arrangements to account for a delay in data for outcome measures.

Response: We understand that there may be a delay in the reporting to a manufacturer of patient outcomes data under a VBP arrangement. We expect that manufacturers, under a VBP arrangement that will result in multiple best prices, will report to us a set of best prices that are associated with outcomes or evidence based measures which will be used for the Federal Medicaid drug rebate calculation. Based on the agreement the state (or other payer) has with the manufacturer relative to the VBP arrangement, states will report outcomes data to the manufacturers when they are available, and states will receive Federal Medicaid rebates based on the outcome measure observed in the quarter it was measured. This means a state may experience revisions to the initial Medicaid drug rebate paid to the state because of a failed outcome for a patient that occurs after the drug has been administered, and the initial rebate would need to be supplemented to account for one of the multiple best prices as a result of the outcome of the VBP arrangement. In other words, a prior period adjustment to a Medicaid Federal rebate that has already been paid to the state may be necessary.

k. Other Payment Models (Warranty, Pay-Over-Time, Subscription, Indication-Based Pricing)

Comment: Several commenters encouraged CMS to provide that additional innovative arrangements that could qualify under the definition of VBP arrangements such as payment-over-time, license or subscription arrangements, indication-based pricing, combination pricing, warranty type models, subscription models and financial risk-based models. One commenter suggested that CMS refine the definition of VBP arrangements to allow payment-over-time arrangements that do not rely on evidence- or outcomes-based measures and recommended that the definition be revised to read: ''(1) an arrangement containing measures (which can be outcome-based, evidence-based, or use other standards) that link the cost of a drug product to a specific outcome in patient or population, whether measures in health outcome, cost savings, or any metric agreed to by the parties, or (2) payment over time arrangements not contingent on specific health outcomes.''

Commenters also requested that ''warranty-type'' insurance models (this model obligates a premium payment by the manufacturer to a health plan to pay for a patient's future healthcare costs if the therapy fails) be outside of the proposed definition of VBP and that the revisions adding VBP arrangements to the proposed bundled sale definition and multiple best price calculations would not apply to such warranty models.

Some commenters suggested that some subscription models may not meet the definition of VBP arrangements; however, those (subscription) models that link to evidence-based or patient outcomes should be included in the definition proposed by CMS.

Response: We recognize that there may be a variety of payment models that industry may adopt that may, or may not satisfy the definition of a VBP arrangement. We do not want to inadvertently narrow the definition of VBP arrangements by identifying specific models or structures and believe the definition of VBP arrangement in this final rule is sufficiently broad to potentially capture the various arrangements noted by the commenters when it would be appropriate.

We note that not all pay-over-time arrangements will meet the definition of a VBP arrangement at § 447.502. For example, while there may be some pay-over-time arrangements that allow payers to pay in increments based upon evidence-based or outcomes-based measures, we do not agree that every pay-over-time or subscription model should be considered in the definition of VBP arrangement. Some pay-over-time measures are simply payment schedules negotiated between the manufacturer and payer and do not have any linkage to the value of the drug to the patient or selected population.

One of our main objectives is to ensure that any VBP arrangement must include evidence-based measures that substantially link the cost of a covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product; or, outcomes-based measures that substantially link payment for the covered outpatient drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses. If one of these models noted above satisfies the definition of a VBP arrangement, then it may appropriately avail itself of applicable regulatory flexibilities.

However, there are questions regarding whether the premiums paid by the manufacturer to a third party can be excluded from, or included in, best price when a manufacturer adopts a warranty-type models. Section 1927(c)(1)(C) of the Act defines best price, in part, to mean with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity within the United States, with certain exclusion applying. The statutory definition of best price is implemented in regulation at § 447.505 and provides that a drug's best price be net of certain transactions including incentives (see § 447.505(d)(1)).

The premium paid by the manufacturer to a third party to warrant a drug and provide benefits to payers and patients when certain clinical or performance measures are not achieved serves as an incentive to payers, providers, and patients to purchase the drug. Therefore, the premium paid by a manufacturer reduces the drug's price, and must be included in ''best price.'' However, the benefits paid by the third party in the event the drug did not meet certain clinical or performance measures are exempt from ''best price'' because payments made from the third party to the payer do not represent a price available from the manufacturer to any best price eligible entity as provided in § 447.505(a) and does not represent a manufacturer sale to an AMP eligible entity consistent with § 447.504(b) or (d).

Therefore, under this warranty model, a manufacturer would pay both Section 1927 rebates for the drug, as well as pay for a premium for a warranty policy, the value of which they would have to be included in the calculation of their best price, regardless of whether the manufacturer uses a VBP arrangement that results in multiple best prices.

Comment: One commenter encouraged CMS to explore carving VBP arrangements out of government price reporting metrics, while creating a mechanism for direct payment of discounts to states could encourage broader adoption of VBP arrangements.

Response: This comment is outside the scope of the rule.

Comment: A commenter requested clarification from CMS regarding two-sided risk VBP arrangements and how they would operate within the context

of the proposed Medicaid best price accommodations.

Response: It is not clear from the comment what is meant by two-sided risk VBP arrangements. However, we believe that any adjustments to the prices available from the manufacturer, including adjustments made by the payer or manufacturer under a VBP arrangement, that adjust the prices available from the manufacturer must be included in the determination of best price as provided at section 1927(c)(1)(C)(ii)(I) of the Act and § 447.505(d)(3).

l. Other Concerns With VBP Arrangements

Comment: Many commenters recommended that CMS work with HHS OIG and Office of Civil Rights (OCR) to provide guidance to address other regulatory obstacles to uptake and operationalization of VBP arrangements, including the Anti-kickback Statute, the Physician Self-Referral Law (Stark Law), privacy laws (such as HIPAA), and civil monetary penalty (CMP) rules relating to beneficiary inducements. A few commenters suggested that CMS collaborate with HHS OIG to issue guidance on relevant safe harbors to accommodate the collection and sharing of patient outcomes data to evaluate VBP arrangements. A few commenters requested that CMS clarify how safe harbors can accommodate for, among other issues, the collection and sharing of data to adjudicate a contract and VBP arrangements that tie payment to outcome measures that are meaningful to manufacturers, payers, and patients but that are not included in a drug's FDA-approved label.

Response: We appreciate the suggestions and will consider whether additional guidance may be needed at a later date. Furthermore, commenters concerns regarding safe harbors under HHS OIG should be addressed directly with the OIG.

Comment: A few commenters requested CMS to clarify whether the new flexibility for state Medicaid programs to enter into VBP arrangements would include claims paid under, or could be applied to, Medicaid MCOs. One commenter encouraged CMS to require Medicaid MCOs to have a VBP agreement signed in the quarter preceding implementation based on their belief that the requirement would address post facto adverse selection.

Response: Medicaid MCOs may enter into their own VBP arrangements with manufacturers including the VBP arrangement offered by the manufacturer on the commercial market. However, the prices negotiated under those VBP arrangements would not be exempt from best price given that the prices are not negotiated pursuant to a CMS- authorized supplemental rebate agreement under the exclusion at § 447.505(c)(7).

Comment: A commenter suggested that CMS should engage in a Request for Information (RFI) process to gather more stakeholder feedback to develop more detailed proposals before finalizing the proposed rule definition of a VBP arrangement. One commenter noted that CMS' request for public comment on additional measures to reflect value from a drug therapy is indicative of a need for a RFI process prior to the release of formal notice and comment rulemaking.

Response: We do not believe feedback via a RFI is necessary before finalizing this rule as there are numerous manufacturers and payers already involved in VBP arrangements and the goal of this rule was to enhance flexibility around Medicaid drug rebate pricing rules for manufacturers and payers as they enter into these arrangements. We appreciated the suggestions that commenters gave regarding the measures to determine a drug's value, which we hope will generate ideas and considerations as manufacturers and payers continue participating in VBP arrangements. CMS may consider issuing best practices in Medicaid regarding VBP arrangements in the future based upon the experiences realized by states, payers, and manufacturers.

Comment: A commenter recommends that CMS work with its fellow agencies to develop and implement strategies and programs to improve the availability, quality, and access to real-world data (RWD) for research and other population health purposes and CMS should establish privacy-related policy principles and recommendations to support the use of RWD and real-world evidence to include patient-generated data for clinical research, regulatory evaluation, and VBP decision-making. The commenter further noted that CMS should collaborate with FDA on ways to generate shared evidence in support of their (CMS) decisions.

Response: While the availability of data to measure and evaluate drug therapies is an essential part of VBP arrangements, improving upon the availability, quality and access of real world data for research and other purposes, is outside the scope of this final rule.

Comment: One commenter recommended CMS consider creating a new type of Healthcare Common Procedure Coding System (HCPCS) code, potentially a modifier, associated with a gene therapy's HCPCS Level II code, preferably issued at the time of FDA approval, which could be used to report whether or not a health outcome was achieved to facilitate payment and financial reconciliation of a value-based contract.

Response: The creation of new types of HCPCS codes associated with this regulation is outside the scope of this final rule.

Comment: One commenter recommended that CMS require state Medicaid agencies that enter into VBP arrangements to provide the manufacturers with audit rights to any data collected for purposes of tracking performance. The commenter noted that access to the data is important to adjudicate the rebates associated with VBP arrangements and to facilitate lessons learned for both parties.

Response: This final rule does not require state Medicaid agencies provide manufacturers with the data collected for purposes of tracking a drug's performance. This final rule focuses on providing manufacturers and payers additional regulatory flexibility to enter into VBP arrangements. We believe if manufacturers desire to seek audit rights as part of the VBP arrangement, manufacturers may consider negotiating these terms as part of the arrangement with the state.

Comment: One commenter noted the proposed rule facilitates uptake of individual-level VBP arrangements for one-time or curative treatments, rather than arrangements requiring population-based approaches. The commenter also noted that without further clarification, uptake of population-based VBP arrangements for chronic conditions would be limited as a result of the administrative burden born by payers and manufacturers to calculate the value of a drug at the individual-level.

Response: We do not agree that the proposed rule facilitates only individual level VBP arrangements for one-time or curative treatments instead of population based approaches because the definition of VBP arrangement does not make such limitations. We also believe that by adopting a broad definition of VBP arrangement, manufacturers will have the flexibility to develop VBP arrangements specific to either individual or population-based approaches.

Comment: A few commenters expressed concern that payers may deny coverage of FDA-approved therapies as a result of not meeting expected outcomes for VBP arrangements, especially for gene therapies and

contraception. Another commenter requested CMS clarify that the lack of a VBP arrangement does not release the state from the drug coverage obligations of section 1927 of the Act.

Response: This final rule does not affect Medicaid coverage of covered outpatient drugs as defined at section 1927(k)(2) of the Act. States are required to cover all covered outpatient drugs of manufacturers that participate in the MDRP, whether the state enters into a VBP arrangement or not.

Comment: A few commenters recommended that CMS consider waiving cost-sharing requirements for beneficiaries participating in VBP arrangements or develop other approaches for sharing savings with beneficiaries.

Response: This comment is outside the scope of this final rule.

After considering the comments received, we believe the definition of VBP arrangement should be broad enough so that manufacturers and payers, including states, have the flexibility to structure a VBP arrangement specific to the drug therapy being offered. Therefore, we are maintaining a broad definition to ensure such arrangements are recognized for purposes of determining and reporting best price and AMP; however, we agree with commenters that the evidence or outcomes-based measures used in a VBP arrangement should be evaluated in a select population and are therefore adding the term ''select'' before populations in the definition to clarify that VBP arrangements are specific to select population groups using the drug therapy, such as a gene therapy specific to a patient with a particular type of cancer. We are also adding the terms ''and/or'' between the two measures in the definition to further clarify that either evidence-based or outcomes-based measures could be used in a VBP arrangement. Furthermore, we agreed with commenters concern that the parenthetical ''that is, outcomes relative to costs'' is confusing given outcomes-based measures are already part of the definition of VBP arrangement. Therefore, we are removing it to reduce redundancy. Also, in response to commenters concerns that the drug covered by the VBP arrangement has demonstrated effectiveness, we are clarifying that VBP arrangements apply to covered outpatient drugs; that is, products that satisfy the definition of a covered outpatient drug, as defined at section 1927(k)(2) of the Act. We are finalizing the definition of a VBP arrangement to mean an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population and includes, but is not limited to:

- Evidence-based measures, which substantially link the cost of a COD to existing evidence of effectiveness and potential value for specific uses of that product; and/or,
- Outcomes-based measures, which substantially link payment for the COD to that of the drug's actual performance in patient or a population, or a reduction in other medical expenses.

3. Inclusion of VBP as a Performance Requirement Under a ''Bundled Sale''

As stated in the June 2020 proposed rule, one of the issues manufacturers contend with in determining best price with the advent of VBP arrangements is that a manufacturer's best price can be reset based upon the outcome of a drug treatment for one patient or one unit of the drug because of the VBP arrangement. When this occurs, the rebate due for that single use of the drug during a quarter that results in a negative outcome will reset the best price to a significantly lower amount, sometimes zero, prompting a significantly higher rebate (sometimes 100 percent of the drug's AMP). We have received stakeholder comments and inquiries regarding how rebates or discounts as part of a VBP arrangement could be considered in a bundled sale when determining best price. Some manufacturers have made reasonable assumptions that such discounts, as a result of a VBP, should be considered part of a bundled sale as defined at § 447.502.

In the COD final rule, we defined bundled sale at § 447.502 as any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit NDC level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. Specifically, the discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement. Also, for bundled sales where multiple drugs are discounted, the current definition indicates that the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle. (See § 447.502; 81 FR at 5182.) We noted that we understand that based on the bundled sale definition, which provides that the rebate, discount or other price concession is conditioned upon the purchase of the same drug, drugs of different types, or another product or some other performance requirement, some manufacturers have made reasonable assumptions to take into account the discounts from a VBP arrangement that has a performance requirement when a measure (such as a performance-based measure) is not met. When manufacturers recognize the VBP arrangement as a bundled sale, the manufacturer, for example, may assume that the discount that resulted from a performance requirement of a single unit is distributed proportionally to the total dollar value of the units of all the drugs sold in the bundled arrangement. This smooths out the discount over all the units sold under the arrangement in the rebate period and does not reset the manufacturer's best price based upon the ultimate price of one unit of a drug.

For example, a manufacturer could structure a VBP arrangement such that to qualify for a patient outcome rebate, the bundled sale VBP arrangement requires the sale of 1000 units of the same drug at $200 per unit, and if one patient fails to achieve an outcomes-based performance measure the manufacturer agrees to a $100 price concession on that one unit. In this example, because all of the drugs in the bundle were subject to the performance requirement, the manufacturer's scheme qualified as a bundled sale VBP arrangement, and thus, the manufacturer's rebate of $100 on that one unit would be allocated across all units in that bundled sale as follows:

1000 units × $200 = $200,000 − $100 price concession = ($199,900/1000 units) = $199.90.

Best price could be set at $199.90 if that $100 rebate available in a qualifying bundled sale resulted in the lowest price available from the manufacturer, and not at $100 ($200/unit − $100).

We agree with the applicability of the bundled sale definition in this context because it will permit manufacturers to have a best price that is not based upon the failure of one patient taking the drug. Therefore, to facilitate the appropriate application of a bundled sale offered in the context of a VBP arrangement to the best price determination, we proposed to revise the definition of bundled sale at § 447.502 to add paragraph (3) that

states VBP arrangements may qualify as a bundled sale, if the arrangement contains a performance requirement such as an outcome(s) measurement metric. We noted that we expect manufacturers, consistent with the manufacturer recording keeping requirements at § 447.510(f), to maintain documentation of the VBP arrangement, including documentation of how the programs meets the new definition of VBP arrangement, to support their calculation of AMP and best price.

We received the following comments on the definition of bundled sale in § 447.502.

Comment: Many commenters expressed support for CMS' proposed changes to the bundled sale definition which would permit manufacturers to allocate discounts or price concessions as a result of a VBP arrangement across a bundled sale. Several commenters expressed support for the proposed revision to the definition of bundled sale to include the ''performance requirement'' and that the bundled sale authority requires a VBP with a performance requirement, like an outcomes metric, but noted that the performance requirement does not need to be an outcomes metric as set forth in the VBP arrangement definition. Another commenter disagreed with the inclusion of the performance requirement and requested that CMS consider changing the language ''if the arrangement contains a performance requirement such as an outcome(s) measurement metric'' to explicitly state ''a value-based purchasing (VBP) arrangement may be treated as a bundled sale.''

Response: We appreciate the support and suggestions related to the proposed revisions to the bundled sale definition at § 447.502. We agree with the commenters, and are revising the proposed definition to remove ''if the arrangement contains a performance requirement such as an outcomes measures metric'' because this phrase is redundant to the definition of VBP arrangement defined at § 447.502 which already requires VBP arrangements include outcomes based measures. We also note that the measures listed in the preamble to the proposed rule (85 FR 37292) are examples for manufacturers to consider and we do not intend to limit VBP arrangements to only those examples.

Comment: A few commenters requested CMS to clarify in the regulations that the ''VBP arrangement'' referenced in the bundled sale proposed regulatory text is or is not associated with the proposed definition of VBP arrangement to be codified at § 447.502.

Response: The definition of VBP arrangement, as finalized at § 447.502 by this final rule, will apply to the bundled sale definition.

Comment: Several commenters did not support the proposed changes to the definition of bundled sale. One commenter noted this change would make the best price requirement ''highly vulnerable to manufacturer gaming and inaccurate reporting that could substantially reduce or delay drug rebate payments.'' Another commenter opined that the proposed changes would ''water down existing discounts, raise best price and lower rebate amounts.'' One commenter expressed the belief that the proposed changes would permit manufacturers to offer a low price to commercial purchasers and payers that would not be available to Medicaid.

Response: It is not completely clear what the commenter means by ''gaming''; however, we do not agree that this clarification to the bundled sale definition makes it highly vulnerable to manufacturer gaming in the context of best price or AMP that would reduce Medicaid drug rebates. Some manufacturers have already been allocating discounts in a bundled arrangement as a result of a performance requirement under a VBP arrangement using reasonable assumptions and have shared those approaches with CMS. While we have not opined on those manufacturer-specific approaches, we have not detected any significant impact on these manufacturers' best price or AMP, or decreases in Medicaid drug rebates. Manufacturers continue to be potentially subject to penalties, including CMPs, for failure to follow pricing and product reporting requirements.

The clarification made to the definition of bundled sale was necessary to specifically address situations when best price is reset based upon the outcome of a drug treatment for one patient or one unit of the drug because of the VBP arrangement. As stated in the preamble to the proposed rule, a single use of the drug in a patient can result in a negative outcome which will reset the best price to a significantly lower amount, sometimes zero, prompting a significantly higher Medicaid drug rebate for the manufacturer (sometimes 100 percent of AMP) (85 FR 37292). We believe the impact of these significantly-higher Medicaid drug rebate deters manufacturers from offering VBP arrangements on the commercial market, as well as Medicaid.

Comment: A few commenters stated that manufacturers should not be permitted to mix prices under a VBP arrangement with those under a non-VBP arrangement. Another commenter recommended the bundled calculation occur at the individual purchaser and individual VBP contract level and that best price for an individual purchaser should equal the average price paid per unit after including (or stacking) all discounts that a purchaser received, whether the discounts were within or outside of a VBP arrangement. One commenter requested from CMS a clearer definition of ''proportional allocation'' of discounts within a bundled sale arrangement with regards to VBP arrangements. Another commenter expressed concern that the proposed rule does not adequately address how stacked discounts would be handled in a bundled arrangement, allowing manufacturers to use evidence-based VBP to spread stacked discounts across all purchases, ultimately, in the commenter's opinion, reducing Medicaid rebates.

Response: The definition of bundled sale at § 447.502(1) indicates that discounts in the bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement. The policy that is being finalized in this rule is that VBP arrangements may qualify as a bundled sale. Therefore, if the manufacturer determines that its VBP arrangement qualifies as a bundled sale, the manufacturer allocates the VBP discounts in the VBP arrangement so that it is proportional to the total dollar value units of all drugs or products sold under the bundled arrangement to the best price (or AMP) eligible entity. Any discounts provided for those units sold to the best price (or AMP) eligible entity outside of the VBP arrangement would not be part of the allocation. Moreover any non-VBP discounts provided to the best price (or AMP) eligible entities should be considered when determining the actual price realized by the entity and would not be part of the bundled sale allocation. That is, the single actual price realized by the entity for the quarter when using a bundled sales approach for a drug would have to be considered by the manufacturer along with any non VBP prices for the same drug.

Comment: A commenter suggested that aggregation of sales and discounts across purchasers under a VBP arrangement to arrive at a bundled sales best price should only be allowed for very small purchasers (such as when that the number of patients expected to take the drug is extremely low). Another commenter requested that CMS change

the rule to require manufacturers to include all VBP rebates in the calculation of a single best price using the bundled sale methodology.

Response: We appreciate the comments; however, we do not agree that the bundled sales approach only applies in certain situations (for example, drug usage in a small number of individuals) or that all discounts of a VBP arrangement could be used in the calculation of a single best price using the bundled sale methodology. Manufacturers may determine that they want to work with one or more different best price eligible entities on a VBP program using a bundled sales approach, whether a small number or large number of patients are involved for each best price eligible entity. Manufacturers would have a distinct price for each entity, taking into account price concessions or discounts inside and outside of the bundled sale arrangement available to the entity, and compare the prices amongst all eligible entities in a quarter to determine the product's lowest price available. That lowest price available amongst the best price eligible entities would presumably be the best price.

We do not believe that the statute supports the inclusion of all VBP prices offered by a manufacturer into the calculation of a single best price under a bundled sales methodology, as the determination of a best price is based on a lowest price available to a specific best price eligible entity, not a price that is an aggregation of sales/discounts/rebates across multiple entities as suggested by the commenter.

Comment: A few commenters expressed concern that the bundled sales approach may not be a workable approach to determining best price because VBP arrangements involving very small patient populations, such as gene therapy or drug therapies that treat rare and orphan diseases, and may not be able to take advantage of the smoothing effect of the bundled sale methodology. Commenters requested whether manufacturers may choose either a bundled or multiple best price approach or whether the manufacturer may determine both depending on the preferences of their negotiating partners and the product characteristics.

Response: We agree that the manufacturer may not want to use the bundled sale approach based upon the characteristics of the drug, such as drugs that treat small populations, rare and orphan disease drugs, and certain gene therapies covered under its VBP arrangement. As discussed in this section, the definition of bundled sale at § 447.502 is being finalized to state that VBP arrangements may qualify as a bundled sale. We believe manufacturers may choose between the bundled sale arrangement approach to calculating best price, or use the multiple best price reporting approach, understanding that it is dependent upon the design of a manufacturer's VBP arrangement such as the product and population characteristics of the drug therapy offered under the VBP arrangement, and whether that arrangement meets the regulatory definition of a VBP arrangement.

We believe that the concern regarding treating small populations will be addressed by the reporting of multiple best prices approach. For example, in the event a state enters a VBP agreement with a manufacturer and a single Medicaid beneficiary has an outcome that results in a very high rebate under the VBP arrangement, the best price used by the manufacturer to set the rebate for that single unit dispensed will be based upon the VBP arrangement best price for that specific outcome. All other Medicaid units dispensed during a quarter that are eligible for rebates but not dispensed to Medicaid beneficiaries enrolled in the VBP arrangement will reflect the best price outside of the VBP arrangement.

Comment: One commenter requested CMS consider replacing the phrase ''may qualify as a bundled sale'' with ''may constitute a bundled sale'' as it is the commenter's opinion that the term ''qualify'' appears to invite a degree of judgment on a matter where there is no clear arbiter.

Response: Bundled sale is already specifically defined in regulation at § 447.502. We believe manufacturers will need to determine whether or not their VBP arrangement qualifies as a bundled sale, and do not believe the suggested regulatory text change is necessary, as we do agree a degree of judgement is required to determine whether a VBP arrangement should be viewed and treated as a bundled sale.

Comment: One commenter noted VBP bundling regulations do not address pro-rating, which may prove burdensome for manufacturers and may increase the possibility of gaming.

Response: This comment is outside the scope of this rule.

Comment: A commenter requested CMS to clarify whether outcomes-based measures created under bundled sales arrangements meet the proposed definition of a VBP arrangement.

Response: A manufacturer may use a bundled sales approach if the payer's or purchaser's rebate or discount is, among other situations, contingent on the existence of a performance requirement. We are finalizing in this regulation that a VBP arrangement could qualify as a bundled sale. Going forward after the effective date of this regulation, a VBP arrangement that does not meet the definition of VBP arrangement in this regulation (which would include evidence and/or outcomes-based measures) will not be recognized as part of the bundled sale definition.

After consideration of the comments received, we are finalizing subparagraph (3) of the definition of bundled sale to remove the phrase ''if the arrangement contains a performance requirement such as an outcome(s) measurement metric'' and read, ''Value-based purchasing (VBP) arrangements may qualify as a bundled sale.''

4. Definitions—Best Price (§ 447.505(a)) and Reporting of Multiple Best Prices, Adjustments to Best Price (§ 447.505(d)(3))

In the preamble to the COD final rule (81 FR 5253), we indicated that we recognized the value of pharmaceutical VBP arrangements in the marketplace, and that we were considering how to give specific guidance on this matter, including how such arrangements affect a manufacturer's ''best price.'' In addition to CMS, States, manufacturers, and commercial payers all have an interest in making new innovative therapies available to patients, and we have heard that there are challenges with the current interpretation of statutes and regulations for how ''best price'' can affect the availability of VBP arrangements. Because the statute was drafted more than 30 years ago, when such arrangements were not prevalent in the market, it is understandable that such interpretations by CMS to date regarding ''best price'' have been limited to one ''best price'' per drug.

The Medicaid statute defines best price in relevant part to mean, for a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, HMO non-profit entity, or governmental entity within the United States, with certain exclusions enumerated at sections 1927(c)(1)(C)(i)(I) through (VI) of the Act. Historically, we have interpreted this language to result in only one best price per drug. The current Medicaid ''best price'' regulation at § 447.505 generally tracks the statutory language, but reads in relevant part that ''best price'' means, for a single source drug or innovator multiple source drug, the lowest price available from the manufacturer during the rebate period *in any pricing*

structure (including capitated payments), in the same quarter for which the AMP is computed (emphasis added).

The current regulation is interpreted further in the preamble language to the COD final rule and MDRP releases where we have indicated that the lowest price available means the lowest price ''actually realized'' by the manufacturer or the lowest price at which a manufacturer sells a covered outpatient drug—that is, one lowest price available per dosage form and strength of a drug. Applied to the VBP arrangement context, this interpretation could result in setting a best price that is either at a greatly reduced price or possibly zero, if a single dosage form or strength dispensed to one patient is subject to a full or very large rebate under a VBP arrangement.

Thus, we need to reconcile the interpretation of the statute in regulation, which currently contemplates that for any quarter, the ''best price'' is a single price for each dosage form and strength of a drug that represents the actual revenue realized by the manufacturer for that drug—in any pricing structure offered by the manufacturer (such as capitated payments)—with the realities of the current evolving marketplace which contemplate that multiple prices could be made available by the manufacturer for a particular drug based on the drug's performance (such as the case with VBP arrangements that use evidence or outcomes-based measures) in a quarter.

In that regard, because VBP and other innovative payment arrangements sometimes result in various price points for a dosage form and strength of a single drug or therapy being available in a quarter, we proposed to reflect this possibility in the June 2020 proposed rule. Specifically, we proposed that a single drug may be available at multiple price points, each of which may establish a ''best price'', based on the relevant or applicable VBP arrangement and patient evidence-based or outcome-based measures.

We explained in the June 2020 proposed rule that we believed we have this authority because we previously interpreted the statutory definition of best price at § 447.505(a) to reference the best price ''in any pricing structure,'' contemplating the possibility of various pricing structures, such as capitated payments. With the new VBP pricing structures that are available in the marketplace, we believe it is appropriate and reasonable to further interpret what pricing structures are available, and account for new VBP pricing structures, which may include introducing the offering of a drug at multiple price points. That is, we proposed to expand our interpretation of ''in any pricing structure'' and also the term ''lowest price available'' by proposing that the price realized in a VBP arrangement by the manufacturer when a measure is not met for a single patient would not reset the best price for the drug in the quarter. That is, a single patient failure on the drug, or lack of attainment of an expected clinical outcome, would not result in the manufacturer having to give that same rebate as a result of the VBP arrangement to Medicaid for that drug as they would have to give to the commercial plan in which that patient was enrolled. However, if a state chooses to participate in the VBP arrangement offered by the manufacturer, the state could receive a URA for each patient's particular outcome that is reflective of the VBP arrangement best price.

Rather, we proposed that, given our interpretations of the statutory phrase ''lowest price available'', and the phrase ''in any pricing structure'' at 42 CFR 447.505, that multiple prices could be realized by the manufacturer for the same drug in a quarter when the prices are tied to a particular VBP outcomes structure. Therefore, multiple price points (price points are offered and available as a result of a VBP program, and price points absent a VBP program) may be reported for one dosage form and strength in a rebate period.

Manufacturers could offer the same or a different set of best price points each quarter for a drug, and those best price points would be applicable to the patient to whom the drug was administered in that particular quarter. Any future best price adjustments for that patient would be reflected in the outcomes that the patient achieves over the period of time of the VBP arrangement, and any price adjustments due to the state (if they participate in the VBP arrangement) would be based on the additional best price rebates reported in that quarter by the manufacturer in which the drug was first administered. Manufacturers would have to make any adjustments to both sets of best prices (VBP and non-VBP best prices) reported if any adjustments are made by the manufacturer subsequent to the quarter in which they are reported.

As an example, when a manufacturer offers a VBP arrangement, and the state chooses to participate, the manufacturer would report a single best price for the drug for the quarter for sales of the drug in that quarter (a non-VBP arrangement best price), and in addition, the manufacturer would also report a distinct set of ''best prices'' that would be available based on the range of evidence-based or outcomes measures for that drug that are possible under the VBP arrangement.

The manufacturer would provide a best price rebate to the state in the quarter in which the drug is administered, and then could offer varying additional rebates based on a patient's response after the drug is administered. The calculated additional MDRP rebate due to the state using the VBP best price would be a function of whether or not the Medicaid rebate is being paid on a unit of a drug dispensed to a Medicaid patient that participated in a VBP, and the level of rebate associated with that patient's outcome. The additional rebate paid for that patient would only represent the amount of rebate due to the state from the manufacturer for that patient, not all patients. That is, the rebate would be specific to that patient's outcome and that price actually realized by the manufacturer, as that price is the lowest price available from the manufacturer based on that patient's outcomes. Otherwise, the best price used in the Medicaid rebate formula would mirror the lowest price available absent a VBP arrangement.

Therefore, we proposed to further interpret the regulatory language ''in any pricing structure'' to include VBP arrangements. Then, we proposed to interpret the statutory and regulatory phrase ''lowest price available'' as used in the definition of best price, to permit, in the context of a VBP arrangement, to include a set of prices at which a manufacturer makes a product available based on that pricing structure. This being the case, we proposed that the definition of best price be expanded at § 447.505(a) to provide that a lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of a VBP (as defined at § 447.502). We noted that we understand the operational challenges this may bring to MDRP systems and that it will take us time to make such system changes. We solicited comments on the proposal, its impact on the MDRP, the commercial market, and its operational implications. Specifically, we requested comments regarding the potential impact of these changes on supporting payment innovation and health care quality. We also sought comment on steps which would be needed by manufacturers and states to implement these Best Price changes, including how states would track health outcomes for Medicaid beneficiaries to align with the outcomes developed in a private market VBP.

Also, to provide consistency between AMP and best price, as we did in the COD final rule (81 FR 5170), we proposed to revise § 447.505(d)(3) to make it consistent with § 447.504(f)(3). Section 447.504(f)(3) provides that the manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of AMP by statute or regulation. We proposed to add a similar qualifying phrase at the end of § 447.505(d)(3) to state that the manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates or other arrangements subsequently adjust the prices available, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of best price by statute or regulation. We believe this is consistent with the requirement at section 1927(c)(1)(C)(ii)(I) of the Act, which provides that best price shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates, and therefore, best price must account for these to the extent they are not excluded by statute or regulation.

We received the following comments on the definitions—Best Price (§ 447.505(a)) and Reporting of Multiple Best Prices, Adjustments to Best price (§ 447.505(d)(3)).

Comment: A few commenters expressed support for CMS' proposed changes regarding the reporting of multiple best prices, specifically regarding adjustments for cumulative discounts, rebates or other arrangements. Several commenters also suggested alternative approaches to CMS' proposals for best price and reporting of multiple best prices such as:

- Include all payments related to VBP arrangements, including administrative fees, in the best price calculation.
- Allow the discounts across various VBP agreements to be pooled together to create an Average Best Price from the VBP agreements or pool outcomes (both successes and failures) across all VBP agreements and apply them to the most favorable VBP agreement to determine a VBP Best Price.
- Require manufacturers to report only one VBP best price in any given quarter in addition to the current best price calculations.
- Use CMS authority under the MDRP to provide technical clarifications about how best price could be reasonably reported under contracts in which discounts vary based on patients' clinical outcomes, without eliminating or dramatically weakening the best price requirement.
- Provide incentives to manufacturers to have VBPs for all new curative therapy drugs for a defined period (for example, 5 years) following a drug's approval, applicable to all Medicaid recipients.
- Administer value-based payments and best price as a true-up model that would allow state Medicaid programs to continue to obtain whatever best price was agreed to at the time a VBP was created and that, by updating the definition of VBP and extending the Best Price adjustment period for VBP only, they would allow for a true-up/rebate adjustment for the MDRP.

Response: We appreciate the support for the proposed changes to best price and the alternatives proposed by commenters, and may consider them in future rulemaking. We are finalizing our proposal that manufacturers be permitted to report multiple best prices based upon commercially-available VBP arrangements made available to states that satisfy the regulatory definition of a VBP arrangement. We believe that we have attempted to address via this regulation technical clarifications about how best price could be reasonably reported without eliminating or dramatically weakening the best price requirement. That is, by permitting manufacturers to report multiple best prices in accordance with § 447.505(a) for VBP arrangements offered to states that satisfy the regulatory definition of a VBP arrangement we are finalizing in this rule, it guarantees those states that agree to participate receive the best price under the VBP arrangement. Furthermore, as explained in section II. G. of this final rule, we are finalizing a policy to permit manufacturers to request a change as a result of a VBP arrangement, as defined in § 447.502, outside of the normally applicable requirement to report within 12-quarters from the quarter in which the data were due, when the outcome must be evaluated outside of the 12-quarter period. Otherwise, states that do not participate will continue to receive a Medicaid rebate based upon the non-VBP best price as reported by the manufacturer.

Comment: Several commenters did not support the proposed changes to best price reporting and stated that these changes violate the Medicaid rebate statute, exceed CMS's authority, and disregard Congressional intent. A few commenters noted that the proposed MDRP best price requirements undermine competition and recommended CMS consider additional reforms to the MDRP to correct the impact it has had on drug market dynamics. One commenter noted that the current Medicaid rebate program is an effective tool for states to control drug prices, combat inflation and egregious price increases and to allow multiple best prices would put states at risk for incorrect price reporting. Several commenters expressed opposition to CMS' proposed changes regarding the language ''in any pricing structure'', and noted that CMS' proposal is inconsistent with the Medicaid Drug Rebate statute's definition of best price and contrary to CMS's treatment of other similar transactions in AMP and best price. Another commenter noted that the proposal contradicts the best price statute citing their belief that ''lowest price'' is understood to be a single lowest price. A few commenters noted that the proposal does not limit the number of unique VBP arrangements a manufacturer may create, nor does it limit the number of pricing tiers within each VBP arrangement and believes that the segmentation this creates significantly weakens best price protection, while one commenter stated that the proposed changes would create higher rebates across all Medicaid units.

Response: We do not believe the policy permitting manufacturers to report multiple best prices in accordance with § 447.505(a) for VBP arrangements offered to states that satisfy the regulatory definition of a VBP arrangement we are finalizing in this rule weakens the best price requirement or exceeds our authority. As discussed above, manufacturers will be required to continue to report, and states not participating in the VBP arrangement would be able to access, a separate best price based upon prices available outside of the VBP arrangement to best price eligible entities for the dosage form and strength of the drug. If a manufacturer chooses not to offer a VBP arrangement to states, or simply chooses not to report multiple best price points resulting from a VBP arrangement, then manufacturer reporting would follow all existing laws and regulations regarding the best price determination.

We reiterate that states will not be required to participate in these VBP arrangements and in cases when a manufacturer is reporting multiple best prices pursuant to a VBP arrangement will receive a Medicaid drug rebate based upon the non-VBP best price for the drug for the quarter in which the drug is administered. The final policy simply permits manufacturers to report

a distinct set of multiple best prices for a VBP arrangement (or multiple sets if there is more than one in the marketplace), in addition to reporting a single best price for the drug not affiliated with a VBP arrangement. This ensures that when a state agrees to participate in one of the manufacturer's VBP arrangements, the additional rebates that could be paid to a state reflects the best prices associated with the VBP arrangement. We reiterate that the initial rebate to all states in the quarter in which the drug is administered, under either the non VBP or VBP arrangement, will be at least equal to the greater of 23.1 percent of the AMP or AMP minus best price (be it a multiple best price or the non-VBP best price).

In order to report multiple best prices, the manufacturer must make available to the states the VBP arrangement (or multiple VBP arrangements) being offered on the commercial market. States may have the option to participate in that VBP arrangement. Manufacturers may also choose not to report multiple best prices approach for their VBP program, and follow existing rules, or, as appropriate, choose another approach to determining best price (and AMP) such as the bundled sales approach. For example, when a manufacturer follows the bundled sales approach, the manufacturer will not report multiple best prices associated with the arrangement and will report one best price using the bundled sales approach. Please see the discussion in section II.G.3. of this final rule, for a more detailed explanation of the bundled sales approach to VBP arrangements.

The rationale for the proposed changes is to give manufacturers the ability to offer VBP arrangements to commercial payers and Medicaid without having the current interpretation of best price result in disincentives for manufacturers to offer these innovative pricing strategies because doing so could dramatically increase their Medicaid drug rebates based on a single sale.

The expanded interpretation of best price, such that a manufacturer could offer multiple best prices for a single dosage form and strength of a drug, in addition to a non-VBP best price, is consistent with the statute, as the MDRP was structured to reduce the cost of drug therapies to all states by allowing Medicaid to take advantage of the negotiating abilities of the private sector. Given the evolution in the marketplace since the original law was drafted in 1990, and the availability of new expensive gene therapies that could have different clinical outcomes in different patients, we believe that it is reasonable for the agency to make an interpretation of the statute and regulations that the ''lowest price available'' ''in any pricing structure'' could be interpreted as a VBP arrangement under which different prices are available based on different outcomes.

Comment: A few commenters noted the proposed changes to multiple best price reporting structure will increase burden on manufacturers. One commenter noted that reporting individual patient prices would not add value to the healthcare system and would create an unnecessary administrative burden upon both CMS and manufacturers.

Response: We do not agree that there is unnecessary burden on manufacturers as we are not requiring manufacturers engage in VBP arrangements or report individual patient prices under this final rule. Instead, this rule gives manufacturers the ability to report more than a single best price (multiple best prices), at their option, when offering a VBP arrangement on the commercial market that they also offer to states. State Medicaid programs will have the option to either participate or not in the commercially available VBP arrangement. Therefore, the change does not place any additional burden on manufacturers or the states, but rather establishes a tool (the ability to report more than one best price) to reduce the disincentives for manufacturers to offer these innovative pricing strategies because doing so could dramatically increase their Medicaid drug rebates based on a single sale.

Comment: Some commenters noted that CMS should determine if the proposed new options in best price reporting will complement, or perhaps inspire, private sector innovations in reinsurance, stop-loss protection and other business insurance products that will make VBP arrangements feasible for payers.

Response: These comments are outside the scope of this rule.

Comment: One commenter recommended CMS remove the option to report multiple best prices in VBP arrangements, and instead use the bundled sale methodology to incorporate all VBP best prices into one URA, such that commercial VBP payments are not treated differently from any other rebate and limit the number of VBP arrangements a manufacturer may offer.

Response: We do not believe using the bundled sale approach will be workable for all manufacturers in all situations, which is why we proposed the change to the determination of best price to permit multiple best prices. Specifically, certain manufacturers of drugs indicated for use in limited populations will not have a large number of sales in a quarter to spread out discounts as a result of a bundled sale. This being the case, a VBP arrangement that results in a significant discount (for example, 75 percent discount) will impact best price significantly if only 1–3 units are dispensed per quarter.

Comment: Several commenters requested clarifying guidance regarding the best price and inclusion of prices from VBP arrangements, as well as the reporting requirements, operational timelines, and the treatment of non-VBP arrangement rebates. A few commenters recommended that CMS update the DDR system to accommodate non-manual reporting of multiple best prices to align with the effective date of the final policy and ensure such system updates accommodate products with both VBP and non-VBP arrangements. A few commenters requested more guidance on CMS' URA reporting mechanism and methodology.

Some commenters recommended CMS not finalize the proposed change to the definition of best price that includes a reference to ''varying price points'' until guidance has been developed and all of the implications on program integrity and other prices have been thoroughly considered. Several commenters urged CMS to establish clear and specific regulatory provisions for codification in the CFR for manufacturers to follow in applying the multiple best prices authority set forth in the proposed rule.

A few commenters also expressed concern regarding the operational implications for manufacturers with CMS' proposals related to best price reporting, as well as the possible resource constraints that, in their opinion, may be too great to overcome. One commenter noted that the multiple best price approach imposes an unreasonable administrative burden on VBP arrangement participants because a drug manufacturer would require data from PBMs and health plans with sufficient detail to support a per product, per customer, per quarter, per unit price to report and certify an accurate best price. Many commenters noted additional resources, including staffing and information technology may need to be invested by CMS, payers, and manufacturers to support the proposed price reporting methodology, with a few commenters further suggesting CMS utilize a single federal contractor to

monitor VBP arrangements available in the market and support data collection and analysis; and allowing multi-state VBP contracts to support pooling of state administrative resources and a larger pool of covered lives for VBP negotiations. One commenter cautioned that the proposal would introduce complexities that would outweigh the benefits for states that the proposal envisions and instead proposed that CMS adopt the weighted average multiple best price calculation as facilitated by the revised bundled sales provision.

Response: We agree with the commenters regarding the operational and administrative challenges for CMS, manufacturers, states and payers and we intend to provide additional necessary technical and operational guidance regarding various aspects of the program, such as the reporting of multiple best prices in MDRP systems. In addition, we have decided to delay the effective date of the revised definition of best price at § 447.505(a) until January 1, 2022, which will permit manufacturer reporting of varying best price points for a single dosage form and strength as a result of a value based purchasing arrangement that meets the definition at § 447.502.

The delayed effective date of this new policy is the direct result of many commenters who described some of the implementation complexities with this new approach. Over the next year, states, CMS, manufacturers and payers will need to make the necessary policy, clinical, contractual, system, and administrative modifications that will be necessary to give the program the best chance for success. We expect manufacturers may want to initially focus the development of these VBP programs on those drugs and therapies that are the most expensive to the Medicaid program, such as gene and cell therapies, and accelerated approval drugs, so that the VBP arrangement can have the most potential impact on making these drugs more available to Medicaid patients.

Comment: A few commenters requested clarification as to whether the manufacturer reporting multiple best prices is voluntary and requested clarification that if a state does not want to track outcomes or participate in a VBP arrangement, their best price will automatically revert to the traditional method as calculated based on the price of the therapy when it is sold outside of a VBP arrangement.

Response: Manufacturers that want to report multiple best prices associated with its VBP arrangement must offer those VBP arrangements to the states. Otherwise manufacturers will not be permitted to report multiple best prices for their VBP arrangements. If a manufacturer does not want to offer the VBP arrangement to the states, it will only be permitted to report one best price for that drug or biological, and that best price must be inclusive of any and all prices as a result of a VBP arrangement offered on the commercial market. When manufacturers offer the VBP arrangement to the states, states will have the option to enter into these VBP arrangements and be guaranteed a Medicaid rebate based upon the multiple best prices. Or, the state may opt not to participate and continue to receive Medicaid drug rebates calculated based on the best price of the drug outside of a VBP arrangement and that rebate would not be impacted by the multiple best prices reported by the manufacturer for its VBP arrangement.

States that choose not to participate in the VBP arrangement that the manufacturer has made available under the multiple best price approach may want to consider entering into their own CMS-authorized VBP supplemental rebates agreement with the manufacturer. States will need to ensure that a supplemental rebate agreement with the manufacturer is approved by CMS via the existing SPA template process. Rebates received as a result of the CMS-authorized supplemental rebate agreement will be exempt from best price.

Comment: A few commenters urged CMS to clarify that states do not need to seek SPAs to enter into VBP arrangements, whether based upon manufacturer arrangements with commercial payers or on their own.

Response: States are not required to submit a SPA if they seek to enter into VBP arrangements offered by manufacturers as part of the multiple best price approach as these arrangements are not CMS-authorized SRAs. States that wish to enter into their own VBP arrangements with manufacturers, where such prices would be exempt from best price, will continue to be required to submit a template that CMS can approve as part of a SPA process.

Comment: Several commenters wanted states to be protected under the expansion of the definition of best price. Several commenters asserted the proposed changes could bar states from benefiting from the best price under VBP arrangements if a manufacturer chooses to report a range of best prices rather than through a bundled sale and if the state's Medicaid program does not have a VBP arrangement with that manufacturer. One commenter expressed concern that manufacturers could potentially exclude states from a VBP arrangement by extending VBP opportunities exclusively to private payers, leaving states subject to only mandatory rebates on high list price products.

Response: There is no risk to states under the multiple best prices reporting. Manufacturers that want to report multiple best prices associated with their VBP arrangements available on the commercial market must make these arrangements available to the states. In order to participate in the VBP arrangement, states must meet the requirements of the VBP arrangement as offered by the manufacturer. While states will be given the opportunity to participate in these VBP arrangements, they will not be required to enter into these arrangements. States will need to assess whether or not they want to participate in these VBP arrangements and if they do not want to participate in the VBP arrangements using the multiple best prices approach, they may continue to receive Medicaid drug rebates based solely upon the best price available outside of the VBP arrangement (even if the manufacturer offers a VBP arrangement and reports multiple best prices to CMS) and may continue to negotiate supplemental rebates with manufacturers under a CMS-authorized SRA, which could include their own VBP arrangements.

Comment: Commenters expressed concern that the proposed rule will facilitate manufacturers entering into VBP arrangements with commercial payers and will provide little benefit to state Medicaid programs, and stated that the proposal would increase Medicaid drug costs citing their belief that the proposed changes would reduce the total rebates drug manufacturers pay to Medicaid. A few commenters opined that the proposed changes would exacerbate existing best price reporting challenges and make it more difficult for states to ensure drug manufacturer compliance with best price requirements. One commenter noted the proposed changes to best price to facilitate adoption of VBP arrangements would undermine the MDRP and enable manufacturers to significantly reduce or delay the rebates they would otherwise have to pay under current law, thereby increasing Medicaid drug costs.

Response: States will benefit from these multiple best price VBP programs as this approach will allow all states to take advantage of and participate in the VBP arrangements which manufacturers may have been heretofore reluctant to offer because of various reasons, including the requirement that

manufacturers only report one best price per quarter. For example, a significant rebate to a commercial payer for a drug that did not achieve its clinical objectives under a VBP arrangement could reset the best price in Medicaid, and require the manufacturer to give that significant rebate to all Medicaid patients, even if the Medicaid patient taking the drug met the clinical objective.

This multiple best price approach will also protect states that do not want to participate in VBP by requiring that, for a dosage form and strength for a drug for each quarter, that a manufacturer report a best price unrelated to a VBP arrangement, and such best price will reflect the lowest price available to a best price eligible entity that is not participating in the VBP arrangement.

This approach may also reduce the need for additional states, beyond the nine that have approved CMS-authorized SRA VBP SPAs, to submit a SPA to CMS to obtain approval for a template to enter into their own CMS-authorized SRAs with a VBP arrangement. This multiple best price approach will allow any state that wants to participate in a manufacturer VBP arrangement to have the option to do so. As always, states may continue to negotiate additional rebates using CMS-authorized SRAs if they so choose.

Thus, we do not believe states will realize a reduction in the federal Medicaid rebate with the implementation of this policy, and/or if they decide not to participate in the VBP arrangement being offered because in all cases the manufacturer will be required to report a separate best price available outside of the VBP arrangement. The separate best price will be the basis for the Medicaid drug rebates for states that choose not to participate.

Comment: A few commenters expressed concern that the rule as written, does not include a mechanism for states to be aware of commercial VBP arrangements or to ensure outcomes measures in VBP arrangements will exactly match those of any commercial payer in any given quarter during the VBP negotiation process. One commenter noted that states would need to know the terms of the commercial patient outcome-based price concession arrangement to ensure Medicaid rebate amounts are properly determined under the multiple best price approach. Another commenter recommended requiring manufacturers to share specific details of their VBP arrangements with CMS and to allow CMS to develop a mechanism to share certain details with states, so the states may consider a similar arrangement.

Response: Manufacturers that want to report multiple best prices associated with their VBP arrangements in the commercial market will be required to offer these arrangements to the states. We will share these multiple best prices with states as we do other manufacturer pricing benchmarks, such as AMP and unit rebate amounts. The mechanism of how these arrangements will be communicated to the states will be set forth in CMS operational guidance. We will not be a party to any of these VBP arrangements, and therefore, will not be privy to the specifics of the VBP arrangements (for example, the terms of the patient outcomes price concession or responsibility of fees associated with data collection and evaluation) negotiated between the payers, including states, and the manufacturer.

Comment: A few commenters expressed concern that commercial VBPs available on the market may be difficult to apply to the Medicaid market. The commenters noted that this would result in states not being eligible for a best price URA based on payments made under a commercial VBPs. One commenter questioned the validity of applying VBP arrangements from the commercial markets to a Medicaid population as the commenter noted the measures are tied to certain evidence- or outcomes-based measures that were carefully selected and tailored to a specific, commercially-insured population. A few commenters requested CMS clarify that a state Medicaid agency should have in place data collection and adjudication processes, inclusive of dispute resolution, that are sufficiently robust to administer the VBP arrangement to the same degree of reliability as it is administered between a drug manufacturer and a commercial payer.

Response: We appreciate the commenters' concerns about the applicability of some commercial VBP arrangements to the Medicaid population. It is our general impression that in some cases, both Medicaid and commercial payers may have similar patient population characteristics that would allow for the applicability of a commercial payer VBP to Medicaid, and in other cases it may not. In those latter cases, the state will have to determine whether it wants to participate in the VBP arrangement that is being offered on the commercial market, and that the manufacturer is reporting to us and offering to all states. While we are not requiring that manufacturers design their VBP arrangements with Medicaid in mind, we would expect that they will consider this to avail themselves of the regulatory flexibilities being finalized in this rule. We believe this policy will help achieve the goal of increasing Medicaid patient access to new innovative drug therapies.

We also believe that there may be multiple manufacturer VBP arrangements in the market, and our policy requires that manufacturers that want to report multiple best prices associated with their VBP arrangements must offer them to states in order to avail themselves of this regulatory flexibility being finalized in this rule. A state will determine which VBP arrangements might work best with its patient population.

Finally, states can use a CMS-approved supplemental rebate agreement to enter into their own VBP agreements with manufacturers for a drug if none of the multiple best price VBP arrangements reported by manufacturers to CMS for that drug would be useful in that state's Medicaid populations.

With respect to dispute resolution, we would expect that states and manufacturers would continue to work cooperatively to resolve any rebate disputes whether they are related to rebates paid under non VBP or VBP arrangements. We have issued several guidances on dispute resolution (see Manufacturer and State Releases [18]).

Comment: Several commenters requested CMS provide funding for VBP arrangements to provide state Medicaid agencies with funding for IT infrastructure needed for performance tracking and interstate or cross-payer interoperability. Commenters believe that the breadth of possible VBP arrangements could pose a serious financial burden for state Medicaid agencies to monitor and would require significant modification of state and vendor rebate systems to incorporate multiple URAs based on each outcome. Another commenter questioned if states are permitted to contract with vendors to perform patient monitoring of outcomes for VBP arrangements. A few commenters requested CMS offer forms of federal support to help commenters build appropriate infrastructure for these proposed arrangements.

Response: We have no plans to provide federal funding to facilitate states' participation in VBP

[18] *https://www.medicaid.gov/medicaid/prescription-drugs/program-releases/index.html?search_api_fulltext=dispute+resolution&field_date%5Bmin%5D=03%2F21%2F1991&field_date%5Bmax%5D=11%2F16%2F2020&sort_by=field_date&sort_order=DESC&items_per_page=10%23content#content.*

arrangements. States are not required to participate in VBP arrangements and will have to make those decisions based on their own administrative and operational considerations. As stated in response to prior comments, states will have a choice as to whether or not they want to enter into VBP arrangements.

Comment: A few commenters suggested that CMS require manufacturers to submit their commercial VBPs to CMS so that it can inform states of the drugs and outcome measures in those commercial VBPs. Another commenter suggested CMS require manufacturers to ''lock in'' an estimated Best Price for the duration of the contract and apply a CMS-overseen reconciliation process to protect states from the uncertainty the proposed change may create, and that CMS could use the commercial VBPs submitted by manufacturers to develop a VBP contract template that states could use to ensure that they were in alignment.

Response: CMS will be looking at ways to make information regarding manufacturer VBP arrangements that are offered on the commercial market available to states. We will not, however, be involved in the approval or review of the specifics of any VBP arrangements offered by manufacturers to commercial payers; nor will we be engaged in the negotiation of terms between manufacturers and payers or states. Furthermore, we will not be imposing additional requirements or requesting manufacturers change their VBP arrangements when they make their arrangements available to the states. At a minimum, as discussed earlier in this section, states will continue to receive the Medicaid drug rebate for a covered outpatient drug consistent with the separate best price reported by the manufacturer outside of the VBP.

Comment: One commenter requested clarification that the duration of a VBP arrangement contract is a term that a state Medicaid agency would need to adhere to in order to take advantage of the proposed multiple best price approach, as it is central to a VBP arrangement (in the commercial sector or otherwise).

Response: This rule does not speak to the specific terms that should or should not be included in VBP arrangement contracts.

Comment: A commenter recommended that the VBP exemption from best price apply only when a pharmaceutical manufacturer pays for the entire cost of a drug during the entire length of the prescription.

Response: We assume the commenter is under the impression that the multiple best prices as they pertain to VBP arrangement offered on the commercial market allows the manufacturer to exempt those prices from ''best price.'' We are not exempting VBP prices from a manufacturer's best price. Rather, we are allowing manufacturers to report both a non-VBP best price for a drug and multiple best prices for a drug based on a VBP arrangement when the manufacturer offers the VBP arrangement to all states.

Comment: One commenter requested CMS clarify if manufacturers would initially calculate the best price they report to the federal government by looking at the expected net price under the VBP arrangement, based on the expectations of the manufacturer and the private purchaser using available clinical data.

Response: Manufacturers permitted to report multiple best prices pursuant to a VBP arrangement would make two best price reports each quarter to CMS, one that includes the best price of the drug net of any discounts or offsets that are unrelated to the VBP arrangement, and the other that includes the set of multiple best prices offered under the VBP arrangement (offset by applicable discounts) based upon the outcomes of the VBP arrangement.

Comment: One commenter urged CMS to ensure that methods other than the bundled sale concept and the multiple best prices are available to accommodate the unique factors associated with extremely rare disorders.

Response: We believe that the final policies in this rule with respect to reporting best price under a VBP arrangement will accommodate manufacturers of covered outpatient drugs for rare diseases because manufacturers will not face the same rebate consequences if one patient fails on the therapy. Furthermore, the publication of this final regulation does not mean CMS may not consider other approaches addressing unique circumstances as part of a future rulemaking.

Comment: One commenter requested CMS mandate that a manufacturer base its best price reporting on the lowest price available in the marketplace, including one that arises from a VBP arrangement offered in the commercial marketplace (either by using the bundled sale calculation rules or reporting multiple best prices), as well as what the manufacturer offers to any state Medicaid program or Medicaid MCO that wishes to engage in the VBP arrangement.

Response: Manufacturers are already required to report the lowest price available to most entities on the commercial market, as included in the definition of best price at § 447.505(a). This rule does not change that, but rather allows manufacturers to report varying best price points for a single dosage form and strength when it offers a VBP arrangement to all states. If the VBP arrangement is not offered to states, the manufacturer will report one best price for the dosage form and strength of the drug which would include any and all prices and rebates, and subsequent adjustments, associated with the manufacturer VBP arrangements in accordance with the best price requirements at § 447.505.

Comment: Some commenters noted that CMS should clarify that ''any pricing structure'' in the definition of best price is inclusive of any and all pricing structures.

Response: We do not believe it is necessary to further clarify the regulatory language ''any pricing structure'' as used in 42 CFR 447.505(a). We are expanding the definition of best price to allow manufacturers to include the lowest price available from a manufacturer to include varying best price points for a single dosage form and strength as a result of a VBP arrangement. The reference to any pricing structure in this case is made to indicate that we consider a VBP arrangement to be a form of a pricing structure.

Comment: A commenter suggested that for a patient to be deemed to have participated in a VBP, the patient must be a patient covered by a state that has an executed, signed agreement with the manufacturer setting forth the same terms and conditions set forth in the corresponding commercial VBP on which the multiple best prices are based.

Response: Manufacturers will be required to offer the same terms and conditions to states as set forth in its corresponding commercial VBP that is used to set its multiple best prices.

Comment: A few commenters noted that expanding the definition of best price to provide that a lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of a VBP could allow pharmaceutical companies to raise the prices of life indispensable medications. One commenter requested CMS clarify the proposal citing their concern that a single best price for a less effective dosage form and strength could limit the ability of coming to VBPs for other dosages.

Response: We do not believe that this regulation encourages pharmaceutical

companies to raise prices for a single dosage form and strength of a drug. The current Medicaid drug rebate regulation continues to include an inflation penalty in the form of an additional rebate if AMP for the dosage form and strength of a drug increases at a rate greater than inflation (as measured by the consumer price index for all urban consumers—United States average) (see sections 1927(c)(2) and (c)(3)(C) of the Act and § 447.509(a)(2) and (7)). These would apply to drugs that are included under a VBP arrangement. Therefore, the Medicaid drug rebate calculation continues to include a disincentive to manufacturers increasing drug prices.

Comment: One commenter recommended excluding any price concessions received under a VBP arrangement from the best price calculation citing their belief that this would increase the adoption of VBP arrangements.

Response: Section 1927(c)(1)(C)(ii) of the Act provides that the term best price shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under section 1927 of the Act). Therefore, manufacturers must include all discounts available, including discounts as a result of a VBP arrangement in best price. This rule did not propose to add an exclusion of all prices as a result of a VBP arrangement when determining best price. Instead, it allows manufacturers to report multiple best prices associated with a VBP arrangement to reflect the discounts/prices available under these arrangements. Manufacturers must make adjustments to best price for a drug (either for a single reported best price or multiple best price arrangement) as a result of any subsequent discounts or price concessions that may occur.

Comment: One commenter requested guidance on how multiple best prices will be audited, especially if predicated on the attainment of patient-specific outcomes that rely on personal health information that may need to be protected under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted August 21, 1996) (HIPAA) and/or other law or regulation.

Response: We will not audit how multiple best prices will be determined or how the parties participating in the VBP arrangements will measure patient-specific outcomes using potentially protected health information under HIPAA. However, parties participating in these VBP arrangements should be aware of potential HIPAA requirements when patient-specific data is used to measure outcomes. Manufacturer information reported under section 1927 of the Act for purposes of the Medicaid rebate (for example, AMP and best price) is subject to audit by the Inspector General of the Department of Health and Human Services in accordance with section 1927(b)(3) of the Act.

Comment: A few commenters urged CMS to safeguard proprietary pricing information, such as the multiple best prices under a VBP arrangement, the terms of which are confidential between the state or payer and manufacturer.

Response: Information disclosed by manufacturers to CMS in accordance with manufacturer reporting requirements set forth at section 1927(b)(3) of the Act, including pricing information related to the reporting of multiple best prices, will be subject to the confidentiality of information requirements at section 1927(b)(3)(C) of the Act.

Comment: One commenter noted the proposed rule does not explain how manufacturers will report initial prices under a VBP arrangement if those prices vary based on anticipated patient outcomes.

Response: Manufacturers will submit a non-VBP best price following the methodology for determining best prices in accordance with § 447.505. We intend to have the manufacturer report the multiple best prices as a separate file in MDRP systems which we will grant access to states that choose to participate in the manufacturer's VBP arrangement. More information regarding the reporting of multiple best prices in our system will be provided in operational guidance.

Comment: One commenter recommended the Medicaid rebate amount true-up process could utilize one of two existing Reconciliation of State Invoice (ROSI) functionalities: A ROSI functionality applicable to SRA or a ROSI functionality applicable to ''extra rebates.''

Response: We will take this recommendation and welcome additional recommendations regarding the intersection between multiple best prices and the functionality of the ROSI.

Comment: A commenter recommended that CMS require manufacturers to pay interest fees based on the statutory late payment penalty rate in the event that evaluation of outcomes-based measures causes rebates to be delayed.

Response: In accordance with the NDRA, manufacturers will continue to be responsible for timely payment of applicable rebates within 30 days so long as the state invoice contains, at a minimum, the number of units paid by NDC under the state plan in accordance with section 1927(b)(1)(A) of the Act. Manufacturers that do not pay rebates in time, regardless of the reason, must follow existing operational guidance relating to interest application found in various Program Releases, including State Releases #29, and #166, as well as Manufacturer Release #7. Program Releases are here—Medicaid Program Releases.

Comment: One commenter recommended CMS consider coupling this final rule with an OIG proposed rule to create a safe harbor for VBP arrangements for medical products or pursuing future rule-making to produce a new safe harbor from the Anti-Kickback Statute, which might consider manufacturers' data monitoring and outcome tracking activities as unlawful inducement.

Response: This regulation is specific to the impact of VBP arrangements on price reporting associated with the MDRP. We will not be providing guidance to manufacturers regarding how their particular VBP arrangements, including data monitoring and tracking activities, may violate the Anti-kickback statute.

Comment: Many commenters requested clarification of the impact of the proposed multiple best price approaches to AMP, average sales price (ASP), and 340B ceiling price. Several commenters urged CMS to issue additional rulemaking before allowing 340B covered entities to leverage VBP-associated prices and clarify the best price to be used when calculating 340B ceiling price as well as ASP. A few commenters requested that HRSA and Medicare Part B be involved so that CMS can carefully examine the impact of VBP agreements on state budgets, safety net provider participation in the 340B program and other government pricing programs such as Part B (including calculation of ASP). Several commenters recommended that CMS consider revising its proposed approach to VBP arrangements to exclude the arrangements from required government price reporting metrics. The commenter noted this is necessary to incentivize broader adoption of VBP arrangements.

Another commenter expressed their belief that that it is essential to exclude drugs purchased through VBPs from ASP determinations. Commenters expressed concern that outcomes-based price discounts made for VBP arrangements could lower the Medicare Part B Drug ASP, reducing ASP-based reimbursements to providers or pharmacies that purchase the drug therapy. The commenters noted that

discounts under VBP arrangements are granted to payers while providers and pharmacies would experience reduced revenue.

Another commenter requested CMS address the uncertainty VBP arrangements may have on 340B ceiling prices, as well as AMP. Another commenter requested that CMS consider the scope of the discounts that could be included in a bundled sale under the proposed change and what the impact would be on Medicaid rebates and, by extension, the 340B program.

Response: While this regulation allows manufacturers to report multiple best prices associated with their VBP arrangements, manufacturers will continue to be required to report a best price for each dosage form and strength of a drug paid for outside of the VBP arrangement (non-VBP best price). Therefore, the 340B ceiling price will continue to reflect a Medicaid drug rebate based upon the non-VBP best price.

Also, while we do not anticipate that this rule will reduce a drug's AMP, manufacturers should also consider the effects of their VBP arrangements on payment amounts that are determined for use in other parts of Medicare, for example the effects of VBP arrangements on AMP if AMP is used to determine payment allowance for a drug in Part B as authorized in section 1847A(d) of the Act.

In consideration of comments received, specifically those comments that requested clarification regarding the manufacturer's allowance to report multiple best prices, we are revising the definition of best price at § 447.505(a) to state that if a manufacturer offers a value based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value based purchasing arrangement. However, in order to address the operational and administrative challenges facing CMS, states, and manufacturers, as noted in the comments, we are delaying the effective date of this final policy at § 447.505(a) such that the revised definition of best price to permit multiple best price reporting will not be effective until January 1, 2022.

C. Changes to Update Definitions in § 447.502 To Reflect Recent Statutory Changes Made by the MSIAA, BBA 2018 and the Affordable Care Act

1. Innovator Multiple Source Drug

The MSIAA clarified the definition of innovator multiple source drug at section 1927(k) of the Act by removing the phrase ''an original new drug application'' and inserting ''a new drug application,'' removing ''was originally marketed'' and inserting ''is marketed,'' and inserting, '', unless the Secretary determines that a narrow exception applies (as described in § 447.502, Code of Federal Regulations (or any successor regulation))'' before the period. Section 1927(k)(7)(A)(ii) of the Act now defines innovator multiple source drug to mean a multiple source drug that is marketed under a NDA approved by the FDA, unless the Secretary determines that a narrow exception applies (as described in § 447.502 (or any successor regulation)). To align the regulatory definition with the definition in the statute, as clarified by the MSIAA, we proposed to define innovator multiple source drug in § 447.502 as a multiple source drug, including an authorized generic drug, that is marketed under a NDA approved by FDA, unless the Secretary determines that a narrow exception applies (as described in the section). We noted that the proposal also included a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a COD approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA).

We have received the following comments regarding the proposed definition of innovator multiple source drug:

a. Prospective Application

Comment: One commenter requested that CMS revise their proposed definition of innovator multiple source drug to only apply prospectively from October 2019 forward, citing their belief that since this is the date the Congress amended the MDRP statute, it would be in accordance with the recent ruling in the United States District Court for the District of Columbia case of *STI Pharma, LLC* v. *Azar.*

Response: The revision to the definition of innovator multiple source drug is to conform the rule with the amended statute. Our longstanding interpretation of the statute (both before and after the 2019 amendments) is that an innovator multiple source drug is a drug approved under an NDA, and noninnovator drugs are those approved under an ANDA. We believe *STI Pharma, LLC* v. *Azar* was wrongly decided. Prior to the 2016 COD final rule, there was no narrow exception to that general rule. Therefore, any drug approved under an NDA that is reported as a noninnovator multiple source drug for quarters prior to 2Q2016 is improperly categorized and the drug manufacturer should request a drug-category change or risk enforcement action.

b. Narrow Exception

Comment: One commenter recommended that CMS maintain and codify the current factors used to determine if a product meets the narrow exception citing their belief that this would provide clarity to both current and future manufacturers, helping to ensure these products are available and do not go into shortage, and therefore, are available to the patients who need them.

Response: We do not agree that we should codify the factors used to determine if a drug qualifies for a narrow exception to the rule that drugs marketed under an NDA should be reported to us as a single source drug or an innovator multiple source drug. Each request for a narrow exception is evaluated individually and we consider many factors in determining whether to use our discretion to grant such an exception. When reviewing a request for a narrow exception, we may reach out to the manufacturer to request additional information to aid in the review of the request, thereby ensuring that we are making decisions based on all of the information pertinent to the request. We are finalizing the definition of innovator multiple source drug as proposed.

2. Line Extension, New Formulation, and Application of Oral Solid Dosage Form Requirement

Section 1927(c)(2)(C) of the Act defines line extension to mean, for a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse deterrent formulation is an extended release formulation. As discussed in the June 2020 proposed rule (85 FR 37288 through 372289), we proposed to define line extension in the February 2, 2012 proposed rule, but did not finalize a definition in the COD final rule or the April 1, 2019 final rule. We reiterated in the April 1, 2019 final rule that manufacturers are to rely on the statutory definition of line extension at section 1927(c)(2)(C) of the Act, and where appropriate are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension (81 FR 5265).

As discussed in the June 2020 proposed rule (85 FR 37294), after several years of experience with manufacturers self-reporting their line extensions, and numerous inquiries from manufacturers regarding the identification of drugs as line extensions, we have noted inconsistency among manufacturers in their identification of drugs as line extensions. In addition, we expressed concern that manufacturers may have a financial incentive to be underinclusive in their identification of drugs as line extensions because a drug identified as a line extension may be subject to a higher rebate. We noted that if manufacturers underreport their line extensions, rebates may be calculated incorrectly and underpaid.

To ensure that section 1927(c)(2)(C) of the Act is fully implemented and the universe of line extensions is comprehensively identified, we proposed to provide further interpretation of the statute in the June 2020 proposed rule.

Based on the definition of line extension that was included in the Affordable Care Act, we believed that the statute gives us discretion and authority to interpret the term ''line extension'' broadly. We expressly solicited comments on our proposed definitions of ''line extension'' and ''new formulation,'' specifically on whether these terms should be interpreted more narrowly. Moreover, if commenters believed that a narrower interpretation is appropriate, we solicited comments on how to identify those drugs that constitute a line extension and a new formulation to apply the alternative URA calculation when required by statute. The comments we received in response to this solicitation are addressed in section II.C. of this final rule.

In the June 2020 proposed rule (85 FR 37294), we proposed that only the initial single source drug or innovator multiple source drug (the initial brand name listed drug) must be an oral solid dosage form. In the 2012 proposed rule (77 FR 5338, 5339), we proposed that both the initial brand name drug and the line extension drug had to be an oral solid dosage form. However, as noted in the June 2020 proposed rule, we did not finalize a regulatory definition of line extension, and instructed manufacturers to make ''reasonable assumptions'' regarding whether a drug is a line extension (81 FR 5265). The statute states that the alternative calculation must be performed in the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form. Upon further evaluation of this statutory language, we believed that the statutory text can be reasonably construed to provide that only the initial single source drug or innovator multiple source drug must be an oral solid dosage form. We believed this interpretation is appropriate because the alternative construction (requiring both the line extension and the initial single source drug or innovator multiple source drug to be an oral solid dosage form) may inappropriately limit the universe of line extension drugs in a manner which would allow a manufacturer to circumvent rebate liability when creating a line extension and to potentially avoid inflation-based additional rebates, in cases where such rebates should apply. Therefore, we proposed that when determining whether a drug is a line extension, only the initial single source drug or innovator multiple source drug must be an oral solid dosage form. That is, we proposed that the line extension of the initial brand name listed drug does not need to be an oral solid dosage form. We believed this is consistent with the statutory language and will assist in appropriately identifying drugs that may be line extension drugs. Therefore, we proposed to amend § 447.509(a)(4)(i) and (ii) to refer to ''a drug that is a line extension of a single source drug or an innovator multiple source drug provided that the initial single source drug or innovator multiple source drug is an oral solid dosage form,'' and § 447.509(a)(4)(i)(A) and (a)(4)(ii)(A) to refer to ''a single source drug or an innovator multiple source drug'' in the regulatory text that describes the alternative rebate calculation.

We received the following comments regarding our proposal that when determining whether a drug is a line extension, only the initial single source drug or innovator multiple source drug must be an oral solid dosage form:

Comment: A few commenters disagreed with the proposal to require that only the initial single source drug or innovator multiple source drug be an oral solid dosage form when determining whether a drug is a line extension because they claim the proposal does not align with Congressional intent. They stated that the legislative history shows that Congress intended that the line extension provision applies only to drugs that were ''slight alterations'' of the previous drug, and that a change from an oral solid dosage form to a different dosage form is a significant alteration. A few commenters stated that if the change requires submission of clinical data to FDA, it would be a significant alteration. Some commenters, in discussing fixed-dose combination tablets in treating diseases such as HIV, noted that innovations that improve patient compliance provide significant improvements that benefit patients.

Response: We believe that our proposal is consistent with section 1927(c)(2)(C) of the Act. Additionally, the statute does not require that in order for a drug to be a line extension, the change to a drug must be a slight alteration. Had Congress intended to limit the definition of line extension to only those drugs for which a slight alteration had been made, we believe they would have included that requirement in the statute. Notably, the example of a new formulation that Congress provided in the statute is ''an extended release formulation.'' The change from an immediate release formulation to an extended release formulation may be considered more than a slight alteration. We agree with commenters that innovations that improve patient compliance provide significant improvements that benefit patients and believe this may include extended release formulations. Had Congress intended to limit the line extension provisions to drugs that were only slight alterations, we believe they would have provided an example of a less significant change than ''an extended release formulation.''

Comment: A few commenters stated that requiring that only the original single source drug or innovator multiple source drug be an oral solid dosage does not align with the statute. One commenter stated that in the statutory language, in the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, Congress plainly intended for the phrase ''that is an oral solid dosage form'' to modify the term ''line extension.'' They stated that because Congress directly addressed this issue, the agency lacks discretion to define ''line extensions'' to include products that are not oral solid dosage forms.

Response: As stated in the June 2020 proposed rule, we believe that the statutory text can be reasonably construed to provide that only the initial single source drug or innovator multiple source drug must be an oral solid dosage. We disagree that the statutory language clearly indicated that the phrase ''that is an oral solid dosage form'' modifies the term ''line extension.'' Although the structure of the sentence does not make it clear which subject is modified by ''that is an oral solid dosage form,'' we believe that

the better reading is that the phrase modifies ''a single source drug or an innovator multiple source drug'' because it appears directly following that subject.

Comment: A few commenters stated that the proposal to require that only the original single source drug or innovator multiple source drug be an oral solid dosage form is contrary to prior guidance and that the existing interpretation is more reasonable and should be retained. Several commenters agreed with CMS' proposal that the line extension of the initial brand name listed drug does not need to be an oral solid dosage form. A few commenters noted that these definition clarifications will expand the universe of drugs that can be line extensions. One commenter noted that requiring that only the initial drug must be an oral solid dosage form would prevent manufacturers from switching forms to avoid higher inflation-related rebates.

Response: We do not agree that our proposal is less reasonable than the interpretation we discussed in the COD final rule. We acknowledge that in the February 2, 2012 proposed rule, we proposed that both the initial brand name listed drug and the drug that is a line extension were required to be an oral solid dosage form in order for the alternative rebate calculation to be required. However, that proposal was not finalized in the COD final rule. Instead, we stated that we will continue to consider the issues and may consider addressing the issues in future rulemaking (81 FR 5265). We are doing so in this final rule.

After consideration of public comments, we are finalizing our proposal that only the initial single source drug or innovator multiple source drug be an oral solid dosage form when determining whether a drug is a line extension. While we initially proposed amending § 447.509(a)(4)(i) and (ii), we are making a technical change to that proposal to more accurately reflect the prospective applicability of the revised policy. In addition, as discussed in section II.C. of this final rule, we are finalizing that the definitions of line extension, new formulation, and oral solid dosage form, as well as the requirement that only the initial brand name listed drug must be an oral solid dosage form, are effective beginning on January 1, 2022. For prior periods, manufacturers should continue to rely on the statutory definition of line extension and may continue to make reasonable assumptions to determine whether their drug is a line extension. We are amending § 447.509(a)(4)(ii) to change ''beginning on or after October 1, 2018'' to ''beginning on October 1, 2019 through December 31, 2021'', redesignating § 447.509(a)(4)(iii) as § 447.509(a)(4)(iv) and adding § 447.509(a)(4)(iii).

3. Definition of Line Extension

In response to requests to provide more specific guidance on how to identify a line extension drug, we proposed to define ''line extension'' and ''new formulation'' at § 447.502. Specifically, we proposed that as provided in section 1927(c)(2)(C) of the Act, the term ''line extension'' means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary).

Most of the comments we received regarding our proposed definition of ''line extension'' more accurately pertain to our proposed definition of ''new formulation,'' and therefore, we will discuss those comments in section II.C.4. of this final rule. We received the following comment regarding our proposed definition of ''line extension'':

Comment: One commenter supported CMS' proposal to exclude abuse-deterrent formulations from the proposed definition of line extension, citing their belief that this exclusion aligns with the Administration's public health goals, as well as other efforts to reduce rates of opioid abuse in communities.

Response: We thank the commenter for the support and note that section 1927(c)(2)(C) of the Act requires that we exclude abuse deterrent formulations from the definition of ''line extension''.

After consideration of public comments, we are finalizing the definition of ''line extension'' as proposed. In addition, as discussed in section II.C. of this final rule, we are finalizing that the definitions of line extension, new formulation, and oral solid dosage form, as well as the requirement that only the initial brand name listed drug must be an oral solid dosage form, are effective beginning on January 1, 2022. For prior periods, manufacturers should continue to rely on the statutory definition of line extension and may continue to make reasonable assumptions to determine whether their drug is a line extension.

4. Definition of New Formulation

Additionally, we proposed to define ''new formulation'' to mean, for a drug, any change to the drug, provided that the new formulation contains at least one active ingredient in common with the initial brand name listed drug. As discussed in the June 2020 proposed rule (85 FR 37295), new formulations (for the purpose of determining if a drug is a line extension) would not include abuse deterrent formulations but would include, but would not be limited to: Extended release formulations; changes in dosage form, strength, route of administration, ingredients, pharmacodynamics, or pharmacokinetic properties; changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC); and combination drugs, such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device. We requested comments about whether a drug approved with a new indication that is not separately identifiable should be considered a new formulation and, if so, how such a drug could be identified in DDR for purposes of calculating the alternative URA.

We received the following comments regarding our proposed definition of ''new formulation''.

Comment: We received many comments that provided general support for our proposed definition of new formulation. Commenters noted that the proposed definition will help ensure that manufacturers identify all their drugs that are line extensions and will prevent manufacturers from circumventing inflation-based rebates. One commenter stated that the current ambiguity has allowed manufacturers to use ''product hopping'' strategies for financial gain and blocking generic competition.

Response: We appreciate the support from the commenters.

Comment: We received several comments generally opposing the proposed definition. Some commenters generally disagreed with any expansion of the definition of line extension. One commenter opposed any measure that expands rebates because it distorts market dynamics and pushes costs onto every other payer. Another commenter stated that CMS was proposing an expansive change to line extension policies without providing context for the programmatic purpose and goals for a substantial change in disposition impacting many products. One commenter stated that the proposed language is filled with inconsistencies that make the proposals impossible to operationalize.

Response: As explained in the June 2020 proposed rule (85 FR 37294), we have noted inconsistency among manufacturers in their identification of drugs as line extensions. In addition, we expressed concern that manufacturers may have a financial incentive to be under-inclusive in their identification of drugs as line extensions because they

may be able to avoid some of the inflation-based rebates they had incurred because of the increases in the price of the original drug that exceeded the rate of inflation. By making certain changes to the original drug, they were often able to establish a new baseline AMP for the line extension drug and essentially start fresh, without the burden of the inflation-based rebates on the original drug. By proposing a definition which clarifies the attributes of a drug that make it qualify as a line extension drug, we believe manufacturers will have a clearer explanation about how to identify their drugs that are line extensions. We disagree that any measure that expands rebates distorts market dynamics and pushes costs onto other payers and the commenter did not substantiate that assertion. We do not believe that that the definitions we are finalizing in this rule contain inconsistencies, and CMS staff is available to assist manufacturers with any operational questions.

a. Statutory Concerns

Comment: We received one comment stating that our proposed definition is grounded in statute.

We received many comments stating that our proposed definition of new formulation exceeds statutory authority because it is too broad or exceeds what Congress authorized (that is, slight alterations). A few commenters stated that CMS exceeds reasonable statutory interpretation by including several product categories clearly not within the common understanding of new formulation.

A few commenters stated that our use of the term ''any change'' is inconsistent with statute. They stated that because the statute provides an example of a change that is a new formulation (that is, an extended release formulation), that only a change in formulation that is similar to an extended release formulation can qualify as a line extension. A few commenters cited the principle of *ejusdem generis,* stating that per that principle, a general term that follows an enumerated list of more specific terms should be interpreted to cover only matters similar to those specified. One commenter stated that the subset of drugs that can be a new formulation must be directly tied to the physical formulation of the two products.

Response: We disagree that our proposed definition of new formulation exceeds statutory authority or that it is not reasonable. The statute does not define new formulation and it provides only one example of a new formulation, that is, an extended release formulation. The example provided does not expressly limit the types of new formulations that are to be treated as line extensions; rather, using the term ''such as,'' Congress provided one example of a new formulation. Had Congress intended to limit the definition to certain types of changes to a drug, it could have done so in the statute.

Regarding our proposed use of the phrase ''any change'', that phrase was followed by specific inclusions and exclusions so that the final definition did not state that any change to a drug qualified the drug as a new formulation. However, the definition we are finalizing in this rule does not contain that phrase.

We disagree that the principle of *ejusdem generis* applies because Congress did not provide a list of types of changes to a drug that should be considered a new formulation. Had they provided a list of changes to a drug that all had similar attributes, then it possibly could be interpreted that a new formulation must have a similar attribute to the types of changes in that list. Additionally, the general term (new formulation) precedes the more specific term (extended release formulation), further indicating that *ejusdem generis* is not applicable here. We do not believe that the language Congress selected limits the definition of new formulation to include only an extended release formulation of the original drug or a change that is closely related to an extended release formulation. Congress merely provided one example of a new formulation, that is, an extended release formulation.

b. Congressional Intent

Comment: A few commenters stated the proposed definition of new formulation is consistent with the intent of Congress. One commenter stated that the intent was to provide protection to taxpayers from drug company pricing practices which are the primary factors in spending increases and that the proposed definition furthered that intent. Another commenter stated that if Congress wanted a more limited definition, it would have included that in the statute; however, it left the interpretation to the Administration. The commenter noted that committee reports show that Congress knew there were multiple ways that a drug could be modified to avoid additional rebate obligations.

Response: We thank those commenters who agreed that our proposed definition is not contrary to Congressional intent. We believe that our proposal is consistent with section 1927(c)(2)(C) of the Act. We do not believe that the modification has to have been made for the purpose of avoiding inflation-based rebates. Rather, the alternative rebate calculation would result in a unit rebate amount that is higher than the standard unit rebate amount when price increases of the initial brand name listed drug exceed the rate of inflation regardless of the reason for the modification.

Comment: Many commenters stated that the proposed definition disregards the intent of Congress and the legislative history. Commenters stated that Congressional intent was to capture slight alterations of existing drugs and the legislative history mandates a narrow reading of the statute. One commenter stated that the legislative history makes it clear that a new formulation is only a slight alteration in an existing drug where no additional studies are required by FDA but the proposed definition captures more than slight alterations. Commenters stated that Congress did not intend to include innovative products and new formulations that provide significant benefits to patients in the definition of line extension. One commenter stated that even after CMS recognized that many combination drugs are not slight alterations, we nonetheless included them in the proposed definition.

Response: We disagree that our proposed definition exceeds what Congress intended in the line extension provisions. We are aware that there have been discussions about slight alterations made to a drug and those alterations permitted a manufacturer to mitigate the effect of inflation-base rebates on the original drug, however, Congress chose not to include that language, or any similar language, when constructing the statutory language. Additionally, Congress did choose to include an example of one change that is a new formulation. The example given is an extended release formulation, which in general is a change to a drug for which FDA requires additional studies and may be considered a significant change to an original drug. Had Congress intended that the change be slight in order to be considered a new formulation, it could have stated so. The change from an immediate release drug to an extended release drug is not a slight change; there may be significantly different technology involved. Therefore, as Congress had considered slight alterations to a drug in their discussions of line extensions, but chose not to include that limitation in statute, and, as Congress ultimately included a more complex change (that is, an extended release formulation) as an

example of a new formulation, we believe that section 1927(c)(2)(C) of the Act is not limited to only slight alterations.

Similarly, Congress could have included language that excluded new formulations that were innovative or provided significant benefits to patients. However, not only was such language not included in the statute, but the only example of a new formulation that was provided (that is, extended release formulation) can provide significant benefits to patients.

c. Prior Guidance

Comment: Several commenters pointed out that some parts of the proposed definition of new formulation conflicts with prior guidance. One commenter stated that prior guidance provided that both the original drug and the line extension drug must be an oral solid dosage form for the application of the alternative rebate formula to be required and that manufacturers have been relying on that guidance for a long time. The commenter stated that the prior guidance is reasonable and appropriate.

Several commenters noted that in the COD final rule, CMS stated that a new strength is not a line extension and provided rationale that the statute did not contemplate that it is. A few stated that our reversal of that position is being done without adequate justification and is arbitrary and capricious.

A few commenters stated that prior guidance instructed manufacturers to rely on the statutory definition to determine if a drug is a line extension and that they may use reasonable assumptions to make that determination.

Response: In the COD final rule, we advised that we were not finalizing a definition of line extension at that time and we reiterated that manufacturers are to rely on the statutory definition of line extension and where appropriate are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension drug. We also stated that if we later decide to develop a regulatory definition of line extension drug, we will do so through our established Administrative Procedures Act compliant process and issue a proposed rule. We have done so by issuing the June 2020 proposed rule and this final rule. We have 10 years' experience with various aspects of the line extension provisions that were enacted in the Affordable Care Act and are using our experience to develop a definition of new formulation that we believe is supported by the statute, and supports the MDRP. We do not believe that any changes we have made to prior guidance conflict with the statute or are unreasonable or unjustified in light of the proposed changes.

d. Effect on Patients

Comment: We received many comments that the proposed definition of new formulation would negatively affect patients. Several commenters stated that patients might be denied access to drugs that are line extensions, as designating some of these new drugs as line extensions might create disincentives for manufacturers to develop such new formulations. Several commenters stated that the proposals will cause states to change their preferred drugs list which will cause changes in patients' drug regimen, resulting in increased medical and drug expenditures due to health consequences of medication changes. Some commenters stated that manufacturers would be less likely to make drugs that would be subject to the alternative rebate calculation, thereby decreasing patients' access to innovative drugs that may benefit them in terms of compliance or side effects. Some commenters stated that this would lead to poorer health outcomes. One commenter stated that the broad definition would impact its ability to provide discounts outside of the Medicaid program that aid patients in other safety-net programs.

Response: We do not agree with the commenters who stated that patients would be harmed because manufacturers will not have incentive to research and develop innovative alternatives that may be considered new formulations and therefore subject to the alternative rebate calculation. Based upon the comments received in response to the proposed definition of line extension and new formulation, the definition was further refined to limit the scope of drugs that are new formulations and thereby subject to the alternative rebate calculation. Because we are not finalizing that certain changes to a drug result in a new formulation, as described later, there is a significantly smaller universe of drugs that will be subject to the alternative rebate calculation. We believe that with the exclusion of these proposed changes from the final definition of line extension, that we have maintained incentives for manufacturers to bring such advances to the market.

Market forces and competition may help determine whether such new formulations are in fact significant clinical advances, given that payers are likely to impose utilization restrictions around their use if they are not. Manufacturers' decisions regarding those drugs to research and market depend on multiple factors, including clinical significance of the drug, prescriber and patient demand, costs of research and development, and possible revenues generated. Whether the drug is a line extension, which could subject it to the alternative rebate calculation, is only one factor in these decisions. The financial effect of the alternative rebate calculation would only be applicable in the Medicaid program, and the new drug may have only limited use in Medicaid. For these and other reasons, we believe that it will continue to be in the interest of a manufacturer to broaden the use of its existing drugs in the form of line extensions, which will lead to increased revenue for the manufacturer.

For those drugs that have a broader use in Medicaid, such as HIV combination drugs, we note that we have decided at this time not to include new combinations in the final regulatory definition of new formulation. We also point out again, that the development of a new formulation does not automatically mean that a manufacturer will be penalized by the alternative rebate calculation for marketing that new formulation. There would only be an alternative inflation penalty on the new formulation to the extent that the increase in price on the initial drug was greater than inflation. Thus, manufacturers that have excessively inflated the price of their older existing drugs, and attempt to market a new formulation to avoid paying inflation penalties on those older existing drugs, may have to pay the alternative inflation penalty on the new formulation. The possibility of paying this penalty would be one consideration that manufacturers would have to take into account when developing a new formulation of an existing oral solid drug, but any increase that they would have to pay over the standard rebate amount would be a result of an increase in prices faster than inflation on these drugs.

We believe that the existence of the alternative inflation calculation requirement can also help serve the interests of the broader population with respect to drug pricing. A manufacturer that knows that an intended new formulation could be subject to an alternative inflation penalty if it excessively inflates the price of its initial oral solid drug, could limit price increases on the initial drug.

We understand that states may wish to reevaluate their preferred drug lists if manufacturers alter their existing state

supplemental rebate agreements. However, we understand that such reevaluation by states occurs on a regular basis, as it does with non-Medicaid insurers. We are confident that state Medicaid programs can continue to effectively manage shifting preferred drug lists and provide appropriate, cost-effective therapies to their beneficiaries as they have been doing. As a result of possible potential increases in the net cost of drugs that are line extensions to a state due to loss of rebates, the state may prefer a drug that is not a line extension. However, per section 1927(d)(4)(D) of the Act, the state plan is required to cover a non-preferred drug pursuant to a prior authorization program that is consistent with section 1927(d)(5) of the Act.

e. Effect on Innovation

Comment: We received many comments addressing the effect that the proposed definition of new formulation will have on innovation. A few commenters stated that they believed the broad definition would be unlikely to have a negative effect on innovation. A few commenters stated that the proposed definition would encourage ''true innovation'' and discourage manufacturer's incentive to ''product hop'' or to seek approval for so-called ''me too'' or patent-extending formulations.

We received many comments discussing that the proposed definition will have a negative effect on innovation by discouraging, disincentivizing or penalizing innovation. In addition, one commenter stated that CMS should not disrupt the innovation cycle that allows manufacturers to take on the challenges of innovation. One commenter stated that the proposed definition could make innovation financially untenable for manufacturers. Several commenters discussed that reducing incentives for innovation, research and development, which are long-term, high-risk and expensive investments, will affect clinical outcomes. A few commenters expressed concern that the proposed definition will stifle the development of new and innovative therapies with particular concern for drugs that treat rare diseases. One commenter stated that the proposed definition distorts incentives to innovate because new active ingredients would be incented over other changes, even though new uses, dosage forms, and combination drugs require significant innovation and may lead to important advancements. Several commenters stated that the proposed definition undermines, or is inconsistent with FDA policies and incentives that encourage innovation.

One commenter stated that the proposed definition of new formulation will result in higher rebates for drugs that are line extensions and because of the higher rebates, 340B prices will be decreased. They stated that lower 340B prices will lead to less incentive for manufacturers to invest in research and development.

Response: We disagree that the definition of new formulation penalizes innovation. If the alternative calculation for a drug that is a line extension results in a higher URA than the standard rebate calculation, it is because the original drug was subject to inflation-based penalties. Therefore, the most important variable that determines if the applicable URA is based on the alternative rebate calculation, rather than the standard calculation, is whether the original drug increased faster than the rate of inflation. The perceived ''penalty'' for a drug that is a line extension is not a penalty on the new drug, rather it is a continuation of the ''penalty'' on the original drug. We agree that the treatment of a line extension drug may result in a URA that is greater than the standard rebate amount, however we do not believe that this treatment would prevent a manufacturer from pursuing innovation. The fact that the innovation may lead to a higher rebate obligation for a drug that is a line extension is not the result of the innovation. Manufacturers will continue to have incentives to innovate based on multiple factors, as noted in the previous response to a comment. In addition to previously described factors, we understand various FDA policies encourage innovation. We do not believe the proposed definition of new formulation changes those FDA policies and incentives.

Regarding the comments that Medicaid rebates will increase and 340B prices will decrease, it is important to note that the alternative calculation does not categorically result in a higher URA for a drug, as there are many factors that enter into the calculation. One of the most important factors in the calculation is the inflation-based rebate that is applied to the initial brand name listed drug for the rebate quarter being calculated. Regardless of the price of the new formulation, if the initial brand name listed drug did not increase in price in excess of the rate of inflation, then the alternative rebate calculation for the line extension should not result in a higher URA than the standard calculation for the drug that is a line extension. However, even in the event that the definition of new formulation results in a decrease to a 340B price, we believe our proposed definition is consistent with section 1927(c)(2)(C) of the Act. We do not believe that decreases in 340B prices will lead to less research and development for same reason that we believe that URA increases will not lead to less innovation.

f. Effect on Manufacturers

Comment: A few commenters described the negative effects that the proposed definition of new formulation will have on manufacturers. A few commenters stated that the proposal would reduce revenue for manufacturers, including decrease revenue due to reduction in 340B prices. One commenter stated that the proposed definition is unnecessarily burdensome on manufacturers. One commenter stated that the proposed definition will cause manufacturers to use existing rebates from the original drug that could be years old.

Response: Applying the alternative rebate calculation should not categorically lead to decreased revenue for a manufacturer; rather, it continues to apply the inflation-based rebate that applies to the initial brand name listed drug. The alternative rebate calculation limits the ability of a manufacturer to negate those inflation-based rebates. We understand that if the alternative rebate calculation leads to a URA that is higher than the standard URA for a new formulation, a manufacturer may not ultimately attain the same revenue as if the alternative rebate calculation was not required. However, by interpreting the statutory definition, and providing this clarification to manufacturers, we are assisting manufacturers in ensuring their compliance with section 1927(c)(2)(C) of the Act.

g. Effect on States

Comment: A few commenters pointed out that any increase in rebates due to the alternative rebate calculation for drugs that are line extensions are offset to the federal government. The commenters stated that states would likely suffer a loss because of the offset and because manufacturers that were providing supplemental rebates to the states for these drugs would likely discontinue those supplemental rebates. Commenters stated that this change in supplemental rebates would lead to the states having to reevaluate their preferred drug lists to ensure that preferred drugs are most cost-effective.

One commenter noted that if the definition was enacted retroactively, it would create an administrative burden for the states and that states would owe money to CMS back to 2011.

Response: The statute provides that any increase in rebates resulting from the alternative calculation for drugs that are line extensions are to be treated as an offset to federal financial participation provided to a state as specified at section 1927(b)(1)(C) of the Act. We understand that states may wish to reevaluate their preferred drug lists if manufacturers alter their existing state supplemental rebate agreements. However, we understand that such reevaluation by states occurs on a regular basis, as it does with non-Medicaid insurers. We are confident that state Medicaid programs can continue to effectively manage shifting preferred drug lists and provide appropriate, cost-effective therapies to their beneficiaries as they have been doing.

The definitions of line extension, new formulation, and oral solid dosage form being finalized in this rule will be effective beginning on January 1, 2022 and will therefore not result in states owing money to CMS for retrospective application.

h. Recognizing Benefits of New Formulations

Comment: A few commenters stated that the proposed definition of new formulation fails to take into account the value of improvements and innovation. One commenter stated that the policy explicitly fails to differentiate between innovation and non-substantive formulation changes. A few commenters stated that CMS fails to recognize the effort and expense that go into developing new formulations and combinations drugs.

Response: We do not believe that the statute requires that the treatment of a drug that is a line extension is dependent on the extent of the improvements, the value of the innovation, or the expense that manufacturers incur when developing new formulations. If Congress had intended these factors to limit the scope of drugs that are line extensions, it would have provided as much in statute. While CMS recognizes the value of innovation and improvements, we also recognize the importance of giving full effect to the statute.

i. New Combination Drugs and Drug/Device Combinations

The statutory definition of line extension does not expressly exclude new combination drugs, such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device, and, as noted in the June 2020 proposed rule (85 FR 37295), our proposed definition of new formulation includes new combination drugs provided that the new formulation contains at least one active ingredient in common with the initial brand name listed drug. It also provided that a drug/device combination is a new formulation.

As noted in the COD final rule (81 FR 5197, 5265 through 5267), we received numerous comments regarding our proposal in the February 2, 2012 proposed rule to include combination drugs in the definition of line extension. In particular, commenters were concerned that our proposal required sharing of proprietary pricing information with competitors. We believed that the commenters' concerns have been mitigated by § 447.509(a)(4)(iii), which requires the additional rebate to be calculated only if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug. Therefore, in the June 2020 proposed rule, we clarified that while our proposed definition of new formulation includes combination drugs, the alternative URA calculation is only required under § 447.509(a)(4)(iii) for a rebate period if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug.

Furthermore, we noted that in the event that the initial brand name listed drug is a combination drug, neither the statutory definition of line extension nor our proposed definitions of line extension or new formulation exclude new formulations of combination drugs. For example, if an initial brand name listed drug is a combination drug consisting of an approved drug plus a new molecular entity, and FDA subsequently approves a new drug consisting only of the new molecular entity, then we would consider the new drug to be a new formulation of the initial brand name listed drug because it would constitute a change to the initial brand name listed drug and contains at least one active ingredient in common with the initial brand name listed drug.

As previously stated, we believed we have the discretion and authority to include a broad range of drugs as a line extension, including combination drugs. However, we also noted that we are aware that some combination drugs appear to be slightly different from an existing drug while other combination drugs are very different drugs than the initial brand name listed drug. For example, if a new combination drug contains a new molecular entity in combination with a previously approved drug, the resultant new combination may appear to be very different from the initial brand name listed drug, however, we believed that it is a new formulation of an initial brand name listed drug. Conversely, we believed that a new combination of two previously approved drugs, or a combination of a previously approved drug and a non-drug product (for example, a dietary supplement or a device), may not be a significant alteration even though it also is a new formulation of an initial brand name listed drug. Given that different commenters have differing thoughts on what constitutes a new formulation of an initial brand name listed drug, and our attempt to provide a reasonable interpretation of the statute to define or describe what constitutes a change that should be considered a new formulation, we solicited comments that may provide a way to define and identify those combination drugs that should be identified as line extensions while excluding those combination drugs that should not be so identified.

We did not receive any comments specific to our solicitation regarding a method to differentiate between combination drugs that should be identified as line extensions while excluding those that should not be so identified. However, we received the following comments regarding our proposal to include a drug that is a new combination in the definition of new formulation:

Comment: A few commenters supported CMS' proposal to include combination drugs in the proposed definition of line extension citing their belief that the proposal could incentivize investment in new drug development rather than less innovative changes and is not expressly excluded by statutory language. One commenter encouraged CMS to recognize as line extensions all combination drugs that include a previously approved drug citing their belief that this would ensure that the Medicaid program is not unduly harmed by manufacturers' choices in product life cycle management.

Many commenters disagreed with CMS' proposal to include combination drugs in the proposed definition of line extension citing their belief that it is contrary to Congressional intent, FDA policies, and statute, minimizes the significant advancements represented by combination drugs, undermines clinical breakthroughs/innovations, especially in the HIV treatment arena, and could be difficult to implement.

One commenter noted that CMS proposes to include certain combination drugs despite the fact that these products may offer a treatment for a novel patient population or even include a new molecular entity. Another commenter noted the proposal is unreasonable, stating that it is impossible to apply the alternative URA formula to combination products. One commenter stated that subjecting combination drugs to the alternative rebate calculation will have unintended pricing consequences. Several commenters disagreed with CMS' proposal to include combination drugs because they stated that the Congress intended the line extension rebate calculation to apply to a single drug as demonstrated by the Congress's deliberate and intentional use of the singular form to describe each drug subject to the line extension drug provision. One commenter disagreed with CMS' proposed definition of new formulation to include a drug that is a combination of a drug and a device citing their belief that combination products, which could include without limitation a drug/biologic active ingredient combined with a medical device, are not similar to extended release formulations, and therefore, cannot qualify as a line extension under the statutory definition. One commenter expressed concern that combination products currently account for substantial federal and supplemental rebates and the high federal rebates on the original products would severely weight the rebate distribution in favor of the federal government, causing an impact to states, who may in turn move line extension products to non-preferred status even if utilization is high, assuming comparable clinical options exist.

Response: We believe that we have statutory authority to include new combination drugs and drug device combinations in the definition of new formulation; however, based on the comments, we have decided not to include a new combination of drugs, and a drug/device combination as a new formulation.

It is important to note that combination drugs are not necessarily excluded from the definition of a new formulation. If an initial brand name listed drug is a combination of two or more drugs, and then a manufacturer begins selling a new formulation of that combination drug, then the new drug satisfies the definition of a new formulation and must be identified as a line extension. For example, consider two single-ingredient drugs, Alpha and Beta. A new combination of these two drugs, AlphaBeta, is not considered a new formulation for the purposes of the line extension alternative rebate calculation. However, a later developed new formulation of AlphaBeta, for example, AlphaBeta XR, is a new formulation with AlphaBeta representing the initial brand name listed drug.

Based on the comments received, we will not be finalizing our proposal that a drug that is a new combination is included in the definition of new formulation.

j. Active Ingredient

Comment: A few commenters agreed with CMS' proposal that ''the new formulation contains at least one active ingredient in common with the initial brand name listed drug'' citing their belief that this would allow manufacturers and CMS to readily answer the threshold question as to whether a product is a line extension. One commenter specifically supported CMS's proposed use of active ingredient to identify a new formulation.

A few commenters disagreed with CMS' proposal that ''the new formulation contains at least one active ingredient in common with the initial brand name listed drug'' citing their belief that comparing active ingredients is technically complicated, the proposal is unworkable in practice and indicative of a policy that stretches beyond CMS' authority. One commenter expressed their belief that defining ''new formulation'' by reference to active moiety would require manufacturers to unnecessarily expend time and resources in identifying original drugs, when doing so could be unlikely to lead to the application of the alternative URA formula. One commenter recommended that CMS modify the proposed definition of new formulation to expressly exclude combination products and clarify that a new formulation must contain the same one active ingredient in common with the original drug, not ''at least one.'' Another commenter requested that CMS clarify that each line extension should have only a single original drug, which is the drug first approved by FDA that contains the same active ingredient as the line extension.

Response: We included the proposal that a new formulation that contains at least one active ingredient in common with the initial brand name listed drug because we proposed that a drug that is a new combination should be identified as a line extension if the new combination contained one of the same active ingredients as the initial drug. We were using that common active ingredient to make the link between the original drug and the drug that is a new combination. As stated, we are not finalizing that new combinations are new formulations and therefore we are not finalizing that the original drug and the drug that is a new combination have an active ingredient in common.

k. New Indication

In the February 2, 2012 proposed rule, we proposed that a drug approved with a new indication for an already approved drug would be a line extension (77 FR 5323). We received several comments stating that the proposal was not feasible because the approval of a new indication for an already approved drug may not result in a different drug product and it would not be logical that a drug is a line extension of itself. Additional commenters noted that it is not possible to apply the alternative line extension calculation to rebate invoices for an NDC only for those claims that were prescribed the newly approved indication. In the June 2020 proposed rule, we agreed that if following the approval of a new indication a manufacturer markets its drug in such a way that it is not a separately identifiable drug product the alternative URA calculation would not apply. However, if following the approval of a new indication the manufacturer markets the drug in such a way that it is a separately identifiable drug product, we proposed that the alternative URA calculation would apply. Thus, as discussed in the June 2020 proposed rule, we proposed a definition of new formulation that included changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC).[19] We requested comments about whether a drug approved with a new indication that is not separately identifiable should be considered a new formulation and, if so, how such a drug could be identified in DDR for purposes of calculating the alternative URA.

We believed that the Congress included the alternative URA calculation for a line extension to address changes to a drug that allow a manufacturer to avoid inflation-based additional rebates by establishing a new

[19] An NDC comprises three segments. The first segment is a labeler code, associated with the labeler, the second segment is a product code, which in association with a specific labeler code identifies the product, and the third segment is a package code, which, in association with the preceding segments, identifies the package size and type. For purposes of reporting to the MDRP, FDA's 10-digit NDC must be converted to an 11-digit NDC. The 9-digit NDC cited here is a combination of the labeler code plus the product code. FDA requirements for an NDC are at 21 CFR 207.33.

market date and base date AMP for the drug. We noted that we agreed with the comments suggesting that if there is a change to a drug but that drug is not separately identifiable, then it is not feasible for the manufacturer to identify the drug as a line extension and perform an alternative URA calculation.

In response to our request for comments about whether a drug approved with a new indication that is not separately identifiable should be considered a new formulation and, if so, how such a drug could be identified in DDR for purposes of calculating the alternative URA, we did not receive specific suggestions. However, we received one comment asking for clarification on what marketing measures, other than a different NDC, would qualify a drug with a new indication as a new formulation. We received the following comments regarding the inclusion of ''new indication'' in the definition of new formulation:

Comment: Many commenters disagreed with CMS' proposal to include ''changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC)'' as part of the proposed definition for new formulation citing their belief that the proposal is overly broad, conflicts with Congressional intent, FDA policies, and CMS' statutory authority, it would disincentivize manufacturers to provide treatment options for rare disease patients, the proposal does not reference the scope of the changes involved where FDA approves a new indication, could freeze or slow research and investment into orphan drug indications, and could adversely impact the COVID–19 pandemic by chilling innovation. One commenter requested that CMS not consider new or expanded indications to treat chronic conditions such as psoriatic disease as a new formulation under the proposed ''line extension'' definition. One commenter expressed their belief that in the case of a new indication—the parent and child drug are the very same drug—and applying the alternative rebate formula will pose problems as the line extension and the parent drug would have the same AMP, and thus, the same rebate. One commenter expressed concern that obtaining approval for new indications of existing therapies can require significant investments in research and development, including new clinical studies. One commenter noted that the introduction of a new indication can have significant benefits for patients. Another commenter was concerned that when a drug is approved with a new indication that is not separately identifiable, considering it a new formulation would create a number of implications on stakeholders throughout the drug delivery system. One commenter stated that a new indication of a drug is not a new formulation because a change to the label of a drug to reflect a new indication does not change the chemical composition of a drug, even if the new indication is marketed as a ''separately identifiable drug.'' One commenter recommended that CMS limit the definition of ''line extension'' to those formulations that are not legitimately distinct products.

A few commenters agreed with CMS' proposal to include ''changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC)'' as part of the proposed definition for new formulation. As stated previously, one commenter recommended that CMS clarify what marketing measures other than a separate NDC would qualify to minimize confusion between manufacturers and CMS.

Response: We believe that we have statutory authority to include a drug that has been approved for a new indication in the definition of new formulation, however, based on the comments, we have decided not to include a new indication accompanied by marketing as a separately identifiable drug (for example, a different NDC) in the definition.

It is important to note that drugs approved for a new indication accompanied by marketing as a separately identifiable drug are not necessarily excluded from the definition of a new formulation. If a drug is approved for a new indication and is marketed as a separately identifiable drug, and also includes one of the changes in formulation that qualifies a drug as a new formulation, then that drug is included in the definition of a new formulation. For example, if an initial brand name listed drug is approved for a new indication, assigned a different NDC, and marketed in a different dosage form than the initial drug, such drug is a new formulation subject to the alternative rebate calculation.

Based on the comments received, we will not be finalizing our proposal that a change in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC) is included in the definition of new formulation.

l. New Strengths

In the COD final rule (81 FR 5267), we indicated that we do not consider a new strength of the same formulation of the initial brand name listed drug to be a line extension because section 1927(c)(2)(C) of the Act does not expressly contemplate that a new strength is a line extension. As noted in the June 2020 proposed rule though, we did not finalize a regulatory definition of line extension, and instructed manufacturers to make ''reasonable assumptions'' regarding whether a drug is a line extension. As noted in the June 2020 proposed rule (85 FR 37295), we proposed to interpret the definition of line extension more broadly, which included proposing a much broader definition of new formulation. The statutory definition of line extension does not expressly exclude a new strength of a drug, and we believed a change in strength is a relatively simple modification to a currently marketed product. Furthermore, changing the strength of an initial brand name listed drug allows a manufacturer to establish a new base date AMP, thereby avoiding inflation based rebate liability, which may incentivize a manufacturer to change the strength of a drug that is losing its exclusivity or patent protection to prolong the lifecycle of the drug, preventing money saving generic substitution. Therefore, we believed that a new strength of a drug, produced or distributed at a later time than the initial strength(s), should be identified as a line extension and made subject to the line extension alternative URA calculation. Therefore, as noted in the June 2020 proposed rule, we proposed a definition of new formulation that included changes in strength.

We received the following comments in response to including a new strength in the definition of new formulation:

Comment: A few commenters agreed with CMS' proposal that ''a new strength of a drug, produced or distributed at a later time than the initial strength(s), should be identified as a line extension and made subject to the line extension alternative URA calculation'' citing their belief that this will expand the universe of drugs that can be line extensions and that CMS is correct in its characterization of manufacturer product life cycle gaming and the unintended consequences for both patients and the Medicaid program that results from this behavior.

Response: We appreciate the support.

Comment: Several commenters disagreed with the proposal that ''a new strength of a drug, produced or distributed at a later time than the initial strength(s), should be identified as a line extension and made subject to the line extension alternative URA calculation'' citing their belief that the

proposal conflicts with prior CMS guidance, statute and Congressional intent. A few commenters stated that since CMS previously stated that they did not believe the statute indicated that a new strength was a line extension, and that the statute did not change, that CMS is making a change in policy without appropriate explanation. They noted that CMS does not provide a policy rationale for why a new strength of an existing formulation would meet the statutory definition for a new formulation. A few commenters pointed out that CMS stated that the statute does not prohibit a new strength from being identified as a line extension but that the lack of prohibition does not mean that it is permissible or advisable.

Response: We believe that our proposed definition of new formulation is consistent with section 1927(c)(2)(C) of the Act, and that it give us discretion to include a new strength in the definition. Although in the 2016 COD final rule we did not include a new strength in the definition of line extension, our continued experience with the application of the statutory provisions for drugs that are line extensions resulted in a reevaluation of our prior position.

Comment: A few commenters stated that the proposed definition of new formulation conflicts with the FFDCA and FDA regulatory understanding of ''formulation''.

Response: FDA and CMS each have different functions and responsibilities and we do not believe that the same terms need to be defined or interpreted in the same manner. We note that CMS and FDA may use the same terms differently for purposes within their own programs and consequently do not agree that the interpretation of terms must always be the same. Until the January 1, 2022 effective date of the definition of new formulation, manufacturers may continue to refer to the statutory definition of line extension and use reasonable assumptions, if necessary, to determine if their drug is a new formulation.

Comment: A few commenters expressed their belief that CMS does not understand the patient needs and/or reasons that different strengths serve, manufacturers may be discouraged from taking steps that would expand patients' treatment options, and manufacturers may be penalized for investing in and pursuing additional improvements to a drug. One commenter stated that despite the proposed rule's suggestion that a new strength is a ''simple modification,'' such a change must be supported by data—which may require conducting clinical trials—and receive FDA approval. One commenter suggested that a new strength might be approved for a drug in connection with a new indication for a drug and that would be a significant change.

Response: We disagree that we do not understand the reasons that different strengths may be developed. We believe that the introduction of a new strength of a drug, regardless of the reason a manufacturer may begin marketing such new strength, is a new formulation that is subject to the alternative rebate calculation. Although we understand there may be a variety of reasons a manufacturer may pursue FDA approval of a new strength of a drug, we do not believe that the reason for creating a new strength affects whether the new strength is a new formulation and thereby required to calculate the alternative rebate for a drug that is a line extension.

We also do not believe that the requirement to perform the alternative rebate calculation penalizes a manufacturer for pursuing changes to a drug. If the initial strength(s) of the drug did not increase in price faster than the rate of inflation, then the alternative calculation for the new strength will generally not result in a higher rebate than the standard calculation. Although the alternative rebate calculation may result in a higher URA for a drug, as compared to the standard URA, the higher URA is not due to the innovations in the new formulation. Rather, if the alternative rebate calculation results in a URA that is higher than the standard calculation, it is because the *original* drug increased in price faster than the rate of inflation and therefore was subject to inflation-based additional rebates.

Thus, an alternative rebate calculation that results in a higher rebate than the standard calculation is not a result of the improvement to the drug, but rather the price increases on the original drug that exceeded the rate of inflation.

Comment: A few commenters stated that the statute was focused on a change in dosage form, and did not discuss a change in strength. A few commenters expressed their belief that the inclusion of a new strength in the definition of new formulation conflates the concepts of ''strength'' and ''dosage form''—concepts that the statute treats as distinct—in a way that is contrary to Congressional intent. The commenters point out that either a change in strength or a change in dosage form may lead to the establishment of a new base date AMP. They noted that since the line extension provision provides a different dosage form as an example of a line extension (that is, an extended release formulation), that only a change to the dosage form (that is, not a change in strength) qualifies a drug as a line extension.

Response: We do not agree that we are conflating ''strength'' with ''dosage form.'' We agree with the commenter that a change in strength or a change in dosage form may be reason to establish a new base date AMP. However, the line extension provision in the statute does not rely on whether the change to a new formulation is a reason to establish a new base date AMP, nor does it preclude considerations of changes in strength.

Comment: Several commenters expressed concern with operational challenges if a new strength could be a line extension. They stated that since one of the variables in the alternative rebate calculation was subject to *any* strength of the original drug, the calculation is difficult, illogical, or impossible.

Response: We understand that the statutory requirement to apply the alternative rebate calculation to a drug that is a line extension may be operationally confusing and difficult, but we do not believe that that it is illogical or impossible. As always, CMS staff is available to assist manufacturers with operational concerns.

Comment: A few commenters stated that CMS presupposes that a manufacturer creates a new strength for the purpose of avoiding inflation-based rebates, or to avoid generic competition. One commenter stated that concerns about generic competition is irrelevant to whether a drug is a line extension and CMS does not have authority to address patent or generic competition issues.

Response: We do not believe that a new strength is necessarily created for the purpose of avoiding inflation-based rebates or to address generic competition. We also do not believe that our language in the proposed rule concerning reasons why a manufacturer may seek approval for a new strength is inappropriately addressing patent or generic competition issues. Rather, we proposed a definition of new formulation in order to provide guidance to manufacturers on how to identify which of its drugs should be identified as a line extension, regardless of the reasons the new formulation was developed.

We are finalizing our proposal that a new strength of a drug is included in the definition of a new formulation.

m. Extended Release Formulation

Comment: One commenter stated that including an extended release

formulation in the definition would undermine the significant improvement Long Acting Injectable (LAI) Antipsychotics offer to people with mental illness.

A few commenters disagreed with CMS' inclusion of any new formulation other than an extended release formulation or similar to an extended release formulation in the proposed definition of new formulation, citing their belief that the proposal conflicts with statute and Congressional intent, and would undermine longstanding statutory incentives that encourage innovation.

Response: The statute defines a line extension, in part, as a new formulation of a drug and provides an extended release formulation as an example. As a result, we do not believe we have discretion to exclude an extended release formulation from the definition of new formulation. Nevertheless, we believe that our proposed definition is consistent with section 1927(c)(2)(C) of the Act and appropriate for the reasons discussed in the June 2020 proposed rule. We do not agree that the alternative rebate calculation required for a drug that is a line extension undermines drug improvements, whether the line extension is an extended release formulation, or any other new formulation. As stated, the alternative calculation does not categorically result in a higher URA for a drug as there are many factors that enter into the calculation. If the initial brand name listed drug did not increase in price in excess of the rate of inflation, then the alternative rebate calculation for the line extension should not result in a higher URA than the standard calculation for the drug that is a line extension.

The application of the alternative rebate calculation does not nullify statutory incentives that encourage innovation as those incentives continue to be a factor in the calculation of the URA for the drug that is a line extension. For example, if FDA has approved a drug exclusively for pediatric indications, or if a drug is identified as a clotting factor, section 1927(c)(1)(B)(iii) of the Act continues to allow for a lower percentage of AMP for the rebate calculation.

n. Change in Pharmacodynamics or Pharmacokinetic Properties

Comment: We received one comment regarding the proposal to include changes in pharmacodynamics or pharmacokinetics in the definition of new formulation. The commenter stated that these types of changes involve more than a slight alteration of an existing product and may result in changes to an active moiety such that it would be considered a different active ingredient.

Response: After considering the comment, we concluded that using the terminology ''pharmacodynamics or pharmacokinetics'' incorporated a broader range of changes than we intended with this language. Therefore, we are simplifying the language to incorporate the more limited types of change in the drug that we intended to capture, using less complex language. Rather than including a change in pharmacodynamics or pharmacokinetic properties, we are modifying the language to include a change in release mechanism. Examples of a change in release mechanism include, but are not limited to, a change from an immediate release formulation to a delayed release formulation, a change from an extended release formulation to an immediate release formulation, and a change from a non-coated tablet to an enteric coated tablet.

After consideration of public comments, we are finalizing a modification of our proposal. Specifically, we are including in the definition of a new formulation a change in release mechanism, rather than changes in pharmacodynamics or pharmacokinetic properties as proposed.

o. Route of Administration

Comment: A few commenters disagreed with CMS' inclusion of changes to route of administration in the proposed definition of new formulation, citing their belief that the proposal fails to consider the benefits of new routes of administration and conveys a lack of recognition of the value of incremental improvements in new formulations. One commenter also stated their belief that there would be fewer financial incentives to develop new and improved drugs, including highly anticipated, long-acting HIV medications for both prevention and treatment.

Response: We believe that our proposal to include a drug with a new route of administration in the definition of new formulation is consistent with section 1927(c)(2)(C) of the Act. The statute does not limit a line extension to only those drugs that do not provide additional clinical benefits over the initial brand name listed drug. Additionally, the statute does not direct that the new formulation of the drug has to be administered by the same route of administration as the original drug. Moreover, we do not agree that when determining if the alternative rebate calculation is required for a drug that is a line extension, it is required to consider the benefits of new routes of administration or the benefits of any other new formulation. As stated, the alternative calculation does not categorically result in a higher URA for a drug as there are many factors that enter into the calculation. If the initial brand name listed drug did not increase in price in excess of the rate of inflation, then the alternative rebate calculation for the line extension should not result in a higher URA than the standard calculation for the drug that is a line extension.

After consideration of public comments, we are including a change in route of administration in the definition of a new formulation as proposed.

p. Recommendations for Modifications to Proposals

We received a few comments that are out of the scope of the proposed rule and we are not addressing those comments in this final rule.

Comment: One commenter recommended that the definition of line extension should follow the statute exactly because it would be less confusing.

Response: We disagree that adopting the statutory language as the regulatory definition of line extension or new formulation would be less confusing. One important reason is that the statute only provides one example of a type of new formulation, that is, an extended release product. In addition, experience has shown us that since the publication of the 2016 final rule, there has been confusion and questions regarding the identification of drugs that are line extensions. In the interest of fairness to all affected parties, including states and manufacturers, therefore, we believe a more detailed regulatory definition, along with the information in the preamble of this rule, will provide more clarity for manufacturers on how to correctly identify their drugs that are line extensions.

Comment: A few commenters stated that although they support the proposed clarification related to line extensions, they believe the proposal could be further strengthened. One commenter recommended that we add non-oral drugs and biosimilars to the definition. Another commenter recommended that CMS explicitly add ''authorized generics'' to the definition of ''line extension'' for purposes of the inflation rebate.

Response: We do not agree with the suggestion that we add authorized generics to the definition of line extension. As discussed in the COD final rule (81 FR 5268), we do not read

section 1927(c)(2)(C) of the Act as treating authorized generic products differently.

Similarly, we do not believe it is necessary to provide separate language regarding biosimilars and non-oral drugs because we do not read section 1927(c)(2)(C) of the Act as treating biosimilars and non-oral drugs differently. Both of those categories of drugs will be treated according to the provisions set forth in this regulation.

Comment: We received a few comments that recommended that a drug should only be identified as a line extension or new formulation if FDA requires only bioequivalence or bioequivalence and bioavailability studies for a drug.

Response: We disagree that we should rely on these types of studies. We are not proposing that bioequivalence or bioavailability are among the criteria for determining if a product is a line extension. Therefore, these studies are not relevant to evaluating whether a drug is a line extension.

Comment: A few commenters stated that CMS should make it clear that the original drug must be the ''truly original drug'' and identify that as the ''first drug approved.'' They wanted it specified that drugs that were approved after the initial drug but before the line extension are not to be treated as an initial brand name listed drug. One commenter stated that the original drug should be based on the chronology of the approval of the original drug. One commenter recommended that it should be written into the regulatory text that a drug must be active in the applicable quarter in order to be considered as a potential initial brand name listed drug.

Response: We do not agree with the commenters who requested us to clarify that the initial brand name listed drug should be limited to the ''truly original drug,'' As stated in the preamble in the proposed rule (85 FR 37289), ''[t]o apply the alternative formula described in section 1927(c)(2)(C)(iii)(I) through (III) of the Act for each line extension and rebate period, the manufacturer must determine which NDC represents the initial brand name listed drug that will be used to calculate the alternative URA. First, the manufacturer must identify *all* potential initial brand name listed drugs by their respective NDCs by considering *all* strengths of the initial brand name listed drug in accordance with section 1927(c)(2)(C)(iii)(II) of the Act.'' (emphasis added). In order to perform the calculation as instructed, all strengths of potential initial drugs must be considered, regardless of the chronology of a drug's approval, or date first marketed. Potential initial brand name listed drugs may be excluded from consideration if they are not manufactured by the same manufacturer of the drug that is a line extension or by a manufacturer with which the line extension manufacturer has a corporate relationship. Also, if a potential initial brand name listed drug is not active in the MDRP during the quarter, it is excluded from consideration for that quarter and we do not believe it is necessary to include that language in the regulatory text.

Comment: A few commenters suggested that CMS revise the proposed definition of line extension to exclude those drugs that have not been assigned a different baseline AMP. The commenters noted that this would minimize administrative burden and would also be consistent with Congressional intent, which is focused on situations where a line extension is subject to a lower additional rebate than the original drug.

Response: We do not agree with revising the definition of line extension or new formulation to exclude those drugs that have not been assigned a new base AMP. The URA for a drug that is a line extension may derive from the standard rebate calculation or the alternative rebate calculation, and the applicable calculation may vary from quarter to quarter. One of the required fields in the product data is an indicator to identify whether a drug is a line extension. If a drug is a line extension, a determination must be made every quarter whether there is an initial brand name listed drug to report for the quarter. If there is more than one potential initial brand name listed drug for the quarter, an evaluation must be conducted to determine which of the potential initial brand name listed drugs has the highest additional rebate (calculated as a percentage of AMP) for that quarter. That NDC must be reported as the initial brand name listed drug for that quarter. Using that NDC for the initial brand name listed drug, if the alternative rebate calculation results in a higher URA than the standard URA, then the alternative URA is used for that quarter. As there are numerous variables considered and utilized in the calculation of the URA for a drug that is a line extension, and the base AMP value is only one of those variables, it is not appropriate to exclude a drug from the definition of line extension or new formulation based only on the base AMP value.

Comment: One commenter recommended that CMS work with FDA to create an exceptions process for manufacturers where they develop criteria for evaluating any petition from companies that believe their products are not line extensions.

Response: We do not agree that we should create an exceptions process and work with FDA to evaluate manufacturer petitions for exceptions to the definition of line extension or new formulation. We believe that the regulatory definition is reasonable, is consistent with section 1927(c)(2)(C) of the Act, and will assist manufacturers in appropriately identifying their drugs that must be reported as a drug that is a line extension.

Comment: We received a comment suggesting that we sever the line extension section of this rule, along with other sections that may interfere with research and development, from the rest of the rule.

Response: We do not believe there is a reason to sever sections of this rule. There is no evidence that the implementation of the line extension alternative calculation, which has been in effect for 10 years now, has affected research and development. Manufacturers have had to make determinations of which drugs constitute a line extension based primarily on reasonable assumptions over this period. This regulation provides more specific direction on identifying those drugs that represent line extensions.

q. Prospective Implementation

Comment: Several commenters requested that CMS confirm that any new regulation defining the terms should be prospective from the date of implementation. One commenter also noted that they believe if these definitions are applied retrospectively, this will dramatically increase the fiscal impact to the states. One commenter requested that CMS clarify that nothing would stop a manufacturer from voluntarily conforming its past reporting to the new definitions. Another commenter requested that CMS clarify that any regulatory definition of ''new formulation'' and application of the oral solid dosage form requirement would only apply for new products as of the effective date of this future final rule and that manufacturers may rely on their reasonable assumptions for existing products.

Response: The definitions of line extension, new formulation, and oral solid dosage form finalized in this final rule will not be applied retrospectively. These definitions become effective for all drugs in the MDRP beginning on January 1, 2022. Prior to the effective date, manufacturers may continue to rely on reasonable assumptions to determine if their drug is a new

formulation in order to comply with the statutory requirements and to use for potential future review of compliance prior to the effective date. If a subsequent review by us, by the Office of the Inspector General (OIG), or another authorized government agency determines or reveals that additional adjustments or revisions are necessary, the manufacturer is responsible for complying with that determination.

r. Delay Effective Date

Comment: A few commenters recommended that CMS consider narrowing the redefinition of line extension in future rulemaking with adequate time for commenters to consider the impact and comment, with one commenter requesting that if that is not possible, that CMS implement the new line extension definition with at least 12 months' notice prior to the effective date to permit states time to make preferred drug list decisions, notify patients, and implement changes. One commenter also requested that CMS specify a compliance date/effective date that is at least 4 quarters following the publication of the final rule, and that the rule should be prospective only.

Response: Based on the comments received, we are finalizing that the definitions of line extension, new formulation, and oral solid dosage form, as well as the requirement that only the initial brand name listed drug must be an oral solid dosage form, are effective beginning on January 1, 2022. For prior periods, manufacturers should continue to rely on the statutory definition of line extension and may continue to make reasonable assumptions to determine whether their drug is a line extension.

Based on the comments, we are revising the proposed definition of new formulation to read: For a drug, a change to the drug, including, but not limited to: An extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients. In addition, as discussed in section II.C. of this final rule, we are finalizing that the definitions of line extension, new formulation, and oral solid dosage form, as well as the requirement that only the initial brand name listed drug must be an oral solid dosage form, are effective beginning on January 1, 2022. For prior periods, manufacturers should continue to rely on the statutory definition of line extension and may continue to make reasonable assumptions to determine whether their drug is a line extension.

s. Corporate Relationship

In the June 2020 proposed rule (85 FR 37295), we noted that under § 447.509(a)(4)(iii), manufacturers are required to calculate the alternative URA if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug. Although a drug may satisfy the definition of line extension, and therefore, should be identified in DDR as a line extension, a manufacturer is not required to calculate the alternative URA unless the manufacturer of the line extension also manufactures, or has a corporate relationship with the manufacturer of the initial brand name listed drug.

Although we did not propose any changes to this policy, we received some comments that were out of the scope of the proposed rule and we are not addressing them in this final rule.

5. Oral Solid Dosage Form

Oral solid dosage form is defined at § 447.502 to mean capsules, tablets, or similar drugs products intended for oral use as defined in accordance with FDA regulation at 21 CFR 206.3 that defines solid oral dosage form. As we now have more experience reviewing and dealing with the line extension provisions from the Affordable Care Act, we believed that manufacturers may not be interpreting the term oral solid dosage form consistently. To mitigate any potential confusion, we believed that manufacturers and other commenters would benefit from a more detailed definition. In the June 2020 proposed rule, we proposed to modify the definition of oral solid dosage form.

In the COD final rule (81 FR 5198), CMS interpreted an oral route of administration as any drug that is intended to be taken by mouth. Because there is potential confusion about whether a dosage form must be swallowed, or otherwise enter the gastrointestinal tract to be considered an orally administered dosage form, we proposed to interpret that an oral form of a drug is one that enters the oral cavity. This includes, but is not limited to, a tablet or film administered sublingually and a drug that is orally inhaled. We believed that this interpretation provides greater clarity to commenters regarding what constitutes an oral form of a drug.

Additionally, we believed that manufacturers may not be interpreting the term solid dosage form consistently. To mitigate any potential confusion, we proposed to interpret that a solid dosage form is a dosage form that is neither a gas nor a liquid.

FDA regulation at 21 CFR 206.3 defines the term ''solid oral dosage form'' for the purpose of identifying drugs for which a code imprint is required to permit identification of the product. The phrase ''capsules, tablets or similar drugs products'' may not encompass the range of dosage forms that we believed should be considered for the application of the line extension provision in the Affordable Care Act. For example, a sublingual film is an oral solid dosage form; however, because of the physical attributes of the dosage form, there may not be a requirement to imprint an identifying code on the dosage form. Another example of an oral solid dosage form is a powdered drug administered by oral inhalation. Therefore, we proposed to modify the definition of oral solid dosage form at § 447.502 to read that it is an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity. Additionally, we noted that an oral solid dosage form that incorporates a medical device would not be exempt from this definition solely due to the addition of a device to the oral solid dosage form. For example, if a manufacturer adds a device to a tablet, the new drug would not be exempt from being a line extension solely due to the addition of a device to the tablet.

We received the following comments regarding the definition of oral solid dosage form:

Comment: A few commenters disagreed with CMS' proposal to expand the definition of an oral solid dosage form citing their belief that the expanded definition would exceed CMS' statutory or delegated authority. A few commenters disagreed with the proposed change because it no longer relies on an FDA definition of oral solid dosage form. One commenter noted the current definition that properly relies on the FDA definition has caused no practical problems. Another commenter noted that not relying on the FDA definition would result in needless confusion, requiring manufacturers to evaluate dosage forms under two incongruous legal standards.

Several commenters disagreed with CMS' proposed definition of oral solid dosage form citing their belief that modifying the definition would result in a substantial chilling effect on drug innovation. One commenter stated that the proposed definition fails to take into account that oral drugs, including inhaled drugs, become the threshold for any subsequent dose form of a particular product brought to market.

Several commenters supported the proposal to expand the definition of oral solid dosage form. One commenter agreed with CMS' proposal to include powdered inhalations and sublingual films in the proposed definition for an oral solid dosage form and also encouraged CMS to clearly state that liquid filled capsules are considered oral solid dosage forms.

One commenter requested that CMS clarify that any regulatory definition of new formulation and application of the oral solid dosage form requirement would only apply for new products as of the effective date of the final rule and that manufacturers may rely on their reasonable assumptions for existing products.

Response: The commenter did not explain how our proposed definition of oral solid dosage form would exceed our statutory or delegated authority. Nevertheless, we believe that our proposed definition is consistent with section 1927(c)(2)(C) of the Act and appropriate for the reasons discussed in the June 2020 proposed rule.

We do not agree that we should retain FDA's regulatory definition at 21 CFR 206.3 for purposes of identifying an oral solid dosage form for the MDRP. As we stated in the proposed rule, the FDA definition at 21 CFR 206.3 is for the purposes of identifying drugs that require a code imprint on the dosage form. Due to physical characteristics of some oral solid dosage forms, it may be impossible to imprint a code on them. Since FDA's regulatory definition is used for the specific purpose of determining when a code must be imprinted on a dosage form, and that identification bears no relationship to identifying what drugs are subject to the alternative rebate calculation for line extension drugs, we believe that it is reasonable to adopt a different definition than FDA's definition for the purposes of identifying an oral solid dosage form for the line extension provisions.

We also do not agree that modifying the definition of oral solid dosage form will necessarily discourage innovation. As stated, the alternative calculation does not categorically result in a higher URA for a drug as there are many factors that enter into the calculation. If the initial brand name listed drug did not increase in price in excess of the rate of inflation, then the alternative rebate calculation for the line extension should not result in a higher URA than the standard calculation for the drug that is a line extension. We also disagree that we failed to take into account that oral drugs become the threshold for any subsequent dose form. The statute requires that the initial drug is necessarily the threshold drug for any line extension of that drug.

We appreciate the support of the commenter who agreed with our inclusion of inhaled powders and sublingual films as an oral solid dosage form and we do understand that adopting this interpretation includes the possibility that an inhaled drug that is an oral solid could be an initial brand name listed drug. We agree that liquid filled capsules satisfy the proposed definition of oral solid dosage form because when the liquid filled capsule enters the oral cavity, it is a solid dosage form.

We do not agree that only products introduced on or after the effective date of the final rule should be subject to the requirement that only the initial brand name listed drug must be an oral solid dosage form and the regulatory definitions of oral solid dosage form, line extension, and new formulation. Although manufacturers will not be required to apply the regulatory definitions and oral solid dosage form requirement when calculating rebates for periods prior to the effective date of the final rule, the definitions become effective for all drugs that are on the market as of and following that effective date.

We are finalizing the definition of oral solid dosage form as proposed. In addition, as discussed in section II.C. of this final rule, we are finalizing that the definitions of line extension, new formulation, and oral solid dosage form, as well as the requirement that only the initial brand name listed drug must be an oral solid dosage form, are effective beginning on January 1, 2022. For prior periods, manufacturers should continue to rely on the statutory definition of line extension and may continue to make reasonable assumptions to determine whether their drug is a line extension.

6. Multiple Source Drug

The MSIAA clarified the definition of multiple source drug in section 1927(k) of the Act by removing ''(not including any drug described in paragraph (5))'' and inserting '', including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4),''. Section 1927(k)(7)(A)(i) of the Act now provides that the term multiple source drug means, for a rebate period, a COD, including a drug product approved for marketing as a non-prescription drug that is regarded as a COD under section 1927(k)(4) of the Act for which there is at least 1 other drug product which: Is rated as therapeutically equivalent (under FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''), except as provided in section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined in section 1927(k)(7)(C) of the Act and as determined by FDA, and is sold or marketed in the United States during the period.

We proposed to revise the definition of multiple source drug at § 447.502 to align with the statutory definition. Specifically, we proposed to revise the definition of multiple source drug to mean, for a rebate period, a COD, including a drug product approved for marketing as a non-prescription drug that is regarded as a COD under section 1927(k)(4) of the Act, for which there is at least 1 other drug product which meets all the following criteria:

- Is rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.accessdata.fda.gov/scripts/cder/ob/*).
- Except as provided at section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined at section 1927(k)(7)(C) of the Act and as determined by the FDA.
- Is sold or marketed in the United States during the period.

We did not receive public comments on the definition of multiple source drug, and therefore, we are finalizing as proposed.

7. Single Source Drug

The MSIAA clarified the definition of single source drug in section 1927(k) of the Act by removing the phrase ''an original new drug application'' and inserting ''a new drug application'', inserting '', including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4),'' after ''covered outpatient drug'', inserting ''unless the Secretary determines that a narrow exception applies (as described in § 447.502 of title 42, Code of Federal Regulations or any successor regulation))'' after ''under the new drug application'' and adding language to specify that such term also includes a COD that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA. Section 1927(k)(7)(A)(iv) of the Act now defines a single source drug to mean a COD, including a drug product approved for marketing as a non-prescription drug that is regarded

as a COD under section 1927(k)(4) of the Act, which is produced or distributed under an NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA unless the Secretary determines that a narrow exception applies (as described in § 447.502 or any successor regulation) and the term includes a COD that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA. To align the regulatory definition with the definition in the statute at section 1927(k)(7)(A)(iv) of the Act, as clarified by the MSIAA, we proposed to revise the regulatory definition of single source drug at § 447.502. We proposed to define single source drug in § 447.502 to mean a COD, including a drug product approved for marketing as a non-prescription drug that is regarded as a COD under section 1927(k)(4) of the Act, which is produced or distributed under an NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA unless the Secretary determines that a narrow exception applies (as described in § 447.502) and includes a COD that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

We received the following comments regarding the definition of single source drug at § 447.502:

Comment: One commenter requested that CMS revise their proposed definition of single source drug to only apply prospectively from October 2019 forward, citing their belief that since this is the date the Congress amended the MDRP statute, it would be in accordance with the recent ruling in the United States District Court for the District of Columbia case of *STI Pharma, LLC* v. *Azar.*

Response: The revision to the definition of single source drug is to conform the rule with the amended statute. Our longstanding interpretation of the statute (both before and after the 2019 amendments) is that a single source drug is a drug approved under an NDA, and noninnovator drugs are those approved under an ANDA. We believe *STI Pharma, LLC* v. *Azar* was wrongly decided. Prior to the 2016 COD final rule, there was no narrow exception to that general rule. Therefore, any drug approved under an NDA that is reported as a noninnovator multiple source drug for quarters prior to 2Q2016 is improperly categorized and the drug manufacturer should request a drug-category change or risk enforcement action.

We are finalizing the definition of single source drug as proposed.

8. CMS-Authorized Supplemental Rebate Agreements (SRAs)

States may enter into separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth under the NDRA. (See section 1927(a)(1) of the Act.) CMS approval to enter directly into such agreements with manufacturers is required under section 1927(a)(1) of the Act, and thus, states are required to use the SPAs process as a means to seek CMS authorization. Supplemental rebates must be considered a reduction in the amount expended under the state plan in the quarter for medical assistance as provided at section 1927(b)(1)(B) of the Act. See program guidance at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd091802.pdf.*

The Affordable Care Act revised section 1927(b)(1)(A) of the Act to require that manufacturers provide rebates for CODs dispensed to individuals enrolled with a Medicaid MCO when the organization is responsible for coverage of such drugs. At that time, states had to re-assess whether or not to directly collect supplemental rebates related to CODs dispensed to Medicaid managed care enrollees if the MCO was responsible for such drug coverage. Some states required their MCOs to collect and share supplemental rebates under the CMS-authorized SRA, while other states permitted their MCOs to negotiate their own rebates with manufacturers outside of the CMS-authorized supplemental rebate agreement, allowing the MCO to keep the savings generated by the supplemental rebates.

The Affordable Care Act amendment to section 1927(b)(1)(A) of the Act also prompted some manufacturers to make assumptions with regard to AMP and best price calculations. Specifically, manufacturers made assumptions that all supplemental rebates paid by manufacturers for prescriptions dispensed to Medicaid managed care enrollees should be excluded from the manufacturer's determination of AMP and best price. That included those rebates paid directly to Medicaid MCOs, even if those rebates were not a result of a CMS-authorized SRA, and therefore, not shared with the state or eventually used to offset state drug expenditures prior to claiming FFP from the federal government. Since CMS-authorized SRA is not defined as it is used at §§ 447.504(c)(19) and (e)(9) and 447.505(c)(7), manufacturers assumed that any supplemental rebates paid based on dispensing to Medicaid managed care enrollees are always a part of a CMS-authorized SRA with the states. However, rebates paid to Medicaid MCOs may be paid by manufacturers that are not part of a CMS-authorized SRA and are not shared with the state to offset drug expenditures prior to claiming FFP. Therefore, to clarify that such rebates paid by manufacturers are not part of a state's CMS-authorized SRA, in the June 2020 proposed rule, we proposed to define CMS-authorized supplemental rebate agreement to mean an agreement that is approved through a SPA by CMS, which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that generate rebates that are at least as large as the rebates set forth in the Secretary's national drug rebate agreement with drug manufacturers.

Furthermore, and consistent with section 1927(b)(1)(B) of the Act which provides that the amounts received by a state under paragraph (a)(1) (federal rebates) or an agreement under paragraph (a)(4) (the existing state rebates) in any quarter shall be considered to be a reduction in the amount expended under the state plan in the quarter for medical assistance for purposes of section 1903(a)(1) of the Act. As proposed, the definition further stated that the revenue from these rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the federal government.

We received the following comments on the proposed definition of CMS-authorized SRA:

Comment: A few commenters requested that CMS confirm that the proposed definition of CMS-authorized SRA permits states and manufacturers to negotiate VBP arrangements with the state Medicaid program's approval and in compliance with this definition, without requiring further levels of approval or submission of a SPA. Another commenter further requested that CMS reinforce the need for states to obtain CMS approval prior to implementing changes to supplemental rebate policies.

Response: The proposed definition of CMS-authorized SRA permits the states and manufacturers to negotiate VBP arrangements; however, state Medicaid programs must seek approval via the SPA process to enter into a CMS-authorized SRA, including SRAs that reference VBP arrangements. We have

also encouraged states and manufacturers to consider negotiating supplemental rebates as part of VBP arrangements by directing them to review the September 18, 2002 State Medicaid Director Letter regarding supplemental rebates and seek authorization under section 1927(a)(1) of the Act from CMS to ensure compliance with section 1927 of the Act when entering directly into SRAs with manufacturers.[20]

Comment: One commenter requested that CMS revise the first sentence of the definition to state that CMS-authorized SRA means an agreement that is approved through a SPA by CMS, which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that may generate rebates in addition to the rebates set forth in the Secretary's national rebate agreement with drug manufacturers. Another commenter requested CMS to revise the definition to clarify that rebates may fall within the definition of CMS-authorized SRA regardless of their amount and that a SRA may be approved by CMS as long as the combined rebate payment under the supplemental and national rebate agreements is greater than or equal to the rebate under the national rebate agreement alone.

Response: In the September 18, 2002 State Medicaid Director letter regarding supplemental rebate agreements, CMS directed that states seek CMS approval under section 1927(a)(1) of the Act to enter directly into agreements with manufacturers and in doing so, must ensure that any such agreement will achieve drug rebates that are at least equal to the rebates set forth in the Secretary's rebate agreements with manufacturers.[21] We continue to believe this is an appropriate interpretation of the statute, and thus, we are not revising the definition of CMS-authorized supplemental rebate agreement as suggested by the commenters.

Comment: A few commenters recommended CMS clarify that any VBP arrangements that states already entered into with manufacturers will continue to be treated as ''CMS-authorized supplemental rebate agreements'', and therefore, exempt from Best Price and AMP calculations. Another commenter also requested that CMS provide confirmation that states will be permitted to use SRAs but would not be required to use the pre-approved template. One commenter recommended that CMS provide additional guidance to enhance SRAs to align with flexibilities granted under the rule.

Response: States that have entered into CMS-authorized VBP SRAs have submitted a different template through the SPA approval process than that used under traditional non-VBP supplemental rebate agreements. Thus, states may have both a SRA approved for a non-VBP based template as well as a VBP-based template. Once CMS approves either template, rebates provided for under agreements entered into between states and manufacturers are exempt from best price. States do not need to submit a SPA to take advantage of the multiple best price VBP approach as described in this final regulation. However, a state could negotiate its own VBP arrangement outcomes based rebate approach under a CMS-authorized SRA, and those rebates would be exempt from Medicaid best price.

Comment: A few commenters supported CMS' proposed definition of CMS-authorized SRA with one commenter specifically recommending that CMS require any Medicaid MCO to utilize only CMS-authorized SRAs.

Response: Medicaid MCOs may enter into their own SRAs with manufacturers, but as noted in this rule, only prices pursuant to CMS-authorized SRAs would be exempt from best price. If a Medicaid MCO enters into their own SRAs with manufacturers, such prices are not exempt from best price. This rule does not address the types of SRAs a Medicaid MCO may enter into, and thus, a MCO is not required to only utilize CMS-authorized SRAs.

Comment: One commenter stated that although they generally support the proposed definition of CMS-authorized SRA, they also requested that CMS edit the definition as follows: ''Revenue from these rebates must be paid directly to the state under section 1927 of the Act and be used by the state to offset a state's drug expenditures resulting in shared savings with the Federal government.'' The commenter noted this will ensure consistency with the existing regulations (see §§ 447.504(c)(19) and (e)(9) and 447.505(c)(7)).

Response: We appreciate the comment but believe the phrase ''under section 1927 of the Act'' is not necessary since it is already included in the exclusions listed in the determination of AMP and best price regulations at §§ 447.504(c)(19) and (e)(9) and 447.505(c)(7).

Comment: One commenter urged CMS to expressly confirm that a manufacturer may exclude rebates paid under a CMS-authorized SRA from AMP and best price, without having to verify that the rebate payments are in fact ''used by the state to offset a state's drug expenditures'' citing their belief that it would not be reasonable to hold manufacturers accountable for how a state uses a rebate payment.

Response: We agree that it is the responsibility of the state, not the manufacturer, to ensure that rebates paid by manufacturers under the CMS-authorized SRA are used by the state to offset a state's drug expenditures resulting in shared savings with the federal government. Manufacturer rebates paid under a CMS-authorized SRA must be excluded from AMP and best price in accordance with §§ 447.504(c)(19) and (e)(9) and 447.505(c)(7).

Comment: Several commenters disagreed with the language in the proposed definition of CMS-authorized SRA that states ''Revenue from these rebates must be paid directly to the state''. A few commenters recommended that CMS exclude rebates that are reported by MCOs from best price/AMP because the commenter noted rebates reported by MCOs are factored into a state's rate setting process, and therefore, are treated as if they had been received directly by the state.

Response: The issue is whether the rebates that are paid for these covered outpatient drugs are paid in accordance with a CMS-authorized supplemental rebate agreement, and thus exempt from inclusion in the calculation of the manufacturer's AMP and best price, or paid directly to the MCO, and are not exempt from the inclusion in the calculation of the manufacturer's AMP and best price.

As stated in the preamble to this final rule, the definition of CMS-authorized SRA is consistent with section 1927(b)(1)(B) of the Act which provides that the amounts received by a state under paragraph (a)(1) (federal rebates) or an agreement under paragraph (a)(4) (the existing state rebates) in any quarter shall be considered to be a reduction in the amount expended under the state plan in the quarter for medical assistance for purposes of section 1903(a)(1) of the Act. The proposed definition provides that these rebates must be paid directly to the state which the states then use to offset its drug expenditures, resulting in shared savings with the federal government. Therefore, any manufacturer rebate revenue collected by the MCOs on behalf of the state that are part of any

[20] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-176.pdf.*

[21] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/smd091802.pdf.*

CMS-authorized SRAs must be shared with the state directly in accordance with section 1927(b)(1)(B) of the Act. We also do not agree that manufacturers should exclude rebates that are directly paid to MCOs outside a CMS authorized supplemental rebate reported by MCOs from AMP or best price. That is because they are not provided directly to the state by the manufacturer under a CMS-authorized supplemental rebate agreement.

Comment: One commenter noted that Medicaid MCOs are critical in maintaining the cost-effectiveness and quality of care for the Medicaid program through medication adherence, care coordination, and timely provider interventions, and stated that it is critical that MCOs are retained as important partners during negotiations between states and manufacturers.

Response: This comment is outside the scope of this regulation.

In consideration of the comments received, we are finalizing the definition of CMS-authorized SRA at § 447.502 as proposed, to mean an agreement that is approved through a SPA by CMS, which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that generate rebates that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers. Revenue from these rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the federal government.

D. Exclusion of Certain Manufacturer Sponsored Patient Assistance Programs (''PBM Accumulator Programs'') From Determination of Best Price (§ 447.505) and AMP (§ 447.504)

Manufacturers participating in the MDRP are required to report certain pricing information to the Secretary, including a COD's best price and AMP. Best price is defined at section 1927(c)(1)(C) of the Act to mean, for a single source or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a NDA approved under section 505(c) of the FFDCA), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity within the United States, subject to certain exclusions. Section 1927(c)(1)(C)(ii) of the Act further defines the term best price to be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section). The definition of best price is further defined at § 447.505(a) and includes the lowest price available from the manufacturer during the rebate period to any provider, which is defined to mean a hospital, HMO, MCO, or entity that provides coverage or services to individuals for illnesses or injuries or providers services or items in the provision of healthcare. Paragraph (b) further indicates that best price includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price eligible entities in paragraph (a).

We have learned that some health plans (which meet the definition of provider when determining best price) are being instructed or encouraged by their PBMs to apply manufacturer sponsored patient assistance programs, such as patient copay assistance programs, to the benefit of the plan, instead of entirely to the patient. (Note that Medicaid patients are not eligible for these manufacturer sponsored programs, but the administration of these programs by commercial health plans and PBMs can affect the rebates that the Medicaid program receives from the manufacturer-sponsor of these programs.)

For example, certain PBMs have instructed health plans to not allow the manufacturer-sponsored patient assistance to be applied towards a patient's plan deductible for a brand name drug not on a plan's formulary. PBMs contend that such programs steer consumers towards more expensive medications when there may be more cost saving options, such as generic substitution. Therefore, PBMs offer health plans that are commonly referred to as PBM accumulator programs and tout them as cost saving measures. For instance, using a copayment assistance card program as an example, instead of applying the manufacturer sponsored patient assistance program in a manner that bestows the entire benefit of the program to the patient or consumer, and ensures no contingency on a purchase requirement, as applicable, the PBM (on behalf of the plan) identifies when a copayment card is used by a patient and adjusts the beneficiary's deductible only in instances when the out-of-pocket contribution is made by the beneficiary. As a result, the manufacturer-sponsored assistance does not accrue towards a patient's deductible and the patient sometimes does not realize this until the manufacturer copayment assistance runs out and the patient receives a significantly larger bill for the drug. This results in the health plan delaying the application of its plan benefit to the patient to the detriment of the patient or consumer, thus generating savings for the plan. We provide the following example in this rule:

Example:

Assume: $2,500 Drug cost

$2,500 Patient Deductible

$10,000 Copayment Assistance Program Maximum

In the no PBM accumulator scenario below, the manufacturer's copayment assistance accrues to the benefit of the patient because the patient has a high deductible, which is what we believed the manufacturer intended. In such cases, it is clear that the manufacturer's program is directly assisting the patient's copayment/deductible costs.

TABLE 1—COPAY ASSISTANCE PROGRAM WITH NO PBM ACCUMULATOR PROGRAM

	Jan	Feb	Mar	Apr	May	June
Plan Pays	$0	$2,000	$2,000	$2,000	$2,000	$2,000
Patient Pays	25	$25	25	25	25	25
Manufacturer Pays	2,475	$475 deductible reached. Manufacturer only pays $475.	475	475	475	475

In the PBM accumulator scenario in Table 2, the PBM does not apply the manufacturer's copayment assistance to the deductible of the patient thus delaying the patient satisfying his or her deductible, which benefits the health plan. The patient usually is not aware of the change until he is subject to a larger cost share of the drug when the manufacturer's support copay benefit maximum is reached (see May column). At that time, the patient receives a significantly a larger bill.

TABLE 2—COPAY ASSISTANCE PROGRAM WITH PBM ACCUMULATOR PROGRAM

	Jan	Feb	Mar	Apr	May	June
Plan Pays	$0	$0	$0	$0	$0	$2,000
Patient Pays	25	25	25	25	$2,400	500
Manufacturer Pays	2,475	2,475	2,475	2,475	100 manufacturer copay benefit max. reached	0

As demonstrated in Table 2, the health plan is benefiting from the manufacturer sponsored copay assistance program instead of the patient (consumer). However, manufacturers, in these instances, claim they are not aware of when these practices by the health plans take place, and therefore, make reasonable assumptions that their discount programs meet the criteria at § 447.505(c) that exclude such programs from best price.

Specifically, manufacturers make reasonable assumptions that their programs meet the best price exclusions listed in § 447.505(c)(8) through (12) which provide:

- Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession (§ 447.505(c)(8)).
- Manufacturer coupons to a customer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession (§ 447.505(c)(9)).
- Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession (§ 447.505(c)(10)).
- Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent or other entity does not receive any price concession (§ 447.505(c)(11)).
- Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such program is passed on to the consumer; and the pharmacy, agent or other entity does not receive any price concession (§ 447.505(c)(12)).

As discussed in the June 2020 proposed rule, we understand from some manufacturers that they do not monitor or place parameters around how the benefits of their manufacturer-sponsored assistance programs are applied when an individual has health plan coverage. Therefore, we proposed to revise these paragraphs to provide expressly that the exclusions discussed in this rule apply only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient. We believe manufacturers have the ability to establish coverage criteria around their manufacturer-sponsored assistance programs to ensure the benefit goes exclusively to the consumer or patient. We noted that nothing in the proposed change should be construed to contradict any OIG guidance. We welcomed comments on the proposal.

The current list of prices excluded from best price as noted in this rule also apply to AMP as specified in § 447.504(c) and (e). As stated in the COD final rule, to provide consistency between the AMP and best price sections, where applicable, and to help with streamlining and clarifying a manufacturer's price reporting responsibilities, the same methodology is applied to AMP (81 FR 5253), and for the same reasons already discussed in this rule, we proposed making corresponding changes for these exclusions in the context of AMP.

Accordingly, we proposed to revise the determination of best price § 447.505 to add a requirement that manufacturers ensure that the benefits of their assistance programs as provided at § 447.505(c)(8) through (12) are provided entirely to the consumer and proposed corresponding changes to the AMP regulations at § 447.504(c)(25) through (29) and (e)(13) through (17).

We received several types of comments on the issue of whether the manufacturer should ensure that the benefits of their assistance programs be provided entirely to the consumer, or are actually passed through to the patient. These comments could, in general, be grouped into the following categories: (1) Impact on Patients; (2) Legal Authority; (3) Existence of Mechanisms to Assist Manufacturers with Compliance; (4) Viability of Manufacturer Assistance Programs; and (5) Impact on other Federal Programs and Policies.

We provide responses to the following comments on the exclusion of certain manufacturer sponsored patient assistance programs (''PBM Accumulator Programs'') from determination of best price (§ 447.505) and AMP (§ 447.504).

(1) Impact on Patients

Comment: Several commenters supported the proposals for manufacturers to account for patient assistance in Medicaid best price reporting when it is not passed through to the patient, and shared CMS' concerns about the role that health carriers and PBMs play in manipulating manufacturer-sponsored assistance programs, and wanted to ensure financial assistance benefits flowed to the patient and not the health plan.

Response: It is our understanding that PBM Accumulator Programs shift costs back to the patient prematurely by not applying the full value of the manufacturer-sponsored assistance to a patient's health plan deductible. Upon exhaustion of the value of the manufacturer's assistance (manufacturer sponsored drug discounts, coupons, copayment assistance or refund/rebate programs) the beneficiary of the manufacturer-sponsored assistance must pay the remaining amount of their deductible for the drug before the plan's benefit begins. We believe the final rule will encourage manufacturers to ensure the full value of manufacturer-sponsored assistance is extended to the patient, as described in greater detail below.

Comment: A few commenters expressed concern that CMS equates the ''full'' value and ''exclusive'' benefit of a manufacturer assistance program with reducing the patient's deductible and maximum out-of-pocket obligation and stated that there is no factual or statutory basis for this proposition. A few commenters stated that regardless of whether a patient is subject to a PBM accumulator program that appropriates part of their assistance, the patient has received the full benefit of manufacturer assistance as long as the manufacturer has helped the patient meet their point-of-sale cost and that manufacturers have

no control over what happens to the benefit after the point-of-sale. One commenter stated that CMS is not entitled to make the conclusion without any supporting evidence that manufacturers allow or acquiesce to a diversion of the manufacturer-sponsored assistance away from the patient to the plans when PBM accumulator adjustment programs are used.

Response: We do not agree with the commenter that, as long as the manufacturer has helped the patient receive manufacturer assistance at the point-of-sale, the patient has received the full benefit of manufacturer-sponsored assistance. By not applying the manufacturer assistance to a patient's deductible or other cost sharing obligations to obtain the drug, the assistance becomes a price concession to the health plan by delaying the point at which the health plan's contribution toward the patient's cost sharing begins, or reducing the value of the assistance to the patient, and thus should be counted in best price and, in certain cases, the calculation of the AMP. When the patient does not receive the full value of the manufacturer's assistance, the end result is that:

- The patient may be subject to a significant out-of-pocket drug bill in the event the manufacturer-sponsored assistance ends in the middle of the plan year, and the patient finds out that he or she is still in the deductible phase of a benefit. If this happens, the patient may need to switch to the less expensive alternative offered by the plan or pay the full bill for the non-formulary or non-preferred drug, neither of which are patient friendly scenarios.
- The patient is unaware of the other more cost effective drugs that his/her health plan offers on its drug formulary at the time that the original prescription is filled. Since the patient likely presents at the pharmacy with the manufacturer-sponsored assistance card, the manufacturer-sponsored assistance is automatically applied by the pharmacy (electronically) and the beneficiary is not made aware of other less expensive drug treatments offered by the health plan. In other words, it is not transparent to the patient at the pharmacy (point-of-sale) which drug may be more affordable to the patient in the long run.

Comment: Several commenters expressed concern about the impact of the proposal on patients with rare, life-threatening illnesses or complex chronic conditions who rely on discounts and copay assistance to access specialty medications, and disagreed that patient assistance steers consumers towards more expensive medications because there is often no generic alternative or clinically appropriate substitute. Many commenters raised concerns about the potential impact of the proposals in this section on medication adherence, medical complications, outcomes, and hospitalizations and requested CMS to take patient's special needs into consideration.

Response: We do not believe that the final policies we are adopting in this final rule will negatively impact patients with rare, life-threatening illnesses who rely on manufacturer assistance programs. Rather, we do believe that there is a corollary benefit to this proposed policy, as it might lead to reforms in manufacturer assistance programs. We understand from many manufacturers and patient groups that PBM accumulator programs are increasing in number, and that the value of these programs to the patient is diminishing. It is not clear how these programs can continue to benefit patients without some modifications and reforms.

We believe manufacturers can implement a system to ensure the full benefit of its manufacturer-sponsored assistance passes on to the patient. By doing so, patients will continue to have access to much needed medication which will in turn increase positive outcomes and also improve adherence.

We are aware of situations when a patient has been subject to significant out-of-pocket costs because the patient has not progressed through the deductible phase of the health plan. That is because the value of the manufacturer-sponsored assistance was not applied to the patient's deductible. When this happens, the patient may be forced to stop taking the drug, switch to an alternative offered by the plan, or pay the full bill for the non-formulary drug, none of which are patient-friendly, especially for those patients with rare and life threatening conditions. The policies we are adopting in this final rule could help avoid these concerns because it will improve transparency in drug pricing and will ensure that the full value of the manufacturers-sponsored assistance programs is passed on to the patient. We believe this will also help assure patient compliance and adherence with medications.

Comment: Several commenters expressed concern that the proposed rule would encourage expansion of PBM accumulator programs and stated that if the federal government continues to permit PBMs to profit from the use of PBM accumulator programs, then manufacturers will either have to set higher prices for new drugs to offset these incremental profits, or withdraw manufacturer-sponsored assistance altogether, resulting in harm to patients.

Response: We understand the concerns about PBM accumulator programs and the impact on manufacturer prices. As noted above, the current regulations at 42 CFR 447.504 and 447.505 already require that best price and AMP exclude manufacturer-sponsored assistance programs (copayment, patient refund/rebate, coupons, discount card programs) when the full value of the assistance is passed on to the consumer, and the pharmacy, agent or other entity does not receive any price concession.

The goal of this final policy is to not affect drug manufacturers' prices, but to make sure that Medicaid programs receive the rebates that they are owed from manufacturers if any value of the manufacturer assistance is accruing to a ''best price'' eligible entity rather than the patient. It is possible that manufacturers, knowing that any assistance not being passed through would have to factor in their Medicaid rebates, will improve their oversight of these manufacturer assistance programs such that they will not have to pay higher rebates to Medicaid. This could actually lead to lower drug prices, and increase the amount of manufacturer assistance that will actually go to patients. This will help reduce the potential for patient harm resulting from a lack of compliance with medications if the patient cannot afford them because they are not receiving the full value of their cost sharing assistance.

Thus, we believe the proposed rule and the policies we are adopting in this final rule will encourage manufacturers to monitor and track their manufacturer-sponsored assistance programs to ensure the full value of the manufacturer-sponsored assistance goes to the consumer and not to health plans.

Comment: Several commenters noted that another justification for prohibiting or increasing oversight of PBM Accumulator Programs is the surprise impact of receiving a significantly larger bill for the drug than expected due to lack of patient awareness of PBM policies that do not count manufacturer-sponsored assistance towards patient cost-sharing obligations.

A few commenters recommended requiring plans to give notice to a patient of its intent to withhold third party funds, and explain in plain language what benefits accrue to the patient, how manufacturer assistance will be affected and applied, and account for third-party assistance, as a potential alternative to the proposals in

this section. One commenter supported a policy alternative requiring health plans and PBMs to apply price reduction instruments for out-of-pocket expenses when calculating an insured individual's cost-sharing requirement.

Response: We appreciate the comments regarding the identification of certain mechanisms to increase patient awareness that the health plan that they are enrolled in may use a PBM accumulator program. We agree with the many comments that we received expressing concern about the impact of these programs on patients, including the sudden impact that such programs can have on patient out-of-pocket spending for their drugs, and lack of patients' awareness of the existence of such programs.

We are only able to regulate this issue within the scope of the Medicaid drug rebate program rules. That is, under the MDRP, the manufacturer can only exclude manufacturer assistance that is fully passed through to a patient/consumer from the calculation of best price, and when applicable, AMP for 5i drugs. We believe the final policies adopted in this rule will help ensure the full benefits of the manufacturer-sponsored assistance program are passed on to the patient, which hopefully, will have the added benefit of reducing some of the negative consequences that patients have faced as a result of manufacturers not making such assurances related to PBM accumulator programs.

Comment: Several commenters supported CMS' proposals on the basis that they may reduce spending on prescription drugs and noted that the use of manufacturer sponsored coupons and similar arrangements are designed to increase drug spending, needlessly drive consumers to high cost treatments and circumvent utilization management tools adopted by health plans. Several commenters stated that manufacturer copay coupons create anti-competitive effects, market disruptions, unreliable access for patients, and undermine more affordable generic or biosimilar drugs, and viewed CMS proposals as an effort to prevent manufacturers from increasing drug prices without market constraints.

Response: We appreciate the comments and agree that manufacturer-sponsored assistance may increase drug spending by circumventing health plan utilization management tools and steering patients towards more expensive treatments not necessarily covered by a patient's plan. We are also concerned that patient out-of-pocket spending will increase significantly when the manufacturer-sponsored assistance runs out, and patients are required to pay for the drug in full much earlier than anticipated. We believe that this rule will encourage manufacturers to examine the structures of their manufacturer-sponsored assistance program(s) so that patients are not surprised by high drug costs when all or part of the cost sharing assistance is passed through to the plan rather than the patient.

Comment: A few commenters defended the existence of PBM accumulator programs as necessary to ensure that benefits will be administered as they are designed, rather than artificially reducing deductibles for patients on specific high cost drugs.

Response: We are aware that PBM accumulator programs are used by health plans to ensure their benefits are administered as they are designed. However, these PBM accumulator programs often do not allow for the full benefit of the manufacturer-sponsored assistance to accrue to the patient. This regulation requires that the manufacturer be aware of this action taken by the PBM so that the manufacturer complies with the regulations that set forth the determination of AMP and best price for the purposes of the MDRP.

Comment: One commenter cited several studies, one of which showed that for 23 branded drugs studied, coupons were associated with a 3.4 percent decrease in the rate of generic utilization and an estimated excess spending of 1.2 percent to 4.6 percent higher total drug spending over 5 years and requested that this be considered a well-documented problem rather than attributing concerned statements only to health plans and PBMs.

Response: We appreciate the information regarding the impact of manufacturer-sponsored assistance programs have on drug benefits and spending. However, as noted above, we believe the final policies adopted in this rule will ensure that the full benefits of the manufacturer-sponsored assistance program pass on to the patient, and that the exclusions to best price and AMP are applied appropriately.

Comment: A few commenters stated that PBM accumulator programs do not only apply to brand name drugs not on a plan's formulary, but to all drugs.

Response: We agree that PBM accumulator programs do not apply only to single source brand name drugs. The use of brand name drugs in the rule was an example of a particular situation where the PBM does not apply the benefit of the manufacturer sponsored assistance to the patient's health plan deductible in circumstances when a health plan's formulary covers a lower cost generic (or brand) alternative. We believe this is one scenario, and not an exclusive example.

(2) Legal Authority

Comment: Several commenters stated that health plan enrollment in a PBM accumulator program, or the existence of the program, has no bearing on manufacturer exclusion of a manufacturer assistance program from AMP and best price. Several commenters stated that requiring manufacturers to include the value of manufacturer assistance that was subsequently taken away from patients by plans in the calculation of best price is contrary to the statutory definition of best price because patient assistance is not a price, or a price concession that is available from a manufacturer to plans. A few commenters suggested that to be consistent with CMS' prior interpretations of the statute, patient assistance can only be viewed as a price concession when the manufacturer develops that program specifically for patients of a particular payer or PBM, but absent such negotiation or coordination, and the assistance is not ''designed to'' adjust prices to the payer or PBM, then the assistance should be excluded from AMP and best price.

Several commenters noted that CMS lacks statutory authority for the proposals in this section, that they are based on erroneous interpretation of the Medicaid drug rebate statute, or that they are based on unexplained or unsupported assumptions, and thus requested that CMS rescind the proposals related to including patient assistance programs in best price and AMP unless manufacturers ''ensure'' that their assistance solely benefits patients and does not benefit third parties. These commenters noted that CMS has not articulated an overall context or reasoning behind their proposed change in treatment of manufacturer sponsored patient assistance programs, specifically the intended outcome for these changes and how this approach would achieve those goals. One commenter stated that implementation of such a dramatic change in the assistance available to patients across the country should not occur without additional explanation accompanied by concrete data and evidence to support it. A few commenters stated that basing the proposals in this section on what one group of commenters ''contend'' constitutes an ''unsupported and conclusory statement'' that renders

CMS' proposals arbitrary and capricious within the meaning of the APA.

Some commenters stated that it is unfair, infeasible, and contrary to statutory intent to hold manufacturers responsible for ensuring that the discount goes exclusively to the consumer or patient when manufacturers are not involved in the application of tools that change how assistance is applied to the patient's insurance benefit, and therefore, cannot monitor or place parameters around them. For these reasons, several commenters stated that these proposals cannot be operationalized if made final and that the agency's proposals are arbitrary and capricious.

Response: We do not agree with the commenters that manufacturer-sponsored assistance is not a price, or a price concession that is available from the manufacturer to the plans, in situations when health plans participate in PBM accumulator programs, and then the value of the assistance does not accrue in full to the patient. Nor do we agree that this proposal is arbitrary and capricious, as current regulations already provide that manufacturers can only exclude manufacturer-sponsored assistance if it is being passed through to the patient. See §§ 447.504(c) and (e) and 447.505(c).

Manufacturers are fully aware of the existence of PBM accumulator programs, and may not have taken action to date to address the potential that they may already be reporting in violation of the regulations at § 447.504(c) and (e) for AMP and § 447.505(c) for the calculation of best price. These sections of the regulation have always stated that the manufacturer-sponsored assistance (coupons, free goods, discounts, refund/rebate programs and copay assistance) exclusions apply only if such assistance is passed on to the consumer and the pharmacy, agent, or other AMP/best price eligible entity does not receive any price concession. In cases where the PBM accumulator programs do not allow any manufacturer-sponsored assistance to apply to the beneficiary' deductible, the health plan is receiving a price concession in the form of delaying the health plan's obligation to provide coverage of the drug under the patient's health plan benefit. This postponement in providing benefits to the patient, or the accrual of the benefit to the plan in whole or part, is a price concession to the health plan.

Since these programs are increasing in scope and number, such that it is no longer the case that such assistance is always passed through to the patient which is an existing requirement, we believe a change in the regulatory text underpinning this exemption is needed. Under this final rule, manufacturers must ensure that the full value of the manufacturer-sponsored assistance is passed on to the consumer or patient regardless of the specific transactions that occur between payers, pharmacies and PBMs.

We believe that we have the statutory authority for this rule and have explained the overall context or rationale to support our proposed policies and now our final policies. Manufacturers participating in the MDRP are required to report certain pricing information to the Secretary, including a COD's best price and AMP. In the proposed rule, we noted that some health plans (which meet the definition of provider when determining best price) are being instructed or encouraged by their PBMs to apply manufacturer-sponsored assistance programs, such as patient copay assistance programs, to the benefit of the plan, instead of entirely to the patient.

Best price is defined at section 1927(c)(1)(C) of the Act to mean, for a single source or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a NDA approved under section 505(c) of the FFDCA), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity within the United States, subject to certain exclusions. Section 1927(c)(1)(C)(ii) of the Act further defines the term best price to be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section). The definition of best price is further defined at § 447.505(a) and includes the lowest price available from the manufacturer during the rebate period to any provider, which is defined to mean a hospital, HMO, MCO, or entity that provides coverage or services to individuals for illnesses or injuries or providers services or items in the provision of healthcare. Paragraph (b) further indicates that best price includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price eligible entities in paragraph (a). We believe the reference to ''other transactions that adjust prices either directly or indirectly'' to the best price eligible entities in paragraph (a) includes the transactions made by the manufacturer indirectly to health plans via manufacturer-sponsored assistance programs should be included.

Comment: Several commenters stated that treating patients as best-price eligible entities exceeds the scope of CMS' statutory authority. Several commenters stated the plain language of the statute requires that to be considered for best price calculations as a ''price available from the manufacturer,'' the manufacturer had to intend to offer the price to a best-price eligible entity. However, several commenters stated that the Congress' only intended best price-eligible entities under the statute are purchasers, wholesalers, retailers, providers, HMOs, non-profit entities, and governmental entities. Several commenters further stated that manufacturer-sponsored assistance designed solely to benefit patients and reduce their out-of-pocket costs cannot constitute a ''price available from the manufacturer'' because the manufacturer did not intend to offer the price to an eligible third party such as the health plan, and therefore should not be required to include the value of assistance in its best price calculations when the health plan denies the manufacturer assistance apply to patients. Other commenters stated that a manufacturer can only have intended to make the price available to eligible entities if the manufacturer negotiated with the PBM to offer manufacturer assistance or designed the manufacturer assistance to benefit the PBM, and further stated that when such coordination, negotiation, or consideration is not present, the assistance cannot by a price ''available from'' the manufacturer and included in best price. One commenter stated that CMS confirmed that patients are not eligible purchasers in the COD final rule in 2016.

Response: This regulation does not treat patients as best price eligible entities. In accordance with current regulations at § 447.505(c)(8) through (12), prices excluded from best price include manufacturer-sponsored assistance programs, but only to the extent that the full value of the assistance is passed on to the consumer, and the pharmacy, agent or other entity does not receive any price concession (see further discussion on these existing policies in preamble to COD final rule at 81 FR 5254). As proposed and finalized in this rule, these regulations have been revised to require that a manufacturer ensure that the value of the manufacturer's assistance accrues to the benefit of the patient and not the plan (a best price eligible entity) before excluding the value of these assistance programs from the determination of best

price and AMP. As stated in current regulation, the manufacturer's assistance can be excluded from best price only if the full value of the assistance is passed through to the patient/consumer. However, if any of the manufacturer-sponsored assistance is diverted to the plan, those amounts should be included when a manufacturer calculates its best price and AMP in certain cases. This final policy requires manufacturers to ensure the full value is passed on to the consumer, consistent with the regulation.

Comment: A few commenters expressed concern about the impact of the proposals in this section on the ability of manufacturers to continue offering manufacturer assistance programs to individuals in the larger commercial market during the COVID–19 pandemic. These commenters stated that during the PHE and economic crisis, patients and families across the country would experience significant harm if the proposal is finalized and they lose access to medications.

A few commenters stated the proposals are contrary to an Executive Order urging federal agencies to rescind, modify, waive, or provide exemptions from regulations and other requirements that may inhibit economic recovery, consistent with applicable law and with protection of the public health and safety. A few commenters stated that to be consistent with that Executive Order, CMS should reconsider and modify its current policies for PBM accumulator programs and to withdraw the current proposal that would impose new standards for exclusions of manufacturer-sponsored assistance amounts to patients in connection with Best Price and AMP determinations.

Response: Since there is concern with the impact of this policy on manufacturer's ability to provide assistance during the COVID–19 crisis, and manufacturers are also concerned that they may not be able to ensure their manufacturer assistance is going to the patient and not being passed through to the health plan via an electronic means right away, we are finalizing this rule, as proposed, but are delaying the effective date until January 1, 2023. This will give manufacturers time to implement a system that will ensure the full value of assistance under their manufacturer-sponsored assistance program is passed on to the patient, such as contracting with a third party vendor to track their assistance when provided at the point of sale, or changing the structure of their manufacturer-sponsored assistance programs to require patients pay for the drug first and then have the patient collect the rebate directly from the manufacturer (outside of the electronic claims process). Manufacturers may also choose to revise the manufacturer-sponsored assistance structure by requiring the patient to submit its claim for the manufacturer-sponsored assistance outside of the electronic claims process (this will allow a patient's cost sharing at the point of sale to apply to the patient's deductible because the pharmacy and PBM will be unable to identify that the patient used manufacturer-sponsored assistance.

(3) Existence of Mechanisms To Assist Manufacturers With Compliance

Comment: Several commenters stated that manufacturers do not have knowledge, visibility, or control over programs deployed by PBMs and health plans regarding the pass through of patient assistance, and suggested that CMS focus on imposing program efficiencies on plan managers and PBMs instead. Other commenters similarly stated that manufacturers are not party to arrangements between, nor do they receive consideration from, health plans and PBMs that withhold discounts from patients.

Several commenters stated that the use of PBM Accumulator Programs is a post-transaction or downstream cost adjustment mechanism into which manufacturers have no insight, and pointed to CMS' acknowledgement that even patients are often not aware when they are enrolled in such programs. Several commenters further stated that despite good faith efforts, they do not have access to data, plan policies, or an information exchange with enough specificity on PBM Accumulator Programs on a per-product, per-customer, per-quarter, or per-unit basis, and therefore, have no awareness of which patients are subject to PBM Accumulator Programs and which ones are not. Several commenters further stated that obtaining such data would create new administrative burdens, citing that documents are private, proprietary, or lengthy and complex.

One commenter challenged manufacturer arguments that there would be too many barriers to knowing when their coupons are absorbed by PBM Accumulator Programs and excluded from deductibles, stating that manufacturers can contract with third parties to obtain such data. Several commenters stated that PBM Accumulator Programs only exist to interfere with or prevent manufacturer-sponsored assistance from being applied to the patient's deductibles and maximum out-of-pocket costs from the consumer, and that instead of ensuring patient accessibility, accumulators penalize patients for using coupons to lower their costs.

Response: We understand the concerns from the commenters that manufacturers may not currently have the ability to track their manufacturer assistance to ensure it is provided in full to the patient. However, we believe that the electronic prescription claims processing infrastructure that is currently in place can serve as a possible foundation for manufacturers to have the ability to ensure their manufacturer-sponsored assistance is going to the patient.

Almost all prescriptions are electronically processed at the pharmacy, and when transmitted from the pharmacy, are routed through a switch to the corresponding PBM based on the information on the patient's prescription card, such as BIN/PCN number. As noted, manufacturers do currently contract with switches and brokers that are electronically connected to this prescription claims processing ''highway'', and which apply manufacturer-sponsored assistance on the manufacturers' behalf at the point-of-service to reduce the amount that a patient might have to pay for a prescription.

Manufacturers also have relationships with PBMs, given that they pay rebates and other price concessions for formulary placement on the PBMs' formularies. Thus, the electronic and contractual infrastructure is in place for manufacturers to better understand how the PBMs are using the manufacturer assistance. We believe and have the expectation that PBMs will work with manufacturers to provide this information to the manufacturers to help them ensure that their assistance is passed though.

Alternatively, manufacturers may consider redesigning assistance programs to require patients pay for the drug first and then have the patient collect the rebate directly from the manufacturer (outside of the electronic claims process). Revising the manufacturer-sponsored assistance structure by allowing the patient to pay first and bill the manufacturer for the assistance after the claim has been processed will guarantee patient's cost sharing applies to the patient's deductible and that the payer does not receive any price concession from the manufacturer-sponsored assistance. This manual approach also allows the patient at the point-of-sale to consider alternatives offered by their own health plan to the drug offered under the manufacturer-sponsored assistance

program, and therefore, supports the Administration's quest for drug pricing transparency.

Comment: Many commenters stated the proposals in this section are unworkable for manufacturers due to the lack of transparency in PBM accumulator programs and rather than finalizing these proposals, requested that CMS ban the use of PBM accumulator programs entirely, or at least prohibit their use when generic alternatives are not available. These commenters noted that this would directly accomplish CMS' stated goals of ensuring that the full value of assistance be passed along to the patient.

Several commenters also requested CMS to regulate cost sharing, transparency, standards for access to plan information, marketing, and benefit design as a means of protecting patients from the potential negative clinical and financial consequences of PBM accumulator programs. A few commenters stated that PBM accumulator programs should not be necessary since health plans have many guardrails in place to ensure that patients are incentivized to use lower cost medications such as prior authorization and step therapy.

Response: While we appreciate the comments, this final rule only addresses situations when the value of manufacturer-sponsored assistance is not passed through to the patient and how that should be reflected by the manufacturer in the determination of best price and calculation of AMP in certain cases. The proposed rule requires manufacturers ensure that the full value of the manufacturer-sponsored assistance is passed on to the consumer and that the entity, in this case the health plan, does not receive any part of the value of the manufacturer assistance in order for that value to be excluded from best price and AMP. Banning PBM accumulator programs is outside the scope of this rule.

Comment: One commenter expressed concern that the proposed changes to the best price determination might require health plans and PBMs to provide additional information to manufacturers beyond what they already provide and stated that this risks giving manufacturers greater market insight that could be leveraged to circumvent plan designs that encourage use of cost effective drugs in new ways, thereby increasing prices for patients and plans alike. One commenter recommended that CMS clarify that drug manufacturers, not PBMs and health plans, are solely responsible for correctly characterizing and accounting for amounts attributable to their manufacturer-sponsored assistance programs for the purposes of best price.

Response: This rule does not require PBMs and health plans disclose or disseminate information they believe to be proprietary to manufacturers. Manufacturers that offer assistance only need to know if the patient is receiving the full value of the assistance for their drug (that is, the assistance is being fully counted towards the patient's deductible and cost sharing). The mechanism by which the manufacturer determines whether or not the full value of its assistance is provided to the patient will be determined by the manufacturer, working with its brokers, the PBMs, and plans.

(4) Viability of Manufacturer Assistance Programs With This Policy

Comments: Several commenters expressed concern that the operational challenges to manufacturers would deter them from offering a broad range of manufacturer assistance currently exempt from best price reporting including coupons, drug discount card programs, patient rebate programs and copay assistance.

Several commenters challenged CMS' assertion that manufacturers can establish ''parameters'' or ''coverage criteria'' for ensuring the full value of assistance to patients' subject to PBM accumulators, stating that it has no factual support. Several commenters requested further explanation or guardrails on such parameters or coverage criteria from CMS to ensure the provision has its intended effect while protecting people who rely on assistance. A few commenters expressed concern that the proposals in this section would also affect the frequency of government price reporting if manufacturers are expected to investigate on a plan by plan basis every suspicion that manufacturer assistance funds were being appropriated by a health plan. One commenter stated that even diligent checks and oversight cannot reveal every instance of plan or PBM capture or misappropriation of patient assistance funds due to the plan's overall lack of transparency.

Response: We do not agree that this regulation creates an insurmountable burden for manufacturers to comply with this new regulatory requirement. This rule does not place a federal mandate on health plans, insurers, and pharmacies to provide specific data or verify data to manufacturers relating to the operation of their manufacturer-sponsored assistance programs. However, our expectation is that manufacturers will work with their contracted patient assistance brokers, prescription claims processing switches, health plans and their contracted PBMs to ensure that they have the information necessary to comply with this regulatory requirement.

The mechanism by which manufacturers will ensure that the full value of the manufacturer-sponsored assistance will be going to the patient will be determined by the manufacturer. However, we believe that one of the approaches that manufacturers may be able to use to capture information regarding how their manufacturer-sponsored assistance is used is through an electronic feedback mechanism at the point-of-sale, which appears to be in place at the present time. We believe that the PBMs will have to work with the manufacturers and their switches and brokers to assure that the manufacturers have the information necessary to comply with this regulatory requirement.

Comment: A few commenters expressed concern that there is no way a manufacturer can certify to the accuracy of data obtained by health plans regarding PBM accumulator programs, subjecting manufacturers to penalties for false reporting or non-compliance with the MDRP requirements. One commenter stated that absent a federal mandate for health plans, insurers, and pharmacies to provide certified reports of the PBM accumulator transactions to manufacturers, manufacturers will not be able to provide accurate price reports.

Response: We understand manufacturers concerns regarding certification of the data that they are required to report to comply with MDRP reporting requirements. Manufacturers currently certify data that are required to be reported to us regarding the calculation of AMP and best price. These calculations currently require that manufacturer sponsored assistance programs be passed through to the patient in full in order to be excluded from the calculation of best price and AMP in certain cases. Manufacturers should only be exempting manufacturer-sponsored assistance from their AMP and best price now if the value of its assistance passed onto the patient in full. If manufacturers are certifying their AMP and best price data at this time, which they are required to do each quarter, they should be doing so only with the knowledge that such their manufacturer-sponsored assistance is being passed through to the patient in compliance with applicable statutes and regulations. This final regulation

emphasizes the need for manufacturers to ensure this is happening. As we have stated, it is our expectation that manufacturers will work with the various components of the electronic prescription processing system, such as PBMs, switches, and brokers, among others, to obtain the information they need to accurately determine the pricing benchmarks they need to report each quarter.

Comment: Several commenters requested that CMS not finalize its proposals in this section unless it establishes safe harbors that clearly identify actions that manufacturers can reasonably take to ensure they have met CMS standards. One commenter expressed concern that although manufacturers typically have terms and conditions governing their patient assistance programs, neither PBMs nor plans are a party to those terms and conditions. The commenter suggested that the only way for manufacturers to ensure that the full value of manufacturer copay assistance programs go exclusively to the patient is to create terms and conditions that prohibit a patient's acceptance of manufacturer support when a PBM accumulator program applies. The commenter recommended that if CMS finalizes its proposal, it should expressly state that such a prohibition would be sufficient to meet the regulatory standard if manufacturers are held responsible for ensuring the full benefit of patient assistance passes to the patient.

Response: We appreciate the commenter's suggestion, but do not agree that shifting the burden to patients is necessary for a manufacturer to be able to determine that the full value of manufacturer assistance has been passed through to the patient. Prohibiting patients from accepting assistance unless they know that an accumulator program does not apply in their plan places undue burdens on patients. We do not agree that such a regulatory standard would satisfy the requirement that a manufacturer ensures that manufacturer sponsored patient assistance is passed through to the patient in full before it may be excluded from the calculation of best price or AMP in certain cases. Satisfying this regulatory requirement is the responsibility of the manufacturer, which is the entity that is regulated by CMS. The patient may not understand what an accumulator is, how it works, or whether their health plan's PBM uses an accumulator.

As noted in prior responses, we believe that there may be multiple ways that manufacturers will be able to meet these new regulatory requirements to ensure that manufacturer patient assistance is passed through fully to the patient or consumer, such as being able to electronically capture information regarding the value of manufacturer-sponsored assistance that is being passed through in PBM accumulator programs through some type of feedback mechanism at the point-of-sale, or by creating coverage criteria for the use of their patient assistance programs.

Comment: One commenter stated that any regulatory language that discourages the use of PBM accumulator programs would have a significant impact on a payer's ability to appropriately manage their prescription drug benefit and leads to increased costs when coupon and copay card amounts must apply to their members' deductibles and out of pocket maximums for certain drugs.

Response: The current regulation already requires that best price and AMP exclude manufacturer-sponsored assistance programs (copayment, patient refund/rebate, coupons, discount card programs) when the full value of the assistance is passed on to the consumer, and the pharmacy, agent or other entity does not receive any price concession. In the interest of program integrity, and to assure that the states receive the rebates that they are due, this final regulation is specifically requiring manufacturers to ensure compliance with that requirement that the manufacturer ensures the full value of the assistance is going to the patient.

We understand that PBMs may be using this accumulator approach to steer patients away from drugs for which lower-cost generics are available, thus potentially impacting the payer's ability to manage their prescription drug benefit if this proposed policy was adopted as final. In that regard, however, we understand that these programs are being used for both single source brands, as well as innovator off patent brands for which there are multiple lower cost generics on the market. However, there is no distinction made in the statute between single source and innovator multiple source drugs for which manufacturers would have to make a best price determination. That is, if a manufacturer's price concession is being realized by a best price eligible entity, whether it is for a single source or innovator multiple source drug, then that price should be considered in the determination of best price.

(5) Impact on Other Federal Programs and Policies

Comment: One commenter expressed concern that the proposals in this section would increase the risk of manufacturers cutting off vital patient assistance. The commenter requested that we work with the HHS' OIG to revisit rebate pass-through policies to ensure patients benefit directly from manufacturer discounts and rebates provided to PBMs.

Response: We appreciate the comment, but do not agree that the final policy will have the effect of cutting off vital manufacturer assistance because manufacturers should only be exempting manufacturer-sponsored assistance from their AMP and best price now if the value of its assistance passed onto the patient in full. If manufacturers are certifying their AMP and best price data at this time, which they are required to do each quarter, they should be doing so only with the knowledge that such their manufacturer-sponsored assistance is being passed through to the patient in compliance with applicable statutes and regulations. This final regulation emphasizes the need for manufacturers to ensure this is happening.

The request to work with HHS' OIG to revisit other policies is outside the scope of this rule.

Comment: Several commenters suggested in response to CMS' concerns about the impacts of the growing use of PBM accumulator programs that CMS revert to the Notice of Benefit and Payment Parameters 2020 (NBPP 2020) proposals (85 FR 78572). Several commenters stated that CMS initially proposed to prohibit the use of PBM accumulator programs when the patient was prescribed a brand name medication for which a generic alternative was not available, and made clear that cost-sharing support for a brand drug on the formulary would always count toward the annual limitation on cost sharing. Several commenters noted that they preferred this earlier proposal, stating it would be simpler and more effective for creating guardrails to ensure provisions on cost-sharing assistance have their intended effect and to mitigate the harmful effects of such programs on patients.

Several commenters also noted that the proposals conflict with the recent Notice of Benefit and Payment Parameters Rule for 2021 final rule (85 FR 29164), that permitted, but did not require, issuers to count toward the annual limitation on cost sharing amounts paid toward reducing out of-pocket costs using any form of direct support offered by drug manufacturers to enrollees for specific prescription drugs. Several commenters stated that CMS did not provide that same degree of flexibility to plans in the proposed rule, and instead, preferred that

assistance programs are counted towards the patient's deductible. One commenter stated that the differing approaches in the two regulations create operational complications for plans participating in both the Marketplace and Medicaid programs, as they have different requirements under each program as it relates to the treatment of patient assistance programs, and expressed concern this would lead to competitive disadvantages for plans that operate in both spaces. A few commenters stated that it is important for plans to have the flexibility to manage pharmaceutical copay assistance programs, as such programs often incentivize enrollees to utilize more expensive medications and stated that the proposals in this section undermine formulary and benefit design and results in higher health care costs.

Response: The CMS Medicaid drug rebate program requires that manufacturers only exclude the value of manufacturer sponsored assistance to patients from the best price when the value of the assistance is passed through to the patient in full. This requirement is the focus of this rulemaking. In the Notice of Benefit and Payment Parameters Rule for 2021 final rule (hereinafter referred to as ''2021 NBPP''), we permitted, to the extent consistent with state law, but did not require, issuers to count toward the annual limitation on cost sharing amounts paid toward reducing out-of-pocket costs using any form of direct support offered by drug manufacturers to enrollees for specific prescription drugs.

The policies we are adopting in this rule require manufacturers ensure that the full value of their assistance programs is passed on to the consumer, and the entity, in this case the payer, does not receive any price concession. In cases when some of the value goes to the payer, manufacturers must include the value of the assistance in their determination of best price and AMP.

In the 2021 NBPP, we stated that issuers and group health plans are allowed to continue longstanding policies with regard to how direct drug manufacturers' support accrues towards an enrollee's annual limitation on cost sharing. When the issuer does not permit the patient to realize the full benefit of the manufacturer's assistance, manufacturers must not exclude such amounts from best price calculations. We suggest ways that manufacturers can become aware of such circumstance and thus include the assistance as a price concession in the manufacturer's determination of best price and AMP. However, we are not prescribing a way that this should be done. The policies we are adopting in this final rule will require manufacturers to ensure that the full benefit of the assistance program goes exclusively to the patient in order for the manufacturer to exclude the manufacturer's assistance from the calculation of best price and AMP. To allow manufacturers to develop mechanisms to obtain the information necessary to know whether the assistance has been in fact passed through to the patient, we are delaying the effective date for this requirement until January 1, 2023.

Comment: A commenter noted that there is no inherent False Claims Act risk in price reporting by properly treating coupon amounts as price concessions.

Response: The determination of whether a manufacturer is at risk of violating the False Claims Act is outside of the scope of this final rule.

Comment: A few commenters noted the proposal to include manufacturer-sponsored assistance in reporting for AMP, unless the manufacturer ensures the full value is passed on to the patient, would result in lowering the AMP, which in turn would lower manufacturers' rebate liability under the MDRP. These commenters stated that CMS' proposal may encourage manufacturers to set higher list prices and offer coupons, rather than simply starting with a lower list price, while not having any greater rebate liability under the MDRP. One commenter provided an example of a drug priced at $10,000 with the offer of a $5,000 coupon from the manufacturer, and stated that in order for that $5,000 to be deducted from AMP, the full value must be passed directly to the patient under the proposal. The commenter expressed concern that this could mean the $5,000 manufacturer copay assistance must count toward the patient's annual deductible and/or maximum out-of-pocket (MOOP) spending and that such a policy may incentivize utilization of higher-priced pharmaceutical products and increase overall health care spending. The commenter also noted that if the discount does have to apply towards the patient's deductible or MOOP, then the drug manufacturer would have subverted the patient's formulary and benefit design by skewing product choice and insulating the patient from financial liability intended to encourage responsible health care decision-making. The commenter suggested in contrast, if the manufacturer set the list price at $5,000, the net price would be the same as the higher priced drug as reduced by the coupon, and the AMP would be the same.

A few commenters expressed concern that CMS' proposal to ensure that the full value of manufacturer-sponsored assistance is passed through to the patient in order for it to be excluded from calculations of best price and AMP would have negative downstream effects on ASP and the 340B ceiling price. These commenters noted that CMS' proposals in this section could result in the inclusion of patient assistance in ASP leading to a reduction in ASP and payer reimbursement in this rule acquisition costs. These commenters stated that in order for drug reimbursement rates not to fall below their costs, manufacturers would discontinue assistance programs and harm patients in need.

One commenter stated that the ASP statute and regulations require that 103 percent of AMP be substituted for the ordinary Part B payment rate (106 percent of ASP) if the ASP for a drug exceeds AMP by 5 percent or more for 2 consecutive quarters, meaning that a decline in AMP could cause such a substitution and thus reduce the Part B drug payment rate. The commenter stated that reducing a drug's Part B payment rate (either through a decline in ASP or through a substitution of 103 percent of AMP) could have detrimental effects on Medicare Part B providers and could hinder patient access to critical drugs.

Response: We do not believe this final rule will have a significant impact on Part B drug payments. First, under section 1927(k)(1) of the Act, AMP is defined as the average price paid to manufacturers for a covered outpatient drug by wholesalers for drugs distributed to retail community pharmacies, as well as for drugs that retail pharmacies purchase directly from manufacturers. The calculation for AMP excludes payments to insurers as found at section 1927(k)(1)(B)(IV) of the Act, meaning these sales (with applicable exclusions) are not reflected in AMP.

However, many Part B drugs can also be classified as ''5i'' drugs under the MDRP, that is, instilled, infused, injected, intraocular, and implanted drugs. The manufacturer's calculation of the AMP for 5i drugs includes a broader set of manufacturer's transactions, including sales, nominal price sales and associated discounts, rebates, payments or other financial transactions to insurers. Thus, the 5i AMP for a drug, may be impacted if the manufacturer fails to ensure that the full value of its manufacturer-sponsored assistance accrues to the patient and the insurer realizes a price concession. In

circumstances when the manufacturer does not assure that the manufacturer assistance is passed through to the patient in full, and thus has to be included in the calculation of 5i AMP for the drug, such a situation could possibly reduce 5i AMP and impact Part B reimbursement.

However, since not all sales of a manufacturer's 5i drug utilizes a manufacturer-sponsored assistance program, we do not believe the amount associated with the manufacturer-sponsored assistance (value of discounts, coupons, rebates) will impact 5i AMP significantly to result in the substitution of AMP to the detriment of Medicare Part B providers and access to critical drugs. Thus, while it is possible that the inclusion of manufacturer assistance in the calculation of the 5i AMP for the drug could affect whether the Secretary makes such a substitution for the Part B drug, we do not believe it is likely. To the extent that manufacturer-sponsored assistance is passed fully through to the patient, there should be no reduction in the value of the 5i AMP. As a result, there should be no increased incidence of substituting 103 percent of AMP for ASP under section 1847A(d) of the Act, which creates an additional incentive for manufacturers to ensure that their assistance is being passed through fully to the patient.

For 340B ceiling prices, such prices are calculated by subtracting the URA (URA = AMP − best price when greater than the statutory rebate percentage based on drug classification) for a drug from the drug's AMP, as described in section 340B(a)(1) of the Public Health Service Act. The URA is the Medicaid rebate amount for a quarter for a dosage form and strength of a drug. To the extent that manufacturer-sponsored assistance is passed through to the payer, rather than the patient, it could be counted in best price, which could affect the calculation of the ceiling price, as it is one component of the URA. The impact on 340B ceiling prices would depend on the inclusion of the manufacturer-sponsored assistance in the best price, and in some cases the AMP, for the drug for that quarter.

Comment: One commenter supported the proposals and recommended that CMS conduct a regulatory impact analysis of the potential impacts on manufacturer pricing behavior before finalizing its proposal to adjust Best Price calculations to include manufacturer coupon payments to patients in copay PBM accumulator programs due to concerns about the unintended effect of manufacturers increasing their overall drug prices to compensate for the additional price concessions.

Response: We do not believe this rule will have a major regulatory impact. More discussion can be found in section IV. of this final rule, the Regulatory Impact Analysis section.

Comment: One commenter recommended as an alternative to the proposed changes to best price and AMP regarding manufacturer-sponsored assistance programs that CMS require insurance companies to remove any reference in their policies regarding cost-sharing assistance, and stated that the health plan should not have knowledge of transactions that are between the patient and manufacturer.

Response: This comment requests action that is outside the scope of the rule.

Comment: One commenter requested clarification on whether the Bona Fide Service Fee test would apply and whether CMS views the portion of the pharmacy reimbursement that is in excess of the wholesaler acquisition cost as a price concession to the pharmacy. The commenter requested CMS to clarify if, for example, if it is determined that payers typically reimburse pharmacies wholesale acquisition cost plus 12.5 percent, whether the pharmacy reimbursement for free good programs would be excluded from AMP and best price up to that threshold.

Response: This comment is outside the scope of this rule.

After consideration of the comments received, we are finalizing the proposed rule without modification, but delaying the effective date of this final policy. While the effective date of this rule is March 1, 2021, this final policy will not be effective until January 1, 2023. This will give manufacturers time to implement a system that helps them track their programs to ensure the manufacturer assistance is being passed through to the patient in full, and no other entity is receiving any price concessions. To be clear, we are providing a later effective date by which manufacturers will have to ensure that their cost sharing assistance is being passed through to the patient in full in order to exempt any such program assistance from the calculation of best price and AMP.

E. Authorized Generic Drugs (§§ 447.502, 447.504, 447.506)

The Continuing Appropriations Act of 2020, and Health Extenders Act of 2019 (Health Extenders Act) made changes to section 1927(k) of the Act, revising how manufacturers calculate the AMP for a COD for which the manufacturer permits an authorized generic to be sold. That is, the law requires that manufacturers that approve, allow, or otherwise permit any drug to be sold under the manufacturer's own NDA approved under section 505(c) of the FFDCA are no longer permitted to include those sales of these drugs in the calculation of AMP.

Specifically, section 1603 of Health Extenders Act, entitled ''Excluding Authorized Generic Drugs from Calculation of Average Manufacturer Price for Purposes of the Medicaid Drug Rebate Program; Excluding Manufacturers from Definition of Wholesaler,'' amended:

- Section 1927(k)(1)(C) of the Act to replace the term ''inclusion'' with ''exclusion'' in the title and further amended paragraph (k)(1)(C) to state that, in the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under *the manufacturer's* NDA approved under section 505(c) of the FFDCA, such term shall be *exclusive* of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies (emphasis added).
- The definition of wholesaler at section 1927(k)(11) of the Act to remove references to manufacturers from the definition of wholesaler.

The amendments to section 1927 of the Act authorized under section 1603 of the Health Extenders Act are effective October 1, 2019. Therefore, manufacturers must reflect the changes to the calculation of their AMPs for rebate periods beginning October 1, 2019 (reported to CMS no later than 30 days after the end of the rebate period). Furthermore, in accordance with § 447.510(b), manufacturers have 12 quarters from the quarter in which the data were due to revise AMP, if necessary.

In accordance with the statutory amendments to section 1927(k)(1)(C) and (k)(11) of the Act described in this rule, we proposed to revise §§ 447.502, 447.504, and 447.506 as they apply to AMP and authorized generic sales as follows:

- We proposed to revise § 447.502 to change the definition of wholesaler to reflect the revised statutory definition of wholesaler at section 1927(k)(11) of the Act. Specifically, we proposed to revise the definition of wholesaler by removing any reference to ''manufacturer(s)'' consistent with the changes to the definition of wholesaler made by section 1603(b) of the Health Extenders Act. We proposed the term ''wholesaler'' to mean a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail

community pharmacies, including but not limited to repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

• Since the definition of wholesaler at section 1927(k)(11) of the Act no longer includes manufacturers, we further proposed to remove from the list of sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions included in AMP, sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies at § 447.504(b)(2). The nominal price sales, and associated discounts, rebates, payments or other financial transactions included in AMP in accordance with § 447.504(d) (AMP for 5i drugs that are not generally dispensed through retail community pharmacies) do not change because the statute at section 1927(k)(1)(C) of the Act only speaks to authorized generic sales from the manufacturer to wholesalers that distribute to retail community pharmacies.

• We proposed to revise § 447.506, which provides specific requirements to manufacturers regarding the treatment of authorized generic drug sales when determining AMP and best price. For purposes of those calculations, the current regulation defines primary manufacturer as the manufacturer that holds the NDA of the authorized generic drug and the secondary manufacturer as the manufacturer that is authorized by the primary manufacturer to sell the drug, but does not hold the NDA.

The regulation further requires that the primary manufacturer must include in its calculation of AMP its sales of authorized generic drugs that have been sold or licensed to a secondary manufacturer, acting as a wholesaler for drugs distributed to retail community pharmacies, or when the primary manufacturer holding the NDA sells directly to a wholesaler. The Health Extenders Act revised the definition of wholesaler at section 1927(k)(11) of the Act by removing ''manufacturer'' and revised the determination of AMP at section 1927(k)(1)(C) of the Act by replacing the term ''inclusion'' with ''exclusion'' in the title and further amended paragraph (C) to state, in the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under *the manufacturer's* NDA approved under section 505(c) of the FFDCA, such term shall be *exclusive* of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies. Therefore, we proposed to revise § 447.506(b) to replace the word ''Inclusion'' with ''Exclusion'' in the first sentence and replace the second sentence in its entirety to state that the primary manufacturer (as defined at § 447.506(a)) must exclude from its calculation of AMP any sales of authorized generic drugs to wholesalers for drugs distributed to retail community pharmacies when reporting the AMP of the brand name drug.

More specifically, we proposed that a separate AMP is determined for the brand drug, which shall be exclusive of any authorized generic sales, and a separate AMP shall be generated for the authorized generic. As discussed in the June 2020 proposed rule, typically, an authorized generic is a product that a manufacturer (primary manufacturer) allows another manufacturer (secondary manufacturer) to sell under the primary manufacturer's FDA-approved NDA but under a different NDC number. The authorized generic is typically the primary manufacturer's brand product offered at a lower price point. Primary manufacturers may sell the authorized generic product to the secondary manufacturer they are allowing to sell an authorized generic of their brand product, and such sales are commonly referred to as transfer sales. Primary manufacturers have included those transfer sales in the determination of the brand product's AMP. Under the amendments made to section 1927 of the Act, a primary manufacturer that sells the authorized generic version of the brand drug to the secondary manufacturer can no longer include the price of the transfer sale of the authorized generic to the secondary manufacturer in its calculation of AMP for the brand product. The exclusion of these transfer sales from the primary manufacturer's brand drug AMP will likely result in higher AMPs for the brand drugs and a potential increase to a manufacturer's Medicaid drug rebates to states. To assist manufacturers, we provided guidance in Manufacturer Release #111 and Manufacture Release #112.[22] In turn, we received inquiries as to what is meant by ''In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under *the manufacturer's* NDA approved under section 505(c) of the FFDCA, such term shall be *exclusive* of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.'' Specifically, we received questions regarding when a primary manufacturer itself, or an affiliate of the manufacturer is also producing the authorized generic, and whether, such a case, constitutes ''a case of a manufacturer that approves, allows, or otherwise permits'' the drug to be sold under the manufacturer's NDA, such that the exclusion applies. And if not, whether the primary manufacturer may include the average price paid for the authorized generic when calculating AMP for the brand drug. We believed that irrespective of the relationship between the manufacturer of the brand drug, and the manufacturer of the authorized generic, if the primary manufacturer ''approves, allows, or otherwise permits'' the drug to be sold under the primary manufacturer's NDA, then the AMP for the brand should be calculated separately from (not include) the sales of the authorized generic. That is, it would not matter whether the manufacturer being approved, allowed, or otherwise permitted to sell the drug under the primary manufacturer's NDA was the same, affiliated or non-affiliated.

Therefore, we interpret section 1927(k)(1)(C) of the Act, which provides that in the case of a manufacturer that approves, allows, or otherwise permits any of its drugs to be sold under the same NDA, the AMP for that brand drug shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies, to mean a separate AMP should be calculated for each drug product—that is, one AMP for the brand drug, and one AMP for the authorized generic product, and the AMP for the brand drug should always exclude sales of the authorized generic product, including transfer sales of the brand name drug to the manufacturer of the authorized generic, as the definition of wholesaler no longer includes a manufacturer. Thus, a manufacturer's sales to manufacturers who act as wholesalers can no longer be included in AMP. This includes a situation when it is the same manufacturer making both the brand name drug and authorized generic, or if the drugs are being manufactured by different, but affiliated manufacturers or even non-affiliated manufacturers. We proposed a policy that applies irrespective of a specific brand manufacturer's sales arrangement.

The amendments made by section 1603 of the Health Extenders Act were effective October 1, 2019. Therefore, manufacturers are required to reflect the changes to the calculation of their AMPs for rebate periods beginning October 1,

[22] *https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-112.pdf.*

2019 (reported to CMS no later than 30 days after the end of the rebate period). Furthermore, in accordance with § 447.510(b), manufacturers have 12 quarters from the quarter in which the data were due to revise AMP, if necessary.

We received the following comments on our proposed policies regarding authorized generic drugs (§§ 447.502, 447.504, 447.506).

Comment: A few commenters supported the proposed regulations regarding how manufacturers should calculate AMP for authorized generic drugs. Several commenters supported the proposed regulations that manufacturers must calculate separate AMPs for their brand drug and authorized generic. One commenter noted the proposed regulation should reduce manufacturer anti-competitive strategies and another noted the proposal successfully addresses one of the ways that authorized generics create marketplace distortions that hurt patients. One commenter supported the proposed approach that this exclusion apply irrespective of whether the authorized generic is sold by an affiliated or unaffiliated manufacturer, or the nature of the sales arrangement.

Response: We appreciate the commenters support, and are finalizing the proposals consistent with the changes made by the Continuing Appropriations Act of 2020, and Health Extenders Act of 2019 (Health Extenders Act) to section 1927(k) of the Act with one modification relative to the regulatory definition of secondary manufacturer.

Comment: A few commenters supported the exclusion of sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP from other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies.

Response: We appreciate the support for this proposal. Since the definition of wholesaler at section 1927(k)(11) of the Act no longer includes manufacturers, we are removing from the list of sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions included in AMP, sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies at § 447.504(b)(2). The nominal price sales, and associated discounts, rebates, payments or other financial transactions included in AMP in accordance with § 447.504(d) (AMP for 5i drugs that are not generally dispensed through retail community pharmacies) do not change because the statute at section 1927(k)(1)(C) of the Act only speaks to authorized generic sales from the manufacturer to wholesalers that distribute to retail community pharmacies.

Comment: A few commenters did not support the proposed regulations that would prohibit manufacturers from blending the brand name AMP and the AMP of the authorized generic in certain situations. For example, one commenter stated that the Health Extenders Act that created the statutory prohibition of the blending of brand name and authorized generic AMPs did not amend the Medicaid drug rebate statute provisions which require the calculation of Medicaid URAs at the drug, dosage form, and strength level. As a result, because the brand product and authorized generic share the same drug, dosage form, and strength, the commenter believes that the provision regarding the calculation of the AMP at the drug, dosage form, and strength level also supports blending of AMPs where the same manufacturer sells both. (The URA for a dosage form and strength of drug for a quarter is calculated using the drug's AMP as one of the inputs.)

Another commenter did not support the proposed regulations requiring the calculation of separate AMPs in certain situations, and stated the statutory AMP exclusion for authorized generics applies only in cases when a manufacturer ''approves, allows, or otherwise permits any drug of the manufacturer to be sold under the manufacturer's [NDA]''. The commenter further indicated that as a result, the requirement to calculate separate AMPs cannot apply where there is no secondary manufacturer. A few commenters did not support CMS' proposal to exclude sales of authorized generics from the AMP calculation of the brand drug when these products are sold without the involvement of a ''secondary'' manufacturer, and stated that the text and history of the Medicaid rebate statute support blending of the AMPs in this circumstance.

Response: We do not agree with the commenters that the statutory text continues to support the blending of the authorized generic sales and brand sales when calculating AMP in certain situations. As described above, and in Manufacturer Releases #111 and #112, section 1603 of the Health Extenders Act made changes to section 1927(k) of the Act, revising how manufacturers calculate the AMP for a COD for which the manufacturer approves, allows or otherwise permits the COD of the manufacturer to be sold under the manufacturer's NDA. That is, manufacturers that approve, allow, or otherwise permit any drug to be sold under the manufacturer's own NDA approved under section 505(c) of the FFDCA shall no longer include those sales in the calculation of the brand name AMP, which includes authorized generic sales.

We have also interpreted this provision regarding the inability of manufacturers to further blend AMPs to apply beyond authorized generic cases to other situations in which a manufacturer approves, allows or otherwise permits the COD to be sold under the manufacturers' NDA. For example, with respect to a manufacturer's importation of drugs under Section 801 of the FFDCA, we issued manufacturer release #114 guidance on September 25, 2020, in which we interpreted that when a manufacturer approves, allows or otherwise permits a drug imported under an NDA to also be sold under the same NDA, then the manufacturer would not be permitted to blend the AMPs of the drug sold in the United States, with the drug that the manufacturer imports which is sold under the same NDA.

With regard to comments suggesting the exclusion not being applicable to situations where both the brand drug and authorized generic drug are approved, allowed, or permitted to sold under the same NDA by the ''same manufacturer'', irrespective of the relationship between the manufacturer of the brand drug, and the entity permitted to sell the authorized generic, if the primary manufacturer ''approves, allows, or otherwise permits'' any drug to be sold under the primary manufacturer's NDA, then the AMP for the brand should be calculated separately from (exclude) the sales of the other drug or drugs that are being sold under that NDA, in this case, an authorized generic. That is, it would not matter whether the manufacturer or entity (that is, the secondary manufacturer) being approved, allowed, or otherwise permitted to sell the drug under the primary manufacturer's NDA was the same, affiliated or non-affiliated from the primary manufacturer as explained further below.

As discussed in the proposed rule (85 FR 37300), after we issued Manufacturer Releases #111 and #112, we received inquiries as to what is meant by ''In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under the manufacturer's NDA approved under section 505(c) of the FFDCA, such term shall be exclusive of the average price paid for such drug by wholesalers for

drugs distributed to retail community pharmacies.'' Specifically, we received questions regarding when a primary manufacturer itself, or an affiliate of the manufacturer is also producing the authorized generic, and whether, such a case, constitutes ''a case of a manufacturer that approves, allows, or otherwise permits'' the drug to be sold under the manufacturer's NDA, such that the exclusion applies. And if not, whether the primary manufacturer may include the average price paid for the authorized generic when calculating AMP for the brand drug.

In Manufacturer release #112, we advised that, until we issue a regulation in final, when a manufacturer approves, allows, or otherwise permits any of its drugs to be sold under the same NDA, a separate AMP should be calculated for each drug product—that is, one AMP for the brand drug, and one AMP for the authorized generic product, and the AMP for the brand drug should exclude sales of the authorized generic product. We also advised that such situation includes both when a manufacturer is the same for both the brand drug and authorized generic version and the situation when the drugs are being manufactured by different, but affiliated companies. For example, the manufacturer making the authorized generic might be a subsidiary of the brand name company, or the two might simply have a corporate or business relationship.

To support this view, we note that the title of section 1603 of the Health Extenders Act amending section 1927(k)(1) and (k)(11) of the Act is ''Excluding Authorized Generic Drugs from Calculation of Average Manufacturer Price for Purposes of the Medicaid Drug Rebate Program,'' and section 1603(a)(1) specifically amended the statutory provision at section 1927(k)(1) by striking ''INCLUSION'' and ''inclusive'' and inserting ''EXCLUSION'' and ''exclusive.'' The statute did not previously, nor was it later amended to distinguish among the different business or corporate relationships, if any, that might exist among the manufacturer of the brand name drug and the entity that that manufacturer approves, allows, or otherwise permits to sell such drug under the same NDA. It simply indicates that the AMP calculation for the brand drug shall be exclusive of (shall not include) the average price paid (sales) of the drug the manufacturer is permitting to be sold under its NDA.

For these reasons, we are also finalizing this rule by not distinguishing among the business or corporate relationships between the companies, such as whether they are subsidiaries, affiliates, or have corporate relationships. However, based on the comments we received, we are amending the current definition of secondary manufacturer found at § 447.506(a) to clarify this point, and are removing the phrase at the end of the definition, ''but does not hold the NDA.'' As noted above, the statute neither before amendment or after distinguishes among the different business or corporate relationships, if any, that might exist among the manufacturer of the brand name drug and the entity that that manufacturer approves, allows, or otherwise permits to sell such drug under the same NDA. And this is likely because in some cases, the primary and secondary manufacturers are one in the same; that is, one manufacturer who holds the NDA makes and markets both the brand name drug and the authorized generic. This regulatory modification will clarify that regardless of the relationship that exists between the primary and secondary manufacturer, that the sales of the authorized generic cannot be blended with the sales of the brand name drug.

Comment: One commenter stated that the AMP for the brand product should still include the price of the authorized generic drug as removing the authorized generic will lead to increasing the price of the brand name medication.

Response: We did not make any proposals related to drug launch prices, have no control over how those are set, and remind the commenter that there is the inflation rebate penalty in the Medicaid drug rebate program for manufacturers that increase prices faster than inflation (CPI–U) on their drugs. This should serve as a disincentive to manufacturers to increase prices faster than inflation.

Moreover, we do not believe that the exclusion of the sales of the authorized generic from the calculation of the brand AMP should increase the price of the brand name drug, as the calculation of the AMP by a manufacturer is done solely to report the AMP value used by CMS to calculate the unit rebate amount for states to bill manufacturers for rebates. While the AMP of the brand name drug will likely increase if the manufacturer can no longer include the sales of the authorized generic, it should not affect the sales price of the brand name drug in the marketplace.

For these reasons, we are finalizing the policy that manufacturers cannot blend the sales of the AMPs for the brand name drug sold under the NDA and the sales of any other drug sold under the NDA, regardless of the relationships between the entities selling the drugs.

After consideration of the comments received, we are finalizing our proposals at §§ 447.502, 447.504 and 447.506 as modified, which includes a clarifying revision to the definition of secondary manufacturer as noted above.

F. Medicaid Drug Rebates (MDR) (§ 447.509)

Manufacturers that participate in the MDRP are required to pay rebates for CODs that are dispensed to Medicaid patients. The rebates are calculated based on formulas described in section 1927(c) of the Act. As described in section I. of the June 2020 proposed rule, the BBA 2015 made revisions to the statutory rebate formula for CODs other than single source or innovator multiple source drugs. That is, section 602 of BBA 2015, amended section 1927(c)(3) of the Act to require that manufacturers pay additional rebates on their CODs other than single source or innovator multiple source drugs (non-innovator multiple source (N) drugs) when the AMP of the N drug increases at a rate that exceeds the rate of inflation. The amendments made by section 602 of BBA 2015 were effective beginning with the January 1, 2017 quarter (that is, first quarter of 2017). The implementation of these amendments was discussed in Manufacturer Release 97 and Manufacturer Release 101.

Prior to the enactment of BBA 2015, the basic quarterly URA calculation for N drugs was equal to 13 percent of a drug's quarterly AMP. However, section 602(a) of BBA 2015 amended section 1927(c)(3) of the Act by adding an inflation-based additional rebate requirement to the URA for N drugs, which is similar to the additional rebate applied to single source (S) and innovator multiple source (I) drugs.

To calculate the additional rebate portion of the URA calculation for N drugs, section 602(a) of BBA 2015 amended section 1927 of the Act to establish a base AMP or base date AMP value for N drugs based, in part, upon each N drug's market date. In general, for N drugs marketed on or before April 1, 2013, the base date AMP is equal to the third quarter of 2014 and the Base CPI–U is the CPI–U for September 2014. For N drugs marketed after April 1, 2013, the base date AMP is equal to the AMP for the fifth full calendar quarter after which the drug is marketed as a drug other than a single source or innovator multiple source drug and the base CPI–U is equal to the CPI–U for the last month of the base AMP quarter.

We proposed to revise § 447.509 to codify the rebate formulas in regulation. Specifically, we proposed to revise paragraph (a)(6) to distinguish the basic rebate for N drugs from this additional rebate. In addition, we proposed to add paragraph (a)(7) to expressly include the additional rebate calculation for N drugs. We proposed that in addition to the basic rebate under paragraph (a)(6), for each dosage form and strength of a N drug, the rebate amount will increase by an amount equal to the product of the following: The total number of units of such dosage form and strength paid for under the state plan in the rebate period, and the amount, if any, by which the AMP for the dosage form and strength of the drug for the period exceeds the base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug. We also proposed to add paragraph (a)(8) to capture that the total rebate amount for noninnovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

In addition to the proposed regulatory changes related to section 602 of BBA 2015 amendments noted in this rule, we also proposed to amend § 447.509 at:

- Paragraph (a)(5) to specify that in no case will the total rebate amount exceed 100 percent of the AMP of the single source or innovator multiple source drug; and
- By adding paragraph (a)(9) to specify that in no case will the total rebate amount exceed 100 percent of the AMP of the noninnovator multiple source drug.
- We also added to paragraph (a)(7)(ii)(B) to state that the base date AMP has the meaning of AMP set forth in section 1927(c)(2)(A)(ii)(II), (c)(2)(B) and (c)(3)(C) of the Act as the regulation did not provide a specific definition of base date AMP for calculating the additional rebate. We believe it is reasonable to include this in regulation to provide further clarity for manufacturers and states with regard to the calculation of the additional rebate, and to ensure the appropriate product data and pricing information is submitted to CMS.

We received the following comments on Medicaid drug rebates (MDR) (§ 447.509).

Comment: A few commenters supported the proposed changes to the calculation for non-innovator multiple source drugs, single source drugs, or innovator multiple source drugs to ensure manufacturers of authorized generic drugs do not take advantage of monopoly situations, and increase prices beyond the rate of inflation.

Response: The proposed changes were made to conform to changes made by section 602 of the BBA 2015 to section 1927(c)(3) of the Act which requires that manufacturers pay additional rebates on their non-innovator multiple source (N) drugs if the AMPs of an N drug increase at a rate that exceeds the rate of inflation. It is not clear what the commenter meant by the statement that these proposed changes would ensure that manufacturers of authorized generics do not take advantage of monopoly situations. Authorized generics are considered innovator multiple source drugs as they are sold under a manufacturer's NDA, and an existing inflation penalty applies to such drugs under section 1927(c)(2) of the Act.

Comment: Several commenters do not support the proposed changes to the inflation rebate or the inclusion of an additional rebate for N drugs. A few commenters noted the additional rebate for non-innovators multiple source drugs (N drugs) would be a disincentive to manufacturers from participating in Medicaid and 340B programs.

Response: While we appreciate the commenters expressing their concerns, the proposed revisions to § 447.509, conform with the changes made by section 602 of the BBA 2015 to section 1927(c)(3) of the Act, which require that manufacturers pay additional rebates on their N drugs if the AMPs of an N drug increase at a rate that exceeds the rate of inflation. This provision of BBA 2015 was effective beginning with the January 1, 2017 quarter, or in other words, beginning with the URAs that are calculated for the January 1, 2017 quarter. Since that date, we have not noticed a decline in manufacturers participating in either the Medicaid program or 340B program.

Comment: One commenter noted the proposed methodology for calculating the basic rebate and the additional rebate could result in a ''double discount'' in situations where products with a price increase that is greater than inflation would also now have to pay an inflation rebate. This commenter recommended rather than add the two rebate components together, a manufacturer should be permitted to sum the total net of the duplicate portion of the rebates.

Response: We believe the commenter is noting that the basic rebate for a non-innovator multiple source drug may already reflect a higher rebate due to price increases on that non-innovator drug resulting in a higher AMP and therefore, the additional rebate duplicates, to some extent, an already increased basic rebate (due to the increase in the AMP). There is no statutory basis to allow for the type of rebate calculation proposal that the commenter is suggesting. We note that section 602 of the BBA of 2015 added section 1927(c)(3) of the Act, which requires that manufacturers pay, in addition to a basic rebate, an additional rebate for their N drugs if the AMPs of an N drug increase at a rate that exceeds the rate of inflation. This provision of BBA 2015 was effective beginning with the January 1, 2017 quarter, or in other words, beginning with the URAs that are calculated for the January 1, 2017 quarter.

After consideration of the public comments received, we are finalizing the proposed changes (described in this section (II.F. of this final rule)) made to § 447.509 without modification.

Additionally, please refer to section II.C.2. of this final rule for a description of other changes we are finalizing to § 447.509 as they relate to drugs that are line extensions.

G. Requirements for Manufacturers (§ 447.510)

In accordance with section 1927(b)(3) of the Act and the terms of the NDRA, manufacturers are required to report pricing information to CMS on a timely basis or face a penalty. Current regulations at § 447.510 implement the manufacturer price reporting requirements including the timing of revisions to pricing data. The current regulation at § 447.510(b)(1) requires that the revision to pricing data be made within the 12 quarters from which the data were due, unless it meets one of the exceptions in paragraphs (b)(1)(i) through (v).

As discussed in section II.B. of the June 2020 proposed rule, VBP has evolved into a possible option for states and manufacturers to help manage drug expenditures. Many VBP arrangements or pay-over-time models may be better suited for periods longer than 12 quarters, and manufacturers entering into such arrangements may need to adjust AMPs and best prices beyond the 12 quarters because the evidence-based or outcomes-based measures are being measured beyond a period of 12 quarters or a final installment payment is being made outside of the 12 quarters. With this evolution it has become apparent that certain manufacturer reporting requirements could be viewed as an impediment to adopting VBP arrangements. For instance, under

current regulations, a manufacturer would not be able to account for any adjustments to prices that may occur outside of the 12 quarters because of VBP arrangements (or even pay-over-time models), as required.

The definition of AMP at section 1927(k)(1)(B)(ii) of the Act, indicates that any other discounts, rebates, payments or other financial transactions that are received by, paid by, or passed through to retail community pharmacies shall be included in AMP for a COD. The special rules in section 1927(c)(1)(C)(ii) of the Act define best price to be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates. Since manufacturers are required to report AMP and best price that capture these statutory required financial transactions, including such financial transactions (for example, rebates, incremental payments) that are a result of VBP arrangements or pay-over-time models, and such pricing structures may be designed to result in transactions taking place outside of the 3-year window, we proposed to add § 447.510(b)(1)(vi) to specify an additional exception to the 12-quarter rule to account for the unique nature of VBP arrangements and pay-over-time models. Specifically, we proposed that the manufacturer may make changes outside of the 12-quarter rule as a result of a VBP arrangement when the outcome must be evaluated outside of this 12-quarter period.

We received the following comments on requirements for manufacturers (§ 447.510).

Comment: Many commenters supported the extension of the price reporting period for VBP arrangements beyond the current 12-quarter restatement window. One commenter noted this will improve the reporting of net prices. Another commenter supported the extension because they noted limiting an outcome measurement to less than the historical 12-quarter maximum, regardless of the clinical data associated with a given treatment, might jeopardize the usefulness of a VBP arrangement.

Response: We appreciate the support for the exception to the 12-quarter restatement window and are finalizing the regulation at § 447.510(b)(1)(vi) as proposed.

Comment: Several commenters provided recommendations for allowing adjustments outside of the 12-quarter window or requested further modifications to CMS' proposals in this section. Specifically, commenters recommended that CMS consider a specific length of the time for the restatement period of AMP and best price for therapies subject to VBP arrangements, such as 5 or 10 years. In addition, commenters requested that CMS address the impact of the amended restatement period on the traditional AMP smoothing methodology. Finally some commenters requested that manufacturers be able to make such restatements in the same way that they can make restatements within the 12-quarter window, that is, without any need for approval by CMS.

Response: This final regulation adds an exception to the 12-quarter rule that allows a manufacturer to request revisions to price reporting (including quarterly AMP and best price reporting) that exceed 12 quarters from which the data was due when the change is a result of a VBP arrangement and the outcome must be evaluated outside of the 12-quarter period. We do not agree with the suggestion that we consider adding a specific length of time for the applicability of the exception outside of the 12 quarters, because our intent is to provide necessary flexibilities understanding the various VBP arrangements will be designed with different protocols, outcomes and timeframes.

For example, there may be a 5-year lag time between the time that a drug is first administered to a patient and the evaluation period for that patient's VBP arrangement. After that, there may be several years of prior period pricing adjustments based on the data that are generated from VBP program's patient results which may affect the pricing data being reported that had already been reported for the initial 5-year period. Manufacturers that use a VBP-based bundled sales approach would also be expected to revise their pricing metrics as additional data are compiled from the VBP arrangement, and make adjustments to AMP and BP, with the ability to make such adjustments outside the 12-quarter reporting window.

We also note that there are currently five exceptions listed at § 447.510(b) to the 12 quarter price reporting rule, and none of these exceptions are time limited. For example, there are currently no time limits on manufacturer requests for changes related to the initial submission of a product (§ 447.510(b)(1)(ii)) or due to a change in drug category or market date (§ 447.510(b)(1)(i)). We do not see a need, therefore, to place a time limit of manufacturer reporting outside the 12 quarter rule regarding VBP arrangements.

We would implement this new exception to the 12-quarter rule in the same manner that we are currently processing requests from manufacturers for other exceptions. That is, the manufacturer would submit its request to us to describe the change they want to make with supporting documentation. If the change is permissible, we will notify the manufacturer that they can make the change in the current reporting system, and then the manufacturer would be able to certify that change.

With respect to permitting revisions to the pricing data under a VBP arrangement, the regulations require manufacturers to request, and for the agency to determine whether or not to ''reopen'' the MDRP for revised pricing outside of the 12 quarters based upon the manufacturer's request and whether it meets an exception at § 447.510(b)(1)(i) through (v). The same practice will apply to this new exception at § 447.510(b)(1)(vi). We will not permit manufacturers to restate pricing data in excess of 12 quarters in MDRP without the manufacturer submitting its request to us.

Comment: A few commenters requested that CMS consider the implications of changes to drug pricing information outside the 12-quarter period on the MDRP and 340B ceiling price calculations.

Response: Price calculations for 340B drugs are made by the Health Resources Services Administration (HRSA) and are based on the pricing data reported to the MDRP each calendar quarter. In accordance with section 340B(a)(1) of the Public Health Service Act, the 340B Ceiling Price and Civil Monetary Penalty final rule defines the 340B ceiling price as calculated as the AMP from the preceding calendar quarter for the smallest unit of measure minus the URA and will be calculated using six decimal places (82 FR 1210). Any retrospective changes to MDRP pricing metrics also affect 340B ceiling prices as the inputs to the ceiling prices would also change. Thus, any changes to MDRP pricing metrics, whether within the 12-quarter adjustment period or outside the 12-quarter adjustment period could affect the 340B ceiling price for the calendar quarter. We would expect manufacturers to make adjustments to their 340B ceiling prices as they have done in the past consistent with any changes to the MDRP pricing metrics.

Comment: A commenter noted the proposal could create a misalignment of discounts and sales volumes in the AMP calculation due to the longer time frame over which patient outcomes will be measured and rebates paid. This commenter recommended CMS engage

commenters to discuss potential solutions to execute through future guidance or rulemaking on a parallel time frame to the effective date of this final rule.

Response: We thank the commenter for this important observation. It is not clear the extent to which ''misalignments'' may occur within AMP calculation as a result of discounts and sales volume under a VBP approach. However, we expect that the ability of manufacturers to request an adjustment of pricing metrics outside the 12 quarter window for VBP-related changes will give manufacturers and payers more flexibility in structuring VBP arrangements as they would know that there could be a longer timeframe for evaluation. This could encourage the use of these programs, which would help increase their use in commercial plans, as well as their use by Medicaid.

Comment: A few commenters requested clarification on specific operational details and implications on the VBP arrangements exception provided in § 447.510(b)(1)(vi). These commenters requested that CMS should consider that out-year payments in VBP approaches do not need to adjust for the time value of money and that the restatement of Best Price should not be necessary as part of a VBP arrangement since the Best Price would have already been reported.

A few commenters requested clarification of how the proposal would address pay-over-time arrangements. One commenter requested clarification on how the proposal would allow for pay-over-time arrangements, specifically, when resetting Best Price more than three years after administration of the drug, and what would qualify as the product's Best Price until the benchmark is met and Best Price is reset, especially as each installment payment may stretch across multiple rebate reporting periods and recommended CMS allow for an annuity payment in the case of one-time therapies/gene-therapies.

Response: We recognize that it will be a challenge for CMS to evaluate and address the impact of every VBP arrangement on government pricing as part of this final rule because there is no standard or ''one-size'' fits all approach to manufacturer VBP arrangements. For example, manufacturers may pay adjustments to payers in the form of rebates if a drug does not work as intended, choose to require payers to pay in installments as the drug meets intended outcomes, or pay premiums to third parties to ''warrant'' their drug products, which would allow a manufacturer to pay the health care costs incurred by a payer as a result of the failure of a particular therapy. All these approaches (and more) may require different calculations to determining best price and AMP, and reporting these figures in MDRP.

We note that some manufacturers that are using a ''pay-over-time'' model that does not involve a VBP component may contract with an intermediary to receive full payment for the drug and thus report it in the manufacturer's AMP when reporting their pricing metrics. That is, the payer makes ''pay-over-time'' payments to the intermediary, and the intermediary makes full payment to the manufacturer so the manufacturer can report the full sale in the quarter in which the drug was administered or dispensed so as not to affect their AMP reporting. The ''best price'' for the quarter would also be reported. However, to the extent that future rebates or discounts adjust the AMP or ''best price'', adjustments would have to be reported as they would under a non pay-over-time model. Finally, because pay-over-time arrangements do not necessarily have an outcomes component and simply allow payers to pay for high cost drugs over a period of time, these types of pay-over-time arrangements would not be subject to the exception at § 447.510(b)(1)(vi) because there is no outcomes related to the pay-over-time payments, and the exception applies only in cases when the VBP arrangement involves an outcome that must be evaluated outside of the 12-quarter period.

We will need to remain flexible as additional VBP design structures come to the market. This being the case, we will consider issuing operational guidance to assist manufacturers in the reporting of AMP and best price and to the extent there is no guidance specific to a manufacturer's VBP arrangement, manufacturers may continue to make reasonable assumptions consistent with statute and regulation regarding the determination of best price and AMP.

Comment: Several commenters did not support the proposed rule providing for an additional exception to the generally applicable 12-quarter reporting rule for certain VBP arrangements. A few commenters noted this would create additional burden on states and fiscal agents to manually review rebates and credits. One commenter noted price reporting requirements for performance-based contracts and annuities with terms greater than 12 quarters are unclear and may cause administrative burden to revise.

Response: We understand and appreciate the comment, as retrospective changes to price reporting can create burdens to states and manufacturers. However, we expect that prior period adjustments resulting from rebates or discounts paid under a VBP program could be made in the same manner as traditional prior period adjustments; that is, through changes to the URA that are sent to states by CMS, and paid by or paid to manufacturers.

Comment: One commenter noted the proposal created opportunity for drug makers to game the system and recommended CMS more clearly define requirements drug makers will need to abide by under the new VBP rules to avoid future gaming.

Response: We appreciate the commenter's concerns. Manufacturers can offer VBP programs to payers under various approaches, such as a ''bundled sales'' approach or a multiple best price approach. These programs must comply with the VBP arrangement definition that we are finalizing in this final regulation in order for a manufacturer to avail itself of the regulatory flexibilities we are finalizing in this regulation.

As has been the case with the MDRP program since its inception, manufacturers are responsible for following all applicable laws, and regulations, including entering into and having in effect a national drug rebate agreement which memorializes these requirements. Such responsibilities will include complying with these new regulations relating to VBP approaches, as applicable. Manufacturers continue to be permitted to make reasonable assumptions where necessary, and remain responsible for documenting and retaining those assumptions as provided at § 447.510(f). Manufacturers will remain subject to enforcement actions, such as CMPs, for false reporting of product and pricing information. In addition, we are delaying the effective date of the multiple best price VBP approach to January 1, 2022. We will provide additional guidance should it be necessary to both protect the integrity of the MDRP, as well as help assure a smooth implementation of the VBP arrangement regulatory flexibilities that will be available under this final regulation.

After consideration of the comments received, we are finalizing the proposed rule without modification.

H. Requirements for States (§ 447.511)

Section 1927(b)(2)(A) of the Act requires that states be held responsible to report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a

standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each COD dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each Medicaid MCO, and shall promptly transmit a copy of such report to the Secretary. The accuracy and timeliness of this SDUD report is important for the MDRP, other programs, and legislative efforts including, but not limited to:

- Actuarial and cost impact projections of legislative or regulatory changes to the MDRP;
- The calculation of Medicaid's portion of the branded prescription drug fee specified at section 9008 of the Affordable Care Act); and
- Ongoing audits that demonstrate that some states still fail to bill rebates for physician-administered drugs (PADs), although it has been 13 years since the requirement began.

States are required to send invoices (CMS–R–144 Medicaid Drug Rebate Invoice) to each manufacturer in the MDRP for which payment was made on behalf of the state and federal government for the manufacturers' drugs, or in the case of MCOs (including PHIPs and PHAPs), drugs dispensed to a beneficiary in a rebate period. States are required to send a copy of their SDUD (a summary report of their invoice utilization data) to CMS each quarter. If a state makes an adjustment to a rebate invoice, the state is required to send an updated SDUD to us in the same reporting period in which the manufacturer received the adjustment.

We have found that some states do not have sufficient edits in place to detect, reject and investigate SDUD outliers, which may distort the rebate amounts due by manufacturers. This results in states overbilling manufacturers and generating disputes on rebate invoices; imposing resource burdens on manufacturers, states, CMS, and other MDRP partners, as well as interrupting the payment of rebates to states and CMS. Many states seemingly fail to implement needed system edits to identify such disputes prior to billing manufacturers. Although both overbilling and underbilling must be disputed, manufacturers often neglect to dispute instances of rebate underbilling.

We have also found that many states do not send the same SDUD to CMS as they transmit to manufacturers. In fact, some states send us ''pre-edited'' SDUD, while the manufacturer's rebate invoice contains edited data. These practices do not comply with section 1927(b)(2)(A) of the Act and § 447.511(b), which require that states submit the same SDUD to us on a quarterly basis that they transmit to the manufacturers. As we move to implement new systems, we expect to put in place data error screening to better reject or alert identified potential inaccuracies to SDUD. States should also be improving current systems and planning updates to future systems to better identify and correct inaccurate SDUD before reporting to manufacturers and CMS.

Accurate reporting of SDUD to CMS is important for a number of reasons that extend beyond the MDR program. We remind states and manufacturers that the state submission of utilization data to us for purposes of the MDR program is also available on our public website (*https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html*), and is reviewed and utilized by various entities (that is, IRS, OIG). State Release 177 (July 21, 2016) (*https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-177.pdf*) addresses ''Non-Compliant State Drug Utilization Data Reporting to CMS.''

We are now providing additional information to assist states in more accurately reporting SDUD to us. SDUD should only contain utilization data on NDCs that are eligible for both FFP and for rebates under the CMS rebate program. Therefore, SDUD reporting should not include an NDC that is not a COD and not eligible for rebates, even though it may be covered by a state as a prescribed drug and eligible for FFP.

States should identify and exclude utilization of those drugs whose NDCs are:

- Paid for with only state funds;
- Not representative of CODs (for example, eligible for FFP as a prescribed drug but not eligible for rebates);
- Prohibited from receiving FFP (for example, COD status 05 and 06, drugs for erectile dysfunction or sexual dysfunction for which there is no other FDA-approved indication); and
- For units utilized for 340B claims prior to submitting their utilization data to CMS.

After an SDUD file is successfully processed by CMS, the system generates a Utilization Discrepancy Report (UDR) that lists edits and alerts that were triggered when the SDUD file was processed. The UDR is routed back to the state via the EFT process and should be received within 2 days of submitting the SDUD file to CMS. While states should review each UDR in its entirety for data issues, certain data edits should be scrutinized more closely as they may affect state rebate billing. These error and alert messages include:

- NDC's COD Status indicates a less-than-effective drug;
- NDC has been terminated for more than 4 quarters;
- Labeler code is terminated for the submitted quarter/year combination;
- Labeler code does not participate in the MDR program;

As states evaluate whether submitted SDUD should be revised, they should also evaluate whether their CMS–64–R reports require revision because they included costs for drugs that do not qualify for FFP. States may find additional helpful information in the Medicaid Drug Rebate Data Guide for States that is located in the ''Documents'' section of DDR.

To better hold states accountable for their data integrity and to mitigate the effects of inaccurate and untimely SDUD, we proposed to revise § 447.511. Specifically, we proposed to revise paragraph (a) to specify that any subsequent updates or changes in the data on the CMS–R–144 must be included in the state's utilization data submitted to CMS. We also proposed to revise paragraph (b) to state that, on a quarterly basis, the state must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers on the CMS–R–144, as specified in § 447.511(a). In addition, to conform to the statutory requirement at section 1927(b)(2)(A) of the Act, we proposed to add in regulatory text that the state data submission will be due no later than 60 days after the end of each rebate period. In the event that a due date falls on a weekend or federal holiday, the submission will be due on the first business day following that weekend or federal holiday. We also proposed that any adjustments to submitted data would be transmitted to the manufacturer and CMS in the same reporting period.

We also proposed to add § 447.511(d) to specify that the state data must be certified by the state Medicaid director (SMD), the deputy state Medicaid director (DSMD), or an individual other than the SMD or DSMD, who has authority equivalent to an SMD or DSMD or an individual with the directly delegated authority to perform the certification on behalf of the individuals noted in this rule.

We also proposed to add § 447.511(e) to specify the state data certification language that must be included in the submission. That is, each data submission by a state must include the following certification language:

I hereby certify, to the best of my knowledge, that the state's data submission is complete and accurate at the time of this submission, and was prepared in accordance with the state's good faith, reasonable efforts based on existing guidance from CMS, section 1927 of the Act and applicable federal regulations. I further certify that the state has transmitted data to CMS, including any adjustments to previous rebate periods, in the same reporting period as provided to the manufacturer. Further, the state certifies that it has applied any necessary edits to the data for both CMS and the manufacturer to avoid inaccuracies at both the NDC/line item and file/aggregate level. Such edits are to be applied in the same manner and in the same reporting period to both CMS and the manufacturer.

We received the following comments on our proposed changes to the requirements for states (§ 447.511).

Comment: One commenter requested clarification as to whether a fiscal agent Rebate Analyst (that is, a contractor) can be delegated the authority from the SMD or DSMD to certify the quarterly file transfer.

Response: The proposed rule specified that the authority to certify may also be delegated to an individual who is authorized to perform the certification on behalf of the SMD or DSMD, and does not limit or restrict a state's ability to delegate the certification function to a fiscal intermediary or contractor. Ultimately, it is the state's responsibility to ensure that the data submitted to CMS complies with the applicable statutory and regulatory requirements and is certified as required.

After consideration of the comments, we are finalizing the proposed rule without modification. However, since CMS will need to develop a collection instrument to address these requirements, we are delaying the effective date of this provision until January 1, 2022.

I. State Plan Requirements, Findings and Assurances (§ 447.518)

Traditionally, states have utilized the SRA pathway to secure additional rebates over and above the federal rebate required of manufacturers participating in the MDRP. To do so, the Secretary must authorize a state to enter directly into these agreements with a manufacturer in accordance with section 1927(a)(1) of the Act. In accordance with section 1927(a)(1) of the Act, we require states to submit a SPA for a SRA which includes a template of the SRA providing the framework for the agreement the state has with the manufacturer. A CMS-authorized SRA provides the parameters the state and manufacturer agree upon regarding the supplemental rebates, including that such rebates are at least as large as the rebates required by the federal government.

To make new and innovative drugs more available to Medicaid patients, states are permitted to use a SRA pathway to negotiate VBP agreements with manufacturers that are intended to be financially beneficial for Medicaid. As with a traditional SRAs, these VBP SRAs must be financially advantageous for states, but may also include an evidence or outcomes-based measure linked to the rebate. As with any other SRA, states are required to seek a SPA approval for a VBP SRA in accordance with section 1927(a)(1) of the Act. Through the SRA SPA process, a state, when approved by CMS, can enter into VBP SRAs directly with manufacturer(s) for both FFS and MCO (including PHIPs and PHAPs) COD claims. Under the SRA VBP arrangement, the state may need to set up processes to report the results of the evidence or outcomes-based measures of the patient back to the manufacturer. This could require the state to take on additional responsibilities and expense to eventually collect a rebate, such as tracking the patient, collecting data on the patient (such as the results of evidence or outcomes-based measures) or providing services to the patient.

We understand that more states want to develop their own VBP arrangements, but states want to better understand the challenges, resources and costs to structure these programs and make them successful. In addition, given that we have a significant interest in the success of these innovative VBP programs, as well as the nature of the drugs that are subject to these agreements, we have an interest in helping evaluate these programs' effectiveness. To accomplish this, we want to create a mechanism to exchange information about state VBP programs. This approach is consistent with section 1902(a)(30)(A) of the Act which requires that methods and procedures be established relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care.

Therefore, in accordance with section 1902(a) of the Act, we proposed that states provide to us specific data elements associated with these CMS-authorized VBP SRAs to ensure that payments associated with Medicaid patients receiving a drug under a VBP structure are consistent with efficiency, economy, and quality of care. To that end, we proposed adding § 447.518(d)(1) and (2) to specify that a state participating in a CMS-authorized supplemental rebate VBP arrangement report data as specified on a yearly basis, and within 60 days of the end of each year, including the following data elements:

- State.
- National Drug Code(s) (for the drugs covered under the VBP arrangement).
- Product's FDA list name
- Number of prescriptions.
- Cost to the state to administer VBP arrangement (for example, systems changes, tracking outcomes, etc.).
- Total savings generated by the supplemental rebates due to VBP arrangement.

We invited comments on this approach and were particularly interested in understanding from the states those issues regarding the burden that such a proposal might create, and from all commenters on whether the data elements being collected are appropriate and useful to meet the goals of the proposal that we have described in this rule.

We received the following comments on state plan requirements, findings and assurances (§ 447.518).

Comment: A few commenters did not support the proposed changes to the state plan requirements section regarding VBP data requirements and recommended CMS clarify that states do not need to seek approval via a SPA to enter into VBP arrangements, whether based upon manufacturer arrangements with commercial payers or on their own. However, one commenter agreed that states should not be able to implement such substantial shifts (for example VBP arrangements) in their operations without federal approval.

Response: We understand that there may have been confusion over the breadth of our proposal. This new state reporting requirement will apply only to the information and data generated under the CMS-authorized VBP SRAs that states enter into with manufacturers under CMS approved templates. Therefore, we are revising the proposed changes to § 447.518(d)(1) and (2) (in this final rule at § 447.518(d)(2) and (3)) to make it clear that the data be specific only to CMS-authorized supplemental rebate agreements. As noted above, several state Medicaid programs already have CMS-authorized supplemental rebate agreements that provide a template for them to enter into VBP

agreements with manufacturers. These specific agreements allow the rebates that are negotiated with the manufacturers to be exempt from best price as found under our regulations at § 447.505(c)(7). We will continue to require that states seek approval of these types of SRAs through the SPA process.

States will not need to seek CMS approval for entering into a VBP agreement with a manufacturer under the new multiple best price approach. Nor will states have to report to CMS any information or data generated under these arrangements. We would expect that states and manufacturers would have to enter into a separate agreement under a multiple best price arrangement to indicate their intent to meet the manufacturer's requirements (for example, patient testing, patient tracking). Should the manufacturer and state negotiate additional rebates over and above those that are offered under theVBP arrangement reported to CMS, then the state would have to do that under a CMS authorized VBP SRA to exempt those prices from ''best price.''

We refer readers to the description of current policy related to state utilization of SRAs as a pathway to securing additional rebates over and above the federal rebate required of manufacturers participating in the MDRP in the proposed rule (85 FR 37302 and 37303), and past guidance regarding SRAs and SPA requirements, which is available at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd091802.pdf and https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-099.pdf.*

Comment: Several commenters supported the proposed changes for states to seek a SPA prior to implementing changes to SRAs. One commenter noted the SPA requirements improve the MDRP and allow those states that have an interest to adopt the same types of agreements that manufacturers have entered into with commercial payers.

Response: We are not revising the state plan requirements related to the SPA process for submission of SRAs. However, we are adding a new requirement relating to the conditions for the approval of such CMS authorized VBP SRAs such that states provide us with certain information relative to the operation and results of the VBP program so that we may evaluate the effectiveness of the programs and share the information with other states. We proposed that states provide to us specific data elements associated with VBP SRAs to ensure that payments associated with Medicaid patients receiving a drug under a VBP structure are consistent with efficiency, economy, and quality of care.

Comment: One commenter noted these requirements improve transparency relevant to the effectiveness of VBP arrangements as part of a state's SRA, but expressed concern that this approach could affect Medicaid MCOs from negotiating between states and pharmaceutical manufacturers.

Response: We agree that the proposed requirements to collect data regarding a state's VBP SRA arrangement may impact Medicaid MCO negotiations with states and manufacturers to the extent the state and the Medicaid MCO have agreed to include Medicaid managed care enrollees in the state's VBP SRA arrangements. If the Medicaid managed care enrollees are part of the state's VBP SRA arrangement, the state and Medicaid MCO will likely need to establish responsibilities regarding the collection and reporting of data so that states meet the data collection requirements set forth in this final rule.

Comment: A few commenters provided additional recommendations to the proposed changes to § 447.518(d) for CMS' consideration. One commenter recommended that CMS develop a federal framework for state Medicaid agencies to design and implement a VBP arrangement, including expanding the existing SRA requirements to better enable state VBP arrangements. Another commenter recommended CMS require VBP arrangements to include minimum and maximum and expected rebates, such as a high cost drug threshold to avoid impact to Preferred Drug List classes and SRAs.

Response: We have an interest in helping states ensure they understand and evaluate these programs' effectiveness. To accomplish this, we proposed the collection of specific data elements to exchange information about state VBP programs, and in the event this information reveals federal involvement is needed we may address it in the future. We believe our proposal is consistent with section 1902(a)(30)(A) of the Act which provides that a state plan must provide, in part, such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care.

Comment: A few commenters agreed with the proposed state reporting requirements and offered additional recommendations to CMS. One commenter recommended additional reporting elements, including identifying the drugs under the VBP arrangement, the number of prescriptions, and the costs and savings attributed to the arrangement, and the number of beneficiaries covered under a VBP arrangement. One commenter recommended states report to CMS the average net price paid per unit and per prescription of each drug in a state's VBP arrangement.

Response: We appreciate the support for the proposed data elements and appreciate the suggestions for additional reporting elements. We are finalizing the regulation as proposed, which includes a requirement for the state to identify the specific drug by NDC, the product FDA list name, and the number of prescriptions, and cost and savings attributed to the VBP arrangement. Further instructions regarding the instrument for collection of these data elements will be provided in guidance. We are not finalizing a requirement for the state to report the number of beneficiaries covered under a particular VBP arrangement, as reporting of a low number of participants may lead to privacy concerns. As for the recommendation to require the reporting of the net price paid per unit and per prescription of each drug, we are not accepting this recommendation as this data element relates to a manufacturer's proprietary drug pricing information.

Comment: A few commenters had concerns about consistency of state reporting and requested further guidance or modifications to the proposed data. Specifically, a commenter recommended CMS provide guidance to states to ensure the accuracy and consistency of state calculations of the required elements. Another commenter recommended CMS mandate that states provide claims-level data as a means of ensuring the accuracy of their calculations and reporting.

Response: We intend to prepare a collection instrument which will allow states to report consistent data. If necessary, we will provide additional guidance as states submit reporting obligations. We will not require state collection and reporting of claims-level data at the federal level. However, a state may review its own claims-level data related to the VBP arrangement to further analyze Medicaid beneficiary impact and overall Medicaid program impact at the state level.

Comment: One commenter noted VBP arrangements may involve measuring outcomes over months or years so reporting that would take place annually may fail to provide an accurate measure of the total savings.

Response: We agree that measuring outcomes may take place over a period longer than a year and annual reporting may not result in a full picture of what savings can be generated by a VBP arrangement. Therefore, we are requesting that the data collected and reported in the annual report be cumulative so that the annual report provides the data elements that are requested, and that the final report on the VBP program is generated within 60 days after the final year of the VBP time period. Therefore, we are revising the regulation at § 447.518(d)(2) and (3) to provide that a state participating in a VBP arrangement approved under a CMS authorized SRA report the required data (including cumulative data to date) found at paragraphs (d)(3)(i) through (vi) within 60 days of the end of each year also include cumulative data.

Comment: One commenter did not support the proposed state VBP reporting requirements and recommended CMS implement reporting requirements at a later date.

Response: These reporting requirements will be effective January 1, 2022. This will give states time to prepare to submit this information to us.

Comment: Several commenters disagreed with the proposed state reporting requirements citing their belief that they will disclose proprietary information between the manufacturer, PBM, and state. These commenters recommended CMS clarify that the actual terms and conditions of the contracts would not be subject to full disclosure.

Response: We do not believe the data elements that will be collected in accordance with this final rule will disclose proprietary information. The reporting requirements do not include a state's reporting of actual terms and conditions of the contracts between the state, manufacturer(s), and PBMs.

Comment: A few commenters recommended CMS establish clear guidance regarding how states should calculate savings in a VBP SRA arrangement and how states should calculate the administrative expenses of entering into a VBP SRA arrangement. Another commenter noted the data element requiring states to report the total savings generated by the supplemental rebate due to the VBP may underestimate savings due to failure to account for rebates that have yet to be paid. One commenter requested clarification on how CMS intends to utilize these annual state reports to evaluate VBP SRA arrangements.

Response: We are finalizing the proposal to require the data elements specified in the proposed rule and will provide further instructions regarding the collection of these data elements in guidance. Given the fact that each VBP arrangement has distinct measures and cost strategies, a one size fits all approach to calculating savings will be a challenge to state Medicaid programs. As stated in the preamble to the proposed rule, these annual reports from states will give CMS and states a better understanding of the challenges, resources and costs to structure these programs and make them successful. To accomplish this, we believe this collection will assist states in evaluating information about savings generated by state supplemental rebates received under VBP arrangements.

Comment: One commenter supported the proposed data elements required to be reported by states to CMS, although noted that many VBP arrangements may show little-to-no economic value in the beginning especially during a multi-year arrangement.

Response: We appreciate the support for the collection of the data elements. The reporting of these data elements will hopefully guide us and the states that choose to participate in VBP arrangements as to whether participating in such arrangements bring economic value to Medicaid.

For the reasons stated above, we are finalizing the policy that states that enter into VBP agreements with manufacturers under a CMS-authorized supplemental rebate agreement template must report to us within 60 days of the end of each calendar year, on the data described in the regulation, including cumulative data to date, regarding the operation and parameters of their VBP arrangements. Thus, for the reasons discussed in the proposed rule (82 FR 37302 and 37303) and after consideration of the comments received we are finalizing the regulations as proposed with modification to 447.518(d) by making it clear that only VBP arrangements approved under a CMS-authorized SRA must submit the data described and ''including cumulative data to date'' in the regulatory text. Furthermore, while we proposed to revise § 447.518(d)(1) and (2), we are redesignating these sections as § 447.518(d)(2) and (3) in this final rule. This section will not be effective until January 1, 2022 to allow time for CMS to generate a collection instrument to collect the state's information.

J. Drug Utilization Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims (§§ 456.700 Through 456.725), Managed Care Standard Contract Requirements and Requirements for MCOs, PIHPs, or PAHPs That Provide CODs (§ 438.3(s))

Section 1004 of the SUPPORT Act requires states to implement certain opioid-specific DUR standards within their FFS and managed care programs. These requirements supplement preexisting DUR standards under section 1927(g) of Act. In Medicaid, DUR involves the structured, ongoing review of healthcare provider prescribing, pharmacist dispensing, and patient use of medication. DUR involves a comprehensive review of patients' prescription and medication data and dispensing to help ensure appropriate medication decision-making and positive patient outcomes. Potentially inappropriate prescriptions, unexpected and potentially troublesome patterns, data outliers, and other issues can be identified when reviewing prescriptions through prospective DUR or retrospective DUR activities. In Prospective DUR, the screening of prescription drug claims occurs to identify problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy and clinical misuse or abuse prior to dispensing of the prescription to the patient. Retrospective DUR involves ongoing and periodic examination and reviews of claims data to identify patterns of inappropriate use, fraud, abuse, or medically unnecessary care, and facilitates corrective action when needed. Often times, these activities are synergistic; information gleaned through retrospective DUR claim reviews can be used to shape effective safety edits that can be implemented through prospective DUR, better enabling prescribers and dispensers to investigate prescription concerns prior to dispensing the medication to the patient. From prospective alerts (which can incorporate information from the beneficiary's claims data), potential issues can be identified to help promote the appropriate prescription and dispensing of outpatient drugs to beneficiaries. DUR programs play a key role in helping health care systems understand, interpret, and improve the prescribing, administration, and use of medications.

Section 1902 of the Act, as amended by section 1004 of the SUPPORT Act,

requires states to implement safety edits and claims review automated processes for opioids as DUR requirements. We interpret ''safety edits'' to refer to the prospective DUR review specified in section 1927(g)(2)(A) of the Act. These prospective safety edits provide for identifying potential problems at point of sale (POS) to engage both patients and prescribers about identifying and mitigating possible opioid misuse, abuse, and overdose risk at the time of dispensing. The POS safety edits provide real-time information to the pharmacist prior to the prescription being dispensed to a patient, but do not necessarily prevent the prescription from being dispensed. When a safety edit is prompted, the pharmacist receives an alert and may be required as dictated by good clinical practice and predetermined standards determined by the state, to take further action to resolve the issue flagged by the alert before the prescription can be dispensed.[23] A claims review automated process, which we interpret to refer to as a retrospective DUR review as defined in section 1927(g)(2)(B) of the Act, provides for additional examination of claims data to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. Retrospective reviews often involve reviews of patient drug and disease history generated from claims data after prescriptions have been dispensed to the beneficiary. For many retrospective reviews, in an effort to promote appropriate prescribing and utilization of medications, claims data is evaluated against state determined criteria on a regular basis to identify recipients with drug therapy issues, enabling appropriate action to be taken based on any issues identified. After these reviews, prescribers often have the opportunity to review prescriptions and diagnosis history and make changes to therapies based on the retrospective review intervention. Retrospective claims reviews provide access to more comprehensive information relevant to the prescriptions and services that are being furnished to beneficiaries and better enable and encourage prescribers and dispensers to minimize opioid risk in their patients, and assure appropriate pain care.

Many of the proposed safety edits and reviews described in the June 2020 proposed rule were designed to implement requirements outlined in the SUPPORT Act. The purpose of these safety edits and claims reviews is to prompt prescribers and pharmacists to conduct additional safety reviews to determine if the patient's opioid use is appropriate and medically necessary. Provisions to address antipsychotic utilization in children and fraud and abuse requirements were also included in the SUPPORT Act and are measures designed to enhance appropriate utilization of medication. In the proposed rule, we recognized that the SUPPORT Act provides considerable flexibility for states to specify particular parameters of the safety edits, claims review automated processes, program for monitoring use of antipsychotic medications in children, and process for identifying fraud and abuse. Additionally, we acknowledged that many states already have effective DUR processes and other controls in place, and that section 1902(oo)(1)(E) of the Act (as added by section 1004 of the SUPPORT Act) clarified that states may meet new opioid-related requirements with such safety edits, claims review automated processes, programs, or processes as were in place before October 1, 2019. However, to ensure a consistent baseline of minimum national standards for these DUR activities, while preserving appropriate flexibility for the states to determine their particular parameters and implementation, we explained our belief that it is necessary under our authority to implement section 1927(g) of the Act, to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, to codify in regulation the proposed safety edits, claims review automated processes, program for monitoring antipsychotic medications in children, and fraud and abuse process requirements as described in the June 2020 proposed rule. Accordingly, we proposed provisions to implement opioid-related requirements established in the SUPPORT Act and further implement requirements under section 1927(g) of the Act, in an effort to reduce prescription-related fraud, misuse and abuse.

In addition to codifying the SUPPORT Act requirements, we proposed additional minimum DUR standards in the June 2020 proposed rule that states would be required to implement as part of their DUR programs. Specifically, section 1927 of the Act provides for drug use review programs for CODs to ensure that prescriptions (1) are appropriate, (2) are medically necessary, and (3) are not likely to result in adverse medical results. Accordingly, under our authority to implement section 1927(g) of the Act and consistent with the goals of the SUPPORT Act to ensure the appropriate use of prescription opioids, we proposed minimum standards for DUR reviews related to medication assisted treatment (MAT) and identification of beneficiaries who could be at high risk of opioid overdose for consideration of co-prescription or co-dispensing of naloxone.

We also sought comments on potential additional standards that we might implement through future rulemaking, to ensure minimally adequate DUR programs that help ensure prescribed drugs are appropriate, medically necessary, and not likely to result in adverse medical results. We interpreted adverse medical results to include medication errors or medical adverse events, reactions and side effects. We noted our anticipation that any such additional standards would be clinically based and scientifically valid and developed with state collaboration, standards development organizations, and entities that support Medicaid DUR programs, and would help ensure all states have established a reasonable and appropriate DUR program. Such proposed standards would align with current clinical guidelines and could address the following: Maintaining policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications, establishing quality assurance measures and systems to reduce medication errors and adverse drug interactions, and improving medication compliance and overall well-being of beneficiaries. We also noted that we would consider other mechanisms to encourage states to adopt additional DUR standards in a timely manner to respond to new and emerging issues in drug use, as the rulemaking process can be a lengthy process. For example, we are considering issuing possible future suggested ''best practices'' or guidance for states in advance of and in anticipation of rulemaking. We sought comments on the best processes for collaboratively developing future minimum DUR standards and sought comments from states and other commenters on potential approaches.

The early signs of the opioid crisis emerged years ago, with groundwork for the crisis being laid in the late 1990s, when providers began to prescribe opioid analgesics at greater rates, which led to widespread misuse and abuse of both prescription and illegal opioids. After what the CDC characterizes as a ''first wave'' of opioid deaths, a second wave followed in 2010, involving heroin, with a third wave beginning in

[23] Prada, Sergio. (2019). Comparing the Medicaid Prospective Drug Utilization Review Program Cost-Savings Methods Used by State Agencies in 2015 and 2016. American Health and Drug Benefits. 12–7–12.

2013 involving overdoses from synthetic opioids.[24] CDC data indicate that from 1999 through 2017, almost 400,000 people died in the United States from an overdose involving any opioid, including prescription and illicit opioids.[25] In 2018, there were an additional 67,367 drug overdose deaths in the United States. The age-adjusted rate of overdose deaths decreased by 4.6 percent from 2017 (21.7 per 100,000) to 2018 (20.7 per 100,000). Opioids—mainly synthetic opioids (other than methadone)—are currently the main driver of drug overdose deaths. Opioids were involved in 46,802 overdose deaths in 2018 (69.5 percent of all drug overdose deaths) [26] and two out of three (67.0 percent) opioid-involved overdose deaths involved synthetic opioids.[27]

In a 2016 informational bulletin titled, ''Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction,'' [28] CMS issued guidance to states to outline how to help curb the opioid crisis, and in 2019, guidance was issued on how states can use statutory authority to expand the treatment of pain through complementary and integrative approaches.[29] Section 6032 of the SUPPORT Act has directed HHS to collaborate with the Pain Management Best Practices Inter-Agency Task Force (PMTF) to develop an action plan on payment and coverage in Medicare and Medicaid for acute and chronic pain, and substance use disorders (SUDs), informed by a RFI and a public meeting held at CMS in September, 2019.[30] The action plan is related to CMS's Fighting the Opioid Crisis Roadmap, which describes our three-pronged approach to managing pain using a safe and effective range of treatment options that rely less on prescription opioids, expanding treatment for opioid use disorder (OUD), and using data to target prevention efforts and identify fraud and abuse.[31]

In 2018, the SUPPORT Act was passed as part of a bipartisan effort to address the opioid crisis, as well as the treatment of pain. The practice of chronic pain management and the opioid crisis have influenced one another as each has evolved in response to different influences and pressures. At the same time CMS seeks to implement these requirements, we want to ensure Medicaid beneficiaries with chronic pain can work with their health care providers to optimize function, quality of life, and productivity while minimizing risks for opioid misuse and harm such as addiction and overdose.[32] Therefore, we discussed in the June 2020 proposed rule that we considered appropriate approaches through which we could collaboratively develop future minimum DUR standards with involvement from states and other commenters, taking into account the need for administrative flexibility and adequate time for operational implementation, which could be implemented more quickly to respond to public health crises that may arise in the future on a more rapid timeframe. We also considered posting DUR recommendations on our website or through guidance to states to allow quick dissemination of the information.

1. Minimum Standards for DUR Programs Under the SUPPORT Act and Section 1927 of the Act

In § 456.703, we proposed to redesignate paragraph (h) as paragraph (i) and to add a new paragraph (h), specifying minimum standards for DUR programs. The proposed minimum standards in § 456.703(h)(1), discussed in greater detail in this rule, would implement the amendments made by section 1004 of the SUPPORT Act and section 1927(g) of the Act and are intended to help ensure DUR programs continue to adapt and improve the quality of pharmaceutical care provided to beneficiaries in the face of evolving healthcare guidelines and technology practices.

We proposed the provisions in this rule for implementation of requirements in the SUPPORT Act [33] consistent with section 1927(g) of the Act. The proposed safety edits and claim reviews were intended to help protect beneficiaries from serious potential consequences of overutilization, including misuse, abuse, overdose, and increased side effects. In addition to the risk of overutilization and diversion, we noted that opioids can have side effects including respiratory depression, confusion, tolerance, and physical dependence.[34]

The CDC has recommended, in 2016 guidance,[35] that primary care providers prescribing to adults in outpatient settings consider non-pharmacologic therapy and non-opioid pharmacologic therapy as the first-line treatment for chronic pain.[36] The CDC guideline defines chronic pain as ''pain continuing or expected to continue for greater than 3 months or past the time of normal tissue healing.'' Regarding chronic pain, CDC states clinicians should use caution when initiating prescribing opioids at any dosage, and should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.[37] Caution is also recommended in prescribing opioids for acute pain, noting that long-term opioid use often begins with treatment of acute pain; when opioids are prescribed for non-traumatic, non-surgical acute pain, primary care clinicians should prescribe the lowest effective dose for the shortest duration possible- usually 3 days or less is sufficient and more than 7 days will

[24] ''Understanding the Epidemic.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 19 Dec. 2018, *https://www.cdc.gov/drugoverdose/epidemic/index.html.*

[25] ''Understanding the Epidemic.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 19 Dec. 2018, *www.cdc.gov/drugoverdose/epidemic/index.html.*

[26] Hedegaard H, Miniño AM, Warner M. Drug Overdose Deaths in the United States, 1999–2018.pdf icon NCHS Data Brief, no. 356. Hyattsville, MD: National Center for Health Statistics. 2020.

[27] Wilson N, Kariisa M, Seth P, et al. Drug and Opioid-Involved Overdose Deaths—United States, 2017–2018. MMWR Morb Mortal Wkly Rep 2020; 69:290–297.

[28] ''Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction.'' CMCS Informational Bulletin available at *www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf.*

[29] ''Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management.'' CMCS Informational Bulletin at *https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib022219.pdf.*

[30] ''Request for Information for the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment.'' CMCS request for information available at *https://www.cms.gov/About-CMS/Story-Page/Opioid-SUPPORT-Act-RFI.pdf.*

[31] ''CMS Roadmap: Fighting the Opiod Crisis.'' Available at *http://wwww.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf.*

[32] Pain Management Best Practices Inter-Agency Task Force. ''Pain Management Best Practices.'' Available at *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

[33] *https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf.*

[34] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Aug. 2017, *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf.*

[35] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' Centers *for Disease Control and Prevention,* Centers for Disease Control and Prevention, 18 Mar. 2016, *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1er.html.*

[36] Dowell, D., Haegerich, T.M., Chou, R. CDC Guideline for Prescribing Opioids for Chronic Pain-United States 2016, *Morbidity and Mortality Weekly Report* March 18, 2016: 65)1 [Accessed February 11, 2019 at *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.*

[37] ''CDC Guidelines for Prescribing Opioids for Chronic pain.'' Available at *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

rarely be needed.[38] Non-pharmacologic therapies pose minimal risks, and many of these treatments, when available and accessible—such as exercise therapy, physical therapy, and cognitive behavioral therapy (CBT)—have been shown to effectively treat chronic pain associated with some conditions.[39] For example, exercise therapy can be effective in treating moderate pain associated with lower back pain, osteoarthritis, and fibromyalgia in some patients.[40]

In 2019, HHS' PMTF issued its report to HHS and Congress, *the Pain Management Best Practices Inter-Agency Task Force Report,* on best practices for the treatment of acute and chronic pain. The CDC has identified 50 million adults in the United States with chronic daily pain,[41] and the National Institutes of Health (NIH) states that chronic daily pain cost the nation between $560 billion and $635 billion annually.[42] [43] The PMTF final report emphasizes a person-centered approach to pain care that includes the use of individualized, multimodal treatment based on an effective pain treatment plan, and the PMTF identified and described five broad treatment categories: Medications; restorative therapies; interventional approaches; behavioral approaches; and complementary and integrative health that can be used through multidisciplinary care. In its report, the PMTF recognized that there have been ''unintended consequences that have resulted following the release of the CDC guideline in 2016, which are due in part to misapplication or misinterpretation of the guideline, including forced tapers and patient abandonment'' [44] and noted the ''CDC has also published a pivotal article in the New England Journal of Medicine on April 24, 2019, specifically reiterating that the CDC guideline has been, in some instances, misinterpreted or misapplied.'' [45] HHS recently issued the Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics, to assure proper tapering and discontinuation of long-term opioids, in part to avoid harms and encourage person-centered care that is tailored to the specific needs and unique circumstances of each pain patient,[46] in addition to the CMS-issued guidance to states in 2016 and 2019 to both outline how to help curb the opioid crisis and provide guidance to states that want to expand care for the treatment of pain.[47] [48]

Accordingly, we proposed to add § 456.703(h)(1)(i) to include minimum standard requirements as described in the June 2020 proposed rule, with the detailed design and implementation specifications left to the state's discretion to meet state-specific needs. We noted that the purpose of these proposed safety edits (specifically, safety edits to implement state-defined limits on initial prescription fill days' supply for patients not currently receiving opioid therapy, quantity, duplicate fills, and early refills) and reviews is to further implement section 1927(g) of the Act to prevent and reduce the inappropriate use of opioids and potentially associated adverse medical events to sufficiently address the nation's opioid overdose epidemic, consistent with the provisions under section 1004 of the SUPPORT Act.

When implementing the SUPPORT Act, we proposed the following safety edits in § 456.703(h)(1)(i) in addition to a comprehensive opioid claims review automated retrospective review process where trends witnessed in safety edits can be reviewed and investigated. We noted that these reviews would allow subsequent appropriate actions to be taken as designed by the states.

a. Opioid Safety Edits Including Initial Fill Days' Supply for Opioid-Naïve Beneficiaries, Quantity, Therapeutically Duplicative Fills, and Early Refill Limits

The SUPPORT Act requires states to have in place prospective safety edits (as specified by the state) for subsequent fills for opioids and a claims review automated process (as designed and implemented by the state) that indicates when an individual enrolled under the state plan (or under a waiver of the state plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the state.[49] As discussed in detail in this rule, consistent with the SUPPORT Act and DUR requirements under section 1927(g)(2)(A) of the Act, we proposed that state-identified limitations must include state-specified restrictions on initial prescription fill days' supply for patients not currently receiving opioid therapy; quantity limits for initial and subsequent fills, therapeutically duplicative fills, and early fills on opioids prescriptions; and a claims review automated process that indicates prescription fills of opioids in excess of these limitations to provide for the ongoing periodic reviews of opioids claim data and other records to identify patterns of fraud, abuse, excessive utilization, or inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization among physicians, pharmacists and individuals receiving Medicaid benefits. To further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT Act, we proposed to require these safety edits to reinforce efforts to combat the nation's opioid crisis and ensure DUR opioid reviews are consistent with current clinical practice. We noted that these proposed safety edits were intended to protect Medicaid patients from serious consequences of overutilization, including overdose, dangerous interactions, increased side effects and additive toxicity (additive side effects). In addition, we noted that overutilization of opioids may serve as an indication of uncontrolled disease

[38] Dowell, D., Haegerich, T.M., Chou, R. CDC Guideline for Prescribing Opioids for Chronic Pain-United States 2016, *Morbidity and Mortality Weekly Report* March 18, 2016: 65)1 [Accessed February 11, 2019 at *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm*].

[39] For a review of the evidence base for CBT, see Ehde D.M., Dillworth, T.M. and Turner, J.A. 2014. Cognitive-Behavioral Therapy for Individuals with Chronic Pain: Efficacy, Innovations, and Directions for Research. *American Psychologist,* 69(2); 153–166.

[40] Additional information on non-opioid treatments for chronic pain are available at *https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf.*

[41] ''Managing Chronic Pain.'' Centers *for Disease Control and Prevention,* Centers for Disease Control and Prevention, 18 Dec. 2019, *www.cdc.gov/learnmorefeelbetter/programs/chronic-pain.htm.*

[42] Gaskin, Darrell J. ''The Economic Costs of Pain in the United States.'' *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.,* U.S. National Library of Medicine, 1 Jan. 1970, *www.ncbi.nlm.nih.gov/books/NBK92521/.*

[43] ''Prevalence of Chronic Pain and High-Impact Chronic Pain among Adults—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 16 Sept. 2019, *www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm.*

[44] Additional information on non-opioid treatments for chronic pain are available at *https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf.*

[45] Dowell D, Haegerich TM, Chou R. No shortcuts to safer opioid prescribing. N Engl J Med 2019; 380: 2285–2287.

[46] HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics. Oct. 2019, *www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf.*

[47] ''Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction.'' CMCS Informational Bulletin available at *www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf.*

[48] ''Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management.'' CMCS Informational Bulletin at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib022219.pdf.*

[49] Section 1902(oo)(1)(A)(i)(I) of the Act, as added by section 1004 of the SUPPORT Act.

and the need of increased monitoring and coordination of care.

i. Limit on Days' Supply for Opioid Naïve Beneficiaries

To further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT Act, we proposed to require states to establish safety edit limitations on the days' supply for an initial prescription opioid fill for beneficiaries who have not filled an opioid prescription within a defined time period to be specified by the state. In most cases, ''Days Supply'' is calculated by dividing the dispensed quantity of medication by the amount of the medication taken by the patient in one day per the prescriber's instructions. ''Days' Supply'' means how many days the supply of dispensed medication will last. This limit would not apply to patients currently receiving opioids and is meant for beneficiaries who have not received opioids within this specified time period (as defined and implemented by the state). The patients who have not received opioids within a specified timeframe are referred to as opioid naïve and would be subjected to the days' supply limit on the opioid prescription. While the SUPPORT Act mentions limits on subsequent fills of opioids, consistent with section 1927(g) of the Act, we proposed this edit on initial fills of opioids to help avoid excessive utilization by opioid naïve beneficiaries, with its attendant risk of adverse effects.

The CDC guideline recommends that opioids prescribed for acute pain in outpatient primary care settings to adults generally should be limited to 3 days or fewer, and more than a 7 days' supply is rarely necessary.[50] Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred and should be considered by practitioners and patients prior to treatment with opioids.[51] Clinical evidence cited by the CDC review found that opioid use for acute pain is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use. An expected physiologic response in patients exposed to opioids for more than a few days is physical dependence and the chances of long-term opioid use begin to increase after just 3 days of use and rise rapidly thereafter.[52] The CDC guideline mentions that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days' supply would minimize the number of pills available for unintentional or intentional diversion.[53]

As discussed in the June 2020 proposed rule, long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.[54] Limiting days for which opioids are prescribed for opioid naïve patients could minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms and help prevent opioid dependence, the risk of which is associated with the amount of opioid initially prescribed.[55]

On state DUR surveys, many states indicated they already have initial fill limitations in place describing the limitations of 100 dosage units or a 34-day supply. Initial opioid analgesic prescriptions of less than or equal to 7 days' duration appear sufficient for many pain patients seen in primary care settings.[56] We noted that, in its 2019 clarification of the guideline, the CDC noted that it was ''intended for primary care clinicians treating chronic pain for patients 18 and older, and examples of misapplication include applying the guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain.'' States can consider the current CDC guideline and other clinical guidelines when implementing initial fill limitations, being mindful of the context in which such guidelines are written (for example, acute pain, chronic pain, treatment setting, population, etc.).

The CDC guideline states primary care clinicians should assess benefits and harms of opioids with patients early on when starting opioid therapy for chronic pain and regularly when escalating doses and continue to evaluate therapy with patients on an ongoing basis. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioid therapy. Consistent with the foregoing clinical recommendations, we proposed to require states to implement safety edits aligned with clinical guidelines alerting the dispenser at the POS when an opioid prescription is dispensed to an opioid naïve patient that exceeds a state-specified days' supply limitation. In consideration of clinical recommendations to limit opioid use to the shortest possible duration and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse events, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT Act. Accordingly, we proposed in § 456.703(h)(1)(i)(A) to require states to implement a days' supply limit when an initial opioid prescription is dispensed to a patient not currently receiving ongoing therapy with opioids.

ii. Opioid Quantity Limits

To further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT Act, we proposed to require states establish safety edits to implement quantity limits on the number of opioid units to be used per day, as identified by the state. We proposed that states take clinical indications and dosing schedules into account when establishing quantity limits to restrict the quantity of opioids per day to ensure dose optimization and to minimize potential for waste and diversion. While the SUPPORT Act mentions quantity limits on subsequent fills of opioids, under section 1927(g) of the Act, we proposed this edit to apply for initial and subsequent fills of opioids to avoid excessive utilization, with its attendant risk of adverse effects.

We proposed that the quantity limits would be required to take into account both dosage and frequency, to allow for

[50] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Aug. 2017, *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf.*

[51] Ibid.

[52] Shah A., Hayes C.J., Martin B.C. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use—United States, 2006–2015. Morbidity and Mortality Weekly Report 2017; 66:265–269 [Accessed February 11, 2019 at *http://dx.doi.org/10.15585/mmwr.mm6610a1*].

[53] Ibid.

[54] ''CDC Guideline for Prescribing Opioids for Chronic Pain.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[55] Shah A, Hayes CJ, Martin BC. Characteristics of initial prescription episodes and likelihood of long-term opioid use—United States, 2006–2015. *MMWR Morb Mortal Wkly Rep.* 2017; 66(10):265–269. doi: 10.15585/mmwr.mm6610a1.

[56] ''Days' Supply of Initial Opioid Analgesic Prescriptions and Additional Fills for Acute Pain Conditions Treated in the Primary Care Setting—United States, 2014 | MMWR.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, *https://www.cdc.gov/mmwr/volumes/68/wr/mm6806a3.htm.*

dose optimization of pills, capsules, tablets, etc. (''pills'') and limit the supply of opioids being dispensed. Dose optimization is a method to consolidate the quantity of medication dispensed to the smallest amount required to achieve the desired daily dose and regimen. Dosage optimization seeks to prospectively identify patients who have been prescribed multiple pills per day of a lower strength medication meant to be taken together to achieve higher dose, when a higher strength of medication already is available, and provides clinicians a tool to switch these patients to a regimen that is an equivalent daily dose given as a single pill (or a smaller quantity of pills). Performing this intervention with medications that are available in multiple strengths, with comparable pricing among these strengths, can yield significant drug cost savings. In addition, dose-optimization simplifies dosing schedules, decreases pill burdens, improves treatment compliance and limits the number of excess units available for diversion.[57] We noted that the proposed safety edit would allow most patients to achieve pain relief while minimizing patient pill burdens and unnecessary unused opioids.[58] When implementing this edit, we noted that we would expect states to also consider current opioid guidelines, clinical indications, and dosing schedules of opioids to ensure prescriptions are appropriate, medically necessary, and not likely to result in adverse events.

Decreasing the initial amount prescribed will lower the risk that patients develop an addiction to these drugs and transition to chronic use or misuse.[59] A survey of adults in Utah estimated that in the previous 12 months, 1 in 5 state residents were prescribed an opioid medication and 72 percent had leftover pills and nearly three-quarters of those with leftover pills kept them.[60] Leftover medications are an important source of opioids that are misused or diverted.[61] We believe that decreasing the initial amount prescribed will lower the risk that patients develop OUD.[62]

Prescribing opioids using lowest dosage at fewest possible units dispensed based on product labeling, and matching duration to scheduled reassessment, helps reduce the quantity of unused, leftover opioid pills. Additionally, clinicians should continue to evaluate benefits and harms of continued ongoing therapy with opioid patients every 3 months or more frequently.[63] As discussed in the June 2020 proposed rule, if benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.[64] In circumstances when beneficiaries are already opioid dependent, providers should consider initiating a treatment program, such as medication-assisted treatment (MAT) and/or behavioral counseling. State Medicaid programs already cover MAT, and as of October 2020, states are required cover MAT drugs and services as a mandatory benefit. We encourage states to consider the situation of opioid-dependent beneficiaries in designing and implementing quantity limits in their comprehensive DUR programs, to minimize any possibility of harm.

In consideration of clinical recommendations to limit opioid units to the fewest number possible and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse events, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT Act. Accordingly, we proposed at § 456.703(h)(1)(i)(B) that states be required to implement quantity limits on opioids prescriptions (both initial and subsequent fills) to help identify abuse, misuse, excessive utilization, or inappropriate or medically unnecessary care.

iii. Therapeutic Duplication Limitations

To further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT Act, we proposed to require states to establish safety edits to alert the dispenser to potential therapeutic duplication before a prescription is filled for an opioid product that is in the same therapeutic class as an opioid product currently being prescribed for the beneficiary. Prescriptions for multiple opioids and multiple strengths of opioids increase the supply of opioids available for diversion and abuse, as well as the opportunity for self-medication and dose escalation.[65] Some patients, especially those living with multiple chronic conditions, may consult multiple physicians, which can put them at risk of receiving multiple medications in the same therapeutic class for the same diagnosis.[66] In some instances, the side-effects produced by overmedication, due to the duplication of prescriptions within the same therapeutic class, are more serious than the original condition.[67] We proposed to require this opioid safety edit to help avoid inappropriate or unnecessary therapeutic duplication when simultaneous use of multiple opioids is detected.

In consideration of clinical recommendations to use caution in combining opioids and to limit opioid use to only when necessary while assessing clinical benefits and harms of opioid treatment on an ongoing basis, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT Act. Accordingly, we proposed at § 456.703(h)(1)(i)(C) that states must implement safety edits for therapeutically duplicative fills for initial and subsequent prescription fills on opioid prescriptions and identify suspected abuse, misuse, excessive utilization, or inappropriate or medically unnecessary care.

iv. Early Fill Limitations

To further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT Act, we proposed to

[57] Calabrese D. Baldinger S., Dose Optimization Intervention Yields Significant Drug Cost Savings. *https://www.jmcp.org/doi/pdf/10.18553/jmcp.2002.8.2.146.*

[58] Daoust R. Limiting Opioid Prescribing. *JAMA.* 2019; 322(2):170–171. doi:10.1001/jama.2019.5844.

[59] *http://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug-abuse_report_09.2013.pdf.*

[60] Ibid.

[61] ''FDA Patient Education Campaign Targets Opioid Diversion, Disposal.'' Available at *https://patientengagementhit.com/news/fda-patient-education-campaign-targets-opioid-diversion-disposal.*

[62] Opioid Use during the Six Months After an Emergency Department Visit for Acute Pain: A Prospective Cohort Study. Friedman, Benjamin W. et al. Annals of Emergency Medicine, Volume 0, Issue 0.

[63] Dowell, Deborah, et al. ''CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016.'' JAMA, U.S. National Library of Medicine, 19 Apr. 2016, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6390846/.*

[64] Frieden TR, Houry D. Reducing the Risks of Relief--The CDC Opioid-Prescribing Guideline. *N Engl J Med.* 2016; 374(16):1501–1504. doi: 10.1056/NEJMp1515917.

[65] Manchikanti, Laxmaiah, et al. ''Opioid Epidemic in the United States.'' Pain Physician, U.S. National Library of Medicine, July 2012, *www.ncbi.nlm.nih.gov/pubmed/22786464.*

[66] Ibid.

[67] ''Therapeutic Duplication.'' Journal of the American Medical Association, vol. 160, no. 9, 1956, p. 780., doi:10.1001/jama.1956.02960440052016.

require that states establish safety edits to alert the dispenser before a prescription is filled early for an opioid product, based on the days' supply provided at the most recent fill or as specified by the state. As discussed in the June 2020 proposed rule, these early fill edits on opioids are intended to protect beneficiaries from adverse events associated with using an opioid medication beyond the prescribed dose schedule and to help minimize the opioid supply available for diversion.

In consideration of clinical recommendations to limit opioid use to only when necessary and as prescribed, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT Act. Accordingly, we proposed at § 456.703(h)(1)(i)(D) that states must implement early fill safety alerts on opioid prescriptions to identify abuse, misuse, excessive utilization, or inappropriate or medically unnecessary care.

b. Maximum Daily Morphine Milligram Equivalent (MME) Limits

Section 1004 of the SUPPORT Act requires state DUR programs to include safety edit limits (as specified by the state) on the maximum daily morphine equivalent that can be prescribed to an individual enrolled under the state plan (or under a waiver of the state plan) for treatment of chronic pain (as designed and implemented by the state) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of any threshold identified by the state.[68] Accordingly, to further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT Act, we proposed that states must include in their DUR programs safety edit limitations identified by the state on the maximum daily MME for treatment of chronic pain and a claims review automated process, discussed in this rule in connection with paragraph (h)(1)(iii), that indicates when an individual is prescribed an MME in excess of these limitations.

Section 1004 of the SUPPORT Act specifically addresses MME limitations in the context of chronic pain. According to the CDC, acute pain (as distinct from chronic pain) usually occurs suddenly and usually has a known cause, like an injury, surgery, or infection. For example, acute pain can be caused from a wisdom tooth extraction, a surgery, or a broken bone after an automobile accident. Acute pain normally resolves as your body heals. Chronic pain, on the other hand, can last weeks, months or years—past the normal time of healing.[69] Regarding chronic pain, CDC states clinicians should use caution when prescribing opioids at any dosage, and should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.[70] With the proposal to require maximum daily MME limits, we did not mean to suggest rapid discontinuation of opioids already prescribed at higher dosages.

The MME/day metric is often used as a gauge of the overdose potential of the amount of opioid that is being given at a particular time.[71] Calculating the total daily dosage of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose. The opioid MME levels discussed in the June 2020 proposed rule typically would not be clinically appropriate for acute, short term pain; moreover, if the prescription were for acute pain, given the risks associated with high acute doses (in particular, respiratory risks), we believe that this limitation also would be appropriate to ensure appropriateness, medical necessity, and avoidance of adverse events. Accordingly, we proposed to require states to establish MME threshold amounts for implementation regardless of whether the prescription is for treatment of chronic or acute pain. We explained this proposal in preamble to the proposed rule (85 FR 37309) but made a technical error in the proposed regulation text, which was erroneously limited to prescriptions ''for treatment of chronic pain.''

We also noted that the proposed prospective safety edit must include a MME threshold amount to meet statutory requirements, to assist in identifying patients at potentially high clinical risk who may benefit from closer monitoring and care coordination. Calculation of MMEs is used to assess the total daily dose of opioids, taking into account the comparative potency of different opioids and frequency of use. The calculation to determine MMEs includes drug strength, quantity, days' supply and a defined conversion factor unique to each drug.[72] Patients prescribed higher opioid dosages are at higher risk of overdose death.[73] Calculating the total MME daily dose of opioids can help identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose.[74] HHS's Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics[75] is also a valuable resource for considering how best to taper and/or discontinue usage in a thoughtful manner, consistent with best clinical practices. We noted that HHS does not recommend opioids be tapered rapidly or discontinued suddenly due to the significant risks of opioid withdrawal, unless there is a life-threatening issue confronting the individual patient. FDA issued a safety announcement on tapering in April 2019 noting concerns about safely decreasing or discontinuing doses of opioids in patients who are physically dependent after hearing reports about serious harm.[76]

When determining MME threshold amounts, states are reminded that clinical resources, including, for example, the CDC guideline,[77] recommend caution when prescribing opioids for chronic pain in certain circumstances, and recommend that primary care practitioners reassess evidence of individual benefits and risks when increasing doses and

[68] Section 1902(oo)(1)(A)(i)(II) of the Act, as added by section 1004 of the SUPPORT Act.

[69] ''Opioids for Acute Pain.'' Centers for Disease Control and Prevention, available at *https://www.cdc.gov/drugoverdose/pdf/patients/Opioids-for-Acute-Pain-a.pdf.*

[70] ''CDC Guidelines for Prescribing Opioids for Chronic pain. '' Available at *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[71] Ibid.

[72] Calculating Total Daily Dose of Opioids For Safer Dosage. Centers for Disease Control and Prevention, available at *https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.*

[73] Guideline for Prescribing Opioids for Chronic Pain. *www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[74] Ibid.

[75] *https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf.*

[76] ''FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering.'' Food and Drug Administration. Available at *https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.*

[77] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. MMWR Recomm Rep 2016; 65(No. RR–1):1–49. DOI: *http://dx.doi.org/10.15585/mmwr.rr6501el. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.*

subsequently, justifying decisions by thoroughly documenting the clinical basis for prescribing in the patient's medical record.[78] As noted, it is important to be cognizant that the CDC guideline states the dosage thresholds referenced therein pertain solely to opioids used to treat chronic pain in primary care settings and that these thresholds, as recommended by the CDC, do not represent hard limits for opioid prescriptions.[79]

In consideration of clinical recommendations and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe the proposed safety edit is necessary to assure at risk individuals are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT Act. Accordingly, we proposed at § 456.703(h)(1)(ii) that states be required to implement safety edits that indicate when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of the MME dose limitation identified by the state.

c. Automated Claims Reviews for Opioids

To further implement section 1927(g) of the Act and section 1004 of the SUPPORT Act, we proposed that states must have in place a claims automated review process (as designed and implemented by the state) that indicates when an individual enrolled under the state plan (or under a waiver of the state plan) is prescribed opioids in excess of proposed limitations identified by the state. In these ongoing, comprehensive reviews of opioid claim data, states should continuously monitor opioid prescriptions, including overrides of safety edits by the prescriber or dispenser on initial fill days' supply for opioid naïve patients, quantity limits, therapeutically duplicative fills, early refills and maximum daily MME limitations on opioids prescriptions.

These opioid claim reviews are necessary to allow states to continually monitor opioid prescriptions beneficiaries are receiving and determine and refine future potential prospective DUR safety edits, based on the findings of the claims reviews. Information obtained through retrospective DUR claim reviews can be used to shape effective safety edits that can be implemented through prospective DUR, better enabling prescribers and dispensers to investigate prescription concerns prior to dispensing the medication to the patient. Through ongoing monitoring and observation of trends over time, these reviews will allow for regular updates to safety edits in an evolving pain treatment landscape.

Accordingly, we proposed at § 456.703(h)(1)(iii) that states must conduct retrospective claims review automated processes that indicate prescription fills in excess of the prospective safety edit limitations specified by the state under paragraph (h)(1)(i) or (ii) to provide for the ongoing review of opioid claims data to identify patterns of fraud, misuse, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits. We explained that, in addition to opioid claims data, we also intended for states to consider incorporating other available records to provide for the ongoing periodic reviews of opioids claim data and other records (including but not limited to prescription histories, diagnoses, medical records, and prescription drug monitoring program (PDMP) files, when available), in their retrospective claims review automated processes order to identify patterns of fraud, misuse, abuse, excessive utilization, or inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization among physicians, pharmacists and individuals receiving Medicaid benefits.

d. Concurrent Utilization Reviews

Section 1902 of the Act, as amended by the SUPPORT Act, requires states to have an automated process for claims review (as designed and implemented by the state) that monitors when an individual enrolled under the state plan (or under a waiver of the state plan) is concurrently prescribed opioids and benzodiazepines or opioids and antipsychotics.[80] This requirement is consistent with the requirement in section 1927(g)(1)(A) of the Act that state DUR programs must assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results.

Clinically, through the use of retrospective automated claim reviews, concurrent use of opioids and benzodiazepines and opioids and antipsychotics, as well as potential complications resulting from other medications concurrently being prescribed with opioids, can be reduced. In the proposed rule, we reminded states that the requirement for a retrospective automated claims review added by section 1004 of the SUPPORT Act does not preclude the state from also establishing a prospective safety edit system to provide additional information to patients and providers at the POS about concurrent utilization alerts.[81] In addition, the state could use the authorities under section 1927 of the Act to subject these patients to appropriate utilization management techniques. We reminded states that section 1927(g)(1) of the Act also currently supports including other potentially harmful opioid interactions as additional prospective or retrospective reviews in state DUR programs, such as opioids and central nervous system (CNS) depressants, including alcohol or sedatives. We noted that we fully support states including such additional opioid interactions or contraindications in prospective or retrospective reviews as part of a comprehensive DUR program.

In consideration of clinical recommendations to limit opioids interactions with certain other drugs, including benzodiazepines and antipsychotics, and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe the retrospective reviews we proposed to require are necessary to help ensure at-risk individuals are receiving appropriate treatment that is not likely to result in adverse medical results, and otherwise to accomplish purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT Act. Accordingly, we proposed at § 456.703(h)(1)(iv)(A) and (B) that states be required to implement a claims review automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines; or opioids and antipsychotics.

i. Opioid and Benzodiazepines Concurrent Fill Reviews

In 2016, FDA added a boxed warning to prescription opioid analgesics, opioid-containing cough products, and

[78] Dowell, Deborah, et al. ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' JAMA, U.S. National Library of Medicine, 19 Apr. 2016, *https://www.ncbi.nlm.nih.gov/pubmed/26977696.*

[79] Staff, News. ''CDC Clarifies Opioid Guideline Dosage Thresholds.'' AAFP Home, 12 Jan. 2018, *www.aafp.org/news/health-of-the-public/20180112cdcopioidclarify.html.*

[80] Section 1902(oo)(1)(A)(i)(III) of the Act, as added by section 1004 of the SUPPORT Act.

[81] See section 1902(oo)(1)(A)(iii) of the Act, as added by section 1004 of the SUPPORT Act.

benzodiazepines with information about the serious risks associated with using these medications concurrently.[82] The CDC guideline recommends that clinicians avoid prescribing benzodiazepines concurrently with opioids whenever possible. Benzodiazepines may be abused for recreational purposes by some individuals, with some opioid overdoses also involving opioids and benzodiazepines or other substances, such as alcohol.[83]

Studies show that people concurrently using both drugs are at higher risk of visiting the emergency department or being admitted to a hospital for a drug-related emergency.[84] Due to the heightened risk of adverse events associated with the concurrent use of opioids and benzodiazepines, physicians should avoid the initial combination of opioids and benzodiazepines by offering alternative approaches.[85] This review would alert providers when these drugs have been prescribed concurrently to assist in avoiding and mitigating associated risks.

ii. Opioid and Antipsychotic Concurrent Fill Reviews

This alert is supported by FDA's boxed warning of increased risk of respiratory and CNS depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives, including extreme sleepiness, slowed or difficult breathing, unresponsiveness or the possibility that death can occur.[86] Patients concurrently prescribed opioid and antipsychotic drugs can benefit from increased coordination of care. Additionally, improving treatment of comorbid mental disorders is an important consideration when trying to reduce the overall negative impacts of pain. As the PMTF report noted, ''the occurrence of pain and behavioral health comorbidities, including depression, post-traumatic stress disorder, and SUDs, is well documented, and it is established that psychosocial distress can contribute to pain intensity, pain-related disability, and poor response to chronic pain treatment.'' [87] Evidence indicates that optimizing mental health and pain treatment can improve outcomes in both areas for patients seen in primary and specialty care settings. Untreated psychiatric conditions may increase the risk of both unintentional and intentional medication mismanagement, OUD, and overdose.[88] Given the intersection between psychiatric/psychological symptoms and chronic pain, it is important that the behavioral health needs of patients with pain are appropriately and carefully evaluated and treated with the concurrent physical pain problem.[89] As such, beneficiaries who are concurrently prescribed both opioids and antipsychotics should be considered from a health system or policy perspective when addressing their treatment.[90] A patient's unique presentation and circumstances should be considered when prescribing opioids and antipsychotics. This review would encourage coordination of care for patients taking antipsychotic and opioid medications concurrently.

e. Other Considerations

Consistent with section 1902(oo)(1)(A)(iii) of the Act, as added by section 1004 of the SUPPORT Act, the provisions proposed to be implemented in § 456.703(h)(1) would not prohibit states from designing and implementing an automated claims review process that provides for other processes for the prospective or retrospective review of claims. Furthermore, none of these proposed provisions would prohibit the exercise of clinical judgment by a provider regarding the best or most appropriate care and treatment for any patient.

We encouraged states to develop prospective and retrospective drug reviews that are consistent with medical practice patterns in the state to help meet the health care needs of the Medicaid patient population. In doing so, we encouraged states to utilize, for example, the 2016 CDC guideline [91] for primary care practitioners on prescribing opioids in outpatient settings for chronic pain.

To avoid abrupt opioid withdrawal, we noted that prior authorization may be necessary for patients who will need clinical intervention to taper off high doses of opioids to minimize potential symptoms of withdrawal and manage their treatment regimen, while encouraging pain treatment using non-pharmacologic therapies and non-opioid medications, where available and appropriate.

When implementing these requirements, we encouraged states to offer education and training and to provide consistent messaging across all healthcare providers. We noted that education and training of all providers on new opioid-related provisions and on the treatment of acute and chronic pain and behavioral health issues related to pain, would help minimize workflow disruption and ensure beneficiaries have access to their medications in a timely manner.

The following is a summary of the comments we received on these proposed minimum standards for DUR programs and under the SUPPORT Act and section 1927 of the Act, and our responses.

Comment: Some commenters expressed support for the availability of the CDC guideline for Prescribing Opioids for Chronic Pain, and approved of our references to the guideline as being a possible resource for states to use in developing their state DUR programs. Other commenters stated a belief that the guideline has been misapplied and is inherently flawed and may result in unintended consequences.

Response: The CDC guideline is intended to help providers determine when and how to prescribe opioids for chronic pain, and also when and how to use nonopioid and nonpharmacologic options that can be effective with less risk. The guideline was developed to help ensure that primary care clinicians work with their patients to consider all safe and effective treatment options for chronic pain management. Some providers have misinterpreted the application of this document, and CDC

[82] Office of the Commissioner. ''Drug Safety Communications—FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning.'' *U.S. Food and Drug Administration Home Page,* Office of the Commissioner, *https://www.fda.gov/media/99761/download.*

[83] Jones, Jermaine D, et al. ''Polydrug Abuse: a Review of Opioid and Benzodiazepine Combination Use.'' Drug and Alcohol Dependence, U.S. National Library of Medicine, 1 Sept. 2012, *www.ncbi.nlm.nih.gov/pmc/articles/PMC3454351/.*

[84] Forum, Addiction Policy. ''Sedative Use Disorder.'' Addiction Policy Forum, *https://www.addictionpolicy.org/sedative-use-disorder.*

[85] ''Reduce Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing Benzodiazepines.'' MLN Matters Number: SE19011. Available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19011.pdf.*

[86] Office of the Commissioner. ''Drug Safety Communications—FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning.'' *U.S. Food and Drug Administration Home Page,* Office of the Commissioner, *https://www.fda.gov/media/99761/download.*

[87] Pain Management Best Practices Inter-Agency Task Force. ''Pain Management Best Practices.'' Available at *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

[88] Ibid.

[89] Ibid.

[90] Davis, Matthew A., et al. ''Prescription Opioid Use among Adults with Mental Health Disorders in the United States.'' The Journal of the American Board of Family Medicine, vol. 30, no. 4, 2017, pp. 407–417., doi:10.3122/jabfm.2017.04.170112.

[91] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Aug. 2017, *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf.*

released a clarification in April 2019 in response.[92] As discussed in the proposed rule and this final rule, the CDC Guideline for Prescribing Opioids for Chronic Pain is one of many clinical guidelines states can consult when implementing DUR safety edits and automated claims review. Section 1004 of the SUPPORT Act amends section 1902 of the Act to include a new paragraph (a)(85), requiring the state plan to provide that the state is in compliance with the new DUR requirements. This statutory provision, as well as the provisions of this final rule, give authority to the states to develop, specify and implement important parameters for these edits and reviews, as determined by the state. In our experience from reviewing the annual FFS and MCO DUR reports, available on *www.Medicaid.gov,* states typically consult multiple authoritative clinical resources and guidelines when designing and implementing their DUR programs.

Comment: Several commenters suggested that CMS establish uniform opioid-related limits or reporting requirements across Medicare Part D and all Medicaid programs instead of allowing Medicaid programs to create unique policies for the relevant state, and require state Medicaid safety edits to be no more restrictive than those implemented in Medicare.

Response: We appreciate the comments in reference to establishing consistency in DUR activities between Medicaid and Medicare; however, requirements for DUR in Medicare are not within the scope of this rulemaking. Additionally, it is important to remember that while Medicare is a federally-operated program, Medicaid is primarily a state-run program. The amendments made by section 1004 of the SUPPORT Act make clear that Congress intended for states to have considerable discretion in determining how to implement opioid-related DUR measures in their state Medicaid programs.

Comment: Several commenters recommended the promotion of non-pharmacological pain management strategies for OUD and suggested CMS promote integrated care models to include counseling, behavioral therapies and physical rehabilitation. Other commenters suggested additional non-pharmacological pain management strategies to include osteopathic principles, including physical therapy, acupuncture, chiropractic care, over-the-counter medications and occupational therapy to improve self-management of pain conditions with the goal of reducing pain, improving function, increasing self-efficacy, and improving quality of life.

Response: We appreciate the suggestions regarding alternative non-pharmacologic therapy and agree that there can be an appropriate clinical role for therapies such as those suggested by the commenters. Several related CMS resources include, but are not limited to, the CMS Roadmap Strategy To Fight The Opioid Crisis, June 2020;[93] the CMS Opioid Misuse Strategy, January 2017;[94] the Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management, February 2019;[95] and Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction, January 2016.[96] These resources provide additional information on Medicaid authorities that states may use for coverage of non-opioid pharmacologic and non-pharmacologic pain management therapies, highlight some preliminary strategies used by several states, and include other useful resources to help states.

Comment: Several commenters expressed concern that the proposed rule would give too much autonomy to the states for determining days' supply for opioid naïve beneficiaries, and quantity, therapeutic duplication and early refill limits. Several commenters also opined that leaving the determination of quantity limits up to the states' discretion will evolve into a highly heterogeneous set of state requirements. Other commenters encouraged alignment and consistency in state DUR programs nationwide, and suggested that CMS should direct state Medicaid agencies to consult existing resources to come into compliance with the proposed requirements, if finalized.

Response: We disagree with the commenters that the proposed policies give too much discretion to the states. In accordance with and the amendments made by section 1004 of the SUPPORT Act, states are required to implement safety edits (as specified by the state) for subsequent fills for opioids and a claims review automated process (as designed and implemented by the state) that indicates when an individual enrolled under the state plan (or under a waiver of the state plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the state. We are finalizing our proposal to implement these provisions, and to further implement section 1927(g) of the Act, by requiring states to specify quantity, days' supply, therapeutic duplication, and early fill safety alerts on opioids prescriptions, the specific parameters of which will be left to the states' discretion to establish minimum standards. We believe these state-established parameters will be effective in helping identify abuse, misuse, excessive utilization, or inappropriate or medically unnecessary care. We encourage states to consult existing resources on safe and appropriate opioid prescribing. We recognize there are many national guidelines and resources available to the states. These include, but are not limited to, guidance issued by associations such as the Pharmacy Quality Alliance (PQA), National Committee for Quality Assurance (NCQA), National Quality Forum (NQF); and federal agencies including, but limited to, the Agency for Healthcare Research and Quality (AHRQ), the Substance Abuse and Mental Health Services Administration, and the CDC. In our experience from reviewing the annual FFS and MCO DUR reports, available on *www.Medicaid.gov,* states typically consult multiple authoritative clinical resources and guidelines when designing and implementing their DUR programs. We agree with commenters who suggested that the proposed policies would result in varying implementations across state DUR programs. However, we believe this variation was specifically contemplated by Congress in enacting the relevant provisions of the SUPPORT Act, and is fully consistent with the overall structure of the Medicaid program, which gives states flexibility to design and administer their programs. Additionally, the flexibility afforded to states will help enable them to ensure the establishment of minimum standards relevant to their state circumstances and beneficiary populations.

Comment: One commenter suggested adopting the models found in the Virginia Medicaid Addiction and Recovery Treatment Services program and the Vermont Blueprint for Health when implementing opioid safety edits.

Response: States can evaluate these and other models when designing and

[92] *https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html.*

[93] *https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf.*

[94] *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf.*

[95] *https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib022219.pdf.*

[96] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib-02-02-16.pdf.*

implementing their DUR programs. States have the flexibility to employ techniques and standards from existing state models, or develop their own, in compliance with the requirements of this final rule.

Comment: One commenter stated that CMS is applying a ''one-size-fits-all algorithm and policies that do not take individual patient's [sic] needs into account'' when suggesting opioid safety edits.

Response: We disagree with the commenter. Consistent with the SUPPORT Act and section 1927(g) of the Act, under the policies in this final rule, states have autonomy to implement safety edits as determined by the state, in consideration of state-specific circumstances and the needs of the state's Medicaid population. For example, we are not prescribing a national limit on the quantity of opioids that may be prescribed or dispensed to a beneficiary, only that each state must determine a limit and implement a safety edit that, if exceeded, would trigger an alert and opportunity for appropriate clinical intervention prior to dispensing. Similarly, we are not establishing a specific national MME limit, but consistent with the statutory requirement added by the SUPPORT Act, we are requiring states to determine an MME limit and implement a safety edit to trigger an alert if it is exceeded. Safety edits provide an opportunity for identifying potential problems at the pharmacy POS before the prescription is dispensed to the individual, which creates an opportunity for engagement between pharmacists, prescribers and patients to identify and mitigate possible opioid misuse, abuse, and overdose risk. POS safety edits provide real-time information to the pharmacist prior to the prescription being dispensed to a patient; however, they do not necessarily prevent the prescription from being dispensed. When a safety edit is prompted, the pharmacist receives an alert and may be required, as dictated by predetermined standards established by the state, to take further action to resolve the issue prior to the prescription being dispensed.

Comment: One commenter requested that CMS require states, when implementing these opioid safety edit requirements, to offer education and training and to provide consistent messaging across all healthcare providers, and noted that coordination between all stakeholders is key to successful policy and DUR program implementation for opioid safety edits.

Response: Based on CMS' Annual DUR Survey, it is apparent that states have implemented a majority of these proposed safety edits already. We agree with the commenter's suggestion that states provide education and training on their DUR programs generally and regarding opioid utilization review initiatives specifically to providers in the state. Currently, states are required to carry out an educational program with respect to their DUR programs, as specified in section 1927(g)(2)(D) of the Act. We believe states generally are providing consistent messaging to their providers through educational mechanisms that include, but are not limited to, state website postings, bulletins and newsletters, educational seminars, and toolkits, as needed and appropriate to promote effective provider education and training.

Comment: A few commenters urged consideration of flexible policies to accommodate the needs of provider groups, such as emergency physicians, and special patient populations, such as cancer survivors and patients with sickle cell disease, through the use of evidence-based, nationally-recognized, and population specific prescribing guidelines. These commenters suggested CMS direct state Medicaid agencies to consult existing resources on safe and appropriate opioid prescribing.

Response: We appreciate the commenters concerns, and believe that the structure of the final regulation will continue to give states flexibility in designing their DUR programs to meet the needs of certain providers, such as emergency physicians and oncologists, and certain special populations, such as cancer and sickle cell patients and those in chronic pain. Consistent with the requirements of section 1004 of the SUPPORT Act, the states will determine and implement specifications for their DUR programs. As discussed below in this final rule, states have the option to exclude certain populations from these opioid-related DUR requirements. Nationally-recognized guidelines and resources are also available to the states and providers. Organizations that have developed relevant materials include, but are not limited to, the PQA, NCQA, NQF, and federal agencies including, but not limited to AHRQ, SAMHSA, and the CDC. We encourage states to consult existing resources on safe and appropriate opioid prescribing. In our experience from reviewing the annual FFS and MCO DUR reports, available on *www.Medicaid.gov,* states typically consult multiple authoritative clinical resources and guidelines when designing and implementing their DUR programs. Therefore, we are finalizing our proposal to allow flexibility in designing implementing the opioid-related DUR parameters under § 456.703(h).

Comment: A few commenters encouraged CMS to gather data on the impact of the proposed opioid safety edits across race and ethnicity as studies have found that although the rate of drug-related deaths is highest among non-Hispanic whites, patients who are African American and Hispanic are less likely to receive any pain medication and more likely to receive lower doses of pain medication, despite higher pain scores.

Response: In implementing statutory requirements added by the SUPPORT Act and in section 1927(g) of the Act, this final rule is intended to improve the clinical use of opioids in all beneficiaries, regardless of race or ethnicity, to promote improved quality of life. As we have noted, the states operate their DUR programs under federal guidelines and are responsible for using their DUR data to improve the use of medications in the Medicaid population. We believe that the use of these new opioid-related safety edits will help identify for states and health care professionals both those patients who might be taking too many opioids, or taking opioids in circumstances where their use could be medically inappropriate or likely to result in adverse medical events. States also retain flexibility to implement opioid and non-opioid related safety edits and claims reviews that are designed to help ensure that patients suffering from pain are receiving adequate treatment. As described in the proposed rule and elsewhere in this final rule, the states through their DUR programs are required to retrospectively review claims and provide feedback to prescribers through the required program of educational interventions, *see* § 456.711. The retrospective review process helps to identify patterns in prescribing and dispensing which can then be used by states in designing interventions to help improve the overall use of these medications.

In addition, to support these state level activities, CMS collects information through collaboration with various CMS components and Department partners to develop and implement initiatives to improve data collection, analysis and reporting by race, ethnicity, primary language, disability, and gender, as well as other characteristics that have been associated with health disparities. We have formulated objectives to disseminate information, identify vulnerabilities and collaborate with states and external organizations on health disparities, to include data collection and strategies for

achieving health equity. Resources, including federal and state initiatives, can be accessed on *Medicaid.gov*.[97] Through collaboration with other CMS, Departmental, and external entities, we hope to determine and correlate claims data to assess impact of the newly required safety edits in the future.

Comment: One commenter expressed concern that utilization management in certain patient populations risks discriminating on the basis of disability, depending on what ''utilization management techniques'' the state may adopt in its implementation of the proposed requirements for opioid-related safety edits and automated claims reviews.

Response: Nothing in the proposed rule or this final rule is intended to interfere with the providers' clinical decision-making or with the provider-patient relationship. The final rule continues to allow providers to make clinical decisions based on each patient's specific situation and relevant clinical principles. Section 1557 of the Affordable Care Act[98] provides that an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794 (disability), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Act or its amendments. States have many years of experience applying utilization management techniques in the context of their Medicaid DUR programs, with the enactment of the DUR provisions of the Omnibus Budget Reconciliation Act (OBRA) of 1990. The safety edits are intended to help protect Medicaid patients from serious consequences of overutilization, including overdose, dangerous interactions, increased side effects and additive toxicity. Safety edits provide for identifying potential problems at pharmacy POS to engage both patient and provider in identifying and mitigating possible opioid misuse, abuse, and overdose risk at the time of dispensing which ultimately assists the provider in making appropriate clinical decisions. States will continue to have flexibility in design, development and implementation of safety edits and respective claims review as specified in section 1004 of the SUPPORT Act.

Comment: One commenter suggested that the proposed rule could create disparities in care between individuals who are and who are not Medicaid beneficiaries, if similar safety edits and claims reviews, specifically including early refill limits, are not established for non-Medicaid beneficiaries. Additionally, one commenter suggested states could build in appropriate flexibilities and exceptions to allow for extenuating circumstances.

Response: Implementing safety edits and claims reviews, including for early refill limits, is beyond the scope of this rulemaking with respect to individuals who are not Medicaid beneficiaries. The non-Medicaid population is not addressed by the relevant provisions of the SUPPORT Act and section 1927 of the Act that we are implementing through this rulemaking. We proposed and are finalizing early fill limitations at § 456.703(h)(1)(i)(D) to apply with respect to Medicaid beneficiaries. However, we agree that there is no reason that the standards of care or protocols for the dispensing of prescription opioids should vary between individuals solely on the basis of the individual's status as a Medicaid beneficiary (or not). Nothing in the SUPPORT Act or section 1927(g) of the Act prohibits states from considering and implementing more broadly applicable requirements for opioid-related safety edits.

Consistent with the provisions in section 1004 of the SUPPORT Act allowing states considerable discretion in their design and implementation of opioid-related safety edits, and with similar flexibility available for states in operating their DUR programs under section 1927(g) of the Act, this final rule affords states flexibility in designing and implementing required safety edits in the manner the state determines would be best adapted to the circumstances in the state, including the particular needs of the state's Medicaid beneficiaries. This flexibility extends to the manner in which the state's design and implementation account for potential extenuating circumstances, including emergency situations and the situations of beneficiaries being treated for particular conditions such as acute or chronic pain. We agree that safety edits should be implemented in a way that is sufficiently flexible to ensure that medically appropriate care is not withheld from beneficiaries in such circumstances, and agree that safety edits generally should be designed to avoid harm. States are encouraged to apply national guidelines and best practices to inform their design and implementation of the required safety edits before implementing any safety edit to ensure coordinated and undisruptive patient care.

Comment: One commenter suggested that states that have existing initial prescription fill limits should be encouraged to align with CMS's initial fill limits.

Response: We do not specify a prescription fill limit for opioid drugs or other Medicaid reimbursed drugs; however, consistent with the SUPPORT Act and DUR requirements under section 1927(g) of the Act, we proposed and are finalizing at § 456.703(h)(1)(i) that states must establish state-identified prospective safety edits that must include limitations on initial prescription fill days' supply for patients not currently receiving opioid therapy; quantity limits for initial and subsequent fills, therapeutically duplicative fill limits, and early fill limits on opioids prescriptions. To further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT Act, we proposed and are finalizing this rule to require states to establish safety edit limitations on the days' supply for an initial prescription opioid fill for beneficiaries who have not filled an opioid prescription within a defined time period to be specified by the state. This limit would not apply to patients currently receiving opioids and is meant for beneficiaries who have not received opioids within this specified time period (as defined and implemented by the state). The patients who have not received opioids within this state-specified timeframe are referred to as opioid naïve and would be subjected to the days' supply limit on the opioid prescription initial fill, as defined and implemented by the state. While the SUPPORT Act requires state-specified limits on subsequent fills of opioids, pursuant to section 1927(g) of the Act, we proposed and are finalizing this rule with edits on initial fills of opioids to help avoid excessive utilization by opioid naïve beneficiaries, with its attendant risk of adverse effects.

Comment: Some commenters requested that CMS modify parts of the proposed opioid safety edits regarding the limit on days' supply for opioid naive beneficiaries, specifically that CMS remove language relating to initial

[97] *https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/quality-of-care-health-disparities/index.html.*

[98] *https://www.hhs.gov/sites/default/files/ppacacon.pdf.*

prescribing as they claim it goes beyond the statute and could be harmful to certain patient groups. Other commenters stated that evidence for strict duration limits is insufficient to support state laws currently in place and that limitations may harm patients with chronic illnesses and injuries. These commenters expressed their belief that states should not implement a days' supply limit that is less than 7 days, and in exceptional circumstances, should allow for a longer supply. A few commenters requested that states build in exceptions for emergencies and extreme situations that could make it possible for patients to receive a needed refill.

Response: We disagree that the proposed requirement that states establish opioid initial fill days' supply limits, which we are finalizing in § 456.703(h)(1)(i)(A), exceeds our statutory authority. As we discussed in the proposed rule, although the amendments made by section 1004 of the SUPPORT Act only require states to establish safety edits (and a claims review automated process) to identify subsequent fills of opioids in excess of any limitation that may be identified by the state, pursuant to our authority under section 1927(g) of the Act, we proposed and are finalizing a requirement to apply limitations to initial fills, as well. In consideration of clinical recommendations to limit opioid use to the shortest possible duration and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, this safety edit is necessary to help ensure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse events, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and section 1004 of the SUPPORT Act. Accordingly, we proposed and are finalizing this rule at § 456.703(h)(1)(i)(A) to require states to implement a days' supply limit when an initial opioid prescription is dispensed to a patient not currently receiving ongoing therapy with opioids. The safety edit requirements under this final rule authorize states to not only design and implement the specific parameters of the safety edits based on existing state-specific criteria, but also allow states to consider all relevant factors in designing and implementing their state-specific limitations, such as the particular needs and circumstances of patients with chronic illnesses or injuries. States are encouraged to consult national guidelines when determining, specifying and implementing any safety edit (to include initial days supply) to ensure appropriate, coordinated patient care and minimize any unnecessary disruption to such care. States are also encouraged to evaluate specific needs that may arise in particular care settings in the state, such as in emergency departments and other acute treatment facilities; in vulnerable populations, such as chronically ill or disabled patients; and in other relevant state programs and initiatives, such as those for managing patients receiving medication-assisted treatment, when considering whether exceptional circumstances could mean that a particular implementation of a days' supply limit may adversely affect patient care.

We note that, under section 1927(d)(5) of the Act, states are required to provide for the dispensing of at least a 72-hour supply of a covered outpatient drug (COD), within 24 hours, in an emergency situation. This statutory requirement helps ensure timely access to needed medications, including when a beneficiary may require an opioid prescription in an emergency situation. Section 1927(d)(5)(B) of the Act ensures that a beneficiary can obtain an emergency supply until the prescriber or pharmacist is able to obtain prior authorization approval for the drug, if such approval is required.

Comment: Some commenters did not support CMS' proposal to require safety edits on initial prescription fill days' supply for patients not currently receiving opioid therapy, quantity, duplicate fills, and early refills to prevent and reduce the inappropriate use of opioids and potentially associated adverse medical events. One commenter noted that ''strict limits on opioid prescription may be counterproductive by increasing opioid dependence and failing to effectively address the need for SUD and OUD treatment.'' The commenter explained that while quantity and other limits on prescriptions for opioids may lead to a decrease in the supply of opioids, there is no guarantee that it will result in a reduction of opioid-related harm.

Response: Based on the requirements added by section 1004 of the SUPPORT Act and our existing authority under section 1927(g) of the Act, we proposed and are finalizing a requirement that state-identified safety edits must include state-specified limitations on initial prescription fill days' supply for patients not currently receiving opioid therapy, quantity limits, therapeutically duplicative fill limits, and early refill limits. These opioid-related safety edits are intended to protect Medicaid enrollees, to include people with disabilities who live with chronic pain, from serious consequences of overutilization, including overdose, dangerous interactions, increased side effects and additive toxicity. In addition, overutilization of opioids may serve as an indication of uncontrolled disease and the need of increased monitoring and coordination of care. We believe these safety edits are not counterproductive, in fact these safety edits, as designed and implemented by the state, are necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse events. Safety edits provide for identifying potential problems at the pharmacy POS to engage both patient and provider in identifying and mitigating possible opioid misuse, abuse, and overdose risk at the time of dispensing, which ultimately assists the provider in making appropriate clinical decisions. Accordingly, we proposed and are finalizing at § 456.703(h)(1)(i)(A) through (D) minimum standards for required safety edits, with the detailed design and implementation specifications left to the state's discretion to meet state-specific needs, to further implement section 1927(g) of the Act and section 1004 of the SUPPORT Act.

Comment: Several commenters recommended that CMS standardize the look-back period for evaluating beneficiaries' opioid medication use in implementing the proposed safety edits and claims reviews, such as considering whether the patient had used opioids within the previous 90 days, as a uniform standard for identifying acute and chronic opioid utilization. Several commenters recommended that we develop guidance on prior authorization standards to avoid abrupt opioid withdrawal.

Response: We did not propose, and are not finalizing, any specific look-back period of time that states must use in their implementation of the required opioid-related safety edits and claims reviews, nor are we developing guidance on prior authorization standards to avoid abrupt opioid withdrawal. However, states may reference guidelines such as the CDC Guideline for Prescribing Opioids for Chronic Pain [99] and/or the HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of

[99] *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.*

Long-Term Opioid Analgesics [100] when designing or implementing these standards to avoid abrupt opioid withdrawal.

Details such as these are left to the states to determine, in consideration of the particular circumstances and needs of beneficiaries in the state. Moreover, we are not aware of authoritative clinical or health policy guidance that suggests a particular length of time for a look-back period for opioid prescription monitoring in patients receiving opioid medications. This time period should be established by the state though consultation with experts, such as their DUR Board.

However, to provide an example of how one state uses a look back period to help avoid possible abuse of short term opioids, Kansas Medicaid requires prior authorization for a patient to obtain another opioid prescription if that patient had already obtained a short term supply of opioids (defined as a quantity of opioids to treat a patient for fewer than 90 days) within the last 4 months.[101] The prior authorization allows for the determination of whether the additional course of treatment is medically necessary, given that the patient recently had another course of treatment with opioids during the designated look back period. The Washington State Hospital Association, which has partnered with the Washington State Medical Association, is another resource to consult when developing and implementing state-specific look-back periods in a comprehensive DUR program.[102]

Comment: One commenter noted that a patient may be taking more than one opioid-based medication for long-term opioid therapy for chronic pain (that is, duplicate therapy), and as result, a significant number of safety edit alerts to the pharmacist may result.

Response: The proposed safety edit we are finalizing in this rule for therapeutically duplicative fills is intended to identify and alert to the prescribing and dispensing of the same drug or two or more drugs from the same therapeutic class where periods of drug administration overlap. We acknowledge that there may be patients who are taking multiple opioids to help manage pain, and these situations may result in safety alerts, depending on the state's implementation of the requirements being finalized in this rule. The alerts are not intended to necessarily limit or deny patients access to a prescribed opioid drug; rather, they are meant to flag for the pharmacist that the beneficiary is taking multiple opioids and that the opportunity should be used to assess the patient's need for the prescribed drugs or possible changes in therapy, including through discussion with the beneficiary and/or the prescriber. Potential effects from taking therapeutically duplicative opioids may include excessive drowsiness, confusion and respiratory distress. Respiratory distress in turn may cause a condition known as hypoxia. Hypoxia can have short- and long-term psychological and neurological effects, including coma, permanent brain damage, or death.[103] Therefore, we proposed and are finalizing at § 456.703(h)(1)(i)(C) that states must implement safety edits for therapeutically duplicative fills for initial and subsequent prescription fills on opioids prescriptions, to help identify potential abuse, misuse, excessive utilization, or inappropriate or medically unnecessary care.

Comment: One commenter noted that the use of an MME to limit opioid use does not correspond to current CDC guidelines. The commenter further requested CMS postpone finalizing any new MME requirements around the treatment of chronic pain until the new CDC Opioid Workgroup has a chance to convene, consider current evidence and best practices, and issue recommendations.

Response: Section 1004 of the SUPPORT Act requires state DUR programs to include safety edit limits (as specified by the state) on the maximum daily MME that can be prescribed to an individual enrolled under the state plan (or under a waiver of the state plan) for treatment of chronic pain (as designed and implemented by the state) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of any threshold identified by the state. Based on the FFY 2018 Annual DUR Survey, most states were already compliant with having established an MME threshold, and those not having this safety edit in place were aware of the requirement added by section 1004 of the SUPPORT Act, effective October 1, 2019. To note, the newly appointed CDC Opioids Workgroup is actively working to update the CDC guideline; however, its release is not expected until late 2021, and is hoped to include new recommendations not only for chronic pain management, but for the treatment of acute, short-term pain. To implement the statutory requirement, we proposed and are finalizing at § 456.703(h)(1)(ii) that states must include in their DUR programs safety edit limitations identified by the state on maximum daily MME for treatment of chronic pain and, under § 456.703(h)(1)(iii), a claims review automated process that indicates when an individual is prescribed a MME in excess of these limitations. The application of this required safety edit does not necessarily prevent the prescription from being dispensed, rather, it provides the opportunity to assure clinical appropriateness of therapy.

Comment: One commenter requested CMS emphasize that Morphine Milligram Equivalent (MME) safety edits are not strict limits, and that individual provider decision-making based on the patient's condition will supersede safety edits. Another commenter recommended that CMS policies should allow physicians to make clinical decisions based on each patient's specific circumstances, and not interfere in the provider-patient relationship.

Response: The safety edits required under this final rule are intended to protect Medicaid patients from serious consequences of overutilization, including overdose, dangerous interactions, increased side effects and additive toxicity. These safety edits provide for identifying potential problems at the pharmacy POS to engage both patient and provider in identifying and mitigating possible opioid misuse, abuse, and overdose risk at the time of dispensing, which ultimately assists the prescriber in making appropriate clinical decisions; however, the required safety edits do not necessarily prevent the prescription from being dispensed. When a safety edit is prompted, the pharmacist receives an alert and may be required, as dictated by predetermined standards established by the state, to take further action to resolve the issue prior to the prescription being dispensed. This rule is not intended to interfere with provider-patient relationship or the provider's exercise of clinical judgment. We are finalizing at § 456.703(h)(1)(ii), to require state DUR programs to include prospective safety edit limitations for opioid prescriptions, as specified by the state, on the maximum daily MME for treatment of pain, for initial and subsequent prescription fills.

[100] *https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf.*

[101] *https://www.kmap-state-ks.us/Documents/Content/Bulletins/18101%20-%20General%20-%20Opioid_2.1.pdf.*

[102] *https://www.wsha.org/quality-safety/projects/opioid-pain-management/opioid-prescribing-reports/.*

[103] *https://www.drugabuse.gov/publications/drugfacts/prescription-opioids.*

Comment: A few commenters expressed concern that due to variance in tolerance among patients receiving long-term opioid treatment and the risks of opioid tapering, it may not be conceptually possible for states to select an MME limit that uniformly achieves the goal of patient safety or that does not create new risks.

Response: Section 1004 of the SUPPORT Act requires state DUR programs to include safety edit limits (as specified by the state) on the maximum daily MME that can be prescribed to an individual enrolled under the state plan (or under a waiver of the state plan) for treatment of chronic pain (as designed and implemented by the state) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of any threshold identified by the state. We would expect that states typically would not establish MME limits that cannot be overridden, but instead would implement them as a safety edit that, when triggered by a prescription for a beneficiary, would prompt the dispensing pharmacist to review the patient's prescribed therapy. We expect that state implementations of maximum MME limits would include a function for exceptions based on specific patient factors affecting treatment protocol, including opioid dose tapering, as applicable. For example, the safety edit might prompt the pharmacist to more closely review all relevant clinical information about the prescription, counsel the beneficiary about the prescription and solicit from him or her additional information about why the drug has been prescribed, and consult directly with the prescriber to confirm the medical appropriateness of the prescription. If activities such as these result in a determination that the prescription is clinically sound and can be dispensed without modification, then we envision that the pharmacist typically would be able to override the safety edit after appropriately documenting that decision (consistent with any applicable documentation requirements, such as those that may be established by the state or a professional licensure or other governance entity). In this regard, we encourage states to consult existing resources on safe and appropriate opioid prescribing. We recognize there are many national guidelines and resources available to the states. Associations including, but not limited to, the PQA, NCQA, NQF, and federal agencies including AHRQ, SAMHSA, and the CDC can be utilized as existing resources. Therefore, we are finalizing as proposed this implementing regulation at § 456.703(h)(1)(ii).

Comment: Some commenters suggested removing the word ''rapid'' from the statement in the CMS proposed rule ''we do not mean to suggest rapid discontinuation of opioids already prescribed at higher dosages,'' as the commenter stated that even slow tapers have resulted in serious harm, which has not been adequately studied. Additionally, commenters noted that withdrawal is one of many risks associated with opioid tapering.

Response: We use the word ''rapid'' as a commonly referenced term to differentiate tapering regimens and agree withdrawal symptoms may be a risk of opioid tapering, which could potentially occur with slow tapering regimens, also. We do not suggest rapid discontinuation of opioids already prescribed at higher dosages. The maximum daily MME metric is often used as a gauge of the overdose potential of the amount of opioid that is being given at a particular time. Please refer to the HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics [104] for more information.

Comment: Some commenters noted that CMS could develop clearer guidance to ensure that safety edits and automated retrospective claims reviews achieve their intended goals without harming certain patient groups, emphasizing flexibility when applying safety edit thresholds, as well as addressing potential burden placed on physicians whose prescriptions might frequently be flagged due to the nature of their specialty, for example, such as cancer pain specialists, orthopedists or dental providers.

Response: We expect that states will continue to allow prescribers to make the best clinical decisions for patients regarding prescription medications needed to treat the patient's medical condition. The safety edits and automated retrospective claims reviews, as determined and implemented by state, that we are requiring under this final rule, are intended to assist providers in making clinical decisions to augment, not jeopardize patient care and clinical decision-making. We expect that many of the safety edit parameters will be reviewed by the state's DUR Board—which must include physicians and pharmacists, *see* § 456.716(b)—prior to implementation by the state. We also know that often times, prescribers may not be aware that patients are taking concomitant drugs that include the same type of active ingredients, such as opioids, and these situations are sometimes only detected at the time that the prescription is filled through a prospective review process, or after the prescription is filled, through a retrospective review process. We view the DUR program as providing an important, positive feedback loop to prescribers and dispensers to assure patient safety and improve therapeutic outcomes.

States will continue to have flexibility in design, development and implementation of safety edits and automated retrospective claims review as specified in section 1004 of the SUPPORT Act and in the provisions of this final rule. We envision that states will consult national guidelines and resources available to develop state policy to provide appropriate flexibility for their providers to ensure prospective safety edits and automated claims reviews will not adversely affect coordinated patient care, but augment clinical decision-making. We recognize there are many national guidelines and resources available to the states. Associations including, but not limited to, the PQA, NCQA, NQF, and federal agencies including AHRQ, SAMHSA, and the CDC can be utilized as existing resources.

Comment: One commenter recommended requiring an additional prospective safety edit to monitor when an individual is concurrently prescribed opioids and either benzodiazepines or antipsychotics.

Response: Under section 1004 of the SUPPORT Act, states are required, as determined and implemented by the state, to establish a retrospective claims review automated process to monitor when an individual is concurrently prescribed opioids, and benzodiazepines or antipsychotics. At the option of the state, the state may also establish prospective safety edits as part of a comprehensive DUR program to monitor for the same. The benefit of prospective safety edits for concurrently-prescribed medications would allow for real-time clinical assessment at the point of dispensing of the prescribed drugs. Additionally, such prospective safety edits could help in the detection of fraud and abuse. State Medicaid DUR programs promote patient safety through state-administered utilization management (UM) tools and systems that interface with the state's claims processing systems. The concurrent prescription monitoring requirement added by section 1004 of the SUPPORT Act is consistent with the requirement in

[104] *https://www.cms.gov/About-CMS/Story-Page/CDCs-Tapering-Guidance.pdf.*

section 1927(g)(1)(A) of the Act that state DUR programs must assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. Therefore, we proposed and are finalizing this rule at § 456.703(h)(1)(iv)(A) and (B) to require states to establish a retrospective claims review automated process and, at the option of the state, prospective safety edits for concurrently prescribed opioids and benzodiazepines or antipsychotics, as determined and implemented by the state.

Comment: One commenter recommended adding nonbenzodiazepine sedative hypnotics to CMS' proposed minimum DUR requirements for monitoring concurrent prescribing with opioids.

Response: We encourage states to determine whether to adopt safety edits for the prescribing of nonbenzodiazepine sedative hypnotics concurrently with opioids as part of their DUR programs. There are many existing resources available to the states, including but not limited to the PQA, NCQA, NQF, and federal agencies including AHRQ, SAMHSA, and the CDC, that have developed clinical guidance that may be relevant to establishing such safety edits and claims reviews. Neither the SUPPORT Act nor this final rule prohibits states from designing and implementing a prospective safety edit and/or retrospective automated claims review process to monitor for concurrent prescribing of opioids and another drug class, which additional monitoring could support enhanced care and treatment for Medicaid beneficiaries.

Comment: A few commenters encouraged CMS to work with various commenters, including NIH and the NIDA, to develop objective measures of pain and to perform ongoing assessment of the DUR activities to ensure that legitimate patient access to appropriate pain treatment is not negatively impacted.

Response: These activities described by the commenters are not within the scope of this rulemaking; however, we acknowledge the commenters' concern regarding the need for beneficiaries to have access to appropriate pain treatment, and the need to assess whether the pain treatment regimen prescribed is working to alleviate the patient's pain. Currently, we publish states' annual responses to the FFS and MCO DUR surveys on *Medicaid.gov*, including national summary comparison reports collated by CMS. These reports help us conduct state oversight and enable states to review other states' reports and compare their own DUR program activity to that of other states. In doing so, CMS and states gain visibility into the effectiveness of various DUR efforts and are better able to ensure that legitimate patient access to appropriate pain treatment is not negatively impacted. Additionally, beginning with state-submitted DUR reporting regarding the state' compliance with requirements of this final rule for FFY 2020, as required under amendments made by section 1004 of the SUPPORT Act, we will submit an annual report to Congress (RTC) that includes this state-submitted information to facilitate improved congressional oversight of the implementation of opioid-related DUR requirements. Finally, regarding the comments on developing objective measures of pain, we note that currently available national pain assessment resources include the CMS Clinical Quality Measures (CQMS) Pain Assessment and Follow-Up criteria [105] and the Joint Commission's Pain Assessment and Management Standards.[106]

Comment: One commenter noted that the proposed DUR standards should specifically require providers to consider benefits of opioid medication along with risks, and to include patients' goals and priorities in any decisions regarding dosage reduction.

Response: Decisions weighing the benefits and risks of opioid prescription treatment are the purview of the prescriber and the patient. We agree that, generally in medical decision-making, the health care provider and the patient should thoroughly consider the benefits and risks of available treatment options together before arriving at a decision about the patient's care. However, the DUR program can provide systematic feedback to prescribers about their opioid prescribing patterns, as compared to other prescribers, which information can help inform their thinking about their clinical treatment practices.

Comment: One commenter stated that flexibility at all levels of DUR program development and implementation is key to ensuring that patient needs are met.

Response: While states will need to comply with the requirements of the SUPPORT Act and the requirements of this final rule, we agree with the commenter that affording states the flexibility to develop and implement prospective safety edits and automated claims review processes in this final rule will allow states to ensure patient and provider needs are addressed in an effective DUR program. The flexibilities afforded to the states in this final rule will allow states to establish state-specific DUR standards to suit their circumstances and beneficiary populations. States also have the flexibility to use standards from existing state DUR models, or develop their own, in complying with the requirements of this final rule. We envision states will consult national guidelines and resources issued by public associations such as the PQA, NCQA, NQF; and federal agencies including, but not limited to, the AHRQ, SAMHSA, and the CDC, to develop, implement and potentially enhance their safety edits and claims reviews for an effective and efficient DUR program.

In consideration of the comments received, with a limited exception, we are finalizing as proposed § 456.703(h)(1)(i) through (iv), to require that the state's DUR program must include certain minimum standards for DUR Programs under the SUPPORT Act and section 1927 of the Act. The limited modification to the proposed regulation text concerns the safety edit for MME in § 456.703(h)(1)(ii), which we explained in preamble to the proposed rule that we intended to apply with respect to opioids prescribed for pain, not limited to chronic pain. 85 FR 37309. We made a technical error in the proposed regulation text that limited the applicability of the MME safety edit to opioids prescribed for chronic pain, which we are correcting in this final rule by removing the errant word ''chronic'' from the regulation text so that the requirement will clearly apply for opioid prescriptions ''for treatment of pain,'' whether chronic or acute.

f. Program To Monitor Antipsychotic Medications in Children

Under section 1004 of the SUPPORT Act, states must have a program (as designed and implemented by the state) to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the state plan (or under a waiver of the state plan), including any Medicaid expansion group for the Children's Health Insurance Program (CHIP).[107] Additionally, states must annually submit information on activities carried out under this program for individuals not more than the age of 18 years old generally, and children in foster care

[105] *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2019_Measure_131_MIPSCQM.pdf.*

[106] *https://www.jointcommission.org/resources/patient-safety-topics/pain-management-standards-for-accredited-organizations/#a98ee961a3184ec899b62579053a24a7.*

[107] Section 1902(oo)(1)(B) of the Act, as added by section 1004 of the SUPPORT Act.

specifically, as part of the annual report submitted to the Secretary under section 1927(g)(3)(D) of the Act, as provided in section 1902(oo)(1)(D) of the Act.

Antipsychotic medications are increasingly used for a wide range of clinical indications in diverse populations, including privately and publicly insured youth.[108] Antipsychotics' adverse metabolic effects have heightened concern over growth in prescribing to youth, including off-label prescribing and polytherapy of multiple antipsychotics.[109] Studies have raised concerns regarding the long term safety and effectiveness of antipsychotics in this broadened population. Studies in adults have found that antipsychotics can cause serious side effects and long-term safety and efficacy for off-label utilization is a particular concern in children.[110]

Some of the most concerning effects include uncontrollable movements and tremors; an increased risk of diabetes; substantial weight gain; elevated cholesterol, triglycerides and prolactin; changes in sexual function; and abnormal lactation.[111] Children appear to be at higher risk than adults for a number of adverse effects, such as extrapyramidal symptoms and metabolic and endocrine abnormalities. Some studies suggests that antipsychotic treatment may be associated with increased mortality among children and youths and the distal benefit/risk ratio for long-term off-label treatment remains to be determined.[112] [113]

In consideration of clinical recommendations to monitor and manage the appropriate use of antipsychotic medications by children and to assess the clinical benefits and harms of treatment on an ongoing basis, we believe this program is necessary to help ensure children are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT Act. Accordingly, we proposed at § 456.703(h)(1)(v) that states be required to implement programs to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the state plan, including any Medicaid expansion groups for CHIP. We noted that we understand states need considerable flexibility when implementing this program. The proposed provisions were not meant to prohibit the exercise of clinical judgment by a provider regarding the best or most appropriate care and treatment for any patient. We noted that states are expected to work with their pharmacy and therapeutics (P&T) and DUR committees to identify clinically appropriate safety edits and reviews. We recommended states consider expanding DUR programs to include reviews on children for polytherapy (therapy that uses more than one medication), inappropriate utilization or off label utilization.

The following is a summary of the comments we received on the proposed minimum standards for DUR programs for monitoring of antipsychotic medications in children, and our responses.

Comment: Some commenters recommended that CMS further define or identify guidelines for appropriate use of antipsychotics in children and encourage states to align their DUR programs on this particular DUR edit with national clinical practice guidelines.

Response: As outlined in the proposed rule, states are expected to consult with their Medicaid P&T and DUR committees, as well as state mental health and behavioral health professionals, to identify clinically appropriate parameters for the safety edits and reviews required under this final rule. We recommend that states, when developing parameters and criteria to implement appropriate prospective and retrospective DUR oversight for children, also consider specifically the applicability of such criteria for children in potentially vulnerable groups, such as children in foster care and those with disabilities. Some states have developed fact sheets to help communicate recommended strategies for prescribing psychotropic medication to children, including those in foster care and those living with disabilities.[114]

Resources to consider using include, but are not limited to, the AHRQ–CMS Pediatric Quality Measures Program (PQMP) fact sheet [115] and the SAMHSA guidance on Strategies to Promote Best Practice in Antipsychotic Prescribing for Children and Adolescents.[116]

After considering the comments received, we are finalizing, as proposed, § 456.703(h)(i)(v), to require states to establish a program to monitor and manage the use of antipsychotic medications by children enrolled under the state plan, including any expansion group for the Children's Health Insurance Program (CHIP). States must annually submit information on activities carried out under this program for beneficiaries not more than the age of 18 years old generally, and children in foster care specifically, as part of the annual report submitted to the Secretary under section 1927(g)(3)(D) of the Act, as provided in section 1902(oo)(1)(D) of the Act.

g. Fraud and Abuse Identification

Section 1902(oo)(1)(C) of the Act, as added by section 1004 of the SUPPORT Act, provides that states must have a process (as designed and implemented by the state) that identifies potential fraud or abuse of controlled substances by individuals enrolled under the state plan (or under a waiver of the state plan), health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled. We proposed to implement this requirement at § 456.703(h)(1)(vi); specifically, we proposed that the state's DUR program must include a process to identify potential fraud or abuse of controlled substances by individuals enrolled under the state plan, health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

We intended that the proposed process would operate in a coordinated fashion with other state program integrity efforts. States would have flexibility to define specific parameters for reviews for fraud and abuse, as well as protocols for recommendation, referral, or escalation of reviews to the relevant Program Integrity/Surveillance Utilization Review (SURS) unit, law enforcement, or state professional board, based on patterns discovered through the proposed DUR process. Additionally, we noted that state policy should specify the documentation required when suspected fraud and/or abuse results in a recommendation,

[108] Crystal, Stephen et al. ''Broadened use of atypical antipsychotics: safety, effectiveness, and policy challenges.'' *Health affairs (Project Hope)* vol. 28, 5 (2009): w770–81. doi:10.1377/hlthaff.28.5.w770.

[109] Ibid.

[110] Ibid.

[111] Marder SR, et al. Physical health monitoring of patients with schizophrenia. Am J Psychiatry. 2004; 161(8):1334.

[112] *https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2717966.*

[113] *https://www.healthline.com/health/consumer-reports-antipsychotics-children#1.*

[114] *https://children.wi.gov/Documents/Psychotropic%20Medication%20Prescribing%20for%20Children%20on%20Medicaid.pdf.*

[115] *https://www.ahrq.gov/sites/default/files/wysiwyg/policymakers/chipra/factsheets/chipra_1415-p011-1-ef_0.pdf.*

[116] *https://store.samhsa.gov/sites/default/files/d7/priv/pep19-antipsychotic-bp_508.pdf.*

referral, or escalation for further review, including the findings of any subsequent investigation into the potential deviation from the standard of care. States would be expected to ensure that DUR reviews conducted under the proposed requirement are aligned with all applicable federal requirements, including those specified in in §§ 455.12, 455.13 through 455.21, and 455.23 and section 1902(a)(64) of the Act.

We acknowledged that other initiatives, which many states are already undertaking, could work synergistically with the proposed requirement to help reduce fraud, misuse, and abuse related to opioids. For example, patient review and restriction programs (lock-in programs) [117] and PDMPs [118] also play an important role in detecting and preventing opioid-related fraud, misuse and abuse. Lock-in programs, also called patient review and restriction or drug management programs, are meant to cut down on ''doctor shopping''—the practice of going to several doctors or pharmacies to obtain or fill multiple prescriptions for opioids or other controlled substances for illicit sale or misuse or to support an addiction. Such programs are used primarily to restrict overutilization of medications. Additionally, we noted that programs may require beneficiaries to receive all prescriptions through one pharmacy, have all prescriptions written by one prescriber, receive health care services from one clinical professional, or all three, depending on how the program is designed.[119]

Section 5042 of the SUPPORT Act requires covered providers who are permitted to prescribe controlled substances and who participate in Medicaid to query qualified PDMPs before prescribing controlled substances to most Medicaid beneficiaries, beginning October 1, 2021. PDMPs are database tools sometimes utilized by government officials and law enforcement for reducing prescription drug fraud, abuse and diversion, but which more frequently can be used to monitor controlled substance use by healthcare providers including prescribers and pharmacists. PDMPs collect electronically transmitted prescribing and some dispensing data submitted by pharmacies and dispensing practitioners. The data are monitored and analyzed to support states' efforts in education, research, enforcement and abuse prevention.[120] Data analytics can help to determine the extent to which beneficiaries are prescribed high amounts of opioids, identify beneficiaries who may be at serious risk of opioid misuse or overdose, and identify prescribers with questionable opioid prescribing patterns for these beneficiaries.[121] [122] The process required under the SUPPORT Act and the proposed rule would identify potential fraud or abuse, and can help ensure that state officials and staff implementing the state's program integrity, PDMP, and DUR functions work collaboratively to identify opportunities for DUR activities to assist in the identification of potential fraud and abuse.

The following is a summary of the comments we received on the proposed minimum standards for DUR programs for fraud and abuse identification processes, and our responses.

Comment: Some commenters urged CMS to work with states to ensure that mechanisms to decrease provider administrative burden are implemented, relative to checking PDMPs, such as allowing PDMP queries and patient history checks to be performed by designated provider staff before patient visits, and the ability for designated provider staff to integrate results into existing electronic health record systems. This would reduce the burden on prescribers to check the PDMP at the time the prescription is written, and reduce patient waiting time. Additionally, some commenters suggested that PDMP interoperability between states would enable more coordinated patient care and better guard against fraud and abuse.

Response: Section 5042 of the SUPPORT Act requires covered providers who are permitted to prescribe controlled substances and who participate in Medicaid to query qualified PDMPs before prescribing controlled substances to most Medicaid beneficiaries, beginning October 1, 2021. We agree this has the potential to increase administrative burden on the prescriber, and that such increased burden could be minimized if designated provider staff are authorized to check patient history prior to patient visits and if PDMP information is integrated into existing electronic health record systems used by prescribers. We encourage states to educate providers on any best practices identified by the state regarding allocation of staff resources for accessing PDMP information and integrating it into clinical care processes. Furthermore, we agree that direct integration of PDMP information into electronic health record systems has the potential to increase the usefulness of PDMPs and promote improved clinical outcomes while minimizing burdens on clinical staff. The process required under section 5042 of the SUPPORT Act and the fraud and abuse identification process required under this final rule will help identify potential fraud or abuse, and help ensure that state officials and staff implementing the state's program integrity, PDMP, and DUR functions work collaboratively to identify opportunities for DUR activities to assist in the identification of potential fraud and abuse. Additionally, national initiatives to promote interoperability of PDMPs is being assessed by the Office of National Drug Control Policy (ONDCP) and the CDC.

Comment: Some commenters noted it may be difficult to fully understand a patient's entire opioid history and use if the patient crosses state lines to receive care, since PDMPs currently are separate, state-specific and non-integrated databases. In many cases, this results in information from one state's PDMP not being easily accessible to or interoperable with PDMPs in other states.

Response: We acknowledge the commenter's concern; however, the accessibility and interoperability of PDMPs is not within the scope of this rulemaking. We note that section 1944(a)(1) of the Act, as added by section 5042 of the SUPPORT Act, requires state Medicaid programs, beginning in October 2021, to require covered providers to check a qualified PDMP for a covered individual's prescription drug history before prescribing a controlled substance. Additionally, the amendments made by section 5042 of the SUPPORT Act incentivize states to enter into

[117] ''Pharmacy Lock-In Programs Slated For Expanded Use.'' OPEN MINDS, *www.openminds.com/market-intelligence/executive-briefings/pharmacy-lock-programs-slated-expanded-use/.*

[118] Office of National Drug Control Policy. Prescription Drug Monitoring Program. Prescription Drug Monitoring Program, April 2011. *https://www.ncjrs.gov/pdffiles1/ondcp/pdmp.pdf.*

[119] ''Pharmacy Lock-In Programs Slated For Expanded Use.'' OPEN MINDS, *www.openminds.com/market-intelligence/executive-briefings/pharmacy-lock-programs-slated-expanded-use/.*

[120] ''Prescription Drug Monitoring Frequently Asked Questions (FAQ): The PDMP Training and Technical Assistance Center.'' *Prescription Drug Monitoring Frequently Asked Questions (FAQ)| The PDMP Training and Technical Assistance Center, www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.*

[121] Beaton, Thomas. ''Preventing Provider Fraud through Health IT, Data Analytics.'' *HealthPayerIntelligence,* 5 Oct. 2018, *https://healthpayerintelligence.com/news/preventing-provider-fraud-through-health-it-data-analytics.*

[122] OIG, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing,* OEI–02–17–00250, July 2017. *https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf.*

agreements with contiguous states to enable covered providers also to check the PDMPs of such contiguous states by providing 100 percent federal matching funds during fiscal years 2019 and 2020 for design, development, and implementation activities for establishing and connecting qualifying PDMPs.

Comment: Some commenters recommended that dosage alone not be used as an indicator of questionable prescribing when there is no other evidence of fraud or abuse, and that CMS should adopt fraud detection measures that do not compromise individualized care.

Response: We agree that using the dosage of drug being prescribed as a sole indicator for fraud and abuse would not be appropriate, and we encourage states to utilize their flexibility to define the specific parameters to be implemented for the detection of fraud and abuse. We intend that this process should operate in a coordinated manner with other state program integrity efforts. States have flexibility to define specific parameters for review for fraud and abuse and to determine how best to ensure these parameters will not compromise or unduly interfere with patient care. Resources states may consult in determining parameters can be found in established national guidelines such as those issued by the PQA, NCQA, NQF, and federal agencies including AHRQ, SAMHSA, and the CDC.

Comment: One commenter expressed concern with CMS' suggestions that states may implement programs such as provider ''lock-in programs'' or programs that require beneficiaries to receive all prescriptions through one pharmacy, have all prescriptions written by one prescriber, or receive health care services from one clinical professional, to enhance existing fraud and abuse policies. The commenter noted that such programs may have unintended negative consequences for patients from a continuity of care perspective if patients are required to change their providers or discontinue using certain providers for services that such providers have appropriately provided to them in the past.

Response: We intend that the process for developing and/or enhancing existing fraud and abuse programs should proceed in a coordinated fashion with other state program integrity efforts. Under this final rule, states have flexibility to define specific parameters for reviews for fraud and abuse, as well as protocols for recommendation, referral, or escalation of reviews to the relevant SURS unit, law enforcement, or state professional board, based on patterns discovered through the state's DUR program. State flexibility in developing and/or enhancing fraud and abuse programs will enable states to mitigate potential negative effects on prescribers' ability to provide coordinated patient care. State parameters should include processes to ensure continuity of care is not adversely affected when developing and implementing new or enhanced fraud and abuse programs. National guidelines such as those issued by the PQA, NCQA, NQF, and federal agencies including AHRQ, SAMHSA, and the CDC can help identify best practices for states to consider in implementing these programs.

In consideration of the comments received, we are finalizing § 456.703(h)(1)(vi) as proposed, to require that the state's DUR program must include a process to identify potential fraud or abuse of controlled substances by individuals enrolled under the state plan, health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

2. Other CMS Proposed Standards

In addition to regulations implementing requirements added by section 1004 of the SUPPORT Act, we proposed additional minimum DUR standards in the June 2020 proposed rule that states would be required to implement as part of their DUR programs at § 456.703(h)(1)(vii). Specifically, under our authority to implement section 1927(g) of the Act and consistent with the goals of the SUPPORT Act to help combat the nation's opioid overdose epidemic, we proposed additional minimum standards related to MAT and identification of beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone. These additional standards were included to ensure prescribed drugs are: (1) Appropriate; (2) medically necessary; and (3) not likely to result in adverse medical results.

Under the proposed policies, state DUR programs would be required to include prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT, and prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state to expand appropriate utilization of naloxone. As discussed in the June 2020 proposed rule, we proposed these minimum requirements to further implement section 1927(g) of the Act to prevent and reduce the inappropriate use of opioids and potentially associated adverse medical results, consistent with the provisions under section 1004 of the SUPPORT Act.

a. Medication Assisted Treatment (MAT)

To further implement section 1927(g)(1) of the Act and consistent with section 1004 of the SUPPORT Act, we proposed to require states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT or had an OUD diagnosis within a specified number of days (as determined by the state), without having a new indication to support utilization of opioids (such as a new cancer diagnosis, new palliative care treatment or entry into hospice).

MAT is treatment for SUD that includes addiction treatment and services plus a medication approved by FDA for opioid addiction, detoxification, or maintenance treatment or relapse prevention. Section 1006(b) of the SUPPORT Act defines MAT to include all FDA approved drugs and licensed biological products to treat opioid disorders, as well as counseling services and behavioral therapies for the provision of such drugs and biological products.[123] MAT has proven to be clinically effective in treating OUD and significantly reduces the need for inpatient detoxification services.[124] Medications such as buprenorphine and methadone, in combination with counseling and behavioral therapies, provide a whole-patient approach to the treatment of OUDs.

Using opioid medications during the course of MAT is dangerous from a clinical perspective. Prospective drug safety edits are also designed to identify other prescription and non-prescription medications that are not indicated for use by patients being treated with opioid therapy. For example, an

[123] Support for Patients and Communities Act, Section 1006(b). Requirement For State Medicaid Plans To Provide Coverage For Medication-Assisted Treatment.

[124] ''Medication and Counseling Treatment''. September 28, 2015. Available at *https://www.samhsa.gov/medication-assisted-treatment/treatment.*

effective prospective DUR program can alert the pharmacist before dispensing that the patient is taking other medications, such as blood pressure or cough and cold medications that might have an additive sedating effect when taken with opioids. These prospective edits are effective only to the extent that the other potential interacting medications are in the patient's prescription record, and not if the patient has obtained them from a non-pharmacy source. That is, the system can only send the alerts to the pharmacist if it includes all the prescription and non-prescription medications being taken by the patient.

We believe states could take effective action to help prevent adverse medical results and possible OUD relapse, and increase coordination of care in patients with a history of OUD. We noted that we understand states need considerable flexibility when implementing these reviews to address complicated patient populations. The proposed prospective safety edits, automatic retrospective claims reviews, or a combination of these approaches, would help identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT or has received an OUD diagnosis. Accordingly, we proposed that states would have flexibility to determine which of these DUR approaches the state would implement, including the flexibility to incorporate both into an effective DUR program. State flexibility also would extend to specifying the time period between the prior episode of MAT or OUD diagnosis (or most recent prior episode of MAT or OUD diagnosis) and the subject opioid prescription that, if not met, would trigger the alert (for example, an opioid prescription within 24 months of the end of the most recent episode of MAT would trigger a prospective safety edit). Flexibility could also extend to diagnoses where opioid use after MAT is appropriate without compromising OUD treatment (for example, in end of life care or in cancer patients with severe pain resulting from their disease or that does not respond to alternative pain management options).

In consideration of clinical recommendations to ensure appropriate MAT treatment, and to prevent opioid related abuse and misuse, we believe the proposed prospective safety edits and/or retrospective claim reviews are necessary to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT Act. This proposed requirement is authorized by and expected to advance the purposes of section 1927(g) of the Act and is consistent with the purposes of section 1004 of the SUPPORT Act. Accordingly, we proposed at § 456.703(h)(1)(vii)(A) that states be required to implement reviews to alert when the beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT for an OUD or has been diagnosed with an OUD, within a timeframe specified by the state, in the absence of a new indication to support utilization of opioids (such as new cancer related pain diagnosis or entry into hospice care). In addition to helping ensure appropriate utilization of medications, we noted that these edits would assist in coordination of care, and potentially in improved treatment of pain.

The following is a summary of the comments we received on these additional minimum standards for DUR programs related to MAT, and our responses.

Comment: One commenter requested clarification as to whether DUR activities are applicable to beneficiaries who receive implantable or injectable formulations of medications for opioid use disorder (MOUD). Additionally, other commenters expressed concern that MOUD dispensed in an Outpatient Treatment Programs (OTPs) or MOUD administered in settings where regulations pertaining to CODs do not apply are vulnerable to adverse reactions that result from concurrent prescribing, particularly for beneficiaries receiving methadone. With respect to OTPs, this concern arises because methadone is generally paid for as part of a single bundled service when used in an OTP, and thus would not be a covered outpatient drug as a result of the limiting definition found at section 1927(k)(3) of the Act; therefore, methadone use may not be detected by DUR systems designed to examine use of covered outpatient drugs.

Response: We interpret the comment regarding MOUD as referring to medications used to treat opioid use disorders, more commonly referred to as medication-assisted treatment (MAT). Medications used in MAT—including methadone, naltrexone, and buprenorphine—are used to treat individuals who have opioid use disorders, such as opioid dependency. Section 1006(b) of the SUPPORT Act amended section 1902(a)(10)(A) of the Act to require state Medicaid plans to include coverage of MAT for OUD for categorically needy populations, added this new required benefit to the definition of medical assistance at section 1905(a)(29) of the Act, and added a definition of the coverage required under the new benefit at section 1905(ee)(1) of the Act. Section 1905(a)(29) specifies that the new mandatory MAT benefit will be in effect for the period beginning October 1, 2020, and ending September 30, 2025.

CMS interprets section 1905(a)(29) and 1905(ee) of the Act to require that states include as part of this new mandatory benefit all forms of drugs and biologicals that FDA has approved or licensed for MAT to treat OUD. At this time, this includes the drugs methadone, buprenorphine, and naltrexone, as there are no biologicals currently licensed by FDA to treat OUD. Before the new mandatory MAT benefit took effect on October 1, 2020, states covered many of these MAT drugs (for all FDA approved and medically-accepted indications) under the optional benefit for prescribed drugs described at section 1905(a)(12) of the Act.

A statutory change was made to sections 1905(a)(29) and 1905(ee) of the Act by section 2601 of the Continuing Appropriations Act of 2021, and other Extensions Act (Pub. L. 116–159), to specify that the Medicaid drug rebate program (MDRP) requirements in section 1927 of the Act shall apply to any MAT drugs or biologicals used to treat OUD described under the definition of the mandatory benefit at section 1905(ee)(1)(A) of the Act, that are furnished as medical assistance under sections 1905(a)(29) and section 1902(a)(10)(A) of the Act, and are covered outpatient drugs, as that term is defined at section 1927(k)(7) of the Act.

In determining whether such a MAT drug or biological satisfies the definition of a covered outpatient drug, such MAT drugs or biologicals are deemed prescribed drugs for such purposes. More specifically, these amendments ensure that MAT drugs and biologicals covered under the new mandatory benefit are included in the MDRP, make it possible for states to seek section 1927 rebates and apply drug utilization management mechanisms (such as preferred drug lists and prior approval) with respect to these drugs and biologicals, and establish a manufacturer's obligation to pay appropriate rebates and comply with all applicable drug product and drug pricing reporting and payment of rebates with respect to these drugs and biologicals. The change in law is effective as if included in the enactment of the SUPPORT Act, which was October 24, 2018.

To the extent the injectable and implantable drugs used for MOUD

satisfy the definition of a covered outpatient drug, such drugs would be subject to the same DUR edits and activities as other drugs that meet the definition of a covered outpatient drug. That is, states would be expected to include such drugs in the prospective claims edits and retrospective claims analysis that would be applicable to other covered outpatient drugs, and apply any of the opioid safety edits and other required DUR activities to the extent that these MAT drugs were also opioids.

Comment: One commenter encouraged CMS to consider how the proposed DUR approaches complement or otherwise interact with other utilization management strategies, to ensure that states are not unduly restricting access to MOUD.

Response: As noted above, MAT drugs, or medications for opioid use disorders, are covered under a new mandatory MAT benefit, but can also be covered outpatient drugs. MAT drugs that are also covered outpatient drugs can thus be subject to the same utilization management approaches, such as prior authorization, and DUR program safety edits and claims reviews, as can other covered outpatient drugs under section 1927 of the Act. Before the new mandatory MAT benefit took effect on October 1, 2020, MAT drugs were available to patients through the optional prescription drug benefit under section 1905(a)(12) of the Act as covered outpatient drugs, and evidence from state DUR program surveys indicate that these medications were made available by states to Medicaid beneficiaries under the optional benefit. We expect that access to these medications will increase given that they are now covered under the new MAT mandatory benefit.

Comment: A few commenters urged CMS to clearly articulate the requirements for a MAT DUR program.

Response: We are not requiring states to implement a DUR program specific to MAT medications. We proposed to require states to implement prospective safety edits, automatic retrospective claims reviews, or a combination of these approaches, as determined by the state, to identify when a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT for an OUD or has been diagnosed with an OUD, within a timeframe specified by the state, in the absence of a new indication to support utilization of opioids (such as new cancer related pain diagnosis or entry into hospice care). Accordingly, we proposed that states would have flexibility to determine which of these DUR approaches—prospective, retrospective, or both—the state would implement as part of an effective DUR program to identify these patients. State flexibility also would extend to specifying the time period between the prior episode of MAT or OUD diagnosis (or most recent prior episode of MAT or OUD diagnosis), as well as the identification of specific indications that could support a new opioid prescription (such as new cancer related pain diagnosis or entry into hospice care) and therefore not trigger a safety edit alert and/or retrospective review under the state's implementation. We are finalizing this provision as proposed in § 456.703(h)(1)(vii)(A).

Comment: One commenter supported the proposed minimum standards for MAT but noted that the proposals for prospective safety edit alerts and retrospective claims review may impact 42 CFR part 2 confidentiality protection of those patients with Substance Use Disorder (SUD) patient records. Another commenter suggested that CMS and SAMHSA provide guidance on how the proposed opioid-related DUR requirements should be implemented in a manner that protects beneficiary information consistent with the requirements in part 2; this commenter was specifically concerned that claims data about services beneficiaries receive from part 2 providers might be disclosed to non-part 2 providers without patient consent.

Response: We believe that it is essential for all states to comply with 42 CFR part 2 regulations in order to uphold the confidentiality of patient medication information held by part 2 providers. We further note the potential applicability of state privacy regulations and Health Information Portability and Accountability Act as referenced in the National Association of State Mental Health Program Directors Technical Assistance Coalition's *Compilation of State Behavioral Health Patient Treatment Privacy and Disclosure Laws and Regulations.*[125] The 42 CFR part 2 regulations serve to protect substance use disorder patient records that are maintained in connection with the performance of part 2 programs (as defined in 42 CFR 2.11). The 42 CFR part 2 regulations have been revised, most recently in 2020, to facilitate better coordination of care activities with providers that are not participating in a part 2 program (considered non-part 2 providers) in response to the opioid epidemic while maintaining patient confidentiality protections against unauthorized record use and disclosure pursuant to 42 CFR part 2. Section 3221 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) will require further revisions to part 2. CMS notes that part 2 records may be disclosed under certain conditions with patient consent and under various exceptions to patient consent requirements (for example, 42 CFR 2.53). Because the application of part 2 regulations to specific disclosures may be complex, state programs should consult legal counsel about DUR programs, applicable privacy laws and regulations and disclosure of patient identifying information. A SAMHSA Part 2 Revised Rule Fact Sheet is available for more information.[126]

Comment: One commenter encouraged CMS to provide more examples of when it may be appropriate to prescribe additional opioid medications to patients receiving MAT.

Response: We included examples in the proposed rule focusing on end of life care or for cancer patients with severe pain resulting from their disease or that does not respond to alternative pain management options. We recommend exploring currently approved and accepted clinical practice guidelines to better understand these and other instances when it may be appropriate to prescribe additional opioid medications to patients receiving MAT, such as SAMHSA's publication, Medication-Assisted Treatment For Opioid Addiction in Opioid Treatment Programs.[127]

Comment: One commenter suggested that certified registered nurse anesthetists' (CRNAs') approach to pain management may reduce the reliance on opioids as primary pain management as CRNAs manage chronic pain in a compassionate, patient-centered, holistic manner, using a variety of therapeutic, physiological, pharmacological, and interventional modalities. Additionally, this commenter stated that moving from a unimodal approach of using opioid drugs to manage chronic and acute pain to a more patient-centered, multidisciplinary, multimodal opioid-sparing treatment approach optimizes patient engagement in their own pain care which would reduce the risk of patients developing SUDs.

Response: We agree that all of a patient's treating providers working in

[125] *https://www.nasmhpd.org/content/tac-assessment-working-paper-2016-compilation-state-behavioral-health-patient-treatment.*

[126] *https://www.hhs.gov/about/news/2020/07/13/fact-sheet-samhsa-42-cfr-part-2-revised-rule.html.*

[127] *https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006.*

coordination have a role to play in reducing the reliance on opioids as a primary pain management modality. Section 1006(b) of the SUPPORT Act amended the Social Security Act to include a new MAT Medicaid benefit, and defined that benefit to not only include FDA approved drugs and licensed biological products to treat OUD, but also counseling services and behavioral therapies related to the provision of the drugs and biological products, and thus recognizes that providing these therapies could help to optimize treatment.

Comment: One commenter noted that for chronic pain management, particularly if opioids are prescribed in the treatment, the clinician should discuss the risk of dependence and OUD, as well as enter into a pain management treatment agreement with the patient.

Response: Generally, to the greatest extent possible, clinical decision-making should be undertaken in the context of the relationship between the provider and the patient and should consider nationally recognized clinical best practices relevant to the patient's specific treatment needs. The provider should educate the patient on any prescribed treatment, to include both benefits and potential risks. Resources and guidance issued by public associations such as the PQA, NCQA, NQF; and federal agencies including, but limited to, the AHRQ, SAMHSA, and the CDC are available to support clinical best practices. Additionally, the safety edits required under this final rule can create an opportunity for additional review and patient consultation that could potentially result in a more clinically appropriate approach to treatment to forge a stronger provider/patient relationship. Another tool available to help foster a better a provider/patient relationship could be to employ the use of a pain management agreement (PMA) which allows for the documentation of understanding between a provider and patient. PMAs, when used, provide a means of facilitating care and improving communication between providers and their patients. It is important to note that the PMA is not designed as a contract, but rather a tool that sets forth important information about potential risks, benefits, safeguards, expectations, and patient and provider responsibilities. In the event the patient gets off-course with his or her treatment, the PMA provides a foundation for discussion as to the potential consequences and solutions.[128]

Comment: One commenter opined that CMS should encourage state Medicaid programs to remove coverage and formulary limits, prior authorization requirements, step therapy requirements, and other administrative burdens or barriers that may inappropriately delay or deny MAT, with respect to all medications approved by FDA for OUD.

Response: MAT is an effective, comprehensive, and evidence-based treatment that is integral to addressing the nation's opioid crisis. Section 1006(b) of the SUPPORT Act amended the Social Security Act to require state Medicaid plans to cover MAT for OUD for the categorically needy populations. Evidence demonstrates that treatment for substance use disorders—including inpatient, residential, and outpatient treatment—is cost-effective compared with no treatment.[129] Existing Medicaid authorities, as well as new opportunities afforded by the SUPPORT Act, are available to help states expand their SUD service continuum, which can include MAT. Additionally, to increase access to MAT for OUD, section 1006(b) of the SUPPORT Act requires states to provide Medicaid coverage of certain drugs and biological products, and related counseling services and behavioral therapy.[130] Additionally, states may use utilization management controls to promote the efficient delivery of care and to control costs.

In consideration of comments received, we are finalizing § 456.703(h)(1)(vii)(A) as proposed, to require states to establish approaches to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT or had an OUD diagnosis within a specified number of days, without having a new indication to support utilization of opioids.

b. Coprescribing or Codispensing of Naloxone When a Patient Is at High Risk for Opioid Overdoses

To further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT Act, we proposed and sought comment on requiring states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone with the goal of expanding appropriate utilization to individuals at risk of opioid overdose. As discussed below, based on comments received, we are modifying the proposal in this final rule by replacing the reference to naloxone with a reference to all FDA-approved opioid antagonist/reversal agents so that the final regulation is broad enough to encompass additional such drugs, should FDA approve any others in the future. An opioid antagonist/reversal agent is a medication designed to rapidly reverse opioid overdose by binding to opioid receptors and reversing the effects of opioids. Opioid antagonist/reversal agents work quickly to restore normal respiration to a person whose breathing has slowed or stopped as a result of an opioid overdose, including both illicit and prescription opioids. However, opioid antagonist/reversal agents only work if a person has opioids in their system; the medication has no effect if opioids are absent.[131] Currently, naloxone is the only FDA-approved opioid antagonist/reversal agent, but it is possible that FDA could approve others in the future.

The prescribing or co-prescribing of an opioid antagonist/reversal agent to patients at elevated risk for opioid overdose or for those who have overdosed on opioids can save lives.[132] We recommended states consider ways to expand access to, and distribution and use of naloxone, or another opioid antagonist/reversal agent that may be approved in the future, when clinically appropriate.

When implementing this safety edit or review, we noted that states should

[128] *https://health.ri.gov/publications/guidelines/provider/PatientViolatesPainAgreement.pdf.*

[129] Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health.* Washington, DC: HHS, November 2016. Chapter 4, Early Intervention, Treatment, and Management of Substance Use Disorders. *https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf.*

[130] SUPPORT for Patients and Communities Act section 1006(b), Public Law 115–271 (2018), *https://www.congress.gov/115/plaws/publ271/PLAW-115publ271.pdf.*

[131] ''Understanding Naloxone.'' Harm Reduction Coalition. Available at *https://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/.*

[132] NEJM Journal Watch: Summaries of and Commentary on Original Medical and Scientific Articles from Key Medical Journals, HHS-recommends-coprescribing-naloxone-with-opioids-high. *https://www.jwatch.org/fw114907/2018/12/20/hhs-recommends-coprescribing-naloxone-with-opioids-high.*

determine standards for identifying individuals at high risk for opioid overdose, such as individuals who have been discharged from emergency medical care following opioid overdose, individuals who use heroin or misuse prescription pain relievers, as well as those who use high-dose opioids for long-term management of chronic pain.[133] Before starting and periodically during continuation of opioid therapy, we stated that clinicians should evaluate risk factors for opioid-related harms. When prescribing opioids, the CDC guideline recommends clinicians should incorporate strategies to mitigate opioid risks, including considering offering an opioid antagonist/reversal agent when factors that increase risk for opioid overdose are present, such as history of overdose, history of SUD, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use.[134] We noted that we understand states need considerable flexibility when implementing this requirement to address a complex problem and proposed that states would have flexibility to determine which DUR approach the state would implement in an effective DUR program: either or both of prospective safety edits and/or retrospective claims reviews. Further, we proposed that states would have flexibility to determine the particular criteria they would use to identify which beneficiaries may be at high risk of opioid overdose such that they should be considered for co-prescription or co-dispensing of an opioid antagonist/reversal agent.

In consideration of clinical recommendations to expand opioid antagonist/reversal agent use to prevent adverse medical events among those who are prescribed opioids or those who may be at high risk of opioid overdose or who have previously overdosed, we believe this requirement is necessary to ensure that at-risk individuals are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT Act. Accordingly, we proposed at § 456.703(h)(1)(vii)(B) that states be required to implement prospective safety edit alerts, automatic retrospective claims reviews, or a combination of these approaches, as determined by the state, to identify when a beneficiary could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone. As discussed below, we are modifying this requirement in this final rule to extend to any FDA-approved opioid antagonist/reversal agent. As noted in the proposed rule, we anticipate that this requirement may help expand appropriate utilization of an opioid antagonist/reversal agent, including the facilitation of dispensing to individuals at risk of overdose.

The following is a summary of the comments we received on additional minimum standards for DUR programs with respect to co-prescribing or co-dispensing of naloxone and our responses.

Comment: One commenter suggested expanding the language in the proposed rule to include therapies that are not naloxone-based, suggesting ''any FDA-approved opioid antagonist/reversal agent'' in the place of naloxone.

Response: We agree with the commenter. The language in our proposed rule referred to naloxone because this is the only FDA approved antagonist/reversal agent at this time. We do understand that other agents may be developed and receive FDA approval within this therapeutic class. We do not want to limit the new safety edit to simply one drug, should another opioid antagonist/reversal agent gain FDA approval in the future; such a limitation would be less effective in accomplishing our goal of promoting the appropriate co-prescribing and co-dispensing of such agents to help mitigate the effects of opioid overdose. To reflect the proactive intent of this rulemaking, we are implementing the commenter's suggestion to revise the regulation text to refer to ''any FDA-approved opioid antagonist/reversal agent.''

Comment: A few commenters encouraged CMS to work with state Medicaid agencies and other commenters to develop recommended best practices for prescribers and pharmacists for communicating with patients about an opioid antagonist/reversal agent. Some commenters recommended that CMS consider approaches to expand education on administering opioid antagonist/reversal agents and in recognizing the signs and symptoms of an overdose.

Response: We agree with the commenters that best practices should be established for providers to educate beneficiaries and their families about opioid antagonist/reversal agents. Currently available relevant materials include the SAMHSA Opioid Overdose Prevention Toolkit.[135] This toolkit provides advice for prescribers and beneficiaries and their families. Additionally, the toolkit encourages providers and others to learn about preventing and managing opioid overdose, promoting access to treatment for individuals who have a SUD, expanding access to naloxone, and it encourages prescribers to use PDMPs. This resource could be helpful to providers, including prescribers and pharmacists, in discussing opioid overdose risk and prevention with patients and their families and caregivers.

Comment: Some commenters expressed the belief that pharmacists should be allowed to dispense any FDA-approved opioid antagonist/reversal agent over the counter (OTC) without a prescription and appropriate related indemnification should be extended to pharmacists. One commenter suggested CMS address prescription status, as well as the cost of opioid antagonist/reversal agents as barriers to utilization. Commenters also opined that Good Samaritan laws should be implemented in every state to shield health care personnel and lay persons from liability when administering an opioid antagonist/reversal agent to individuals suspected of opioid overdose.

Response: Although this is not in scope of this rule, most states do allow pharmacists to dispense FDA-approved opioid antagonist/reversal agents. Forty-seven states (94 percent) allow pharmacists to dispense these agents independently or through collaborative practice agreements, standing orders, or other predetermined protocols developed by entities including State Boards of Professional Regulations, Boards of Pharmacy, and/or Boards of Medicine, as applicable.[136] This allows greater access and less barriers to obtain these agents by patients and/or their family members and caregivers. Additionally, FDA-approved opioid antagonists/reversal agents are available without prior authorization in all states.[137]

Comment: Some commenters suggested standards for healthcare providers who administer naloxone or any FDA-approved opioid antagonist/reversal agent such as educational programs designed to inform providers on proper administration and patient communication.

[133] Ibid.

[134] ''CDC Guidelines for Prescribing Opioids for Chronic pain. '' Available at *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[135] *https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf.*

[136] *https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html.*

[137] Ibid.

Response: We agree that clinical standards for healthcare providers who administer any FDA-approved opioid antagonist/reversal could be useful and that providers should be properly educated on the correct use of drugs in this class, of which naloxone currently is the only one. The SAMHSA Opioid Overdose Prevention Toolkit is a resource available to states, providers, and beneficiaries; it contains helpful information regarding the proper use of naloxone.[138]

In consideration of comments received, with a limited exception, to further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT Act, we are finalizing, as proposed, § 456.703(h)(1)(vii)(B) to require states to establish approaches to identify beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone. Based on comments received, we are revising the final regulation text in § 456.703(h)(1)(vii)(B) to replace the proposed reference to naloxone with a reference to all FDA-approved opioid antagonist/reversal agents, so that the final regulation is broad enough to encompass additional such drugs, should FDA approve any others in the future.

3. Exclusions

The foregoing DUR requirements added to section 1902(oo) of the Act by section 1004 of the SUPPORT Act, which we proposed to implement along with additional related proposals under section 1927(g) of the Act at § 456.703(h)(1)(i) through (h)(1)(vii)(B), do not apply for individuals who are receiving hospice or palliative care or those in treatment for cancer; residents of a long-term care (LTC) facility, a facility described in section 1905(d) of the Act (that is, an intermediate care facility for the intellectually disabled), or of another facility for which frequently abused drugs are dispensed for residents through a contact with a single pharmacy; or other individuals the state elects to treat as exempted from such requirements.

We understand states need considerable flexibility when implementing these safety edits and claims reviews to address complicated patient populations. We noted our expectation that states would consult national guidelines and work with their P&T and DUR committees to identify other clinically appropriate patient populations for possible exclusion from the safety edits and claims reviews specified in § 456.703(h)(1)(i) through (vii), to avoid impeding critical access to needed medication when managing specific complex disease states.

We proposed to implement this statutory exclusion at § 456.703(h)(2), such that states would not be required to implement the specified DUR requirements for these populations. However, while states are not required to comply with these requirements for these individuals, we clarified, and proposed to codify in the regulation, that states voluntarily may apply the prospective safety edits and claims review automated processes otherwise required under the SUPPORT Act to exempt populations.[139]

The following is a summary of the comments we received on the proposed exclusion standards for DUR programs, and our responses.

Comment: One commenter expressed concern that more information would be needed from the states for the pharmacist and other providers to properly identify beneficiaries who are receiving hospice or palliative care, or who are residents in certain LTC facilities, to ensure exemptions from opioid safety edits and automated claims reviews are correctly applied.

Response: We understand states have multiple patient information systems and data sources available to help identify beneficiaries that are exempt from opioid-related safety edits and/or claims reviews, including their claims systems, PDMPs, and information from the databases of pharmacy benefit managers with which the state (or the state's managed care plans) has contracted to administer COD benefits for beneficiaries. As drug utilization review is performed through claims processing systems, linking to other sources to identify these populations should help states implement their safety edits and claims reviews. Ideally, a comprehensive DUR program that optimizes such system linkages would present safety edit information at the point of care, including to the provider (such as through an EHR system) before the prescription is written and to the pharmacist before it is dispensed. This way, clinical issues can be resolved proactively and the beneficiary will be able to receive his or her clinically-indicated opioid therapy without undue disruption.

We remind states that they should not impose a greater burden on medication access for individuals with disabilities residing in community-based settings than that applied to similar individuals residing in institutional settings, consistent with the Americans with Disabilities Act (ADA) and the Supreme Court's decision in *Olmstead* v. *L.C.*, 527 U.S. 581 (1999).

CMS will consider adding additional questions to the annual state and MCO DUR surveys that may help provide additional information on policies relating to patient populations that the state exempts from the opioid-specific DUR requirements, and how states implement such policies.

Comment: One commenter suggested that CMS identify beneficiaries residing in assisted living facilities (ALFs) as a population that would be excluded from these opioid safety edits. Additionally, some commenters recommended that patients with sickle cell disease and cancer survivors should be considered as potential excluded populations. Other commenters requested that we delete from the regulatory exemption text proposed at § 456.703(h)(2) the following sentence: ''While States are not required to apply these requirements for these individuals, States may elect to do so,'' due to the commenters' belief that the statement is inconsistent with the clear expression of the Congress that the specified groups should be exempt from the DUR requirements.

Response: Under this final rule, states have flexibility to determine additional populations to exclude from the application of the required opioid-related safety edits and claims reviews. This includes the flexibility to exclude, for example, patients with sickle cell disease or cancer survivors. Additionally, we proposed to codify in the regulation, that states voluntarily may apply prospective safety edits and claims review automated processes, as well as the program for monitoring antipsychotic use in children and the process for identifying potential fraud or abuse of controlled substances that are otherwise required under the SUPPORT Act to otherwise exempt populations. As stated, this is not a requirement; however, we believe beneficiaries in the excluded populations would benefit from the safety edits and claims reviews and other measures otherwise required under this final rule, to help ensure their opioid-related treatment is clinically appropriate and their risk of opioid-related harm is minimized. For example, beneficiaries in the excluded populations would also benefit from safety edits and reviews being finalized in this rule to help avert unintended therapeutic duplication and drug interactions, which would be more

[138] *https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf.*

[139] Section 1902(oo)(3) of the Act, as added by section 1004 of the SUPPORT Act.

likely to be missed if the beneficiaries were not subject to opioid-related safety edits and claims reviews. States would benefit from subjecting as broad a population as possible to opioid-related safety edits and claims reviews, too, as comprehensive data collection better ensures all populations are accounted for when further developing the DUR program and making other policy decisions. States that opt not to exclude otherwise excluded beneficiaries from the activities required under § 456.703(h)(1)(i) through (vii) would do so under the authority of section 1927(g) of the Act, not the amendments made by the SUPPORT Act. Furthermore, as discussed above, the safety edits and claims reviews required under this final rule are not intended to prevent any beneficiary from receiving clinically appropriate prescribed treatment, but rather, to help ensure their prescribed treatment is appropriate and medically necessary.

Comment: One commenter requested clearer guidance to ensure that safety edits and retrospective claims reviews, if voluntarily implemented by the state for otherwise exempt populations, achieve their intended goal without harming these excluded patients.

Response: This final rule is intended to ensure that certain patient and clinical information is provided to prescribers and pharmacists to help ensure that beneficiaries who take opioids are taking them correctly and are not unnecessarily subjected to increased potential for clinical harm. State flexibility to voluntarily implement safety edits and claims reviews on otherwise excluded patient populations should help ensure coordinated patient care and avoid harm that could be associated with excessive or otherwise inappropriate use of opioids. We encourage states to consult nationally-recognized guidelines when implementing these safety edits, including but not limited to those issued by PQA, NCQA, NQF, and federal agencies such as AHRQ, SAMHSA, and the CDC.

In consideration of the comments received, we are finalizing § 456.703(h)(2) as proposed, specifying that the requirements in § 456.703(h)(1)(i) through (vii) do not apply with respect to individuals receiving hospice or palliative care or treatment for cancer; individuals who are residents of long-term care facilities, intermediate care facilities for the intellectually disabled, or facilities that dispense frequently abused drugs through a contract with a single pharmacy; or other individuals the state elects to exempt. While states are not required to apply these requirements with respect to these individuals, states may elect to do so, pursuant to section 1927(g) of the Act.

4. Managed Care Requirements

Pursuant to section 1902(oo)(1)(A)(ii) of the Act, as added by section 1004 of the SUPPORT Act, states also must ensure that their contracts with MCOs under section 1903(m) of the Act and MCEs under section 1905(t)(3) of the Act require that the MCOs or MCEs have safety edits, an automated review processes, a program to monitor antipsychotic medications in children, and fraud and abuse identification requirements as described in the June 2020 proposed rule for individuals eligible for medical assistance under the state plan (or waiver of the state plan) who are enrolled with the entity, subject to the exclusions of individuals specified in section 1902(oo)(1)(C) of the Act. We noted that states must include these DUR provisions in managed care contracts by October 1, 2019. Although the foregoing provisions added by the SUPPORT Act address only MCOs and MCEs in the managed care context, we proposed also to extend these requirements to contracts with PAHPs and PIHPs under our authority in section 1902(a)(4) of the Act, under which existing PIHP and PAHP requirements are authorized. Thus, as proposed, states would be required to include PAHPs and PIHPs when uniformly implementing the updates and requirements specified in amendments made by section 1004 of the SUPPORT Act for all Medicaid managed care programs, regardless of whether the services are covered through a contract with an MCO, MCE, PIHP, or PAHP.

As required by section 1004 of the SUPPORT Act, each Medicaid MCO and MCE within a state must also operate a DUR program that complies with specified requirements. We proposed to define MCEs in § 438.2 to have the meaning given to the term under section 1932(a)(1)(B) of the Act, which defines the term to mean a Medicaid MCO, as defined in section 1903(m)(1)(A), that provides or arranges for services for enrollees under a contract pursuant to section 1903(m) of the Act, or a primary care case manager, as defined in section 1905(t)(2) of the Act. Managed care regulations at § 438.3(s)(4) require Medicaid managed care DUR programs in which an MCO, PIHP, or PAHP contracts to provide coverage for CODs to operate consistently with section 1927(g) of the Act and part 456, subpart K, and that state contracts must be updated to include these requirements. We proposed to amend the regulation at § 438.3(s) introductory text and (s)(4) and (5) to require that MCEs comply with the requirements in section 1902(oo)(1)(A) of the Act as implemented in these proposed regulations, similar to MCOs, PIHPs, and PAHPs.

Although no comments were received, we are not finalizing our proposed definition of managed care entities and MCE in § 438.2 and we are finalizing amendments to § 438.3(s) introductory text and (s)(4) and (s)(5) replacing all proposed references to MCE to ''PCCM'' in the final version of § 438.2(s) to implement our proposal that PCCMs be added to the list of managed care plans that must comply with § 438.3(s)(4) and (5). Because MCO and PCCM are already defined terms, we believe it would be simpler and less potentially confusing to add a reference to PCCM in each of the amended provisions, rather than define MCE as a new term that would only group two already-defined entity types. No substantive change in meaning from the proposal is intended by this change in the final rule.

5. State Plan Amendment (SPA) Requirements

Section 1004 of the SUPPORT Act amended the state plan requirements in section 1902 of the Act to include a new paragraph (a)(85), which requires the state plan to provide that the state is in compliance with the new drug review and utilization requirements set forth in section 1902(oo) of the Act, as also added by the SUPPORT Act. The SUPPORT Act also requires all states to implement these requirements by October 1, 2019, and to submit an amendment to their state plan no later than December 31, 2019, consistent with the SPA requirements in 42 CFR part 430, subpart B, to describe how the state addresses these provisions in the state plan. States are also expected to give appropriate tribal notification, as required, if applicable. Guidance regarding state plan amendment requirements was issued to states in a CMS informational bulletin in August 2019.[140] In the proposed rule, we noted that, if the proposed provisions implementing section 1004 of the SUPPORT Act and section 1927(g) of the Act were finalized, then an additional SPA potentially could be needed to ensure that state plans are in compliance with the applicable final regulations. We stated that we would

[140] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf.*

expect to provide related guidance in connection with any final rule.

The following is a summary of the comments we received on SPA requirements, and our responses.

Comment: One commenter noted that CMS is proposing a number of minimum DUR standards that restate the requirements of the SUPPORT Act, with which states have already submitted state plan amendments to comply. This commenter noted that states should be required to follow their approved state plans, which the state can seek to further amend based on best practices in medicine. This commenter also opined that CMS is overstepping its authority to regulate by proposing to prescribe other DUR practices in regulation beyond those that are included in the SUPPORT Act.

Response: We agree with the commenter that all states have submitted state plan amendments to comply with the amendments made by section 1004 of the SUPPORT Act, and all have been approved. Additionally, the state plan must be amended as necessary so that it accurately and comprehensively describes how the state complies with the requirements added to section 1902 of the Act by section 1004 of the SUPPORT Act, as well as the requirement in section 1902(a)(54) of the Act that a state plan that includes coverage of CODs must comply with the applicable requirements of section 1927 of the Act.

We do not believe that we have exceeded our statutory authority with respect to the proposed requirements, which we are finalizing as discussed elsewhere in this final rule, for safety edits and claims reviews beyond those that are expressly required pursuant to amendments made by the SUPPORT Act. To further implement section 1927(g)(1) of the Act, which requires that a state DUR program assures that covered outpatient drugs are appropriate, medically necessary, and not likely to result in adverse events, and consistent with section 1004 of the SUPPORT Act, we proposed to require states to establish several new safety edits and/or claims reviews. Specifically, these requirements are: To develop prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT or had an OUD diagnosis; and where beneficiaries who could be at high risk of opioid overdose should be considered for co-prescription or co-dispensing of any FDA-approved opioid antagonist/reversal agent. This final rule affords states flexibility in designing and implementing required safety edits and claims reviews in the manner the state determines would be best adapted to the circumstances in the state, including the particular needs of the state's Medicaid beneficiaries. These requirements implement section 1927 of the Act, and while consistent with them, do not directly implement amendments made by section 1004 of the SUPPORT Act.

6. Reporting Requirements

Consistent with section 1927(g)(3)(D) of the Act, we require each state Medicaid agency to submit to us an annual report on the operation of its Medicaid DUR program. Under § 456.712(a), the state must require the DUR Board to prepare and submit, on an annual basis, a report to the state Medicaid agency. Under § 456.712(b), each state Medicaid agency must in turn submit this report to us, as well as specified additional information, including but not limited to descriptions of the nature and scope of the state's prospective and retrospective DUR programs, detailed information on the specific DUR criteria and standards in use, a description of the actions taken to ensure compliance with predetermined standards requirements in § 456.703, a summary of the educational interventions used and an assessment of their effect on quality of care, and an estimate of the cost savings generated as a result of the DUR program. We have compiled state FFS Medicaid DUR annual reports since 1995 and have published them on *Medicaid.gov* since 2012. Since 2016, § 438.3(s)(4) requires any MCO, PIHP or PAHP that covers CODs to operate a DUR program that complies with section 1927(g) of the Act and 42 CFR part 456, subpart K, as though these requirements applied to the MCO, PIHP, or PAHP instead of the state, including requirements related to annual DUR reporting. Given the commercial nature of many MCEs, incorporation of information posted to *Medicaid.gov* provides new considerations with regard to public disclosure of information received by CMS.

In an effort to share and encourage innovative and collaborative practices, we also proposed to publish all information received in annual DUR reports from FFS and managed care programs on a CMS website. We proposed to add new paragraph (c) to § 456.712 to provide that all FFS and managed care DUR reports received by CMS under § 456.712(b) and, as applicable, under § 438.3(s), will be publicly posted on a website maintained by CMS for the sharing of reports and other information concerning Medicaid DUR programs.

The following is a summary of the comments we received on the proposed minimum standards for DUR program reporting requirements, and our responses.

Comment: One commenter recommended CMS provide a standardized template for Medicaid MCOs reporting DUR program information, to help ease administrative burdens.

Response: CMS does currently provide a standardized template for Medicaid MCOs to complete. In response to section 1004 of the SUPPORT Act, revised and additional survey questions have been incorporated to the annual MCO survey to address recently enacted provisions. Reports can be accessed on *www.Medicaid.gov*.[141]

In consideration of comments received, CMS is finalizing § 456.712(c) as proposed, to provide that all FFS and managed care DUR reports received by CMS under § 456.712(b) and, as applicable, pursuant to § 438.3(s), will be publicly posted on a website maintained by CMS for the sharing of these reports and other information concerning Medicaid DUR programs.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. With respect to the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether a collection of information should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the collection of information and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the

[141] *https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html.*

affected public, including automated collection techniques.

Our June 2020, proposed rule (85 FR 37286) solicited public comment on each of these issues for our proposed information collection requirements, burden estimates, and assumptions. PRA-related comments were received for ICR #1 Regarding State Plan Requirements, Findings, and Assurances and ICR #3 Regarding the Payment of Claims 18. Summaries of the public comments and our response can be found below under the respective ICR. We did not receive any PRA-related comments for ICR #2 Regarding Requirements for States.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). Table 3 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 3—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Chief Executives	11–1011	93.20	93.20	186.40
Data Entry and Information Processing Workers	43–9020	17.52	17.52	35.04
General Operations Manager	11–1021	59.15	59.15	118.30

We are adjusting our employee hourly wage estimates by a factor of 100 percent since fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believed that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Revised Wage and Cost Estimates: While our proposed rule's costs were based on BLS's May 2018 wages, this final rule's cost estimates are based on BLS's more recent May 2019 wages. Changes to BLS' mean hourly wage figures are presented in the Table 4.

TABLE 4—COMPARISON OF PROPOSED AND FINAL RULE MEAN WAGE DATA

Occupation title	Occupation code	CMS–2482–P: May 2018 ($/hr)	CMS–2482–F: May 2019 ($/hr)	Difference ($/hr)
Chief Executives	11–1011	96.22	93.20	−3.02
Data Entry and Information Processing Workers	43–9020	17.05	17.52	+0.47
General Operations Manager	11–1021	59.56	59.15	−0.41

B. Information Collection Requirements (ICRs)

1. ICRs Regarding State Plan Requirements, Findings, and Assurances (§ 447.518(d)(2) and (3))

The following changes will be submitted to OMB for approval under control number 0938–1385(CMS–10722).

Under section 1902(a)(30)(A) the Act, we are granted the authority to require that methods and procedures be established by states relating to the utilization of, and the payment for, care and services available under the state plan process (including but not limited to utilization review plans) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that state payments to providers of Medicaid services are consistent with efficiency, economy, and quality of care.

To that end, as part of the state plan approval process relative to the CMS authorized VBP SRA, we are finalizing new reporting requirements that would affect the 51 state Medicaid programs (the 50 states and the District of Columbia). Specifically, a state participating in CMS authorized supplemental rebate VBP arrangements will be required to report data described in § 447.518(d)(2) and (3) on an annual basis within 60 days of the end of each year, as well as cumulative data if a CMS authorized SRA VBP program ended in that year. The reported data must include: The state name; NDC(s) (for drugs covered under the CMS authorized SRA VBP); product FDA list name; number of prescriptions; cost to the State to administer the CMS authorized SRA VBP (for example: Systems changes, tracking evidence or outcomes-based measures, etc.); and the total savings generated by the supplemental rebate due to the CMS-authorized SRA VBP. The reporting requirements will be applicable to both FFS and MCO COD claims.

We estimate it would take an additional 6 hours at $118.30/hr for a general operations manager to collect the SRA VBP drug utilization information when due annually (we will choose the quarter in which the annual data will be due), and submit the report to CMS. In aggregate we estimate an ongoing annual burden of 306 hours (6 hr/report × 1/year × 51 respondents) at a cost of $36,200.60 (306 hr × $118.30/hr).

Other than our adjusted costs as discussed above under Wage Estimates, our proposed requirements and burden estimates are being finalized in this rule without change.

Comment: Several commenters raised concerns about the proposed data reporting requirements for states participating in CMS-authorized SRA VBP arrangements and the burden it may place on state Medicaid agencies, such as additional administrative expenses. A few commenters noted that if more CMS-authorized SRA VBP contracts are signed between manufacturers and state Medicaid agencies, the administrative burden may become too great for current state Medicaid staff and require additional resources, such as additional staff,

system changes, and physical office space. Another commenter suggested that CMS delay finalizing the proposal for states to provide CMS specific data elements associated with CMS-authorized VBP SRAs to ensure that the data elements can be easily collected and would not unintentionally create additional administrative burden to state Medicaid agencies in collecting and reporting the data elements.

Response: This final regulation does not require that states participate in CMS authorized VBP SRAs with manufacturers, or any other VBP arrangement. Rather, this regulation addresses the challenges faced by manufacturers and states regarding the impact of the VBP arrangements on MDRP price reporting obligations and the regulatory challenges that may impede manufacturers and payer progress in structuring and implementing VBP arrangements. However, we recognize that states may encounter administrative burden associated with CMS-authorized SRA VBP arrangements. This is one of the reasons that we have requested that states provide specific data elements associated with participating in VBP arrangements via CMS-authorized SRAs, so that we can determine how we can help states reduce these burdens, which may facilitate their contracting with manufacturers.

2. ICRs Regarding Requirements for States (§ 447.511(b), (d) and (e))

The following changes will be submitted to OMB for approval under control number 0938–0582 (CMS–R–144). Subject to renewal, the control number is currently set to expire on June 30, 2023.

Under § 447.511(b) states, territories, and the District of Columbia will be required to ensure by certification that the quarterly rebate invoices sent to manufacturers that participate in the MDRP no later than 60 days after the end of each rebate period via CMS–R–144 (Quarterly Medicaid Drug Rebate Invoice), mirrors the data sent to us. This rule does not impose any changes to the CMS–R–144 form.

Under § 447.511(d) states will be required to certify that their SDUD meets the requirements specified under § 447.511(e) via a certification statement. We believe the certification will not impose a significant burden as we will provide systems access to state certifiers to log in once per quarter to certify their SDUD report. Certifiers would have to apply for a CMS user ID and password, and keep current with required annual computer-based training, as current state staff with access to our systems must do. To comply with the certification requirements, states must already have system edits in place to find and correct SDUD outliers prior to reporting to manufacturers and CMS.

We estimate it would take 5 hours at $186.40/hr for the State Medicaid Director, Deputy State Medicaid Director, another individual with equivalent authority, or an individual with directly delegated authority from one of the above to obtain current CMS systems access. In aggregate we estimate a one-time system ID/password access burden of 280 hours (5 hr × 56 respondents) at a cost of $52,192 (280 hr × $186.40/hr).

We also estimate an additional annual burden of 2 hours (or 30 minutes/quarter) at $186.40/hr for a chief executive to certify such data and to add the state data certification language in their submission. In aggregate we estimate an annual burden of 112 hours (2 hr × 56 respondents) at a cost of $20,877 (112 hr × $192.44/hr).

Other than our adjusted costs as discussed above under Wage Estimates, our proposed requirements and burden estimates are being finalized in this rule without change.

3. ICRs Regarding the Payment of Claims (§ 433.139(b)(2), (b)(3)(i), and (b)(3)(ii)(B))

The following changes will be submitted to OMB for approval under control number 0938–1265 (CMS–10529). Subject to renewal, the control number is currently set to expire on April 30, 2021. It was last approved on June 10, 2019, and remains active.

This final rule would implement provisions of BBA 2018 which includes several provisions that modify COB and TPL in both statute and regulation related to special treatment of certain types of care and payment in Medicaid and Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3, enacted February 4, 2009). Section 53102 of BBA 2018 amended the TPL provision at section 1902(a)(25) of the Act. Effective February 9, 2018, section 53102(a)(1) of the BBA 2018 amended section 1902(a)(25)(E) of the Act to require states to cost avoid claims for prenatal care for pregnant women including labor and delivery and postpartum care, and to allow the state Medicaid agency 90 days instead of 30 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments. Effective April 18, 2019, section 7 of the MSIAA amended section 1902(a)(25)(E) of the Act to allow 100 days instead of 90 days to pay claims related to medical support enforcement services, as well as requiring all states, the District of Columbia, and the territories (56 respondents) to collect information on TPL before making payments.

Additionally, effective October 1, 2019, section 53102(a)(1) of the Bipartisan Budget Act of 2018 amended section 1902(a)(25)(E) of the Act, to require a state to make payments without regard to third party liability for pediatric preventive services unless the state has made a determination related to cost-effectiveness and access to care that warrants cost avoidance for 90 days.

Under the authority in section 1902(a)(25)(A) of the Act, our regulations at part 433, subpart D, establishes requirements for state Medicaid agencies to support the COBs effort by identifying TPL. Section 433.139(b)(2), (b)(3)(i), and (b)(3)(ii)(B) detail the exception to standard COB cost avoidance by allowing pay and chase for certain types of care, as well as the timeframe allowed prior to Medicaid paying claims for certain types of care. Title XIX of the Act requires state Medicaid programs to identify and seek payment from liable third parties, before billing Medicaid.

We estimate it would take 1 hour at $35.040/hr for a data entry/information processing worker to collect information on TPL and report that information to CMS on CMS–64 (approved by OMB under the aforementioned OMB control number and CMS ID number) on a quarterly basis. In aggregate we estimate an annual burden of 224 hours (1 hr/response × 4 responses/year × 56 respondents) at a cost of $8,550 (224 hr × $35.04/hr).

Other than our adjusted costs as discussed above under Wage Estimates, our proposed requirements and burden estimates are being finalized in this rule without change.

C. Summary of Finalized Requirements and Annual Burden Estimates

Table 5 sets out our annual burden estimates.

TABLE 5—SUMMARY OF ANNUAL REQUIREMENT AND BURDEN

Section under title 42 of the CFR	Number of respondents	Total responses (per year)	Time per response (hours)	Total time (hours)	Labor rate ($/hr)	Total cost ($)	OMB control number (CMS ID No.)
§ 447.518(d)(1) and (2).	51	51	6	306	118.30	36,200	0938–1385 (CMS–10722)
§ 447.511	56	56	5	280	186.40	52,192	0938–0582 (CMS–R–144)
§ 447.518(d) (1) and (2).	51	51	6	306	18.3 0	36,200	0938–1385 (CMS–10722)
§ 447.511	56	224	0.5	112	186.40	20,877	0938–0582 (CMS–R–144)
§ 433.139(b)(2), (b)(3)(i), and (b)(3)(ii)(B).	56	224	1	224	35.04	7,849	0938–1265 (CMS–10529)
Total	56	555	Varies	922	Varies	117,118	n/a

IV. Regulatory Impact Statement

A. Statement of Need

This final rule will implement:

- Changes to section 1927 of the Act;
- Statutory changes from the Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116–16, enacted April 18, 2019), BBA 2018 and the Affordable Care Act;
- Section 602 of BBA 2015, which amended section 1927(c)(3) of the Act;
- Section 2501(d) of the Affordable Care Act, which added section 1927(c)(2)(C) of the Act;
- Section 1927(b)(2)(A) of the Act requiring states to report to each manufacturer not later than 60 days after the end of each rebate period;
- Changes and additions to sections 1902 and 1927(g)(1) of the Act as set forth by section 1004 of the SUPPORT Act;
- Title XIX of the Act and section 7 of the Medicaid Services Investment and Accountability Act of 2019 amending section 1902(a)(25)(E) of the Act ((§ 433.139(b)(2), (b)(3)(i), and (b)(3)(ii)(B)); and
- Changes made by section 1603 of Public Law 116–59, the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Health Extenders Act), which amended sections 1927(k)(1) and 1927(k)(11) of the Act.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We believe that this rule does reach the economic threshold and thus is considered a major rule.

We received the following comments regarding the impact of this rule:

Comment: A few commenters disagreed with CMS' conclusion that the proposed rule did not reach the necessary threshold for economically significant effects (of $100 million or more in any 1 year), and therefore, did not require a regulatory impact analysis. The commenters noted that the proposed changes to best price, line extension, drug rebate payments, drug pricing reporting requirements, and DUR would greatly impact state Medicaid agencies and manufacturers and would meet the financial threshold for a regulatory impact analysis. A few commenters suggested that CMS conduct a regulatory impact analysis prior to publication of a final rule or withdraw the proposed rule in order to conduct a regulatory impact analysis.

Several commenters expressed concern that the proposed rule does not include an impact analysis of the proposed changes on state Medicaid programs or Medicaid program spending specific to the proposed changes or potential decreases to the Medicaid manufacturer rebate amounts and increase to Medicaid drug costs. The commenters requested CMS analyze the proposed changes to best price reporting and how it may impact state Medicaid programs. One commenter also requested that CMS provide financial impact estimates on states' rebates due to their belief that this will ensure transparency and provide states adequate time to address budget shortfalls created from the proposed rule. A few commenters expressed concern that CMS did not conduct an impact analysis of the proposed VBP-related regulations on the U.S. healthcare system.

Response: For the following reasons, we agree with the commenters that a regulatory impact analysis is necessary. The projections below are based on the assumptions and projections for Medicaid expenditures in the President's FY 2021 Budget. As with any projections of health care spending and changes to health care regulations, these projections are uncertain and impacts could be higher or lower than projected here. In addition, these projections do not account for any impacts related to COVID–19, which has had a major impact on health care spending and coverage in 2020.

- *Implementation of Minimum DUR Standards:* The requirement under section 1927 of the Act to provide for DUR (prospective and retrospective) for CODs to assure that prescriptions (1) are appropriate, (2) are medically necessary, and (3) are not likely to result in adverse medical results, is longstanding. Under our authority to implement section 1927(g) of the Act and the SUPPORT Act, to ensure the appropriate use of prescription opioids, the minimum standards for DUR in this final regulation, including standards related to MAT and co-prescribing or co-dispensing of any FDA-approved opioid antagonist/reversal agent, have already been adopted by state Medicaid programs as reflected in our most recent

DUR survey.[142] Therefore, such DUR standards and the addition of minimum standards as set forth under this rule will not have a substantial impact on state Medicaid programs. Furthermore, these standards establish a baseline for minimally adequate DUR programs that help ensure prescribed drugs are appropriate, medically necessary, and not likely to result in adverse medical results, which ultimately may result in savings to the states and Federal government.

• *Line Extension and New Formulation:* Since the line extension provision came into effect on January 1, 2010, manufacturers have been making reasonable assumptions as to the meaning of line extension at section 1927(c)(2)(C) of the Act, and where appropriate, have been permitted to use such reasonable assumptions in their determination of whether their drug qualifies as a line extension. Thus, manufacturers have been applying the alternative rebate calculation approach for ten years to determine their rebate obligations for drugs that are line extensions. The economic impact of the new policies for line extensions would be dependent on the change in the number of drugs that are reported to us as line extensions, the differences between the standard rebate amount and the alternative rebate amount that is calculated for that line extension drug, and that the impact of the new policies on the incentives to bring new formulations of existing drugs to market that represented true advancements in treatment of particular conditions.

Notably, only 1.5 percent of all drugs that are reported to the Medicaid Drug Rebate Program (MDRP), or 408 drugs, are currently classified by their manufacturer as a line extension. This reporting is based on the manufacturer making its own reasonable assumptions that the new formulation of their drug is a line extension.

With respect to innovation, we also note that since we added a specific indicator in the Drug Data Reporting (DDR) system in 2016 for manufacturers to self-identify drugs that are line extensions, the rate at which the number of line extension drugs reported has been relatively stable, but increasing, thereby providing evidence that the line extension policies in existence have not resulted in a sharp change in the number of line extensions brought to market by manufacturers. For example, in 2016, 320 line extensions were reported to us, 360 in 2017, 373 in 2018, 389 in 2019, and 397 in 2020.

We have reviewed the impacts of the final regulatory definition of line extension on Medicaid drug rebates. The final rule clarifies the definition of ''line extension'' drugs. Drugs classified as line extensions are subject to an alternative rebate. The additional rebate amounts under the alternative rebate are collected entirely by the federal government. To calculate this impact, we determined which drugs were likely to be classified as line extensions under the definition in this final rule. We reviewed the top 100 drugs by total spending (from data in the second quarter of 2020 in the MDR), and then identified which of those drugs would be defined as line extension drugs under the definition in the final rule. There were 17 drugs identified of the top 100 that would likely be classified as line extensions, which would not now be currently classified as line extensions under the statutory definition of line extension.

We then calculated the alternative rebate per unit for these drugs (defined as the inflationary or additional rebate divided by the AMP for the original drug, multiplied by the AMP of the line extension drug). Note that only 6 of the 17 drugs had alternative rebates that were higher than the standard rebate. For these 6 drugs, the rebates would increase by 6.5 percent and reduce spending net of rebates by 19.3 percent. We estimate that this would represent an increase of about 1.1 percent on rebates for the top 100 drugs, while decreasing net drug spending by 3.3 percent. We extrapolated the estimates on these drugs to the impact on all Medicaid drug spending. This assumes that the number of drugs classified as line extensions under the new regulatory definition of line extension, and the relative impacts on those drugs for the rest of the brand-name drug market is comparable to the top 100 drugs; it is possible that the impact on the rest of the drug market could be greater than or less than we have estimated here.

	Total spending	Total rebates	Net spending	Change in rebates due to line extension definition	Percentage change in rebates	Percentage change in net spending
Top 100 drugs	$25,265	$18,894	$6,371	$209	1.1	−3.3
Top 100 drugs identified as line extensions	4,295	3,212	1,083	209	6.5	−19.3
All drug spending	86,017	39,802	46,215	381	1.0	−0.8

The table below shows the projected impacts by fiscal year in millions of dollars.

Lower bound	2021	2022	2023	2024	2025	2021–2025
Federal government	−$400	−$430	−$460	−$490	−$520	−$2,300
State government	0	0	0	0	0	0
Total	−400	−430	−460	−490	−520	−2,300

There are several caveats to the estimates. First, the estimates do not assume any impact on future drug pricing or new line extension introduction changes. It is possible manufacturers might reconsider future

[142] *https://www.medicaid.gov/medicaid/prescription-drugs/downloads/2019-dur-ffs-summary-report.pdf.*

drug launch strategies (including pricing and formulations) in light of this change. Second, we have not considered if there might be impacts on state supplemental rebate agreements that states negotiate directly with manufacturers. It is possible that there are some drugs for which states have some supplemental rebates that could be affected by the line extension rebates. Finally, the estimates rely on an analysis of a limited number of drugs; however, these drugs do represent a substantial share of Medicaid prescription drug spending (about 29 percent of prescription drug spending, and about 37 percent of brand-name prescription drug spending). The impact on the drugs affected could be significant, but given the small number of drugs affected, the overall impact may be smaller as a percentage of total spending. Depending on the final number of drugs determined to be line extensions and the relative increase in the rebates for those drugs, the actual impact could be greater than or less than estimated here.

We also note with respect to comments on the proposed definition of line extension and new formulation that there would be a negative impact on manufacturers' incentive to continue to innovate, that we refined the final definitions to limit the scope of drugs that are new formulations, and thereby subject to the alternative rebate calculation relative to our proposed definitions.

As previously stated, the proposed definitions included combination drugs and drugs approved with a new indication; however, we are not finalizing those changes. We believe that the exclusion of combination drugs and drugs that obtain new indications from the final definition of line extension will help ensure that we have maintained incentives for manufacturers to bring such advances to the market, such as new HIV drugs, or new uses for drugs that could be used to treat COVID–19.

Finally, the amount of additional rebate amounts that may be due from manufacturers as a result of the new regulatory definition of line extension are a function of the net change in the number of drugs that may be considered a line extension, as well as the difference between the standard rebate calculated on the line extension drug and the alternative rebate calculation, as noted above. The existence of a line extension drug does not categorically result in a higher URA for a line extension of a drug, as there are many factors that enter into the URA calculation. As previously noted, one of the most important factors in the calculation is the inflation-based rebate that is applied to the initial brand name listed drug for the rebate quarter being calculated. Regardless of the price of the line extension drug, if the initial brand name listed drug did not increase in price in excess of the rate of inflation, then the alternative rebate calculation for the line extension should not result in a higher URA than the standard calculation for the drug that is a line extension. That is, if a manufacturer's price increases over the years have been within the CPI–U, then there is reduced chance that they will be subject at all to the alternative rebate calculation.

• *VBP Arrangements and Changes to Best Price and Manufacturer Reporting requirements:* As stated previously, this final regulation makes revisions to the determination of best price and AMP and manufacturer reporting requirements to address the regulatory challenges that manufacturers, states and private payers encounter when considering the development and implementation of VBP arrangements. The changes made by this regulation ensure that the regulatory framework is sufficient to support such arrangements and to promote transparency, flexibility, and innovation in drug pricing without undue administrative burden on states and manufacturers. They also clarify certain already-established policies to assist manufacturers and states in participating in VBP arrangements in a manner that is consistent with the law and maintains the integrity of the MDRP.

The change being finalized in this rule, which provides for the reporting of multiple best prices pursuant to a VBP arrangement (which meets the definition of VBP arrangement, also being finalized in this rule), is the most significant from a policy perspective, and could result in an increased use of VBP among commercial payers, and thus Medicaid programs. The estimated impacts of these VBP arrangements under the final rule are significantly uncertain. Primarily, this is due to lack of experience with such arrangements and the fact that the impacts will be highly dependent on the interest of states and manufacturers to enter into such arrangements.

As of 2020, there are only 9 such state arrangements of which we are aware, and we do not have data or estimates on the impact of these arrangements. Moreover, the impact will depend on 3 factors: (1) How many states would take up such arrangements; (2) how many drugs and which drugs would be covered under these arrangements; and (3) the nature of these arrangements (for example, what will be the terms for payment and coverage of drugs under these arrangements). These are all unknowable at this time.

In an attempt to estimate the possible impacts of such arrangements, we have estimated a range of impacts. At the upper bound of impacts on the federal government and the states, we estimate the impact would be 0. In these circumstances, it could be a combination of (1) no states or manufacturers enter into these VBP arrangements and (2) while states and manufacturers enter into VBP arrangements, these do not reduce net prescription drug spending.

At the lower bound (on impacts on the federal government and the states), we have estimated that there could be some savings. We made the following assumptions: (1) Half of states would enter into VBP arrangements; (2) states would enter into arrangements with 50 percent of the top 100 drugs as measured by price per unit; and (3) these arrangements would reduce net spending on these drugs by 50 percent.

Based on data from the Medicaid Drug Rebate (MDR) database from 2020, we estimate that these drugs account for about $1.1 billion in spending and about $320 million in net drug spending (net of rebates) in 2020. Using the assumptions described above, this would reduce net drug spending by $40 million in 2020 ($24 million federal share, $16 million state share). This would represent about a 7,000 percent increase in the number of such arrangements, and it assumes a significant reduction in spending on the drugs under these arrangements. Therefore, we believe it is more likely the actual impact would be smaller than the lower bound of the estimates (that is, it would generate fewer savings for the federal government and the states).

The tables below shows the projected impacts by fiscal year in millions of dollars at the lower bound and upper bound.

Lower bound	2021	2022	2023	2024	2025	2021–2025
Federal government	−$25	−$26	−$27	−$29	−$30	−$137

Lower bound	2021	2022	2023	2024	2025	2021–2025
State government	−17	−17	−18	−19	−20	−91
Total	−42	−43	−45	−48	−50	−228

Upper bound	2021	2022	2023	2024	2025	2021–2025
Federal government	$0	$0	$0	$0	$0	$0
State government	0	0	0	0	0	0
Total	0	0	0	0	0	0

We note that the policy finalized in this rule permitting manufacturers to report multiple best price points pursuant to a VBP arrangement, still requires a manufacturer to report a non-VBP best price. Thus, a key consideration for states would be determining whether the expected savings achieved by participation in the VBP arrangement (in excess of the non-VBP rebate rebate that they would receive) would outweigh any additional administrative costs that might occur as a result of participating in the VBP arrangement itself, for example, costs associated with tracking patients' outcomes. Thus, states that decide not to participate in multiple best price VBP arrangements will continue to receive a Medicaid drug rebate that is based upon a non-VBP best price as reported by the manufacturer.

Encouraging the use of VBP arrangements by permitting manufacturers to report multiple best price points also alleviates burdens on states to submit a SPA to enter into their own CMS-authorized SRAs in order to participate in VBP arrangements with manufacturers. That is because this approach allows states to take advantage of the approaches made available to commercial payers. Thus, the administrative burden of participating in VBP arrangements through the submission of a CMS-authorized SRA is no longer required unless a state wants to negotiate its own VBP arrangements with manufacturers. However, there will be costs to states and manufacturers of tracking patients, and engaging with health care professionals to track and evaluate outcomes of these VBP arrangements.

With respect to the additional administrative costs to states of participating in a VBP arrangement resulting in the reporting of multiple best price points, we will use existing operational mechanisms to make states aware of such manufacturer VBP arrangements that have been reported to us. We will provide additional unit rebate amounts that states can earn under these programs through quarterly file transfers that we currently provide each quarter, which will happen through the Medicaid Drug Rebate (MDR) system that will become fully functional in July, 2021.

Finally, it is possible that the increased use of VBP arrangements as a result of the new flexibilities provided in this regulation will encourage manufacturers to increase launch prices of new therapies to payers in an attempt to compensate for the additional rebates that they may have to give these payers under a VBP arrangement. This regulation does not control the launch prices of new drugs, and such is beyond the scope of this rulemaking, or our ability to assess economic impact.

However, we expect that commercial payers will negotiate rebates and price concessions under VBP arrangements with manufacturers for high cost therapies, and that states will consider whether to take advantage of such arrangements if offered to the states by the manufacturers based on those prices. Notably, the ability of manufacturers to set high launch prices for new expensive gene and cells therapies are facilitated by the fact that these therapies are usually used to treat a small number of patients and often do not have therapeutic competitors. This lack of competition limits the ability of payers in the marketplace to manage the prices of drugs without therapeutic competitors.

We would expect that commercial payers would, as they do now for drugs that are not provided for under a VBP arrangement, negotiate as aggressively as they could, and Medicaid programs would be able to take advantage of such negotiations. States that thought they could obtain better price concessions from a manufacturer under a VBP arrangement could do so by themselves by using a CMS-authorized SRA.

• *Assuring Pass Through of Manufacturer Patient Assistance:* We heard from patient groups expressing concerns that, while the value of manufacturer cost sharing assistance programs is rapidly eroding due to PBM accumulator programs, and that patients were paying more out of pocket for their drugs, the implementation of the pass through assurance policy in the proposed rule would lead manufacturers to reduce or eliminate these programs. Commenters contended that our proposal could result in great economic harm to patients who would have to spend more for the drugs, or go without if they are unable to afford them. We offer the following impact analysis of the finalized policy we are adopting in this regulation.

First, we view the required ''pass through'' of manufacturer's cost sharing assistance to patients as a condition of exclusion from AMP and best price as a program integrity issue relating to the MDRP. Manufacturers have a legal obligation to certify each quarter that their AMPs and best prices are calculated accurately based on the inclusions and exclusions permitted based on law and regulation. This is not new policy, but long-standing policy. Moreover, rebates to states should reflect the discounts that manufacturers provide to best price eligible entities, whether they are provided directly or indirectly.

While we do not require manufacturers to provide us with documentation regarding their AMP or best price calculations, they should maintain records regarding such calculations, including any reasonable assumptions that they use in making such calculations. Should they be audited by OIG or DOJ, manufacturers would likely have to provide such documentation, including any documentation regarding their treatment of patient assistance programs in the calculation of their AMP and best price. Under this final policy, we will not be requiring manufacturers to provide us with any additional documentation regarding the assurance that the patient assistance is passed through, but they should maintain such documentation in their records. However, we understand that there may be additional costs to manufacturers of modifying their patient assistance programs if necessary, working with their business partners,

and keeping records of such pass through assurance, to ensure compliance with the regulations.

Second, we also understand through discussions with manufacturers, patient groups, and from information included in publicly-available reports, studies, and documents, that PBM accumulator programs are growing in number and quickly eroding the value of the manufacturer assistance programs for patients. As a result, there is significant tension between manufacturers and payers regarding copay assistance, with patients caught in the middle.

According to a February 2019 survey of 43 payer/health plan decision makers (representing over 80 million lives), nearly 60 percent of respondents are targeting limiting manufacturer commercial copay assistance, up from 40 percent in 2018. That same report found that the drug categories targeted for limiting copay assistance by payers include rheumatoid arthritis drugs, high cholesterol drugs, and hepatitis drugs, with the HIV drug category and orphan drug category on the horizon.[143]

Another study noted that as of early 2018, approximately 60 percent of covered commercial lives were under payers that had already implemented a copay accumulator program, whereas an additional approximately 30 percent of covered commercial lives were encompassed by plans projected to implement such a program in 2019 and beyond.[144] This study also noted that manufacturers are concerned about these accumulator programs because of the lack of transparency regarding how the associated cost sharing is being used in practice, and manufacturers' inability to determine the impact on their public financial statements. As a result, many are considering changing the design of their programs to prepaid debit cards and/or rebate refunds provided directly to patients. Thus, manufacturers already appear to be considering changes to these programs for various reasons.

Additionally, another recent survey of large employers found that 30 percent implemented a copay accumulator program for 2019, and 21 percent were considering implementing them in 2020 or 2021.[145] Yet, another recent employer survey found that 54 percent of respondents did not credit third party copay assistance programs toward patient deductibles.[146] Thus, based on these studies, it seems clear that as the value of these patient assistance programs to patients continues to erode, and the economic benefits to health plans increase, given that the health plans' spending on drugs for a patient decreases.

CMS has had long standing policy under § 447.505(b) that best price includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price eligible entity. Therefore, states and the Federal government may be eligible for additional rebates which they are now not earning if the value of these patient assistance programs is accruing to the health plans, which are best price eligible entities, and the plan's best price is the one that has to be reported to us by the manufacturer for that drug for the quarter because it is the lowest price available.

Accordingly, the provisions in the final regulation are a clarification to the existing exclusions to best price and AMP by stating that manufacturers must ensure their manufacturer assistance programs pass on the full value of discounts to the consumer and that the pharmacy, agent, or other entity (in this case, the commercial insurer) does not receive any price concession. Since this is a clarification to an existing requirement, we believe manufacturers will take the steps necessary (if they have not already done so) to ensure the exclusion of their manufacturer assistance programs will apply appropriately to their calculations and determinations of AMP and best price.

We also believe that there are potential future economic and health care consequences to patients that will result if these copay accumulator programs are not reformed and restructured. That is because the benefit of the manufacturer cost sharing assistance is increasingly not accruing to the patient, potentially impeding their ability to obtain their medications. As a result, a patient's out-of-pocket costs for medications in a health plan with accumulators can be thousands of dollars, due largely to plans with coinsurance and deductibles.[147] This factor could have an impact on patients' accessibility to medications, medication adherence, and thus long term health.

For example, a recent study found that following implementation of a copay accumulator program, in which patients with autoimmune disease had to pay a higher percentage of drug costs, a significant share of these patients either reduced or discontinued the use of autoimmune specialty drugs.[148] Thus, the PBM accumulator program, which can increase patient out of pocket costs for drugs, could potentially lead to higher overall health care spending in private plans, as well as eventually in Medicare and Medicaid. Recognizing this potential increase in spending, several states have also taken action to ban these accumulator programs in certain health care plans.[149]

Finally, we understand that some manufacturers may eliminate, reduce, or restructure their programs as a result of this policy, which could result in increased medication costs to some patients. However, patient assistance programs serve as important marketing tools for manufacturers to start a patient on a therapy, and to promote and maintain adherence once patients are taking their medications. We are hopeful that manufacturers will not eliminate these programs under this policy, but will work with their current partners to reform or restructure the programs as has been stated in public documents, or find another mechanism to provide the assistance. We believe that any changes manufacturers may make to their assistance programs may be in response to multiple factors, such as corporate integrity issues, including shareholder concerns about how this cost sharing is being used; continued patient demand for this assistance given the increasing costs of new drugs; and the need to respond to competition from other manufacturers.

As we noted above in our responses to comments regarding this issue, we believe that the current prescription claims processing system—which consists of switches, manufacturer cost sharing assistance brokers, PBMs, and pharmacies, among others—can be used to help assure manufacturer compliance with the requirement that patient cost sharing assistance is being passed through to the patient. There are also other entities in the marketplace that manufacturers already work with to ensure compliance with Federal laws and regulations such as third party vendors and switches. These companies can help manufacturers comply with various Federal laws regulations relating

[143] Rolling Back the Tide: Deploying a Consultative Approach to Tackle the Growing Expansion of Copay Accumulators, Xcenda, February 2019.

[144] Pharmacy Times, Co-pay Accumulator Programs: Behind the Controversy, Lee Feigert Pharm.D, July 22, 2019.

[145] Large Employers 2018 Health Plan Design Survey, Washington DC, National Business Group on Health, 2018.

[146] Trends in Specialty Drug Benefits. Plano, TX: Pharmacy Benefits Management Institute, 2018.

[147] CMS Maximizers are Displacing Accumulators—But CMS Ignores how Payers Leverage Patient Support, Drug Channels, May 19, 2020.

[148] Impact of Copay Accumulator Adjustment Programs on Specialty Drug Adherence, American Journal of Managed Care, Vol 25 No 7, July 2019.

[149] See 148.

to patient copay assistance programs by reducing possible government sanctions, and improve compliance efforts in a real time manner.

Given the existence of the electronic infrastructure in place that manufacturers are already using with these partners in applying and tracking patient assistance; the competitive nature of manufacturers with respect to marketing their drugs to patients, and wanting them to continue to take them; and the 2-year time frame before the effective date of this policy, we believe that manufacturers will both retain their cost sharing assistance programs, as well as continue to be able to meet their legal obligations under section 1927 of the Act to ensure that manufacturer patient assistance accrues to the patient.

However, we recognize that there may be impact to patients as a result of some period of time when manufacturers may modify or restructure their patient assistance programs such they are able to track the pass through of patient assistance and fulfill their legal obligations under section 1927 of the Act.

Comment: A few commenters noted that CMS did not analyze the impact of the proposed changes in the rule on Medicare prices and the 340B drug discount program. One commenter suggested that failure to consider these potential impacts could potentially make the proposed rule ''susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem.''

Response: This rule makes no changes to either the pricing program under 340B of the PHSA or Medicare Part B payment policies. Furthermore, we do not believe we have failed to consider the impacts on these programs because we believe the changes made by this final rule will not have a significant impact on best price, AMP or Medicaid drug rebates that would impact either Medicare Part B payment allowances or 340B pricing. That is, because manufacturers will continue to be required to report a non-VBP best price when reporting multiple best prices generated from a VBP arrangement, and that non-VBP best price will be used to calculate the 340B ceiling price.

The bundled sale approach's impact on best price will be minimal since it is permitting the manufacturer to allocate the discounts or price concessions as a result of a VBP arrangement across a bundled sale, thus spreading out the discounts over multiple units in the bundled sale. This approach to a bundled sale is already being adopted by manufacturers using reasonable assumptions, and we do not expect that codifying this practice in regulatory text will significantly reduce the best price to the point it increases the Medicaid drug rebate which may impact 340B pricing.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, small pharmaceutical manufacturers participating in the MDRP, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule with comment period will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this regulation does not impose any substantial direct compliance costs on state or local governments, preempt state law, or otherwise have federalism implications, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.''

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and Recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 456

Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 433—STATE FISCAL ADMINISTRATION

■ 1. The authority citation for part 433 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Section 433.139 is amended by–

■ a. Removing and reserving paragraph (b)(2); and

■ b. Revising paragraphs (b)(3)(i) and (b)(3)(ii)(B).

The revisions read as follows:

§ 433.139 Payment of claims.

* * * * *

(b) * * *

(3) * * *

(i) The claim is for preventive pediatric services, including early and periodic screening, diagnosis and treatment services provided for under part 441, subpart B, of this chapter, that are covered under the State plan; or

(ii) * * *

(B) For child support enforcement services beginning February 9, 2018, the provider certifies that before billing Medicaid, if the provider has billed a third party, the provider has waited 100 days from the date of the service and has not received payment from the third party.

* * * * *

PART 438—MANAGED CARE

■ 3. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Section 438.3 is amended by revising paragraphs (s) introductory text and (s)(4) and (5) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(s) *Requirements for MCOs, PCCMs, PIHPs, or PAHPs that provide covered outpatient drugs.* Contracts that obligate MCOs, PCCMs, PIHPs, or PAHPs to provide coverage of covered outpatient drugs must include the following requirements:

* * * * *

(4) The MCO, PCCM, PIHP, or PAHP must operate a drug utilization review program that complies with the requirements described in section 1927(g) of the Act and part 456, subpart K, of this chapter, as if such requirement applied to the MCO, PCCM, PIHP, or PAHP instead of the State.

(5) The MCO, PCCM, PIHP, or PAHP must provide a detailed description of its drug utilization review program activities to the State on an annual basis.

* * * * *

PART 447—PAYMENTS FOR SERVICES

■ 5. The authority citation for part 447 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1396r–8.

■ 6. Section 447.502 is amended—

■ a. In the definition of ''Bundled sale'' by adding paragraph (3);

■ b. By adding the definition of ''CMS-authorized supplemental rebate agreement'' in alphabetical order;

■ c. By revising the definitions of ''Innovator multiple source drug'', ''Multiple source drug'', and ''Single source drug'';

■ d. By adding the definitions of ''Value-based purchasing (VBP) arrangement'' in alphabetical order; and

■ e. By revising the definition of ''Wholesaler''.

The additions and revisions read as follows:

§ 447.502 Definitions.

* * * * *

Bundled sale * * *

(3) Value-based purchasing (VBP) arrangements may qualify as a bundled sale.

* * * * *

CMS-authorized supplemental rebate agreement means an agreement that is approved through a state plan amendment (SPA) by CMS, which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that generate rebates that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers. Revenue from these rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the Federal Government.

* * * * *

Innovator multiple source drug means a multiple source drug, including an authorized generic drug, that is marketed under a new drug application (NDA) approved by FDA, unless the Secretary determines that a narrow exception applies (as described in this section). It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA).

* * * * *

Multiple source drug means, for a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, for which there is at least 1 other drug product which meets all of the following criteria:

(1) Is rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.accessdata.fda.gov/scripts/cder/ob/*).

(2) Except as provided at section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined at section 1927(k)(7)(C) of the Act and as determined by FDA.

(3) Is sold or marketed in the United States during the period.

* * * * *

Single source drug means a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in this section), and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

* * * * *

Value-based purchasing (VBP) arrangement means an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population and includes, but is not limited to:

(1) Evidence-based measures, which substantially link the cost of a covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product; and/or

(2) Outcomes-based measures, which substantially link payment for the covered outpatient drug to that of the drug's actual performance in patient or a population, or a reduction in other medical expenses.

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

■ 7. Section 447.502 is further amended, effective January 1, 2022, by—

■ a. Adding the definitions of ''Line extension'' and ''New formulation'' in alphabetical order; and

■ b. Revising the definition of ''Oral solid dosage form''.

The additions and revision read as follows:

§ 447.502 Definitions.

* * * * *

Line extension means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary).

* * * * *

New formulation means, for a drug, a change to the drug, including, but not

limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients.

* * * * *

Oral solid dosage form means, an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity.

* * * * *

§ 447.504 [Amended]

■ 8. Section 447.504 is amended by removing paragraph (b)(2) and redesignating paragraph (b)(3) as paragraph (b)(2).

■ 9. Section 447.504 is further amended, effective January 1, 2023, by revising paragraphs (c)(25) through (29) and paragraphs (e)(13) through (17) to read as follows:

§ 447.504 Determination of average manufacturer price.

* * * * *

(c) * * *

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the manufacturer ensures the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the manufacturer ensures: the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the manufacturer ensures the full value of the discount is passed on to the consumer and the pharmacy, agent, or the other AMP-eligible entity does not receive any price concession.

(28) Manufacturer–sponsored patient refund/rebate programs, to the extent that the manufacturer ensures that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(29) Manufacturer copayment assistance programs, to the extent that the manufacturer ensures the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession

* * * * *

(e) * * *

(13) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the manufacturer ensures the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the manufacturer ensures: the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the extent that the manufacturer ensures the full value of the discount is passed on to the consumer and the pharmacy, agent, or the other AMP-eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer ensures the manufacturer provided a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy agent, or other AMP-eligible entity does not receive any price concession.

(17) Manufacturer copayment assistance programs, to the extent that the manufacturer ensures the program benefits are provided entirely to the patient and the pharmacy agent, or other AMP-eligible entity does not receive any price concession

* * * * *

■ 10. Section 447.505 is amended—

■ a. Effective January 1, 2022, in paragraph (a), by revising the definition of ''Best price'';

■ b. Effective March 1, 2021, by revising paragraph (d)(3).

The revisions read as follows:

§ 447.505 Determination of best price.

(a) * * *

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. If a manufacturer offers a value-based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value based purchasing arrangement.

* * * * *

(d) * * *

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of best price by statute or regulation.

■ 11. Section 447.505 is amended, effective January 1, 2023, by revising paragraphs (c)(8) through (12) to read as follows:

§ 447.505 Determination of best price.

* * * * *

(c) * * *

(8) Manufacturer-sponsored drug discount card programs, but only to the extent the manufacturer ensures that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(9) Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent the manufacturer ensures that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession.

(10) Manufacturer copayment assistance programs, to the extent that the manufacturer ensures the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.

(11) Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer ensures the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession.

(12) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers

and patient assistance programs, but only to the extent that the manufacturer ensures the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession.

* * * * *

■ 12. Section 447.506 is amended—

■ a. In paragraph (a) by revising the definition of ''Secondary manufacturer of an authorized generic drug''; and

■ b. By revising paragraph (b).

The revisions read as follows:

§ 447.506 Authorized generic drugs.

(a) * * *

Secondary manufacturer of an authorized generic drug means a manufacturer that is authorized by the primary manufacturer to sell the drug.

(b) *Exclusion of authorized generic drugs from AMP by a primary manufacturer.* The primary manufacturer must exclude from its calculation of AMP any sales of authorized generic drugs to wholesalers for drugs distributed to retail community pharmacies when reporting the AMP of the brand name drug of that authorized generic drug.

* * * * *

■ 13. Section 447.509 is amended—

■ a. Revising paragraph (a)(5);

■ b. In paragraph (a)(6) introductory text, by removing word ''rebate'' and adding in its place the phrase ''basic rebate''; and

■ c. By adding paragraphs (a)(7), (8), and (9).

The revision and additions read as follows:

§ 447.509 Medicaid drug rebates (MDR).

(a) * * *

(5) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP of the single source or multiple source innovator drug.

* * * * *

(7) *Additional rebate for noninnovator multiple source drugs.* In addition to the basic rebate described in paragraph (a)(6) of this section, for each dosage form and strength of a noninnovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period.

(ii) The amount, if any, by which:

(A) The AMP for the dosage form and strength of the drug for the period exceeds the base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug.

(B) The base date AMP has the meaning of AMP set forth in sections 1927(c)(2)(A)(ii)(II), 1927(c)(2)(B) and 1927(c)(3)(C) of the Act.

(8) *Total rebate.* The total rebate amount for noninnovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(9) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP for the noninnovator multiple source drug.

* * * * *

■ 14. Section 447.509 is further amended, effective January 1, 2022, by—

■ a. By revising paragraphs (a)(4)(ii) introductory text;

■ b. By redesignating paragraph (a)(4)(iii) as paragraph (a)(4)(iv); and

■ c. Adding a new paragraph (a)(4)(iii).

The revision and addition read as follows:

§ 447.509 Medicaid drug rebates (MDR).

(a) * * *

(4) * * *

(ii) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation for the rebate periods beginning on October 1, 2018 through December 31, 2021 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the amount computed under paragraph (a)(1) of this section plus the product of all of the following:

* * * * *

(iii) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug, provided that the initial single source drug or innovator multiple source drug is an oral solid dosage form, the rebate obligation for the rebate periods beginning on and after January 1, 2022 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the amount computed under paragraph (a)(1) of this section plus the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

* * * * *

■ 15. Section 447.510 is amended by adding paragraph (b)(1)(vi) to read as follows:

§ 447.510 Requirement for manufacturers.

* * * * *

(b) * * *

(1) * * *

(vi) The change is a result of a VBP arrangement, as defined in § 447.502, requiring the manufacturer to make changes outside of the 12-quarter rule in this paragraph (b), when the outcome must be evaluated outside of the 12-quarter period.

* * * * *

■ 16. Section 447.511 is amended, effective January 1, 2022—

■ a. In paragraph (a) introductory text, by removing the phrase ''following data:'' and adding in its place the phrase ''following data and any subsequent changes to the data fields on the CMS–R–144 Medicaid Drug Rebate Invoice form:'';

■ b. By revising paragraph (b); and

■ c. By adding paragraphs (d) and (e).

The revision and additions read as follows:

§ 447.511 Requirements for States.

* * * * *

(b) *Data submitted to CMS.* On a quarterly basis, the State must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers on the CMS–R–144, as specified in paragraph (a) of this section. The state data submission will be due no later than 60 days after the end of each rebate period. In the event that a due date falls on a weekend or Federal holiday, the submission will be due on the first business day following that weekend or Federal holiday. Any adjustments to previously submitted data will be transmitted to the manufacturer and CMS in the same reporting period.

* * * * *

(d) *State data certification.* Each data submission in this section must be certified by one of the following:

(1) The State Medicaid Director (SMD);

(2) The Deputy State Medicaid Director (DSMD);

(3) An individual other than the SMD or DSMD, who has authority equivalent to an SMD or DSMD; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in paragraphs (d)(1) through (3) of this section.

(e) *State data certification language.* Each data submission by a state must include the following certification language: ''I hereby certify, to the best of my knowledge, that the state's data submission is complete and accurate at the time of this submission, and was prepared in accordance with the state's good faith, reasonable efforts based on existing guidance from CMS, section 1927 of the Act and applicable Federal regulations. I further certify that the state has transmitted data to CMS, including any adjustments to previous rebate periods, in the same reporting period as provided to the manufacturer. Further, the state certifies that it has applied any necessary edits to the data for both CMS and the manufacturer to avoid inaccuracies at both the NDC/line item and file/aggregate level. Such edits are to be applied in the same manner and in the same reporting period to both CMS and the manufacturer.''

■ 17. Section 447.518 is amended, effective January 1, 2022, by—

■ a. Redesignating the text of paragraph (d) as paragraph (d)(1); and

■ b. Adding paragraphs (d)(2) and (3).

The additions read as follows:

§ 447.518 State plan requirements, findings, and assurances.

* * * * *

(d) * * *

(2) A State participating in VBP arrangements approved under a CMS-authorized supplemental rebate agreement (SRA) must report data described in paragraph (d)(3) of this section on an annual basis.

(3) Within 60 days of the end of each year, the State must submit all of the following data, including cumulative data to date:

(i) State.

(ii) National drug code(s) (for drugs covered under the CMS-authorized VBP SRA).

(iii) Product's FDA list name.

(iv) Number of prescriptions.

(v) Cost to the State to administer the CMS-authorized VBP SRA (for example, systems changes, tracking outcomes, etc.).

(vi) Total savings generated by the supplemental rebate due to the CMS-authorized VBP SRA.

PART 456—UTILIZATION CONTROL

■ 18. The authority citation for part 456 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 19. Section 456.703 is amended by—

■ a. Redesignating paragraph (h) as paragraph (i); and

■ b. Adding a new paragraph (h).

The addition reads as follows:

§ 456.703 Drug use review programs.

* * * * *

(h) *Minimum standards for DUR programs*—(1) *Minimum standards.* In operating their DUR programs, States must include the following minimum standards:

(i) Prospective safety edit limitations for opioid prescriptions, as specified by the State, on:

(A) Days' supply for patients not currently receiving opioid therapy for initial prescription fills;

(B) Quantity of prescription dispensed for initial and subsequent prescription fills;

(C) Therapeutically-duplicative initial and subsequent opioid prescription fills; and

(D) Early refills, for subsequent prescription fills.

(ii) Prospective safety edit limitations for opioid prescriptions, as specified by the State, on the maximum daily morphine milligram equivalent for treatment of pain, for initial and subsequent prescription fills.

(iii) A retrospective claims review automated process that indicates prescription fills of opioids in excess of the prospective safety edit limitations specified by the state under paragraph (h)(1)(i) or (ii) of this section to provide for the ongoing review of opioid claims data to identify patterns of fraud, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits.

(iv) A retrospective claims review automated process and, at the option of the State, prospective safety edits that monitor when an individual is concurrently prescribed opioids and:

(A) Benzodiazepines; or

(B) Antipsychotics.

(v) A program to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan, including any Medicaid expansion groups for the Children's Health Insurance Program (CHIP).

(vi) A process to identify potential fraud or abuse of controlled substances by individuals enrolled under the State plan, health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

(vii) Prospective safety edits, retrospective claims review automated processes, or a combination of these approaches as determined by the State, to identify when:

(A) A beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for Medication Assisted Treatment (MAT) of an opioid use disorder or has been diagnosed with an opioid use disorder, within a timeframe specified by the State, in the absence of a new indication to support utilization of opioids (such as new cancer diagnosis or entry into hospice care); and

(B) A beneficiary could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of any FDA-approved opioid antagonist/reversal agent.

(2) *Exclusion.* The requirements in paragraphs (h)(1)(i) through (vii) of this section do not apply with respect to individuals receiving hospice or palliative care or treatment for cancer; individuals who are residents of long-term care facilities, intermediate care facilities for the intellectually disabled, or facilities that dispense frequently abused drugs through a contract with a single pharmacy; or other individuals the State elects to exempt. While States are not required to apply the requirements in paragraphs (h)(1)(i) through (vii) with respect to these individuals, States may elect to do so.

* * * * *

■ 20. Section 456.712 is amended by adding paragraph (c) to read as follows:

§ 456.712 Annual report.

* * * * *

(c) *Public availability.* All fee-for-service (FFS) and managed care DUR reports received by CMS under paragraph (b) of this section and, as applicable, pursuant to § 438.3(s) of this chapter, will be publicly posted on a website maintained by CMS for the sharing of reports and other information concerning Medicaid DUR programs.

Dated: November 30, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 11, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–28567 Filed 12–22–20; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 85 Thursday,

No. 251 December 31, 2020

Part III

Securities and Exchange Commission

17 CFR Parts 240, 242 and 249

Regulation ATS for ATSs That Trade U.S. Government Securities, NMS Stock, and Other Securities; Regulation SCI for ATSs That Trade U.S. Treasury Securities and Agency Securities; and Electronic Corporate Bond and Municipal Securities Markets; Proposed Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 240, 242 and 249

[Release No. 34–90019; File No. S7–12–20]

RIN 3235–AM45

Regulation ATS for ATSs That Trade U.S. Government Securities, NMS Stock, and Other Securities; Regulation SCI for ATSs That Trade U.S. Treasury Securities and Agency Securities; and Electronic Corporate Bond and Municipal Securities Markets

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule; request for comment; concept release.

SUMMARY: The Securities and Exchange Commission is proposing amendments to Regulation ATS under the Securities Exchange Act of 1934 (''Exchange Act'') for alternative trading systems (''ATSs''). The Commission is proposing to amend Regulation ATS for ATSs that trade government securities as defined under Section 3(a)(42) of the Exchange Act (''government securities'') or repurchase and reverse repurchase agreements on government securities (''Government Securities ATSs'') to: Eliminate the exemption from compliance with Regulation ATS for an ATS that limits its securities activities to government securities or repurchase and reverse repurchase agreements on government securities, and registers as a broker-dealer or is a bank; require the filing of public Form ATS–G, which would require a Government Securities ATS to disclose information about its manner of operations and the ATS-related activities of the registered broker-dealer or government securities broker or government securities dealer that operates the ATS and its affiliates; require, among other things, public posting of certain Form ATS–G filings and to provide a process for the Commission to review Form ATS–G filings and, after notice and opportunity for hearing, declare Form ATS–G filings ineffective; and apply the fair access rule under Rule 301(b)(5) of Regulation ATS to Government Securities ATSs that meet certain volume thresholds in U.S. Treasury Securities or in a debt security issued or guaranteed by a U.S. executive agency, or government-sponsored enterprise (''Agency Securities''). The Commission is also proposing changes to correct and modernize Regulation ATS, Form ATS, Form ATS–N, and Form ATS–R. In addition, the Commission is proposing to amend Regulation Systems Compliance and Integrity to apply it to ATSs that meet certain volume thresholds in U.S. Treasury Securities or Agency Securities. Finally, the Commission is issuing a concept release on the regulatory framework for electronic platforms that trade corporate debt and municipal securities.

DATES: Comments should be received on or before March 1, 2021.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/proposed.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–12–20 on the subject line.

Paper Comments

- Send paper comments to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–12–20. 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 (*http://www.sec.gov/rules/proposed.shtml*). Comments are also available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

Studies, memoranda, or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any materials will be made available on the Commission's website. To ensure direct electronic receipt of such notifications, sign up through the ''Stay Connected'' option at *www.sec.gov* to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: Regulation ATS: Tyler Raimo, Assistant Director, at (202) 551–6227; Matthew Cursio, Special Counsel, at (202) 551–5748; David Garcia, Special Counsel, at (202) 551–5681; Megan Mitchell, Special Counsel, at (202) 551–4887; and Joanne Kim, Law Clerk, at (202) 551–4393, and for Regulation SCI: David Liu, Special Counsel, at (312) 353–6265 and Sara Hawkins, Special Counsel, at (202) 551–5523, Office of Market Supervision, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Commission is proposing to: (1) Amend Rule 300 (17 CFR 242.300) and Rule 301 (17 CFR 242.301) of Regulation ATS under the Exchange Act to eliminate the current exemption from compliance with Rules 300 through 304 (17 CFR 242.300 through 242.304) (''Regulation ATS'') under the Exchange Act for an ATS that limits its securities activities to government securities or repurchase and reverse repurchase agreements on government securities, and registers as a broker-dealer or is a bank and require such ATS to comply with applicable provisions of Regulation ATS; (2) amend Rule 3a1–1(b) (17 CFR 242.3a1–1(b)) under the Exchange Act to require a Government Securities ATS, which otherwise qualifies for the Rule 3a1–1(a) exemption, to register as a national securities exchange if the ATS meets certain, specified volume levels in U.S. Treasury Securities and Agency Securities, and the Commission determines that such exemption is not necessary or appropriate in the public interest or consistent with the protection of investors; (3) include Government Securities ATSs within the scope of Rule 304 (17 CFR 242.304) of Regulation ATS,[1] which would provide new requirements for Government Securities ATSs seeking to use the exemption from the definition of ''exchange'' under Regulation ATS; (4) require that Government Securities ATSs use new Form ATS–G in accordance with Rule 3a1–1(a) (17 CFR 240.3a1–1(a)); (5) amend Rule 301(b)(5) (17 CFR 242.301(b)(5)) of Regulation ATS (''Fair Access Rule'') to require Government Securities ATSs that meet certain trading volume thresholds in transactions in U.S. Treasury Securities or Agency Securities to comply with the Fair Access Rule; (6) amend Rule 301 of Regulation ATS and Form ATS and Form ATS–R to provide that such forms must be electronically filed; and (7) amend Rule 1000 (17 CFR 242.1000) of Regulation Systems Compliance and Integrity (''Regulation SCI'') under the Exchange Act by expanding the definition of ''SCI alternative trading system'' to include Government

[1] The Commission adopted Rule 304 on July 18, 2018. *See* Securities Exchange Act Release No. 83663 (July 18, 2018), 83 FR 38768 (August 7, 2018) (''NMS Stock ATS Adopting Release'').

Securities ATSs that meet a specified volume threshold in transactions in U.S. Treasury Securities or Agency Securities, and as a result subject these Government Securities ATSs to the requirements of Regulation SCI.[2]

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I. Government Securities ATS: Background

A. ATS Markets for U.S. Government Securities

An ATS is a trading system for securities that meets the definition of ''exchange'' under federal securities laws but is not required to register with the Commission as a national securities exchange if it complies with the conditions to an exemption provided under Regulation ATS. Since Regulation ATS was adopted in 1998, ATSs have become increasingly important venues

[2] The Commission adopted Regulation SCI on November 19, 2014. *See* Securities Exchange Act Release No. 73639 (November 19, 2014), 79 FR 72252 (December 5, 2014) (''Regulation SCI Adopting Release'').

for trading government securities.[3] Currently, ATSs, particularly those that operate in the secondary interdealer markets for on-the-run U.S. Treasury Securities, have become a significant source of orders and trading interest for government securities.[4] ATSs for government securities now operate with complexity similar to that of markets that trade NMS stocks in terms of automation and speed of trading, the use of limit order books, order types, algorithms, connectivity, data feeds, and the active participation of principal trading firms (''PTFs'') on ATSs.[5] Furthermore, government securities [6] make up more than half of the outstanding debt issuances in the U.S. bond market [7] and play a critical role in the U.S. and global economies. Over the last six months of 2019, the average daily trading volume in government securities was approximately $835 billion, or roughly 95 percent of all fixed income trading volume in the U.S.[8]

The most liquid and commonly traded government securities are U.S. Treasury Securities, which are direct obligations of the U.S. Government issued by the U.S. Department of the Treasury (''Treasury Department''). The Treasury Department issues several different types of securities, including Treasury bills, nominal coupons notes and bonds, Floating Rate Notes, and Treasury Inflation Protected Securities. For each security type, the most recently issued (''on-the-run'') securities are generally considered most liquid in the secondary market.[9] Market participants commonly refer to securities issued prior to ''on-the-run'' securities as ''off-the-run'' securities.[10] Market participants use U.S. Treasury Securities as an investment instrument, hedging vehicle, and to source orders and trading interest, among other things. U.S. banks commonly own U.S. Treasury Securities due to their low risk and strong liquidity characteristics. Additionally, U.S. Treasury Securities are often used as collateral in lending arrangements or as margin on other financial transactions.

For U.S. Treasury Securities, the secondary market is generally bifurcated between the dealer-to-customer market, in which dealers trade with their customers (*e.g.,* investment companies, pension funds, insurance companies, corporations, or retail) and the interdealer market, in which dealers and specialty firms trade with one another.[11] Trading in the U.S. Treasury Securities dealer-to-customer market is generally—and has historically been—conducted through bilateral transactions. Customers, also referred to as ''end users,'' have not traditionally traded directly with other end users.[12] Rather, end users primarily trade with dealers, and dealers use the interdealer market as a source of orders and trading interest to help facilitate their trading with clients in the dealer-to-customer market. Such trading often occurs either over the phone or on trading venues that facilitate the matching of buy and sell orders through electronic systems. Broker-dealers also internalize a portion of their customer flow, although the extent to which broker-dealers internalize is unclear.[13]

In the interdealer market, the majority of trading in on-the-run U.S. Treasury Securities currently occurs on ATSs using central limit order books supported by advanced electronic trading technology.[14] For off-the-run U.S. Treasury Securities,[15] the majority of interdealer trading occurs via bilateral transactions through traditional voice-assisted brokers and electronic trading platforms that offer various trading protocols to bring together buyers and sellers,[16] though, some interdealer trading of off-the-run U.S. Treasury Securities does occur on ATSs.[17] Furthermore, interdealer trading for on-the-run U.S. Treasury Securities is generally concentrated within a very small number of ATSs, especially when compared to the market for NMS stocks, which is dispersed among many trading venues. Specifically, over the past several years, the majority of overall trading in the interdealer secondary market for on-the-run U.S. Treasury Securities has

[3] A venue for trading government securities can include, among other things, an exchange, an ATS, an OTC market maker, or any other broker or dealer operated platform for executing trading interest internally by trading as principal or crossing orders as agent.

[4] *See infra* Section X.B.1.

[5] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38771 for a discussion about the current operational complexities of ATSs that trade National Market System stocks (''NMS Stock ATSs'').

[6] Under the Exchange Act, government securities are defined as, among other things, securities which are direct obligations of, or obligations guaranteed as to principal or interest by, the United States. *See* 15 U.S.C. 78c(42)(A). Government securities include U.S. Treasury securities, debt securities issued or guaranteed by a U.S. executive agency, as defined in 5 U.S.C. 105, or government-sponsored enterprise, as defined in 2 U.S.C. 622(8), and Agency Mortgage-Backed Securities. Government securities also include (i) securities which are issued or guaranteed by the Tennessee Valley Authority or by corporations in which the United States has a direct or indirect interest and which are designated by the Secretary of the Treasury for exemption as necessary or appropriate in the public interest or for the protection of investors; (ii) securities issued or guaranteed as to principal or interest by any corporation the securities of which are designated, by statute specifically naming such corporation, to constitute exempt securities within the meaning of the laws administered by the Commission; and (iii) any put, call, straddle, option, or privilege on one of the aforementioned (subject to limited exceptions). 15 U.S.C. 78c(42)(B)–(C).

[7] *See infra* Section X.B.1.

[8] *See* SIFMA Fixed Income Trading Volume, *available at https://www.sifma.org/resources/research/us-fixed-income-trading-volume/.* This includes U.S. Treasury Securities, Agency Mortgage-Backed Securities, and Federal Agency Securities. The six-month average is the mean of the average daily trading volume for these instruments from July to December 2019.

[9] On-the-run U.S. Treasury Securities are the most recently issued nominal coupon securities. Nominal coupon securities pay a fixed semi-annual coupon and are currently issued at original maturities of 2, 3, 5, 7, 10, 20, and 30 years. These standard maturities are commonly referred to as ''benchmark'' securities because the yields for these securities are used as references to price a number of private market transactions.

[10] Off-the-run or ''seasoned'' U.S. Treasury Securities are the issues that preceded the current on-the-run securities. The U.S. Treasury Securities market also comprises futures and options on U.S. Treasury Securities, and securities financing transactions in which U.S. Treasury Securities are used as collateral. *See* Department of the Treasury Release No. 2015–0013 (January 22, 2016), Notice Seeking Public Comment on the Evolution of the Treasury Market Structure, 81 FR 3928, 3928 (''Treasury Request for Information''). For the purpose of this proposal, the Commission focuses on the secondary cash market.

[11] *See id.*

[12] *See id.*

[13] *See id.* For the purposes of this proposal, internalization refers to a broker filling a customer order either from the firm's own inventory or by matching the order with other customer order flow, instead of sending the order to an interdealer market for execution. *See id.* at 3928 n.5.

[14] *See* Joint Staff Report: The U.S. Treasury Market on October 15, 2014, at 11, 35–36, *available at https://www.sec.gov/files/treasury-market-volatility-10-14-2014-joint-report.pdf* (''October 15 Staff Report''). The October 15 Staff Report is a joint report about the unusually high level of volatility and rapid round-trip in prices that occurred in the U.S. Treasuries market on October 15, 2014. Among other things, the October 15 Staff Report provides an overview of the market structure, liquidity, and applicable regulations of the U.S. Treasury market, as well as the broad changes to the structure of the U.S. Treasury market that have occurred over the past two decades.

[15] Also, as noted in the October 15 Staff Report issued by the U.S. Department of the Treasury, Board of Governors of the Federal Reserve System, Federal Reserve Bank of New York, the Commission, and U.S. Commodity Futures Trading Commission, trading in off-the-run U.S. Treasury Securities has always been less active than trading in on-the-run U.S. Treasury Securities, and price discovery in the cash markets primarily occurs in on-the-run securities. *See id.*

[16] *See id.* at 35.

[17] While trading in on-the-run securities likely accounts for more than half of total daily trading volumes, off-the-run U.S. Treasury Securities make up over 95 percent of the outstanding marketable U.S. Treasury Securities. *See* James Clark, Chris Cameron, and Gabriel Mann, *Examining Liquidity in On-the-Run and Off-the-Run Treasury Securities,* Treasury Notes Blog, *https://www.treasury.gov/connect/blog/Pages/Examining-Liquidity-in-On-the-Run-and-Off-the-Run-Treasury-Securities.aspx.*

occurred on ATSs.[18] For example, during the 4th quarter of 2019, one ATS accounted for $15.60 trillion in total dollar volume in all U.S. government securities, the majority of which were on-the-run U.S. Treasury Securities.[19]

Another type of government securities is Agency Securities. Agency Securities include securities issued by or guaranteed by U.S. Government corporations and U.S. Government sponsored enterprises (''GSEs'').[20] For example, the Government National Mortgage Association (''Ginnie Mae'') is a U.S. Government corporation that issues mortgage-backed securities guaranteed by the full faith and credit of the U.S. Government. The assets collateralized into the securities issued by Ginnie Mae are federally insured and guaranteed mortgage loans. Agency Securities issued by GSEs include those issued by the Federal Home Loan Banks (''FHLBs''), the Federal National Mortgage Association (''Fannie Mae''), the Federal Home Loan Mortgage Corporation (''Freddie Mac''), and the Student Loan Marketing Association (''Sallie Mae'').[21] Agency Securities issued by GSEs are not normally backed by the full faith and credit of the U.S. Government and therefore, may present some default and credit risk.

Agency Securities, while often not backed by the full faith and credit of the U.S. Government, are generally considered to be very liquid and offer state and local tax advantages to the holder. Market participants frequently use ATSs to buy and sell Agency Securities, although, based on the Commission's review of Form ATS–R filings, transaction volume of Agency Securities is not as large as that of U.S. Treasury Securities on ATSs.[22] Investors, banks, and other market participants often acquire Agency Securities in the secondary market to support various investing strategies, such as hedging against other more risky investments in a given portfolio.

Trading of both U.S. Treasury Securities and Agency Securities has become increasingly electronic, and ATSs that trade government securities have evolved into very complex markets. This is particularly true for the trading of on-the-run U.S. Treasury Securities,[23] but is also the case for the trading of other U.S. Treasury Securities and Agency Securities.[24] For example, based on the Commission's review of Form ATS filings by ATSs that trade government securities, and discussions with market participants for government securities, the Commission believes that Government Securities ATSs often offer subscribers a variety of order types to pursue both aggressive and passive trading strategies, and low latency, high-speed connectivity to the ATS. These ATSs frequently use automated systems, such as a central limit order book, to match orders anonymously on a price/time priority basis, and offer subscribers direct data feeds and co-location services. Some Government Securities ATSs also segment orders into categories by participants or allow participants the ability to interact with specific counterparty groups on the ATS and facilitate order interaction and execution.[25]

With regard to the interdealer secondary markets for on-the-run U.S. Treasury Securities, the continued growth of electronic trading has contributed to an increased presence of PTFs in the marketplace.[26] Currently, PTFs account for the majority of trading and provide significant top-of-the-book liquidity for on-the-run U.S. Treasury Securities on electronic interdealer trading venues.[27] From July 1, 2019 to December 31, 2019, PTFs traded on 13 Government Securities ATSs accounting for approximately 55 percent of total Government Securities ATS trading volume.[28] PTFs usually have direct access to electronic interdealer trading venues for U.S. Treasury Securities, and as is the case with the equity markets, PTFs trading on the electronic interdealer trading venues for on-the-run U.S. Treasury Securities often employ automated algorithmic trading strategies that rely on speed and allow the PTFs to cancel or modify quotes in response to perceived market events.[29] Furthermore, most PTFs trading U.S. Treasury Securities on these trading venues for on-the-run U.S. Treasury Securities also restrict their activities to principal trading and do not hold positions long term[30] while dealers use the interdealer market as a source of orders and trading interest to help facilitate their trading with clients in the dealer-to-customer market. As explained in the October 15 Staff Report, the increase in trading by PTFs in the interdealer market may affect the amount of liquidity available to end users in the dealer-to-customer market.[31]

B. Current Regulatory Framework for Government Securities ATSs

Despite the critical role of government securities in the U.S. and global economy, the significant volume in government securities transacted on ATSs, and these ATSs' growing importance to investors and overall securities market structure, an ATS that limits its securities activities to government securities or repurchase and reverse repurchase agreements on

[18] *See* text accompanying *infra* note 583; Table X.2 and accompanying text.

[19] For an additional discussion of trading volume in the U.S. bond market as a whole and U.S. Treasury Securities, *see infra* Section X.B.

[20] *See* U.S. Department of the Treasury Resource Center, ''Fixed Income: Agency Securities,'' *available at https://www.treasury.gov/resource-center/faqs/Markets/Pages/fixedfederal.aspx.*

[21] *See id.* The housing sector GSEs are Fannie Mae, Freddie Mac, and the FHLB institutions, the latter of which issue debt through the joint Office of Finance. Sallie Mae is a higher education sector GSE that currently is in the transition process to full privatization. *See id.*

[22] Additionally, repurchase and reverse repurchase agreements on government securities are also traded on some ATSs.

[23] The growth of electronic trading has contributed to a marked shift in the composition of the interdealer cash market for U.S. Treasury Securities over time. Traditionally, interdealer brokers only allowed primary dealers to access their trading venues. After 1992, however, interdealer brokers expanded access to all entities that were netting members of the Government Securities Clearing Corporation (which is now the Fixed Income Clearing Corporation's Government Securities Division). Thereafter, other entities gained access to these trading venues through their prime brokers, who themselves had access, and in recent years the trading venues granted direct access to an even wider range of participants, including non-dealer PTFs, which account for more than half of the trading activity in the futures and electronically brokered interdealer cash markets. *See* October 15 Staff Report, *supra* note 14, at 36. *See also* Treasury Request for Information, *supra* note 10, at 3928.

[24] *See* James Collin Harkrader and Michael Puglia, *Fixed Income Market Structure: Treasuries* vs. *Agency MBS,* Board of Governors of the Federal Reserve System: FEDS NOTES (August 25, 2020), *available at https://www.federalreserve.gov/econres/notes/feds-notes/fixed-income-market-structure-treasuries-vs-agency-mbs-20200825.htm* (''August 25th FEDS Notes'') (explaining the recent evolution of the government securities market structure).

[25] This evolution in the interdealer secondary cash markets for U.S. Treasury Securities was also highlighted in the October 15 Staff Report, *see* October 15 Staff Report, *supra* note 14, the Treasury Request for Information, *see* Treasury Request for Information, *supra* note 10, at 3928, and public comment received by the Commission, *see infra* Section I.C.

[26] PTFs are not, however, very active in the electronic markets for Agency Securities. *See* August 25th FEDS Notes, *supra* note 24 (''Though parts of the agency MBS market have moved from voice-based to screen-based trading since the early 2000s, algorithmic high-frequency electronic trading still does not comprise a meaningful share of average daily volume and the market remains devoid of PTF participation.'').

[27] *See* October 15 Staff Report, *supra* note 14, at 36; Remarks of Deputy Secretary Justin Muzinich at the 2019 U.S. Treasury Market Structure Conference (September 23, 2019), *available at https://home.treasury.gov/news/press-releases/sm782* (''Muzinich Remarks'').

[28] *See infra* Table X.2. (ATS PTF volume/ATS volume) × 100 = PTF share of ATS volume (%).

[29] *See* October 15 Staff Report, *supra* note 14, at 32, 35–36, 39.

[30] *See id.* at 38.

[31] *See id.* at 37.

government securities (''repos''), and registers as a broker-dealer or is a bank (''Currently Exempted Government Securities ATS'') is exempt from exchange registration and is not required to comply with Regulation ATS. Furthermore, ATSs that trade *both* government securities and non-government debt securities (*e.g.,* corporate bonds) are not subject to all the provisions of Regulation ATS, such as the Fair Access Rule, and are not subject to Regulation SCI.

Regulation ATS and its related rules provide an exemption from the definition of ''exchange'' under Section 3(a)(1) of the Exchange Act,[32] coupled with alternate regulatory requirements with which ATSs must comply to achieve and maintain their eligibility for the exemption. Exchange Act Rule 3b–16(a) provides a functional test to assess whether a trading platform meets the definition of ''exchange'' under Section 3(a)(1) of the Exchange Act.[33] Under Rule 3b–16(a), an organization, association, or group of persons shall be considered to constitute, maintain, or provide a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange, if such organization, association, or group of persons: (1) Brings together the orders for securities of multiple buyers and sellers; and (2) uses established, non-discretionary methods (whether by providing a trading facility or by setting rules) under which such orders interact with each other, and the buyers and sellers entering such orders agree to the terms of a trade.[34] Accordingly, an entity that provides a marketplace for bringing together buyers and sellers for government securities, regardless of the applied technology, would need to consider whether its activities meet the definition of an ''exchange'' under the federal securities laws.[35]

Section 5 of the Exchange Act[36] requires an organization, association, or group of persons that meets the definition of ''exchange'' under Section 3(a)(1) of the Exchange Act,[37] unless otherwise exempt, to register with the Commission as a national securities exchange pursuant to Section 6 of the Exchange Act.[38] Exchange Act Rule 3a1–1(a)(2)[39] provides an exemption from national securities exchange registration for ATSs, which are systems that meet the Rule 3b–16(a) criteria and do not perform self-regulatory activities.[40] As a result of the exemption, an organization, association, or group of persons that meets the definition of an exchange and complies with Regulation ATS is not required by Section 5 of the Exchange Act to register as a national securities exchange pursuant to Section 6 of Exchange Act and is not a self-regulatory organization (''SRO''), and therefore, is not required to comply with regulatory requirements applicable to national securities exchanges and SROs.[41]

The vast majority of ATSs that operate today do so pursuant to the exemption provided by Exchange Act Rule 3a1–1(a)(2), which requires the ATSs to comply with Regulation ATS and register as broker-dealers. Currently Exempted Government Securities ATSs, however, operate pursuant to Exchange Act Rule 3a1–1(a)(3)[42] and Rule 301(a)(4)(ii)(A).[43] These provisions currently exempt an ATS from compliance with the requirements in Rule 301(b) of Regulation ATS[44] if, in relevant part, the ATS is registered as a broker-dealer under Sections 15(b)[45] or 15C[46] of the Exchange Act, or is a bank, and limits its securities activities to government securities, as defined in Section 3(a)(42) of the Exchange Act, repos, any puts, calls, straddles, options, or privileges on government securities, other than puts, calls, straddles, options, or privileges that: (1) Are traded on one or more national securities exchanges; or (2) for which quotations are disseminated through an automated quotation system operated by a registered securities association, and commercial paper.[47] Accordingly, such Currently Exempted Government Securities ATSs are not required to register as a national securities exchange or comply with Regulation ATS.[48] To the Commission's knowledge, most Currently Exempted Government Securities ATSs operating pursuant to this exemption limit their securities activities solely to government securities and register as broker-dealers with the Commission.[49]

ATSs that trade government securities or repos and other securities—such as corporate bonds or municipal securities—cannot use this exemption

[32] 15 U.S.C. 78c(a)(1). Pursuant to Section 3(a)(1) of the Exchange Act, the statutory definition of ''exchange'' means any organization, association, or group of persons, whether incorporated or unincorporated, which constitutes, maintains, or provides a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange as that term is generally understood, and includes the market place and the market facilities maintained by such exchange.

[33] *See* 15 U.S.C. 78e and 78f.

[34] 17 CFR 240.3b–16(a). Exchange Act Rule 3b–16(b) explicitly excludes from that definition certain systems that do not meet the definition of ''exchange,'' such as order routers and systems that allow persons to enter orders for execution against the bids and offers of a single dealer. *See* 17 CFR 240.3b–16(b). *See also* NMS Stock ATS Adopting Release, *supra* note 1, at n.32 and accompanying text.

[35] For example, whether or not a particular system is an exchange does not turn solely on the level of automation used; ''orders'' can be given over the telephone, as well as electronically. *See* Securities Exchange Act Release No. 40760 (December 8, 1998), 63 FR 70844, 70850 (December 22, 1998) (''Regulation ATS Adopting Release'').

[36] 15 U.S.C. 78e.

[37] 15 U.S.C. 78c(a)(1).

[38] 15 U.S.C. 78f.

[39] *See* 17 CFR 240.3a1–1(a)(2).

[40] *See* 17 CFR 242.300(a). Rule 300(a) of Regulation ATS defines an ATS as any organization, association, person, group of persons, or system: (1) That constitutes, maintains, or provides a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange within the meaning of Rule 3b–16; and (2) that does not: (i) Set rules governing the conduct of subscribers other than the conduct of such subscribers' trading on such organization, association, person, group of persons, or system; or (ii) discipline subscribers other than by exclusion from trading.

[41] *See* 15 U.S.C. 78e (Section 5 of the Exchange Act); 78f (Section 6 of the Exchange Act); and 78s (Section 19 of the Exchange Act). *See also* NMS Stock ATS Adopting Release, *supra* note 1, at 78772. An ATS that fails to comply with Regulation ATS would no longer qualify for the exemption provided under Rule 3a1–1(a)(2) and thus risks operating as an unregistered exchange in violation of Section 5 of the Exchange Act. *See* 15 U.S.C. 78e. *See also* NMS Stock ATS Adopting Release, *supra* note 1, at 78772.

[42] 17 CFR 240.3a1–1(a)(3).

[43] 17 CFR 242.301(a)(4)(ii)(A).

[44] 17 CFR 242.301(b).

[45] *See* 15 U.S.C. 78o(b) (Section 15(b) of the Exchange Act pertains to the registration and regulation of brokers and dealers).

[46] *See* 15 U.S.C. 78o–5 (Section 15C of the Exchange Act pertains to government securities brokers and dealers).

[47] *See* 15 U.S.C. 78c(a)(42). The Commission notes that the definition of ''government securities'' in Section 3(a)(42) of the Exchange Act includes certain puts, calls, straddles, options, or privileges on government securities, other than puts, straddles, options, or privileges that: (1) Are traded on one or more national securities exchanges; or (2) for which quotations are disseminated through an automated quotation system operated by a registered securities association. *See supra* note 6. Therefore, references to ''government securities'' throughout this proposal include such puts, calls, straddles, options, or privileges on government securities.

[48] *See* 17 CFR 242.301(a)(4)(i) and (ii)(A). Although not required to register as a national securities exchange or comply with Regulation ATS, a Currently Exempted Government Securities ATS may need to register as a broker-dealer under Section 15(b) or as a government securities broker or government securities dealer pursuant to Exchange Act Section 15C, and comply with associated regulatory requirements. *See, e.g.,* 17 CFR, Subchapter A—Regulations under Section 15C of the Securities Exchange Act of 1934.

[49] Some ATSs that are eligible for the exemption voluntarily comply with Regulation ATS, even though ATSs that trade only government securities are not required to comply with Regulation ATS at all.

because these ATSs do not limit their securities activities solely to government securities or repos. Such ATSs must either register as a national securities exchange or comply with Regulation ATS pursuant to Exchange Act Rule 3a1–1(a)(2), which includes, among other things, registering as a broker-dealer under Section 15 of the Exchange Act. As a registered broker-dealer, an ATS must also, in addition to complying with Regulation ATS, comply with broker-dealer filing and conduct obligations, including becoming a member of an SRO, such as the Financial Industry Regulatory Authority (''FINRA''). Among other things, Government Securities ATSs that are currently subject to Regulation ATS must report transactions in U.S. Treasury Securities and Agency Securities to the Trade Reporting and Compliance Engine (''TRACE''),[50] and FINRA publicly disseminates data about these transactions. Currently, FINRA publishes weekly aggregated transaction information on U.S. Treasury Securities and disseminates certain transaction information on Agency Securities immediately upon receipt of a transaction report.[51]

In addition to registering as a broker-dealer, an ATS that trades government securities or repos and securities other than government securities or repos must file notices with the Commission on Form ATS (which are ''deemed confidential'' and ''available only to the examination of Commission staff, state securities authorities, and the self-regulatory organizations'') to disclose their operations to the Commission pursuant to Rule 301(b)(2); cooperate with the Commission's or an SRO's inspection, examination, or investigation of the ATS or any of the ATS's subscribers pursuant to Rule 301(b)(7); make, keep current, and preserve certain records as prescribed under Rule 302 and Rule 303 of Regulation ATS pursuant to Rule 301(b)(8); periodically report certain information about trading activities on Form ATS–R pursuant to Rule 301(b)(9); adopt written safeguards and written procedures to protect subscriber confidential trading information and separate ATS functions from other broker-dealer functions, including principal and customer trading pursuant to Rule 301(b)(10); and not use in its name the word ''exchange,'' or derivations of the word ''exchange'' pursuant to Rule 301(b)(11).[52]

Such Government Securities ATSs, however, are subject to only certain provisions of Regulation ATS because not all the provisions of Regulation ATS are applicable to trading in government securities. In particular, government securities are not included in any category of securities under the Fair Access Rule.[53] Today, the categories of securities under the Fair Access Rule include NMS stocks, equity securities that are not NMS stocks and for which transactions are reported to an SRO, municipal securities, and corporate debt securities.[54] Under the Fair Access Rule, an ATS that meets the average daily volume threshold for a category of securities during at least four of the preceding six calendar months must: (1) Establish written standards for granting access to trading on its system; (2) not unreasonably prohibit or limit any person in respect to access to services offered by such ATS by applying the above written standards in an unfair or discriminatory manner; and (3) make and keep certain records. In addition, Regulation SCI does not apply to ATSs with respect to their trading in government securities.[55] The capacity, integrity, and security of automated systems provisions of Rule 301(b)(6) under Regulation ATS (''Capacity, Integrity, and Security Rule'')[56] also do not apply to the government securities activities of an ATS.[57]

Finally, Government Securities ATSs that trade only government securities or repos are not required to comply with rules applicable to ATSs that trade NMS stocks, including Rule 304 of Regulation ATS.[58] Rule 304 requires only NMS Stock ATSs to file a public Form ATS–N, which discloses the manner of the NMS Stock ATS's operations and the ATS-related activities of the broker-dealer operator and its affiliates. Form ATS–N disclosures are subject to review by the Commission and an NMS Stock ATS is prohibited from operating unless the Form ATS–N is effective. ATSs that transact in government securities or repos are also not required to comply with the order display and execution access provisions under Rule 301(b)(3)[59] and the related fee restrictions of Rule 301(b)(4),[60] both of which only apply to an ATS's NMS stock activities.

C. Prior Comments Received About Government Securities Markets

On July 18, 2018, the Commission adopted amendments to Regulation ATS and Exchange Act Rule 3a1–1 to enhance operational transparency of,

[50] *See* FINRA Rule 6730(a)(1) requires FINRA members to report transactions in TRACE-Eligible Securities, which FINRA Rule 6710 defines to include U.S. Treasury Securities and Agency Securities. For each transaction in U.S. Treasury Securities and Agency Securities, a FINRA member would be required to report the CUSIP number or similar numeric identifier or FINRA symbol; size (volume) of the transaction; price of the transaction (or elements necessary to calculate price); symbol indicating whether transaction is a buy or sell; date of trade execution (''as/of'' trades only); contra-party's identifier; capacity (principal or agent); time of execution; reporting side executing broker as ''give-up'' (if any); contra side introducing broker (in case of ''give-up'' trade); the commission (total dollar amount), if applicable; date of settlement; if the member is reporting a transaction that occurred on an ATS, the ATS's separate Market Participant Identifier (''MPID''); and trade modifiers as required. For when-issued transactions in U.S. Treasury Securities, a FINRA member would be required to report the yield in lieu of price. *See* FINRA Rule 6730(c).

[51] FINRA Rule 6750(a) requires FINRA to disseminate information on all transactions on certain securities, including Agency Securities (but excluding U.S. Treasury Securities), immediately upon receipt of the transaction report. FINRA is permitted to publish or distribute weekly aggregated transaction information and statistics on U.S. Treasury Securities, and has stated that it intends to publish weekly volume information aggregated by U.S. Treasury subtype (*e.g.,* Bills, Floating Rate Notes, Treasury Inflation-Protected Securities, and Nominal Coupons). *See* Securities Exchange Release No. 87837 (December 20, 2019), 84 FR 71986 (December 30, 2019) (approving a proposed rule change to allow FINRA to publish or distribute aggregated transaction information and statistics on U.S. Treasury Securities).

[52] *See* 17 CFR 242.301(b)(1); 301(b)(2); and 301(b)(7) through (b)(11). The order display and execution access provisions under Rule 301(b)(3) and the related fee restrictions of Rule 301(b)(4) of Regulation ATS only apply to an ATS's NMS stock activities. *See* 17 CFR 242.301(b)(3)–(4).

[53] 17 CFR 242.301(b)(5).

[54] *See id.*

[55] *See infra* Section VI (describing the types of entities that are currently subject to the requirements of Regulation SCI).

[56] 17 CFR 242.301(b)(6).

[57] Rule 301(b)(6) requires an ATS that trades only municipal securities or corporate debt securities with 20 percent or more of the average daily volume traded in the United States during at least four of the preceding six calendar months to comply with the Capacity, Integrity, and Security Rule. Prior to the Commission's adoption of Regulation SCI, the requirements of Rule 301(b)(6) also applied to ATSs with regard to their trading in NMS stocks and non-NMS stocks; however, Regulation SCI superseded and replaced the requirements of Rule 301(b)(6) with regard to ATSs that trade NMS stocks and non-NMS stocks. *See infra* Section VI (describing each requirement of Regulation SCI).

[58] 17 CFR 242.304.

[59] Rule 301(b)(3) only applies to ATSs that (1) display subscriber orders in an NMS stock to any person (other than an employee of the ATS) and (2) during at least four of the preceding six calendar months, had an average daily trading volume of 5 percent or more of the aggregate average daily share volume for that NMS stock, as reported by an effective transaction reporting plan. *See* 17 CFR 242.301(b)(3).

[60] Under Rule 301(b)(4), an ATS must not charge any fee to broker-dealers that access the ATS through a national securities exchange or national securities association that is inconsistent with the equivalent access to the ATS that is required under Rule 301(b)(3)(iii), and thus, the requirements of Rule 301(b)(4) also only apply to ATSs that transact in NMS stock and trigger the order display requirements of Rule 301(b)(3). *See* 17 CFR 242.301(b)(4).

and increase Commission oversight for, NMS Stock ATSs.[61] In the Commission's proposal for these amendments, the Commission solicited comment about whether the proposal should apply to other types of ATSs, including Currently Exempted Government Securities ATSs and Government Securities ATSs. The Commission also acknowledged the observations made in the October 15 Staff Report about the significance of the government securities markets and the rapid and continuing evolution of the electronic secondary market in U.S. Treasury Securities. The Commission solicited comment about removing the exemption for Currently Exempted Government Securities ATSs and amending Regulation ATS to apply provisions of Regulation ATS to Government Securities ATSs, including the Fair Access Rule.[62]

The Commission received several comments regarding Government Securities ATSs.[63] Commenters generally supported increasing operational transparency for Government Securities ATSs.[64] Several commenters suggested that the current exemption should be eliminated or that Regulation ATS should be amended to apply to Currently Exempted Government Securities ATSs,[65] and several commenters stated that the proposal relating to the oversight of NMS Stock ATSs should be expanded to include Government Securities ATSs.[66] One commenter, however, stated that Government Securities ATSs should not be subject to increased regulation, as such requirements would place such ATSs at a disadvantage with respect to non-ATS trading venues that trade government securities.[67] Another commenter stated that Government Securities ATSs should be excluded from the scope of the Form ATS–N-like requirements because of the different trading characteristics they offer and the relatively recent entry of ATSs into this space.[68] The commenter also stated that any additional regulatory proposals with respect to Government Securities ATSs should be informed by the results of any review of the U.S. Treasury Securities market structure in connection with the October 15 Staff Report.[69]

Of the several commenters that expressed support for expanding the ATS–N disclosure regime to include Government Securities ATSs,[70] one commenter in particular described the importance of the U.S. Treasury Securities market and the depth, liquidity, and significant volume in recently issued benchmark or on-the-run U.S. Treasury Securities transacted on ATSs.[71] This commenter also stated that the U.S. Treasury Securities market has undergone significant changes with the transition to electronic trading and the entry of new liquidity providers.[72] The commenter stated that removing the exemption for Government Securities ATSs would subject them to appropriate oversight and that market participants using these ATSs would benefit from increased operational transparency

[61] *See* NMS Stock ATS Adopting Release, *supra* note 1.

[62] *See* Securities Exchange Act Release No. 76474 (November 18, 2015), 80 FR 80998, 81018–20 (December 28, 2015) (''NMS Stock ATS Proposing Release'').

[63] All comments received on the NMS Stock ATS Proposing Release regarding Government Securities ATS are available at: *https://www.sec.gov/comments/s7-23-15/s72315.shtml.*

[64] *See, e.g.,* Letter from Venu Palaparthi, Senior Vice President, Virtu Financial, to Brent J. Fields, Secretary, Commission, dated December 2, 2015 (''Virtu Letter''), at 2; Letter from Dennis M. Kelleher, President and Chief Executive Officer, Stephen W. Hall, Legal Director & Securities Specialist, and Allen Dreschel, Attorney, Better Markets, Inc., to Brent J. Fields, Secretary, Commission, dated February 26, 2016 (''Better Markets Letter''), at 8; and Letter from Theodore R. Lazo, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, to Brent J. Fields, Secretary, Commission, dated March 7, 2016 (''SIFMA Letter''), at 36. *See also* Letter from Jonathan A. Clark, Chief Executive Officer, and James C. Dolan, Chief Compliance Office, Luminex Trading & Analytics LLC, to Brent J. Fields, Secretary, Commission, dated February 23, 2016 (''Luminex Letter''), at 3 (supporting public disclosure of Form ATS for all ATSs); Letter from David W. Blass, General Counsel, Investment Company Institute, to Brent J. Fields, Secretary, Commission, dated February 25, 2016 (''ICI Letter''), at 11–12; and Letter from Marc R. Bryant, Senior Vice President and Deputy General Counsel, Fidelity Investments, to Brent J. Fields, Secretary, Commission, dated February 26, 2016 (''Fidelity Letter''), at 7 (generally supporting improving transparency into the operations of non-NMS Stock ATSs by providing public disclosure of Form ATS).

[65] *See* Virtu Letter, *supra* note 64, at 2 (stating that Regulation ATS should be amended to include electronic platforms for government securities because greater public transparency and enhanced monitoring of trading activity in these securities would result in greater investor confidence with respect to U.S. Treasury Securities markets); Letter from Rick A. Fleming, Investor Advocate, Office of the Investor Advocate, Commission, to Brent J. Fields, Secretary, Commission, dated September 9, 2016 (''OIA Letter''), at 16–19 (supporting the elimination of the exemption for Currently Exempted Government Securities ATSs and making their Form ATS public as an interim step); and Letter from Adam C. Cooper, Senior Managing Director and Chief Legal Officer, Citadel LLC, to Brent J. Fields, Secretary, Commission, dated March 1, 2016 (''Citadel Letter''), at 4. Another commenter also did not object to applying the requirements of Regulation ATS to systems that cross trades in government securities. *See* Letter from Howard Meyerson, General Counsel, Liquidnet, Inc., to Brent J. Fields, Secretary, Commission, dated February 26, 2016 (''Liquidnet Letter''), at 3.

[66] *See, e.g.,* Letter from Kurt N. Schacht, Managing Director, Standards & Advocacy, CFA Institute, and James C. Allen, Head, Capital Markets Policy, CFA Institute, to Brent J. Fields, Secretary, Commission, dated February 26, 2016, at 3–4 (stating that there is not a compelling case that public disclosure of relatively fundamental organizational structure would harm trading venues and should, therefore, be hidden from market participants); Letter from Micah Hauptman, Financial Services Counsel, Consumer Federation of America, to Brent J. Fields, Secretary, Commission, dated February 26, 2016, at Section II.A (stating that requiring all ATSs to publicly disclose their Form ATS–N should foster greater competition for order flow among ATSs on terms that are beneficial to investors); Better Markets Letter, *supra* note 64, at 8 (stating that all investors in securities deserve equally robust protections against conflicts of interest and assurances of access to transparent information relating to their trading venues, and that all trading venues should be able to conduct their businesses on a level regulatory playing field regardless of the types of securities trading they seek to offer to investors); Letter from Dave Lauer, Chairman, Healthy Markets Association, to Brent J. Fields, Secretary, Commission, dated February 26, 2016 (''HMA Letter''), at 5–6 (stating that while market characteristics across asset classes are different and such differences may render information that is extremely material for one asset class irrelevant to trading in another asset class, those circumstances are generally rare); Citadel Letter, *supra* note 65, at 4; and Letter from Stuart J. Kaswell, Executive Vice President, Managing Director, and General Counsel, Managed Funds Association, and Jiří Król, Deputy Chief Executive Officer, Global Head of Government Affairs, Alternative Investment Management Association, to Brent J. Fields, Secretary, Commission, dated February 26, 2016 (''MFA/AIMA Letter''), at 2–4.

[67] *See* Letter from John A. McCarthy, General Counsel, KCG Holdings, Inc., to Brent J. Fields, Secretary, Commission, dated March 15, 2016 (''KCG Letter''), at 13. *See also* Liquidnet Letter, *supra* note 65, at 3 (stating that the enhanced transparency requirements should be limited to the trading of equity securities). This commenter, however, did not object to the requirements of Regulation ATS applying to ATSs that cross trades in government securities. *See id.*

[68] *See* SIFMA Letter, *supra* note 64, at 35–36. This commenter, however, generally supported increased transparency for Government Securities ATSs, although it stated that disclosure to give effect to this goal should be tailored to the unique characteristics of the government securities market, and that it would support making current Form ATS for Government Securities ATSs publicly available as an interim step. *Id.* at 36. Another commenter stated that the disclosure required by Form ATS–N might not be appropriate for securities other than NMS stocks at this time in their development, and recommended that the Commission carefully study these other markets before proceeding with an enhanced disclosure regime for ATSs that offer trading exclusively in non-NMS stocks. *See* ICI Letter, *supra* note 64, at 11. However, this commenter did not explicitly comment on Government Securities ATSs, or whether ATSs that currently transact solely in government securities should or should not be required to comply with the Regulation ATS requirements or be subject to any transparency requirements at this time. *Id.*

[69] *See* SIFMA Letter, *supra* note 64, at 35. *See also* October 15 Staff Report, *supra* note 14, at 47 (stating that the authors of the report, among other items, support a review of the current regulatory requirements applicable to the government securities market and its participants).

[70] *See supra* note 64.

[71] *See* Citadel Letter, *supra* note 65, at 4.

[72] *See id.*

regarding subscriber segmentation, potential conflicts of interest, order types, and fees.[73]

Another commenter stated that many of the concerns surrounding potential conflicts of interest that arise between an ATS and the activities of its broker-dealer operator and affiliates are equally relevant with respect to Government Securities ATSs as with NMS Stock ATSs.[74] This commenter stated that there is little information available to investors and the public about Government Securities ATSs and that Form ATS–N-like disclosures for these ATSs could greatly enhance public transparency of these markets.[75] Another commenter stated that making the Form ATS public for Government Securities ATSs would enhance transparency and provide important disclosures to market participants and the public about increasingly important venues of cash trading in government securities.[76] In addition, of the commenters who stated that Government Securities ATSs should be subject to similar obligations as NMS Stock ATSs,[77] one commenter specifically asserted that Government Securities ATSs should be subject to the Fair Access Rule to prevent them from arbitrarily excluding specific market participants.[78] This commenter stated that these requirements would not only promote market safety, stability, and integrity, but would also improve conditions for investors through increased transparency, more competition, better pricing, and new sources of orders and trading interest.[79] Moreover, this commenter supported a comprehensive review of the current regulatory framework for electronic trading platforms for government securities in an effort to improve market transparency, fairness, and resiliency. This commenter stated that requiring electronic trading platforms for government securities to comply with the systems compliance and integrity standards in Regulation SCI, among other things, would promote a transparent, efficient, and resilient market.[80]

II. Proposed Amendments to Regulation ATS for Government Securities ATSs

The Commission recognizes that Form ATS and the requirements of Regulation ATS were designed before Government Securities ATSs operated as electronic platforms with the automation, speed, and complexity that they do today, and that market conditions for government securities have substantially changed since the adoption of Regulation ATS in 1998. The Commission has carefully considered prior comments it received relating to Government Securities ATSs, the significant role of Government Securities ATSs in today's government securities market structure, and the complexity of Government Securities ATS operations, and is proposing the amendments described below.[81]

A. Proposed Amendment to Exchange Act Rule 3a1–1(b)

The Commission is proposing to amend the existing classes of securities set forth in Exchange Act Rule 3a1–1(b)(3)[82] to add U.S. Treasury Securities and Agency Securities for which transactions are reported to an SRO.[83] As a result of the proposed change, the Commission could require a Government Securities ATS, which otherwise meets the conditions to the Rule 3a1–1(a) exemption,[84] to register as a national securities exchange if the ATS meets specified volume levels in U.S. Treasury Securities or Agency Securities[85] and the Commission finds that the exemption would not be necessary or appropriate in the public interest or consistent with the protection of investors.[86]

The Commission would provide a Government Securities ATS with notice and an opportunity to respond before determining the exemption from national securities exchange registration is not necessary or appropriate in the public interest or consistent with the protection of investors. The Commission would take into account the requirements for exchange registration under Section 6 of the Exchange Act and the objectives of the national market system. This amendment would extend the existing provision under Rule 3a1–1(b) applicable to ATSs that trade NMS stocks, corporate debt, municipal securities, and OTC equity securities to ATSs that trade U.S. Treasury Securities or Agency Securities and enhance the Commission's ability to regulate certain large volume ATSs whose registration as a national securities exchange, and the associated increased obligations that arise therefrom, may be in the public interest.

Request for Comment

1. Should the Commission amend Exchange Act Rule 3a1–1(b) to add U.S. Treasury Securities and Agency Securities to the list of existing classes of securities set forth in Rule 3a1–1(b)(3)?

B. Proposed Definitions for Government Securities ATSs Rules

The Commission is proposing to amend Rule 300 of Regulation ATS to define ''Government Securities ATS'' to mean an alternative trading system, as defined in Rule 300(a), that trades government securities, as defined in section 3(a)(42) of the Exchange Act (15 U.S.C. 78c(a)(42)),[87] or repurchase and reverse repurchase agreements on government securities.[88] To meet the definition of a Government Securities ATS, the organization, association, person, group of persons, or system must meet the definition of an alternative trading system under Rule 300(a) of Regulation ATS.[89] The Commission is also proposing that a Government Securities ATS shall not trade securities other than government securities or repos[90] and that trading of securities other than government securities or repos would require the separate filing of either a Form ATS or a Form ATS–N, depending on the types of securities traded.[91] This amendment would not, however, impose new compliance requirements on such ATSs other than complying with Rule 304 and

[73] *See id.*

[74] *See* MFA/AIMA Letter, *supra* note 66, at 3.

[75] *See id.* This commenter also stated that at a minimum, a trading venue should clearly disclose the manner of its operations. *See id.* at 4.

[76] *See* OIA Letter, *supra* note 65, at 19.

[77] *See supra* note 64.

[78] *See* Citadel Letter, *supra* note 65, at 4. This commenter also stated that government securities trading venues that do not currently meet the definition of ATS, such as trading venues that use request for quote systems, should be subject to equivalent regulation as well. *Id.* at 5.

[79] *See id.* at 4.

[80] *See id.*

[81] *See infra* Sections II.A–H and III.

[82] 17 CFR 240.3a1–1(b).

[83] The Commission is proposing to specify that Rule 3a1–1(b) would apply to U.S. Treasury Securities and Agency Securities for which transactions are reported to an SRO to allow the Commission and market participants to calculate the volume level threshold provided under the rule.

[84] *See supra* note 40 and accompanying text.

[85] The volume thresholds are met if during three of the preceding four calendar quarters, the ATS had (i) fifty percent or more of the average daily dollar trading volume in any security and five percent or more of the average daily dollar trading volume in any class of securities; or (ii) forty percent or more of the average daily dollar trading volume in any class of securities. *See* 17 CFR 240.3a1–1(b)(1).

[86] *See* 17 CFR 240.3a1–1(b)(2).

[87] The definition of government security in section 3(a)(42) of the Exchange Act encompasses ''any put, call, straddle, option, or privilege'' on any government security listed in subsections (A)–(C) of the definition, other than any put, call, straddle, option or privilege that is traded on one or more national securities exchanges, or for which quotations are disseminated through an automated quotation system operated by a registered securities association. 15 U.S.C. 78c(a)(42)(D).

[88] *See* proposed Rule 300(l).

[89] 17 CFR 242.300(a). *See* Regulation ATS Adopting Release, *supra* note 35, at 70851–52.

[90] *See* proposed Rule 300(l).

[91] An ATS that does not trade NMS stocks or government securities, as proposed, must file Form ATS.

filing Form ATS–G.[92] Under the proposal, if a registered broker-dealer or government securities broker or government securities dealer that operates the ATS (''broker-dealer operator'') that currently operates an ATS for government securities and non-government securities such as, for example, corporate bonds, the broker-dealer operator would operate two separate ATSs: (1) A Government Securities ATS that would trade government securities, which would be subject to Rule 304, and file disclosures on proposed Form ATS–G and (2) a non-Government Securities ATS that would trade corporate bonds, which would not be subject to Rule 304, and file disclosures on its existing Form ATS, as amended to remove references to government securities. To provide that the same approach applies to broker-dealers that operate NMS Stock ATSs and non-NMS Stock ATSs, and to clarify requirements applicable to NMS Stock ATSs, the Commission is proposing to amend the definition of ''NMS Stock ATS'' to state that an NMS Stock ATS shall not trade securities other than NMS stocks.[93] Today, securities other than NMS stocks are not traded in any NMS Stock ATS and the proposed amendment to the definition of NMS Stock ATS would have no impact on any existing ATS nor on the requirements applicable to existing NMS Stock ATSs.[94]

The Commission is also proposing to amend Rule 300 of Regulation ATS to define the terms ''Covered ATS'' and ''Covered Form.''[95] The proposed terms would be used throughout Rule 304 because Government Securities ATSs, in addition to NMS Stock ATSs, would be subject to Rule 304 of Regulation ATS.[96] ''Covered ATS'' would mean an NMS Stock ATS or Government Securities ATS and ''Covered Form'' would mean a filing on Form ATS–N or Form ATS–G, as applicable. To facilitate the orderly transition to the heightened requirements for Government Securities ATSs that are currently operating, the Commission is defining such ATSs as ''Legacy Government Securities ATSs.''[97] The Commission believes these proposed definitions are non-substantive and enhance the readability of the rule text.

The Commission is also proposing to add definitions of ''U.S. Treasury Security'' and ''Agency Security'' for purposes of Regulation ATS.[98] ''U.S. Treasury Security'' would mean a security issued by the U.S. Department of the Treasury. ''Agency Security'' would mean a debt security issued or guaranteed by a U.S. executive agency, as defined in 5 U.S.C. 105, or government-sponsored enterprise, as defined in 2 U.S.C. 622(8). The proposed definitions are designed to provide the scope of securities a Government Securities ATS must include when calculating whether the fair access requirements set forth in Rule 301(b)(5) are applicable and to facilitate compliance with the Fair Access Rule.[99] In addition, the Commission is proposing to use these definitions in the proposed amendment to Exchange Act Rule 3a1–1(b)(3) to provide the scope of securities for which the Commission could remove the exemption from national securities exchange if certain volume thresholds are met.[100]

Request for Comment

2. Should the Commission adopt a more limited or expansive definition of Government Securities ATS than the definition that is being proposed?

3. Should the Commission cite to the section 3(a)(42) (15 U.S.C. 78c(a)(42)) definition of government securities for purposes of defining Government Securities ATS? Should the securities encompassed by the definition (*e.g.,* certain options on government securities) be considered ''government securities'' for purposes of this regulation?

4. Should the Commission modify the proposed definitions of U.S. Treasury Securities and Agency Securities in any way?

5. The proposed amendments to the definitions of NMS Stock ATS and Government Securities ATS are not designed to limit a broker-dealer operator for an NMS Stock ATS or Government Securities ATS with respect to other types of securities that the broker-dealer operator may wish to trade in an ATS that is subject to Rule 301(b)(2) of Regulation ATS or how the broker-dealer operator may elect to structure the operations of its ATS businesses. Would the proposed amendments to the definitions of NMS Stock ATS and Government Securities ATS impose any operational or other burdens on the broker-dealer operator, other than those related to filing Form ATS, Form ATS–R, Form ATS–G or Form ATS–N, as applicable?

C. Proposed Elimination of the Exemption for ATSs That Limit Securities Activities to Government Securities and Repos

The Commission is proposing amendments to Regulation ATS that would require a Currently Exempted Government Securities ATS that seeks to operate pursuant to the exemption from the definition of an ''exchange'' under Exchange Act Rule 3a1–1(a)(2), and thus not be required to be registered as a national securities exchange, to comply with Regulation ATS. A Currently Exempted Government Securities ATS that opts to comply with Regulation ATS would then be subject to the conditions to the exemption from exchange registration that are designed to provide its subscribers with investor protections and enable Commission oversight, including the surveillance and examination of ATSs, and to help assure fair and orderly markets.[101] The Commission is also proposing to subject Currently Exempted Government Securities ATSs to the enhanced public transparency requirements of Rule 304 and Form ATS–G.

At present, Exchange Act Rule 3a1–1(a)(3) and Rule 301(a)(4) of Regulation ATS exempt from the definition of an ''exchange'' under Section 3(a)(1) of the Exchange Act an ATS that is operated by a registered broker-dealer or a bank that solely trades government securities or repos.[102] The Commission is proposing to amend Regulation ATS to eliminate the exemption under Rule

[92] Broker-dealers that operate Government Securities ATSs that are currently subject to Regulation ATS already must have established written safeguards and written procedures to protect subscribers' confidential trading information, pursuant to Rule 301(b)(10), and already must make and keep records pursuant to Rule 301(b)(8) that are tailored to the types of securities the ATS trades and the subscribers that trade those securities on the ATS. The Commission believes the proposal is broadly consistent with the manner in which broker-dealers that operate NMS Stock ATSs and non-NMS Stock ATSs currently comply with Regulation ATS. For further discussion, *see infra* Section II.E.

[93] *See* proposed Rule 300(k).

[94] Broker-dealer operators of NMS Stock ATSs are currently required to file a Form ATS–N for NMS Stock ATS operations and a separate Form ATS for any non-NMS Stock ATS operations. *See* current Rule 301(b)(2)(viii). This would not change under this proposal.

[95] *See* proposed Rule 300(m)–(n).

[96] *See infra* Section II.F–H.

[97] *See* proposed Rule 300(o). Legacy Government Securities ATSs would include all Government Securities ATSs operating as of [the date 120 calendar days after the date of publication of the final rule in the **Federal Register**] (''Compliance Date''), including both (1) Currently Exempted Government Securities ATSs and (2) Government Securities ATSs operating pursuant to a Form ATS on file with Commission as of the Compliance Date.

[98] *See* proposed Rule 300(p)–(q).

[99] *See infra* Section II.D. The proposed definitions are similar to those in FINRA's rules. *See* FINRA Rule 6710(l) and FINRA Rule 6710(p).

[100] *See supra* Section II.A.

[101] *See* Regulation ATS Adopting Release, *supra* note 35, at 70878. *See also infra* notes 121–131 and accompanying text.

[102] *See* 17 CFR 240.3a1–1(a)(3) and 17 CFR 242.301(a)(4).

301(a)(4) of Regulation ATS for ATSs that solely trade government securities and repos. As a result of this proposed amendment, any system that meets the definition of an ''exchange'' under Section 3(a)(1) of the Exchange Act and Rule 3b–16(a) thereunder and solely trades government securities or repos would no longer be exempt from the definition of an ''exchange'' and would either have to register as a national securities exchange or operate pursuant to an exemption to such registration, such as the exemption under Regulation ATS.[103]

The Commission is also proposing to amend Rule 301(b)(1) of Regulation ATS, which currently requires an ATS to register as a broker-dealer under Section 15 of the Exchange Act,[104] to allow an ATS to register either as a broker-dealer under Exchange Act Section 15 or a government securities broker or government securities dealer under Exchange Act Section 15C(a)(1)(A).[105] Registration pursuant to Section 15C(a)(1)(A) specifically applies to government securities brokers and dealers other than registered broker-dealers or financial institutions.[106] Registration as a broker-dealer under Section 15 or government securities broker or government securities dealer under Section 15C(a)(1)(A) of the Exchange Act is important because, among other things, it requires membership in an SRO, such as FINRA.[107] Because ATSs that register as broker-dealers or government securities brokers or dealers do not have self-regulatory responsibilities, the Commission believes it is important for these ATSs to be members of an SRO and thus subject to SRO examination and surveillance,[108] trade reporting obligations,[109] and certain investor protection rules.[110] Like ATSs registered as broker-dealers under Section 15, an ATS registered as a government securities broker or government securities dealer under Section 15C(a)(1)(A) would be subject to oversight and surveillance by an SRO.[111]

In contrast, SRO membership is not required for a bank or other financial institution that registers as a government securities broker or dealer.[112] Accordingly, the amendment to Regulation ATS would not permit a bank or other financial institution to satisfy the broker-dealer registration requirement by registering as a government securities broker or government securities dealer under Section 15C(a)(1)(B) of the Exchange Act.[113] The Commission believes it is important for an ATS to be a member of an SRO, and unlike registrants under Sections 15 and 15C(a)(1)(A), a bank or other financial institution that registers under Section 15C(a)(1)(B) is not required to be a member of an SRO.[114]

As a result, a bank-operated ATS that trades only government securities or repos would be unable to rely on the exemption provided by Regulation ATS, as proposed to be amended, and could not otherwise operate unless registered as a national securities exchange pursuant to Section 5 of the Exchange Act. However, this is the case currently with respect to bank-operated ATSs that trade securities other than government securities, and it is the Commission's understanding that these ATSs often are operated by bank affiliates that are themselves registered broker-dealers, rather than by the banks themselves. The Commission believes that a bank that operates an ATS that trades only government securities might adopt a similar registered affiliate structure for its government securities operations. The Commission is requesting comment, however, on whether it should amend Rule 301(b)(1) to make the Regulation ATS exemption available to entities registered under Section 15C(a)(1)(B), and whether some transition period is required if a bank decides to restructure the operation of its Government Securities ATS. Eliminating the exemption from the definition of ''exchange'' for broker-dealers and banks that operate an ATS for solely government securities or repos would bring these markets within the Commission's regulatory framework for exchanges and, as discussed in more detail above, enhance regulatory oversight, protect investors, and help ensure fair and orderly markets for government securities and repos.[115] Additionally, this proposal seeks to bring greater transparency to a very important market, and removing the exemption under Rule 301(a)(4) of

[103] The Commission is proposing to delete the text of Rule 301(a)(4)(ii)(A)–(C) and replace each paragraph with the term ''Reserved.'' The Commission is not proposing to eliminate Rule 301(a)(4)(ii)(D), which exempts an ATS from compliance with Regulation ATS if the ATS limits its securities activities to commercial paper. Accordingly, the only ATSs that would continue to be exempt under Rule 301(a)(4) would be ATSs that are registered broker-dealers or are banks and limit their securities activities to commercial paper.

[104] 15 U.S.C. 78o.

[105] *See* 15 U.S.C. 78o–5. Exchange Act Section 15C(a)(1)(A) makes it unlawful for a government securities broker or government securities dealer (other than a registered broker or dealer or a financial institution) to make use of the mails or any means or instrumentality of interstate commerce to effect a transaction in any government securities unless the government securities broker or government securities dealer is registered with Commission pursuant to Exchange Act Section 15C(a)(2). *See* 15 U.S.C. 78o–5(a)(1)(A). Section 15C(e) in turn generally requires that a government securities broker or government securities dealer that is registered or required to be registered under Section 15C(a)(1)(A) must be a member of a registered national securities exchange or registered securities association such as FINRA.

[106] Broker-dealers that limit their activity to government securities require specialized registration under Section 15C of the Exchange Act and do not have to register as general-purpose broker-dealers under Section 15(b). *See* 15 U.S.C. 78o–5.

[107] *See* Regulation ATS Adopting Release, *supra* note 35, at 70863 (discussing the importance of an ATS being a member of an SRO because ATSs registered as broker-dealers will not have self-regulatory responsibilities). As noted above, Section 15C(e) generally requires SRO membership for a government securities broker or government securities dealer that is registered or required to be registered under Section 15C(a)(1)(A). Similarly, Section 15(b)(8) generally requires a registered broker-dealer to be a member of a registered securities association such as FINRA.

[108] *See, e.g.,* FINRA Rule 1000 Series, FINRA Rules 4140, 4510, 4520, 4530, and 8210.

[109] *See, e.g.,* FINRA Rule 6730.

[110] *See, e.g.,* FINRA Rules 3110, 4370, 5210, 5220, 5230, 5310, and 5340.

[111] *See* Regulation ATS Adopting Release, *supra* note 35, at 70863.

[112] As proposed, Currently Exempted Government Securities ATSs that are operated by banks would be required to structure their business to either comply with Regulation ATS or register as a national securities exchange. For example, to comply with Regulation ATS, the Government Securities ATS might move its ATS operations into a new or existing broker-dealer affiliate of the bank. Unlike registered broker-dealers (Section 15(b)(8)) and government securities brokers or government securities dealers that are registered or required to be registered under Section 15C(a)(1)(A) (Section 15C(e)), there is no statutory requirement of SRO membership for banks. Because banks typically operate in reliance on exceptions from broker or dealer status, they are not required to become a member of an SRO, such as FINRA. In this regard, Exchange Act Section 3(a)(4)(B)(iii)(II) excludes from the definition of ''broker'' a bank that effects transactions in ''exempted securities'' such as government securities. 15 U.S.C. 78c(a)(4)(B)(iii)(II). *See* Exchange Act Section 3(a)(12) (defining ''exempted securities'' to include ''government securities' as defined in Section 3(a)(42) of the Exchange Act). Exchange Act Section 3(a)(5)(C)(i)(II) similarly excepts from the definition of ''dealer'' a bank that buys or sells exempted securities. 15 U.S.C. 78c(a)(5)(C)(i)(II).

[113] Exchange Act Section 15C(a)(1)(B) makes it unlawful for any government securities broker or government securities dealer that is a registered broker or dealer or a financial institution to make use of the mails or any means or instrumentality of interstate commerce to effect any transaction in, or to induce or attempt to induce the purchase or sale of, any government security unless such government securities broker or government securities dealer has filed with the appropriate regulatory agency written notice that it is a government securities broker or government securities dealer. 15 U.S.C. 78o–5(a)(1)(B)(i).

[114] *See* Exchange Act Sections 3(a)(6) (defining ''bank'') and 3(a)(46) (defining ''financial institution'').

[115] *See supra* text accompanying note 101 (describing that the proposed amendments would provide better Commission oversight of and public transparency over Currently Exempted Government Securities ATSs).

Regulation ATS would accomplish this goal.

In addition to Rule 301(b)(1) of Regulation ATS, with which most Currently Exempted Government Securities ATSs currently comply,[116] a Currently Exempted Government Securities ATS would be required to comply with the conditions of the Regulation ATS exemption, as proposed to be amended. This includes Rule 304, which would require that Government Securities ATSs file Form ATS–G. Government Securities ATSs would not, however, be subject to the order display and execution access provisions under Rule 301(b)(3) or the fees provision of Rule 301(b)(4) that are applicable only to NMS Stock ATSs.[117] As discussed further below, the Commission is proposing to require Government Securities ATSs that meet a certain volume threshold to comply with the Fair Access Rule with respect to trading in U.S. Treasury Securities and Agency Securities.[118] Because the Commission is proposing to apply Regulation SCI to certain Government Securities ATSs that trade U.S. Treasury Securities and/or Agency Securities, the Capacity, Integrity, and Security Rule under Rule 301(b)(6) would not apply to the trading of government securities on ATSs.[119]

The Commission believes that it is important to apply these conditions to the exemption to Currently Exempted Government Securities ATSs because the conditions are designed to protect investors and to facilitate Commission oversight. Therefore, the Commission is proposing that a Currently Exempted Government Securities ATS must:

- Permit the examination and inspection of its premises, systems, and records, and cooperate with the examination, inspection, or investigation of subscribers, whether such examination is being conducted by the Commission or by an SRO of which such subscriber is a member, pursuant to Rule 301(b)(7).[120] The Commission believes that because subscribers to whom the Commission's inspection authority does not extend could use a Currently Exempted Government Securities ATS to manipulate the market in a security, it is important that these ATSs cooperate in all inspections, examinations, and investigations.[121]
- Make and keep certain records specified in Rule 302 [122] and preserve records specified in Rule 303,[123] pursuant to Rule 301(b)(8).[124] The recordkeeping requirements would require the Currently Exempted Government Securities ATSs to create a meaningful audit trail and allow the Commission to examine whether the ATS is in compliance with federal securities laws.[125]
- Periodically report certain information about transactions on the ATS and information about certain activities on Form ATS–R within 30 calendar days after the end of each calendar quarter in which the market has operated pursuant to Rule 301(b)(9).[126] The information reported on Form ATS–R by Currently Exempted Government Securities ATSs will permit the Commission to monitor the trading on these ATSs for compliance with the Exchange Act and applicable rules thereunder and enforce the Fair Access Rule.[127]
- Adopt written safeguards and written procedures to protect confidential trading information and to separate ATS functions from other broker-dealer functions, including principal and customer trading pursuant to Rule 301(b)(10).[128] The Commission believes that applying the requirements of Rule 301(b)(10) to Currently Exempted Government Securities ATSs will help prevent the potential for abuse of subscriber confidential trading information.[129]
- Not use in its name the word ''exchange,'' or any derivation of the word ''exchange'' pursuant to Rule 301(b)(11).[130] The Commission believes that the use of the word ''exchange'' by an ATS, including a Currently Exempted Government Securities ATS, would be deceptive and could lead investors to believe incorrectly that such ATS is registered as a national securities exchange.[131]

Request for Comment

6. Should the Commission amend Regulation ATS to eliminate the exemption from compliance with Regulation ATS under Rule 301(a)(4)(ii)(A) for all Currently Exempted Government Securities ATS, including those operated by banks?

7. Should the proposed elimination of the exemption from compliance with Regulation ATS only apply to Government Securities ATSs that trade a certain type of government security (*e.g.,* only U.S. Treasury Securities or only Agency Securities)? Should the proposed elimination of the exemption from compliance with Regulation ATS only apply to Government Securities ATSs that trade government securities (and not repos)? If so, for which type of Government Securities ATS should the exemption be eliminated?

8. Should Government Securities ATSs seeking to operate pursuant to the exemption provided by Regulation ATS have the alternative option to satisfy broker-dealer registration with the

[116] *See supra* text accompanying note 49 (stating that most Currently Exempted Government Securities ATSs register as broker-dealers with the Commission).

[117] *See* 17 CFR 242.301(b)(3)–(4).

[118] *See infra* Section II.D.

[119] *See infra* Section VI.

[120] *See* 17 CFR 242.301(b)(7). *See also* Regulation ATS Adopting Release, *supra* note 35, Section IV.A.2.f.

[121] *See* Regulation ATS Adopting Release, *supra* note 35, at 70877.

[122] Rule 302 requires all ATSs to make and keep current certain records, including: A record of subscribers to the ATS; daily summaries of trading in the ATS; and time-sequenced records of order information in the ATS. *See* 17 CFR 242.302.

[123] Rule 303, and specifically Rule 303(a)(1), requires an ATS to preserve: All records required to be made pursuant to Rule 302; all notices provided to subscribers, including notices addressing hours of operations, system malfunctions, changes to system procedures, and instructions pertaining to access to the ATS; documents made or received in the course of complying with the Capacity, Integrity, and Security Rule in Rule 301(b)(6), if applicable; and, if the ATS is subject to the Fair Access Rule under Rule 301(b)(5), a record of its access standards. Rule 303(a)(2) requires that certain other records must be kept for the life of the ATS and any successor enterprise, including partnership articles or articles of incorporation (as applicable), and copies of reports filed pursuant to Rule 301(b)(2), which includes current Form ATS, and records made pursuant to Rule 301(b)(5). In particular, reports required to be maintained for the life of the ATS or any successor enterprise include initial operation reports, amendments, and cessation of operations reports, filed on Form ATS.

[124] *See* 17 CFR 242.301(b)(8). *See also* Regulation ATS Adopting Release, *supra* note 35, Section IV.A.2.g.

[125] *See* Regulation ATS Adopting Release, *supra* note 35, at 70878.

[126] *See* 17 CFR 242.301(b)(9). *See also infra* Section II.E; Regulation ATS Adopting Release, *supra* note 35, Section IV.A.2.h (Rule 301(b)(9)). Form ATS–R requires the ATS to report, among other things, the aggregate quarterly volume data for specified categories of securities, a list of all securities traded on the ATS during the quarter, and a list of all subscribers that were participants during the quarter. In addition, Form ATS–R requires an ATS that is subject to the fair access obligations under Rule 301(b)(5) of Regulation ATS to report a list of all persons granted, denied, or limited access to the ATS during the period covered by the Form ATS–R and designate for each person: (a) Whether access was granted, denied, or limited; (b) the date the ATS took such action; (c) the effective date of such action; and (d) the nature of any denial or limitation of access. Rule 301(b)(9) requires an ATS to complete and file Form ATS–R within 10 calendar days after ceasing to operate. *See* Form ATS–R.

[127] *See* Regulation ATS Adopting Release, *supra* note 35, at 70874 and 70878.

[128] *See* 17 CFR 242.301(b)(10); NMS Stock ATS Adopting Release, *supra* note 1, Section VI.

[129] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38864.

[130] *See* 17 CFR 242.301(b)(11); Regulation ATS Adopting Release, *supra* note 35, Section II.C.

[131] *See* Securities Exchange Act Release No. 39884 (April 17, 1998), 63 FR 23504, 23523 (April 29, 1998) (''Regulation ATS Proposing Release'').

Commission pursuant to Section 15C(a)(1)(A)?

9. Should the Commission adopt any alternatives to requiring Government Securities ATSs to register with the Commission as broker-dealers under Section 15 or Section 15C(a)(1)(A)? For example, should the Commission amend Rule 301(b)(1) of Regulation ATS to include an alternative for a bank to register as a government securities broker or dealer pursuant to Section 15C(a)(1)(B), which would not require the bank to become a member of an SRO?

10. Should there be a transition period for Currently Exempted Government Securities ATSs that are currently operated by banks to comply with the proposed amendments to Rule 301(b)(1), including ATSs provided and operated by an affiliate of the bank? If so, how long should the transition period be?

11. Should there be a transition period for Currently Exempted Government Securities ATSs to comply with all or some of the requirements of Regulation ATS? If so, which requirements would require such a transition period, and how long should such transition period be?

12. Should the Commission amend Regulation ATS to remove the exemption from Regulation ATS for ATSs that limit their securities activities to commercial paper? Do market participants use ATSs to trade commercial paper? If so, how is commercial paper traded on an ATS? Should the Commission remove any other exemption from Regulation ATS available under Rule 301?

13. Should the Commission require Currently Exempted Government Securities ATSs to comply with all of the requirements of Regulation ATS applicable to all ATSs that are currently required to comply with Regulation ATS? If not, which requirements should a Currently Exempted Government Securities ATS not be required to comply with and why?

D. Application of Fair Access to Government Securities ATSs

The Commission believes that the proposal to amend Regulation ATS to include U.S. Treasury Securities and Agency Securities as categories of securities under the Fair Access Rule would promote fair and orderly markets given the importance of Government Securities ATSs. When Regulation ATS was adopted, the Commission explained that the fair treatment by ATSs of potential and current subscribers is particularly important when an ATS captures a large percentage of trading volume in a security, because viable alternatives to trading on such a system are limited.[132] The Commission further explained that if an ATS has a significantly large percentage of the volume of trading in a security or type of security, unfairly discriminatory actions can hurt investors lacking access to that ATS.

Currently, Rule 301(b)(5) only applies to the trading of NMS stocks, equity securities that are not NMS stocks and for which transactions are reported to an SRO, municipal securities, and corporate debt securities, but not to trading in government securities.[133] An ATS subject to the Fair Access Rule must, among other things, establish written standards for granting access to trading on systems and apply these standards fairly, and is prohibited from unreasonably prohibiting or limiting any person with respect to trading in the stated security when that trading exceeds certain volume thresholds.[134] These requirements are designed to ensure that qualified market participants have fair access to the nation's securities markets.

Government Securities ATSs have become a significant source of orders and trading interest in U.S. Treasury Securities and Agency Securities for investors.[135] Regulation ATS, however, does not provide a mechanism to prevent unfair denials or limitations of access by Government Securities ATSs that trade U.S. Treasury Securities or Agency Securities or regulatory oversight of such denials or limitations of access. The Commission believes that today, the principles undergirding the Fair Access Rule are equally relevant to a Government Securities ATS and amending the Fair Access Rule to include the trading of U.S. Treasury Securities and Agency Securities would help ensure the fair treatment of potential and current subscribers to ATSs that consist of a large percentage of trading volume in these two types of securities.[136]

Under the proposed amendments to Rule 301(b)(5), a Government Securities ATS would be subject to the Fair Access Rule if during at least four of the preceding six calendar months, the Government Securities ATS had, (1) with respect to U.S. Treasury Securities, five percent or more of the average weekly dollar volume traded in the United States as provided by the self-regulatory organization to which such transactions are reported, and (2) with respect to Agency Securities, five percent or more of the average daily dollar volume traded in the United States as provided by the self-regulatory organization to which such transactions are reported.[137]

The Commission is proposing five percent volume thresholds for subjecting a Government Securities ATS to the Fair Access Rule. Specifically, a Government Securities ATS would be subject to the Fair Access Rule for its trading of U.S. Treasury Securities if its volume surpasses the five percent threshold for U.S. Treasury Securities. Similarly, a Government Securities ATS would be subject to the Fair Access Rule for its trading in Agency Securities if its volume surpasses the five percent threshold for Agency Securities.[138] When the Commission adopted Rule 301(b)(5), the Fair Access Rule threshold was 20 percent of the average daily trading volume.[139] Currently, the Fair Access Rule applies on a security-by-security basis for NMS stocks and equity securities that are not NMS stocks, and on a category basis for corporate bonds and municipal securities. The original volume threshold was reduced to five percent for all categories of securities when the Commission adopted Regulation NMS, and the Commission proposes to apply

[132] *See* Regulation ATS Adopting Release, *supra* note 35, at 70872.

[133] *See* 17 CFR 242.301(b)(5)(i).

[134] *See supra* Section I.B.

[135] *See infra* Section X.B.1.

[136] Under the proposal, the Fair Access Rule would not apply to Government Securities ATSs that trade repos, including repos on U.S. Treasury Securities and Agency Securities. Based on information available to the Commission, the Commission does not believe that ATSs today capture a significant market share for trading repos or that these markets are as liquid as the markets for securities currently covered by the Fair Access Rule. The Commission also notes FINRA does not require ATSs to report transactions for repos. The Commission is requesting comment on its preliminary assessment and on whether the Commission should amend Regulation ATS to require Government Securities ATSs that trade repos, including repos on U.S. Treasury Securities and Agency Securities, to be subject to the requirements of the Fair Access Rule.

[137] Dollar volume is measured in par value, where par value is the face value or nominal value of a bond. The Commission notes that TRACE Security Activity Report and TRACE Fact Book report volume in the same unit, ''par value volume'' or ''par value traded.'' *See* FINRA Rule 7730(g)(7). *See also* FINRA, TRACE Fact Book, *available at https://www.finra.org/filing-reporting/trace/trace-fact-book.*

[138] As such, a Government Securities ATS with high trading volume in U.S. Treasury Securities and low trading volume in Agency Securities might only be subject to the Fair Access Rule for U.S. Treasury Securities. Likewise, a Government Securities ATS with high Agency Securities trading volume and low U.S. Treasury Securities trading volume might only be subject to the Fair Access Rule for Agency Securities. A Government Securities ATS that surpasses each of the two thresholds would be subject to the Fair Access Rule for U.S. Treasury Securities and Agency Securities.

[139] *See* Regulation ATS Adopting Release, *supra* note 35, at 70873.

five percent volume thresholds for the trading of U.S. Treasury Securities and Agency Securities.[140]

The proposed thresholds include only such securities for which transactions are reported to an SRO. FINRA publishes weekly aggregate data on U.S. Treasury Securities based on the mandatory transaction reports of its members to TRACE, and disseminates transactions data about Agency Securities immediately upon receipt of a transaction report.[141] Because weekly dollar volume data about transactions in U.S. Treasury Securities and daily dollar volume data about transactions in Agency Securities are publicly available via TRACE, Government Securities ATSs will be able to readily calculate whether they meet the applicable thresholds.

The Commission believes that separate volume thresholds for U.S. Treasury Securities and Agency Securities would advance the investor protection goals of the Fair Access Rule. U.S. Treasury Securities and Agency Securities make up the vast amount of government securities traded on ATSs today, and also constitute different sources of potential orders and trading interest for market participants.[142] The proposed volume thresholds would help ensure that the Fair Access Rule applies to the category of security for which an ATS has significant trading volume. If a Government Securities ATS has significant trading volume in U.S. Treasury Securities but not Agency Securities, for example, the proposed rule would help ensure that investors are provided fair access to the ATS's services with respect to U.S. Treasury Securities, even if the ATS's combined trading volume in both U.S. Treasury Securities and Agency Securities would not exceed a five percent volume threshold. The Commission believes that it would be unnecessary and overly burdensome to require a Government Securities ATS to comply with the Fair Access Rule for a category of government security for which that ATS does not have significant volume. Additionally, given that U.S. Treasury Securities and Agency Securities are types of debt securities, the Commission believes that it is appropriate to determine these five percent volume thresholds on a category basis because doing so would be consistent with the Fair Access Rule's application to other categories of fixed income securities (*i.e.,* corporate bonds and municipal securities).

The Commission believes that the proposed five percent volume threshold test is consistent with the Commission's current threshold for identifying significant markets for purposes of the Fair Access Rule and is appropriate for determining whether a Government Securities ATS should be subject to the Fair Access Rule for trading in the categories of U.S. Treasury Securities and Agency Securities. Currently, the Commission estimates that three ATSs trading U.S. Treasury Securities and one ATS trading Agency Securities would be subject to the Fair Access Rule under the proposed five percent volume thresholds.[143] The ATS with the largest market volume in U.S. Treasury Securities has approximately 24 percent of market volume, while the second and third largest are both slightly above five percent market share. The one ATS that would exceed the proposed threshold for Agency Securities accounts for roughly 13 percent of volume in Agency Securities. If the Commission were to propose a four percent volume threshold, the number of ATSs that would be subject to the Fair Access Rule for U.S. Treasury Securities and Agency Securities would not change, but if the Commission proposed a three percent volume threshold test, the Commission estimates a total of four ATSs would be subject to the Fair Access Rule for U.S. Treasury Securities and the number of ATSs subject to the Fair Access Rule for Agency Securities would remain at one.[144]

If the proposed volume thresholds were 10 percent, however, only one ATS trading U.S. Treasury Securities and one ATS trading Agency Securities would be subject to the Fair Access Rule.[145] The Commission believes that the proposed five percent volume thresholds—in addition to being consistent with the current volume threshold for categories of debt securities under the Fair Access Rule—are appropriately designed to capture those ATSs that are significant liquidity venues for U.S. Treasury Securities or Agency Securities. That said, as further specified below, the Commission is requesting comment on whether these proposed volume thresholds should be set higher or lower for ATSs trading government securities.

The proposed fair access volume threshold for U.S. Treasury Securities would have a different data benchmark than that for Agency Securities. The former would be based on average weekly dollar volume traded, and the latter would be based on average daily volume traded. This proposed difference is because FINRA only provides weekly aggregated transaction information on U.S. Treasury Securities but provides individual trade reports for Agency Securities transactions. Currently, FINRA neither provides individual trade reports nor aggregate daily volume data for U.S. Treasury Securities transactions to TRACE subscribers (or to the public). Thus, Government Securities ATSs will only have weekly-volume data upon which to make fair access determinations for U.S. Treasury Securities. FINRA, however, provides individual trade reports for all Agency Securities transactions to TRACE subscribers, and therefore,[146] Government Securities ATSs will be able determine the average daily trading volume for a given month by aggregating these trade reports. Accordingly, the Commission proposes an average daily volume threshold for Agency Securities, which is consistent with the current volume thresholds in 301(b)(5).[147]

Lastly, the Commission is proposing that a Government Securities ATS would only be required to comply with the Fair Access Rule only if it has met at least one of the applicable volume thresholds during at least four of the preceding six calendar months.[148] This is the same time period for evaluating the applicability of the Fair Access Rule to ATSs that trade U.S. Treasury Securities or Agency Securities that is currently applied to ATSs that trade NMS stocks, equity securities that are not NMS stocks and for which transactions are reported to an SRO, municipal securities, and corporate debt securities. Because of the similarity of Government Securities ATSs to the other ATSs, the Commission believes that the range of time is an appropriate

[140] *See* Securities and Exchange Act Release No. 51808 (June 9, 2005) 70 FR 37496, 37550 (June 29, 2005) (File No. S7–10–04).

[141] *See supra* notes 50–51.

[142] *See infra* Section X.B.1. *See also supra* Section I.A.

[143] *See infra* Table X.1.

[144] *See id.*

[145] *See id.*

[146] The Commission believes that the vast majority—and likely, all—broker-dealer operators of Government Securities ATSs that trade Agency Securities currently subscribe to TRACE. The Commission is, however, requesting public comment on the extent to which Government Securities ATSs (both Currently Exempted Government Securities ATSs and those subject to current Regulation ATS) have access to TRACE trade reports for Agency Securities.

[147] *See supra* notes 138–140.

[148] However, if, for example, during the six month period from January to June, the Government Securities ATS met the threshold for U.S. Treasury Securities only during January and April and met the threshold for Agency Securities only during February and May, the Government Securities ATS would not be subject to the Fair Access Rule in July because the ATS would not have met the threshold for either type of security during at least four of the preceding six months in either U.S. Treasury Securities or Agency Securities.

period to evaluate the trading volume of an ATS and strikes an appropriate balance; the threshold will not be triggered by atypical periods of increased trading or a few occurrences of very large trades, but will be timely triggered after an ATS attains a significant role in the market.

Request for Comment

14. Should any other type of government securities be included as a category of securities under Rule 301(b)(5)? Should the Commission apply Rule 301(b)(5) to all Government Securities ATSs? What would be the costs and benefits associated with such a requirement?

15. Should the proposed five percent fair access threshold for U.S. Treasury Securities be applied to all types of U.S. Treasury Securities or only to a subset(s) of U.S. Treasury Securities? For example, should the five percent fair access threshold be applied to transaction volume in only on-the-run U.S. Treasury Securities? Should the five percent fair access threshold should be applied to all Agency Securities or only to a subset(s) of Agency Securities?

16. Should the proposed five percent fair access threshold for U.S. Treasury Securities be set higher or lower than five percent? If so, what should that percentage threshold should be? Should there be no threshold? Please support your views. Is the five percent threshold an appropriate threshold to capture ATSs that are significant markets for trading in U.S. Treasury Securities or Agency Securities? Would the five percent threshold capture ATSs that are not significant markets for U.S. Treasury Securities and Agency Securities? If there should be a percent threshold for a subset of U.S. Treasury Securities, for example on-the-run U.S. Treasury Securities or off-the-run U.S. Treasury Securities, what should that threshold should be?

17. Would the proposed four out of six month period be an appropriate period to measure the volume thresholds for U.S. Treasury Securities, Agency Securities, or both? If not, what period of time would be appropriate?

18. Would it be appropriate to use five percent of average weekly dollar volume traded in the United States as a fair access threshold for U.S. Treasury Securities?

19. If the average weekly dollar volumes were to include transactions for U.S Treasury Securities by non-FINRA members, which currently are not reported to, or collected by, the SRO that makes public average weekly dollar volume statistics, should the fair access threshold change? If so, what should be the appropriate threshold?

20. Would it be appropriate to use five percent of average daily dollar volume traded in the United States as a fair access threshold for Agency Securities? Do ATSs that trade Agency Securities currently subscribe to TRACE and, therefore, receive TRACE trade reports for Agency Securities? If not, what percentage of these ATSs do not currently subscribe to TRACE?

21. Should the requirements under the Fair Access Rule be amended specifically for Government Securities ATS? If so, how?

22. Should the proposed five percent fair access threshold for U.S. Treasury Securities be applied on a security-by-security basis?

23. Should the proposed fair access volume threshold measurement for Government Securities ATSs, and current fair access threshold measurements applicable to ATSs that trade NMS stock, OTC equity securities, corporate bonds, and municipal securities, take into account whether the ATSs are under common control share the same technology platform? A broker-dealer may be the registered broker-dealer for multiple types of ATSs that trade different types of securities (*e.g.,* an NMS Stock ATS and a non-NMS Stock ATS) or a broker-dealer may also be the registered broker-dealer for multiple ATSs that trade the same type of securities but are separate and distinct from each other (*e.g.,* a broker-dealer registered for, and operates, two NMS Stock ATSs that each maintains a separate book of orders that are governed by distinct priority and order interaction rules). In both instances, each of the ATSs operated by the broker-dealer operator is separate from each other and must independently comply with Regulation ATS. Should two or more ATSs under common control and operated by the same broker-dealer be viewed as a single ATS required to aggregate volume of transactions for purposes of determining whether the fair access threshold has been satisfied? If yes, what factors should be considered when determining the fair access threshold test for multiple ATSs operated by the same broker-dealer, and why?

E. Filing Requirements for Broker-Dealers That Operate ATSs That Trade Government Securities and Non-Government Securities

The Commission is proposing to revise Rule 301(b)(2)(viii) [149] of Regulation ATS to provide that a Legacy Government Securities ATS that is operating pursuant to a Form ATS as of the Compliance Date will continue to be subject to the Rule 301(b)(2) requirements to file a Form ATS. However, once the ATS files a Form ATS–G, it will no longer be subject to Rule 301(b)(2)(i) through (vii) and will instead be subject to the reporting requirements under Rule 304, which provides the rules for filing of Form ATS–G. The Commission is also proposing to provide that as of the Compliance Date, an entity seeking to operate as a Government Securities ATS will not be subject to the requirements of Rule 301(b)(2)(i) through (vii) and will instead be required to file reports under Rule 304. In addition, the Commission is proposing rules to make clear that a Currently Exempted Government Securities ATS would be subject to Rule 304 and would not be subject to Rule 301(b)(2)(i) through (viii). Other than changes to refer to Government Securities ATSs, the relevant compliance dates, and the treatment of Currently Exempted Government Securities ATSs, these rules are identical to the existing rules that were applied to Legacy NMS Stock ATSs operating during the Commission review period for Form ATS–N and would avoid Government Securities ATSs from being subject to potentially duplicative requirements in Rule 304 and Rule 301(b)(2).

The Commission is proposing to amend Rule 301(b)(2)(viii) to make clear that NMS Stock ATSs and Government Securities ATSs are required to file reports pursuant to § 242.304 and ATSs that are not NMS Stock ATSs or Government Securities ATSs are subject to Rule 301(b)(2). A broker-dealer may be the registered broker-dealer for multiple types of ATSs that trade different types of securities (*e.g.,* NMS Stock ATS and non-NMS Stock ATS) or a broker-dealer may be the registered broker-dealer for multiple ATSs that trade the same type of securities but are separate and distinct from each other (*e.g.,* a broker-dealer registered for, and

[149] 17 CFR 242.301(b)(2)(viii). Current Rule 301(b)(2)(viii) provides that NMS Stock ATSs must file with the Commission the reports and amendments required by Rule 304 and that NMS Stock ATSs are not subject to Rule 301(b)(2). NMS Stock ATSs or entities seeking to operate as NMS Stock ATSs would continue to file reports pursuant to Rule 304. Because the Commission review period for all Forms ATS–N filed by Legacy NMS Stock ATSs ended in October 2019, the Commission is proposing to delete references in Rule 301(b)(2)(viii) to Legacy NMS Stock ATSs. The Commission is also proposing to consolidate the current provisions of Rule 301(b)(2)(viii) applicable to NMS Stock ATSs to state that NMS Stock ATSs or entities seeking to operate as an NMS Stock ATS shall not be subject to the requirements of Rule 301(b)(2)(i) through (vii) and would be subject to Rule 304.

operates, two NMS Stock ATSs, each of which maintains a separate book of orders that is governed by distinct priority and order interaction rules for one type of security). In both instances, each of the ATSs is separate from the other and must independently comply with Regulation ATS.[150] The Commission is proposing to add to Rule 301(b)(2)(viii) to provide that an NMS Stock ATS or a Government Securities ATS that is operated by a broker-dealer that is the registered broker-dealer for more than one ATS must independently comply with Regulation ATS, including the filing requirements of Rule 304. The Commission believes that the proposed language makes clear that the proposal would not require compliance with the heightened transparency requirements of Regulation ATS for ATSs that are not NMS Stock ATSs or Government Securities ATSs. Under the proposal, a broker-dealer operator, for example, for an ATS that noticed on its initial operation report on Form ATS that the ATS trades government securities and corporate debt securities would be the broker-dealer operator for two types of ATSs that would be separate from each other with regard to trading these securities and independently comply with Regulation ATS. These two types of ATSs would be (1) a Government Securities ATS that would file a Form ATS–G with respect to government securities and (2) a non-Government Securities ATS that would file a Form ATS with respect to corporate debt.[151] In addition, each of the two ATSs would be required to comply with the conditions to Regulation ATS, including, among other things, each adopting written safeguards and written procedures to protect subscriber confidential trading information for the ATS pursuant to Rule 301(b)(10) and each making and keeping records for the ATS pursuant to Rule 301(b)(8).[152]

The Commission also is proposing to amend Rule 301(b)(9) of Regulation ATS.[153] This rule requires an ATS to report transaction volume in various types of securities, including government securities and repos, on Form ATS–R on a quarterly basis and within 10 calendar days after it ceases operation.[154] As discussed above, the Commission is proposing to define ''Government Securities ATS'' and to clarify the definition of ''NMS Stock ATS'' to make clear that a Government Securities ATS cannot trade securities other than government securities or repos and that an NMS Stock ATS cannot trade securities other than NMS stocks.[155] For example, a Government Securities ATS operated by a broker-dealer that is also the registered broker-dealer for a non-Government Securities ATS would be separate from the non-Government Securities ATS and would be required to file a Form ATS–R for the Government Securities ATS. The broker-dealer would be required to file a separate Form ATS–R for the non-Government Securities ATS. The Commission is proposing to amend Rule 301(b)(9) by removing language stating that an ATS must ''separately file'' a Form ATS–R for transactions in NMS stocks and for transactions in securities other than NMS stocks to simplify the text and convey that each ATS, whether operated by a broker-dealer that operates multiple types of ATS, must file a Form ATS–R. This is consistent with the current Form ATS–R filing process for a broker-dealer that operates an NMS Stock ATS and non-NMS Stock ATS.[156]

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24. Should an NMS Stock ATS or Government Securities ATS that is operated by a broker-dealer that is a registered broker-dealer for more than one ATS be subject to Rule 304 independently from any other ATS for which its broker-dealer is registered?

25. Should a broker-dealer that is the registered broker-dealer for more than one ATS be required to file separate Forms ATS–R for each of the ATSs it operates?

F. Enhanced Filing Requirements for Government Securities ATSs

The Commission is proposing a process for the Commission to review disclosures on Form ATS–G and declare a Form ATS–G ineffective if the Commission finds, after notice and opportunity for hearing, that such action is necessary and appropriate in the public interest and the protection of investors. The proposed effectiveness process is not merit based and is the same effectiveness process that is currently applicable to NMS Stock ATSs. The effectiveness process is designed to facilitate the Commission's oversight of Government Securities ATSs, as the process has facilitated the review of NMS Stock ATSs, and address, for example, material deficiencies with respect to the accuracy, currency, and completeness of disclosures on Form ATS–G.

The Commission is proposing to amend Rule 304(a) to require that a Covered ATS, which will include a Government Securities ATS, must comply with Rules 300 through 304 of Regulation ATS as applicable to be exempt pursuant to Rule 3a1–1(a)(2).[157] As proposed, all Government Securities ATSs would be required to comply with Rule 304, as amended, to, among other things, file Form ATS–G with the Commission. The Commission is proposing to apply to Government Securities ATSs the existing provisions of current Rule 304(a) for the filing and Commission review of an initial Covered Form, which will include Form ATS–G,[158] with a modification to the circumstances under which the Commission can extend the review period for an initial Covered Form.[159] The Commission believes this process is appropriate for the same reasons stated in the NMS Stock ATS Adopting Release.[160] The Commission believes that this review process will facilitate the Commission's oversight of Government Securities ATSs and help ensure that information is disclosed in a complete and comprehensible manner. The differences between Form ATS–G and Form ATS–N would not warrant a different review and effectiveness process and the Commission is proposing to apply the same provisions

[150] *See* Rule 3a1–1(a)(2) (providing that an organization, association, or group of persons shall be exempt from the definition of ''exchange'' if it is in compliance with Regulation ATS) and Rule 301(a) (providing that an ATS shall comply with the requirements of Rule 301(b)).

[151] Under the proposed rules, a broker-dealer operator for an ATS that currently trades government securities and corporate bonds, for example, would file a Form ATS–G to disclose its government securities activities for the Government Securities ATS. The broker-dealer operator would disclose the corporate bond activities of its existing ATS by filing with the Commission a material amendment to its Form ATS pursuant to Rule 301(b)(2)(ii) of Regulation ATS to remove information regarding government securities activities. *See* Regulation ATS Adopting Release, *supra* note 35, at 70864 (discussing circumstances under which an ATS would file a material amendment to Form ATS pursuant to Rule 301(b)(2), which, among other things, includes changes to the operating platform, the types of securities traded, or types of subscribers).

[152] *See supra* note 92 and accompanying text.

[153] *See* 17 CFR 242.301(b)(9).

[154] The information filed on Form ATS–R permits the Commission to monitor trading on an ATS. *See* Regulation ATS Adopting Release, *supra* note 35, at 70878.

[155] *See supra* note 94 and accompanying text.

[156] *See* NMS Stock ATS Adopting Release, *supra* note 1, Section III.B.5.

[157] As proposed, references to ''NMS Stock ATSs'' throughout Rule 304 would be changed to refer to ''Covered ATSs,'' which would encompass Government Securities ATSs. *See supra* Section II.B.

[158] *See infra* notes 161–167 and accompanying text.

[159] *See infra* notes 168–170 and accompanying text.

[160] *See* NMS Stock ATS Adopting Release, *supra* note 1, Section IV, at 38782.

that are applicable to NMS Stock ATSs to Government Securities ATSs, which include the following:

• No exemption is available to a Government Securities ATS pursuant to Exchange Act Rule 3a1–1(a)(2) unless the Government Securities ATS files with the Commission an initial Form ATS–G,[161] and the initial Form ATS–G is effective.[162]

• To permit the Commission, by order, to declare ineffective an initial Form ATS–G no later than 120 calendar days from the date of filing with the Commission, or, if applicable, the end of the extended Commission review period.[163] During the Commission review period, the Government Securities ATS shall amend its initial Form ATS–G by filing updating amendments and correcting amendments, as applicable.[164]

• An initial Form ATS–G, as amended, will become effective, unless declared ineffective, upon the earlier of: (1) The completion of review by the Commission and publication pursuant to Rule 304(b)(2)(i); or (2) the expiration of the Commission review period, or, if applicable, the end of the extended review period.[165]

• The Commission will, by order, declare an initial Form ATS–G ineffective if it finds, after notice and opportunity for hearing, that such action is necessary or appropriate in the public interest, and is consistent with the protection of investors.[166] If the Commission declares an initial Form ATS–G ineffective, the Government Securities ATS shall be prohibited from operating as a Government Securities ATS pursuant to Exchange Act Rule 3a1–1(a)(2). An initial Form ATS–G declared ineffective does not prevent the Government Securities ATS from subsequently filing a new Form ATS–G.[167]

The Commission is proposing to amend Rule 304(a)(1)(ii)(A)(1), which currently provides that the Commission may extend the initial Form ATS–N review period for an additional 90 calendar days if the Form ATS–N is unusually lengthy or raises novel or complex issues that require additional time for review.[168] The Commission is extending the rule to Form ATS–G, and furthermore, the Commission believes that it is appropriate to extend the Commission review period for a Covered Form if it finds that an extension is appropriate.[169] For example, if an ATS's disclosures on an initial Form ATS–G are difficult to understand or appear to be incomplete, the Commission may need additional time to discuss the disclosures with the ATS to ascertain whether to declare the Form ATS–G ineffective, even if the form is not unusually lengthy or does not raise novel or complex issues. Rather than moving to declare an initial Form ATS–G ineffective because of material deficiencies with respect to completeness and comprehensibility, the Commission could extend the review period to allow the filer to resolve the deficiencies. The Commission is therefore proposing that the Commission may extend the initial Covered Form review period by an additional 90 calendar days if it determines a longer period is appropriate. The proposed standard is the same standard for extending the Commission review period for SRO rule filings under Section 19 of the Exchange Act.[170] As under current Rule 304(a)(1)(ii)(A)(1), in such case, the Commission will notify the Covered ATS in writing within the initial 120-calendar day review period and will briefly describe the reason for the determination for which additional time for review is required.

The Commission is also proposing that Legacy Government Securities ATSs that have a Form ATS on file with the Commission as of the Compliance Date be subject to identical rules (other than changes to terminology) during the transition from operating pursuant to a Form ATS to operating pursuant to a Form ATS–G as those that were applied to Legacy NMS Stock ATSs during the Commission's review period. In addition, to allow a Currently Exempted Government Securities ATS to continue to operate without disruption while its initial Form ATS–G is under Commission review, the Commission is proposing to amend Rule 304(a)(1)(i) to provide that a Currently Exempted Government Securities ATS may continue to operate pursuant to Regulation ATS until its initial Form ATS–G becomes effective. The Commission believes that all Legacy Government Securities ATSs—whether they are operating pursuant to a Form ATS or whether they have operated as a Currently Exempted Government Securities ATS—should be permitted to continue to operate during the Commission review period. The Commission is therefore proposing that Legacy Government Securities ATSs can operate pursuant to Form ATS–G on a provisional basis during the Commission review period. A Government Securities ATS would file with the Commission an initial Form ATS–G no earlier than the Compliance Date[171] and no later than the date 150

[161] The Commission staff may reject a Form ATS–G filing that is defective because, for example, it is missing sections or missing responses to any sub-questions, or does not comply with the electronic filing requirements. This is a separate process from the determination to declare a Form ATS–G ineffective. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38791.

[162] *See* Rule 304(a)(1)(i). Because NMS Stock ATSs must file a Form ATS–N and Government Securities ATSs must file a Form ATS–G, the Commission is proposing a change to current Rule 304(a)(1)(i) to state that no exemption is available to a Covered ATS pursuant to § 240.3a1–1(a)(2) unless the Covered ATS files with the Commission an ''applicable'' initial Covered Form.

[163] *See* proposed Rule 304(a)(1)(ii). As proposed, the Commission may extend the initial Form ATS–G review period for: (1) An additional 90 calendar days, if the Commission determines that a longer period is appropriate, in which case the Commission will notify the Government Securities ATS in writing within the initial 120-calendar day review period and will briefly describe the reason for the determination for which additional time for review is required; or (2) any extended review period to which a duly authorized representative of the Government Securities ATS agrees in writing. *See infra* note 169.

[164] As proposed, to make material changes to its initial Form ATS–G during the Commission review period, the Government Securities ATS shall withdraw its filed initial Form ATS–G and may refile an initial Form ATS–G pursuant to Rule 304(a)(1). *See* Rule 304(a)(1)(ii)(B).

[165] *See* proposed Rule 304(a)(1)(iii)(A).

[166] Like the review process for Form ATS–N, the Commission's review of Form ATS–G would not be merit-based; instead it would focus on the completeness and comprehensibility of the disclosures. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38790. In the NMS Stock ATS Adopting Release, the Commission discussed the circumstances under which the Commission would declare a Form ATS–N amendment ineffective. Such circumstances would also apply to the Commission's review of an amendment to Form ATS–G filed by a Government Securities ATS. For example, the Commission believes it would be necessary or appropriate in the public interest, and consistent with the protection of investors, to declare ineffective a Form ATS–G if, for example, the Commission finds, after notice and opportunity for hearing, the Form ATS–G was filed by an entity that does not meet the definition of a Government Securities ATS; one or more disclosures reveal non-compliance with federal securities laws, or the rules or regulations thereunder, including Regulation ATS; or one or more disclosures on Form ATS–G are materially deficient with respect to their completeness or comprehensibility. For further discussion, *see id.* at Section IV.B.2.

[167] *See* Rule 304(a)(1)(iii)(B).

[168] *See* Rule 304(a)(1)(ii)(A)(1). As proposed, the Commission may also extend the initial Covered Form review period for any extended review period to which a duly authorized representative of the Covered Form agrees in writing. *See* Rule 304(a)(1)(ii)(A)(2).

[169] In the Commission's experience reviewing Forms ATS–N, the Commission review period was extended (either by the Commission or by the agreement of a duly authorized representative of the ATS) for 31 of the 35 Forms ATS–N that the Commission has reviewed and published. In its review of each Form ATS–N, the Commission staff engaged in extensive conversations with the NMS Stock ATS with regard to the NMS Stock ATS's disclosures on its initial Form ATS–N.

[170] *See* 15 U.S.C. 78s(b)(2).

[171] *See supra* note 97.

calendar days after the date of publication of the final rule in the **Federal Register**. An initial Form ATS–G filed by a Legacy Government Securities ATS would supersede and replace a previously filed Form ATS of the Legacy Government Securities ATS. A Legacy Government Securities ATS that fails to comply with the requirements of Regulation ATS by filing Form ATS–G by the 150th calendar day and continues operating as a Government Securities ATS would no longer qualify for the exemption provided under Rule 3a1–1(a)(2), and thus, risks operating as an unregistered exchange in violation of Section 5 of the Exchange Act. If a Legacy Government Securities ATS that has a Form ATS on file with the Commission to trade, for example, government securities and corporate bonds fails to file a Form ATS–G by the 150th calendar day, the ATS must either file a cessation of operations report on Form ATS or file a material amendment on Form ATS to remove information related to government securities.

For the same reasons discussed above,[172] the Commission is proposing to amend Rule 304(a)(1)(iv)(B) to provide that the Commission can extend the initial Form ATS–G review period by an additional 120 calendar days if it determines that a longer period is appropriate, even if the form is not unusually lengthy or does not raise novel or complex issues.

Other than the proposed changes to the circumstances under which the Commission may extend the Commission review period, the Commission is also proposing that the process for the Commission review and ineffectiveness determination for an initial Form ATS–G filed by a Legacy Government Securities ATS would be the same as the process for an initial Form ATS–N filed by a Legacy NMS Stock ATS.[173] Given the intended uses of proposed Form ATS–G to allow the Commission to monitor developments and carry out its oversight functions over Government Securities ATSs and to enable market participants to make more informed decisions about how their orders will be handled by the ATSs, the Commission believes that it is important for a Government Securities ATS to maintain an accurate, current, and complete Form ATS–G.[174] Providing the Commission with the opportunity to review Form ATS–G disclosures would help ensure that information is disclosed in a complete and comprehensible manner.[175]

As the intended uses of Form ATS–G and Form ATS–N disclosures are similar, the Commission is proposing the same filing requirements that are currently applicable to Form ATS–N amendments filed by NMS Stock ATSs to Form ATS–G amendments filed by Government Securities ATSs. A Government Securities ATS would be required to amend Form ATS–G:

- At least 30 calendar days prior to the date of implementation of a material change to the operations of the Government Securities ATS or to the activities of the broker-dealer operator or its affiliates that are subject to disclosure on the Form ATS–G, other than changes related to order display or fair access, which will be contingent amendments reported pursuant to Rule 304(a)(2)(i)(D).[176]
- No later than 30 calendar days after the end of each calendar quarter to correct information that has become inaccurate or incomplete for any reason and was not required to be reported to the Commission as a material amendment, correcting amendment, or contingent amendment.[177]
- Promptly to correct information in any previous disclosure on the Form ATS–G, after discovery that any information previously filed on a Form ATS–G was materially inaccurate or incomplete when filed.[178]
- No later than seven calendar days after information required to be disclosed in Part III, Item 24 on Form ATS–G, which addresses fair access, has become inaccurate or incomplete. Because the order display and execution access rule under Rule 301(b)(3) does not apply to Government Securities ATSs, Form ATS–G does not include a requirement to disclose information pertaining to order display and execution access. Accordingly, Rule 304(a)(2)(i)(D) will only apply to the fair access disclosure on Form ATS–G.[179]

Like amendments to Form ATS–N, the Commission will, by order, declare ineffective any Form ATS–G amendment filed pursuant to Rule 304(a)(2)(i)(A) through (D), no later than 30 calendar days from filing with the Commission, if it finds that such action is necessary or appropriate in the public interest and is consistent with the protection of investors.[180]

The Commission is further proposing to apply current Rule 304(a)(3) to require a Government Securities ATS to notice its cessation of operations on a Form ATS–G at least 10 business days prior to the date it will cease to operate

[172] *See supra* notes 168–170 and accompanying text.

[173] *See* Rule 304(a)(1)(iv)(B), which, as proposed, will provide that the Commission may, by order, as provided in Rule 304(a)(1)(iii), declare an initial Form ATS–G filed by a Legacy Government Securities ATS ineffective no later than 120 calendar days from the date of filing with the Commission, or, if applicable, the end of the extended review period. As proposed, the Commission may extend the initial Form ATS–G review period for a Legacy Government Securities ATS for: (1) An additional 120 calendar days if the Commission determines that a longer period is appropriate, in which case the Commission will notify the Legacy Government Securities ATS in writing within the initial 120-calendar day review period and will briefly describe the reason for the determination for which additional time for review is required; or (2) any extended review period to which a duly-authorized representative of the Legacy Government Securities ATS agrees in writing. *See supra* note 172.

[174] *See* NMS Stock ATS Proposing Release, *supra* note 62, at 81025 (discussing the proposed process for amendments to, and Commission review of, Form ATS–N).

[175] *See* NMS Stock ATS Adopting Release, *supra* note 1, Section IV.A.3.

[176] *See* Rule 304(a)(2)(i)(A). Scenarios that are particularly likely to implicate a material change include: (1) A broker-dealer operator or its affiliates beginning to trade on the Government Securities ATS; (2) a change to the broker-dealer operator's policies and procedures governing the written safeguards and written procedures to protect the confidential trading information of subscribers pursuant to Rule 301(b)(10)(i) of Regulation ATS; (3) a change to the types of participants on the Government Securities ATS; (4) the introduction or removal of a new order type on the Government Securities ATS; (5) a change to the order interaction and priority procedures; (6) a change to the segmentation of orders and participants; (7) a change to the manner in which the Government Securities ATS displays orders or trading interest; and (8) a change of a service provider to the operations of the Government Securities ATS that has access to subscribers' confidential trading information. This list is not intended to be exhaustive, and does not mean to imply that other changes to the operations of a Government Securities ATS or the activities of the broker-dealer operator or its affiliates could not constitute material changes. Further, the Government Securities ATS should generally consider whether the cumulative effect of a series of changes to the operations of the Government Securities ATS or the activities of the broker-dealer operator or its affiliates with regard to the Government Securities ATS is material. In addition, in determining whether a change is material, an ATS generally should consider whether such change would affect: (1) The competitive dynamics among ATS subscribers; (2) the execution quality or performance of the orders of any subscriber or category of subscribers; (3) the fees that any subscriber or category of subscribers would pay to access and/or use the ATS; (4) the nature or composition of counter-parties with which any subscriber or category of subscribers interact; and (5) the relative speed of access or execution of any subscriber or group of subscribers. For further discussion, *see* NMS Stock ATS Adopting Release, *supra* note 1, Section IV.B.1.a.

[177] *See* Rule 304(a)(2)(i)(B).

[178] *See* Rule 304(a)(2)(i)(C). For a discussion of when an ATS should file a correcting amendment, *see* NMS Stock ATS Adopting Release, *supra* note 1, at 38806.

[179] The Commission is proposing to revise Rule 304 to replace references to ''Order Display and Fair Access Amendments'' with ''Contingent Amendments.'' The term ''Contingent Amendment'' would apply to the relevant amendments under Rule 304(a)(2)(i)(D) to both Form ATS–N and Form ATS–G.

[180] *See* Rule 304(a)(2)(ii).

as a Government Securities ATS and to cause the Form ATS–G to become ineffective on the date designated by the Government Securities ATS. In addition, the Commission is proposing to apply Rule 304(a)(4) to Government Securities ATSs, which would provide that the Commission will, by order, if it finds, after notice and opportunity for hearing, that such action is necessary or appropriate in the public interest and is consistent with the protection of investors, suspend for a period not exceeding twelve months,[181] limit, or revoke the exemption for a Covered ATS pursuant to Rule 3a1–1(a)(2).[182] Rule 304(a)(4)(ii) would provide that if the exemption for a Government Securities ATS is suspended or revoked pursuant to Rule 304(a)(4)(i), the Government Securities ATS would be prohibited from operating pursuant to the Rule 3a1–1(a)(2) exemption.[183] If the exemption for a Government Securities ATS is limited pursuant to Rule 304(a)(4)(i), the Government Securities ATS shall be prohibited from operating in a manner otherwise inconsistent with the terms and conditions of the Commission order.

In addition, Rule 304(a)(4) would provide that prior to issuing an order suspending, limiting, or revoking a Government Securities ATS's exemption pursuant to Rule 304(a)(4)(i), the Commission will provide notice and opportunity for hearing to the Government Securities ATS, and make the findings specified in Rule 304(a)(4)(i) described above, that, in the Commission's opinion, the suspension, limitation, or revocation is necessary or appropriate in the public interest and is consistent with the protection of investors.[184]

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26. Should Government Securities ATSs be required to file proposed Form ATS–G instead of Form ATS?

27. Should Form ATS, or parts thereof, for ATSs that effect transactions in government securities or repos and securities other than government securities or repos be made available to the public? Is current Form ATS sufficient to elicit information for the public about the operations of Government Securities ATSs?

28. Do commenters believe that broker-dealers that effect transactions in government securities or repos generally, or U.S. Treasury Securities or Agency Securities, specifically, might choose to modify their business models so that they would not be required to comply with enhanced regulatory or operational transparency requirements for Government Securities ATSs?

29. Should Government Securities ATSs be subject to Rule 304(a), in whole or in part?

30. Should Rule 304(a) be amended to provide that an initial Covered Form be made effective by Commission order or any other means instead of upon publication by the Commission?

31. Should Rule 304(a) only apply to Government Securities ATSs that trade a certain type of government security (*e.g.,* U.S. Treasury Securities, Agency Securities)? If so, to which type of Government Securities ATS should Rule 304 apply (*e.g.,* Government Securities ATSs that trade U.S. Treasury Securities or Government Securities ATSs that trade Agency Securities)?

32. Should the Commission require a Currently Exempted Government Securities ATS to file Form ATS–G and comply with the requirements of Rule 304 to qualify for the exemption from the definition of exchange?

33. Would the proposal to require a Currently Exempted Government Securities ATS to file Form ATS–G by the date 150 calendar days after the date of publication of the final rule in the **Federal Register** provide the ATS sufficient time to transition to compliance with Regulation ATS and the proposed requirements under Rule 304? Would the proposal to require a Legacy Government Securities ATS to file a Form ATS–G by the date 150 calendar days after the date of publication of the final rule in the **Federal Register** provide the ATS sufficient time to transition to compliance with Rule 304?

34. Should the Commission be permitted to extend the initial Covered Form review period if it finds that it is appropriate to extend such review period?

35. Should a Legacy Government Securities ATS be allowed to continue operations during the Commission's review of its initial Form ATS–G? Should the Commission make a Legacy Government Securities ATS's Form ATS–G publicly available upon filing?

36. Are there any aspects of Rule 304(a)(2) relating to the filing and review of amendments that should be modified specifically for Form ATS–G amendments filed by Government Securities ATSs?

37. What changes or types of changes to an ATS's operations or the activities of the broker-dealer operator or its affiliates do commenters believe are particularly likely to be material as so to require a material amendment to Form ATS–G?

38. Currently, and as proposed, Rule 304(a)(2) does not provide for the Commission to extend the length of the Commission review period for amendments to a Covered Form.[185] The Commission has 30 days to review the amendment, engage in discussion with the ATS, and, if necessary or appropriate in the public interest, and consistent with the protection of investors, declare the amendment ineffective. If, however, after the end of the Commission review period for an amendment, the Commission finds that, in light of such amendment, it is necessary or appropriate in the public interest and consistent with the protection of investors, the Commission may, after notice and opportunity for hearing, suspend, limit, or revoke a Covered ATS's exemption from the definition of ''exchange'' pursuant to Rule 3a1–1(a)(2). Should the Commission amend Rule 304(a)(2) to allow the Commission to extend the length of the Commission review period for amendments to a Covered Form? If so, under what circumstances should the Commission be permitted to extend the length of the Commission review period for a Covered Form amendment and how long should an extension be (*e.g.,* 15, 30, 45 calendar days)?

[181] The proposed limitation on the time frame for suspension is consistent with federal securities law provisions pursuant to which the Commission may suspend the activities or registration of a regulated entity. *See, e.g.,* Exchange Act Section 15(b)(4) (15 U.S.C. 78o(b)(4)) and 15B(c)(2) (15 U.S.C. 78o–4(c)(2)). *See* NMS Stock ATS Proposing Release, *supra* note 62, at 81031 n.322.

[182] *See* proposed Rule 304(a)(4)(i).

[183] *See* Rule 304(a)(4). In making a determination as to whether suspension, limitation, or revocation of a Government Securities ATS's exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors, the Commission would, for example, take into account whether the entity no longer meets the definition of Government Securities ATS under Rule 300(l), does not comply with the conditions to the exemption (in that it fails to comply with any part of Regulation ATS, including Rule 304), or otherwise violates any provision of federal securities laws. For further discussion of such examples as applied to NMS Stock ATSs, *see* NMS Stock ATS Proposing Release, *supra* note 62, at 81032.

[184] Pursuant to the Commission's current information sharing practices with the Department of the Treasury, the Commission expects to provide the Department of the Treasury with prompt notice in certain cases, such as when the Commission is requiring registration for certain large volume Government Securities ATSs under Rule 3a1–1(b), declaring a Form ATS–G ineffective under Rule 304(a)(1)(iii)(b), or suspending, limiting, or revoking the exemption of a Government Securities ATS under Rule 304(a)(4).

[185] Based on the Commission's review of Form ATS–N filings, the Commission has observed that material amendments are often complex and the Commission staff has frequently engaged in extensive dialogue with the ATS regarding such disclosures. To date, the Commission has not declared a Form ATS–N amendment ineffective.

39. Should the Commission consider any other factors in determining whether a Form ATS–G filed by a Government Securities ATS should become effective or ineffective? If so, what are they and why?

40. Is the process for the Commission to suspend, limit, or revoke an NMS Stock ATS's exemption from the definition of ''exchange'' to Government Securities ATSs necessary or appropriate to protect investors?

G. Public Disclosure of Form ATS–G and Related Commission Orders

The Commission is also proposing to make public certain Form ATS–G reports filed by Government Securities ATSs by applying existing Rule 304(b) to Covered Forms, which would include Form ATS–G.[186] Commission orders related to the effectiveness of Form ATS–G would also be publicly posted on the Commission's website. Applying existing Rule 304(b) to Government Securities ATSs would mandate greater public disclosure of the operations of these ATSs through the publication of Form ATS–G and related filings available on the Commission's website.[187] Accordingly, the Commission is proposing the following:

- Similar to Form ATS–N, every Form ATS–G filed pursuant to Rule 304 shall constitute a ''report'' within the meaning of Sections 11A, 17(a), 18(a), and 32(a) and any other applicable provisions of the Exchange Act.[188]
- The Commission will make public via posting on the Commission's website, each: (1) Effective initial Form ATS–G, as amended; (2) order of ineffective initial Form ATS–G; (3) Form ATS–G amendment to an effective Form ATS–G; (4) order of ineffective Form ATS–G amendment; (5) notice of cessation; and (6) order suspending, limiting, or revoking the exemption for a Government Securities ATS from the definition of an ''exchange'' pursuant to Exchange Act Rule 3a1–1(a)(2).[189]

The Commission is proposing to apply Rule 304(b)(3) to require each Government Securities ATS that has a website to post a direct URL hyperlink to the Commission's website that contains the documents enumerated in Rule 304(b)(2), which include the Government Securities ATS's Form ATS–G filings.

In addition, to promote further transparency, the Commission is proposing to amend Rule 304(b)(3) to require each Covered ATS to post on its website the most recently disseminated Covered Form (excluding Part IV, which is non-public information) within one business day after publication on the Commission's website, except for any amendment that the Commission has declared ineffective or that has been withdrawn. The most recently disseminated Covered Form shall be maintained on the Covered ATS's website until: (a) The Covered ATS ceases operations; or (b) the exemption of the Covered ATS is revoked or suspended, in which cases the Covered ATS shall remove the Covered Form from its website within one business day of such cessation, revocation or suspension, as applicable.[190] A Covered ATS that has submitted a Covered Form or amendment thereto that is under Commission review prior to dissemination could monitor the Commission's website to ensure that the ATS's website reflects the most current version of the form.[191]

Request for Comment

41. Should the requirements of Rule 304(b) apply to Form ATS–G reports filed by Government Securities ATSs, in whole or in part? Should the Commission modify Rule 304(b) in any way for all Covered ATSs?

42. Rule 304(b)(2) currently provides that the Commission make Form ATS–N filings available on its website. The Commission disseminates Form ATS–N and amendments thereto through the Commission's Electronic Data Gathering, Analysis, and Retrieval system (''EDGAR''). Should Rule 304(b) be amended so that only filers of a Covered Form make filings public, rather than the Commission (by EDGAR or by any other form of filing)?

43. Should Rule 304(b) be amended to require Covered ATSs to post the Covered Form on their websites? Should Covered ATSs be required to post the Covered Form on their websites in addition to or instead of posting a hyperlink to the Commission website?

44. Should Rule 304(b) only apply to Government Securities ATSs that trade a type of government securities (*e.g.,* U.S. Treasury Securities, Agency Securities)? If so, to which type of Government Securities ATS should Rule 304 apply?

45. Are there any other requirements that should apply to making public a Form ATS–G report filed by a Government Securities ATS? Please support your arguments, and if so, please list and explain such procedures in detail.

46. Should Rule 304(b) apply to Form ATS–G reports filed by a Currently Exempted Government Securities ATS? If not, which aspects of Rule 304(b) should not apply and why?

H. Form ATS–G Requirements

The Commission is proposing to apply existing Rule 304(c) to Covered ATSs, which would include Government Securities ATSs. As proposed, Rule 304(c) would require Government Securities ATSs to file a Form ATS–G in accordance with the instructions therein. Other than references to Government Securities ATSs and Form ATS–G and the relevant compliance dates, the proposed instructions to Form ATS–G are identical to the instructions to Form ATS–N. They require, among other things, that a Government Securities ATS provide all the information required by Form ATS–G, including responses to each Item, as applicable, and the Exhibits, and disclose information that is accurate, current, and complete.[192] Given that the Commission expects market participants will use Form ATS–G to decide where to send their orders for execution, the Commission believes that it is important that Form ATS–G filings comply with the instructions and that the information provided on Form ATS–G is accurate, current, and complete. The Commission is also proposing that Form ATS–G, like Form ATS–N,[193] be filed electronically in a structured format through EDGAR.[194]

[186] *See* proposed revisions to Rule 304(b)(1) (providing that every Form ATS–G filed pursuant to Rule 304 shall constitute a ''report'' within the meaning of Sections 11A, 17(a), 18(a), and 32(a) and any other applicable provisions of the Exchange Act).

[187] *See infra* Section III.

[188] *See* Rule 304(b)(1).

[189] *See* Rule 301(b)(2).

[190] If the broker-dealer operator has not created a website specific for the ATS, the broker-dealer operator would place the Covered Form, the hyperlink to the Commission's website, and any other information related to the Covered Form (*e.g.,* aggregate platform-wide data or direct/indirect ownership information) on the broker-dealer operator's website in a conspicuous place for the public to view.

[191] The Commission believes that Covered ATSs could reasonably anticipate when an initial Covered Form and amendments thereto would be disseminated. Filers receive an automated notice when a filing is accepted by EDGAR. Once accepted, amendments to a Covered Form (other than material amendments) would be disseminated. Material amendments would be made public following the expiration of the 30-calendar day Commission review period. Although an initial Covered Form may be disseminated at any time within the 120-calendar day Commission review period or any extension thereof, the Commission expects to engage in dialogue with the Covered ATS during such review period so that the ATS could reasonably anticipate when its initial Covered Form would be disseminated.

[192] *See* Instructions to proposed Form ATS–G.

[193] *See* NMS Stock ATS Adopting Release, *supra* note 1, Section VII.

[194] *See infra* Section IV.

The Commission is proposing to apply Rule 304(c)(2) to Government Securities ATSs, which would provide that any report required under Rule 304 shall be filed on a Form ATS–G, and include all information as prescribed in the Form ATS–G and the instructions to the Form ATS–G. Rule 304(c)(2) would provide that a Form ATS–G be executed at, or prior to, the time the Form ATS–G is filed and shall be retained by the Government Securities ATS in accordance with Rules 302 and 303, and the instructions in the Form ATS–G. In the Regulation ATS Adopting Release, the Commission stated that the requirements to make and preserve records set forth in Regulation ATS are necessary to create a meaningful audit trail and permit surveillance and examination to help ensure fair and orderly markets [195] and that expanding Rule 304(c) to encompass Form ATS–G would further these goals for Government Securities ATSs.

Request for Comment

47. Should Rule 304(c) be applied, in whole or in part, to Government Securities ATSs?

48. Should Rule 304(c) only apply to Government Securities ATSs that trade a certain type of government security (*e.g.,* U.S. Treasury Securities, Agency Securities)? If so, to which type of Government Securities ATS should it apply?

III. Proposed Form ATS–G for Government Securities ATSs

As outlined above, the Commission proposes to require Government Securities ATSs to file a proposed Form ATS–G, which would be a public report that provides detailed information about the manner of operations of the ATS and about the ATS-related activities of the broker-dealer operator and its affiliates. Despite the significant role of ATSs in the government securities market structure and the complexity of their operations, most market participants have limited access to information that permits them to adequately compare and contrast how their orders would be handled by different Government Securities ATSs. The Commission believes that proposed Form ATS–G's public disclosures would provide important information to market participants that would help them better understand these operational facets of Government Securities ATSs and select the best trading venue based on their needs. In addition, in the Commission's experience reviewing disclosures on Form ATS–N, the Commission observed that the information responsive to the form is not proprietary or commercially sensitive. Because the disclosures that would be required on proposed Form ATS–G are similar to those of Form ATS–N, the Commission believes that likewise, the vast majority of responsive information would not be proprietary or commercially sensitive.[196]

The Commission also believes that the proposed disclosures on Form ATS–G about the conflicts of interest that might arise from the business structures of the Government Securities ATS and the ATS-related activities of the broker-dealer operator and its affiliates would help subscribers protect their interests when using the services of the ATS.[197] As the Commission has previously stated, the broker-dealer operator controls all aspects of the ATS's operations and the broker-dealer operator's non-ATS and ATS functions may overlap.[198] Currently, market participants have limited information about conflicts of interest that might arise from the non-ATS activities of the broker-dealer operator of a Government Securities ATS, and different classes of subscribers may have different levels of information about the operations of the ATS.[199] Because of overlap between a broker-dealer's ATS operations and its other operations, there is a risk of information leakage of subscribers' confidential trading information to other business units of the broker-dealer operator or its affiliates. The Commission believes that some market participants would want to consider the trading activity of the broker-dealer operator, or its affiliates, when evaluating potential conflicts of interest on a Government Securities ATS and may also like to know the range of services and products that the broker-dealer operator or its affiliates offer subscribers for use on the ATS because such services or products may have an impact on the subscribers' access to, or trading on, the ATS. Some commenters have also stated that there are close similarities between the operations of NMS Stock ATSs and some Government Securities ATSs, particularly with respect to U.S. Treasury Securities, and that trading in U.S. Treasury Securities may present potential conflicts of interest similar to those for NMS Stock ATSs.[200] The Commission also believes that the disclosures on proposed Form ATS–G would better inform the Commission and other regulators about the activities of Government Securities ATSs and their role in the government securities markets, which in turn, would facilitate better oversight of these ATSs and the markets to the benefit of investors.

Given the similarities of operations between NMS Stock ATSs and Government Securities ATSs, almost all requests for information on proposed Form ATS–G are similar to or derived from Form ATS–N; however, certain requests have been tailored for Government Securities ATSs. The differences between the forms include that: Form ATS–G does not have an item corresponding to Part III, Item 16 (Routing) of Form ATS–N; Form ATS–G does not have an item corresponding to Part III, Item 24 (Order Display and Execution Access) of Form ATS–N as the associated rule is inapplicable to government securities; and Form ATS–G added proposed Part III, Item 16 requiring information about non-government securities markets (*e.g.,* futures, currencies, swaps, corporate bonds) used in conjunction with the ATS. The Commission is requesting comment on each of the requests for information on proposed Form ATS–G and information about the operations of Government Securities ATSs and ATS-related activities of the broker-dealer operator and its affiliates that would be important to subscribers and market participants.

A. Cover Page and Part I of Form ATS–G

1. Cover Page

To make clear that the Commission is not conducting a merit-based review of Form ATS–G disclosures filed with the Commission, the Commission proposes to include a legend on the Form ATS–G cover page stating that the Commission has not passed upon the merits or accuracy of the disclosures in the filing. On the cover page of proposed Form ATS–G, the ATS would be required to identify whether it is a Legacy Government Securities ATS currently operating as of the Compliance Date (either pursuant to a Form ATS or an exemption under Exchange Act Rule 3a1–1(a)(3)). In addition, the Government Securities

[195] *See* Regulation ATS Adopting Release, *supra* note 35, at 70877–78.

[196] *See infra* Section III.

[197] *See infra* Section III.B.

[198] *See* NMS Stock ATS Proposing Release, *supra* note 62, at 81010, 81041.

[199] *See id.* at 81010.

[200] *See* MFA/AIMA Letter, *supra* note 66, at 3; OIA Letter, *supra* note 65, at 18–19.

ATS would indicate the type of filing by marking the appropriate checkbox.[201]

If the Government Securities ATS is filing an amendment, the ATS would be required to indicate the Part and Item number of the Form ATS–G that is the subject of the change(s), provide a brief summary of the change(s), and state whether or not the change(s) applies to all subscribers and the broker-dealer operator.[202] In addition, the Government Securities ATS would be required to provide the EDGAR accession number for the Form ATS–G filing to be amended so that market participants can identify the filing that is being amended. The Commission is proposing to apply Rule 304(b)(2)(iii) to Form ATS–G to provide that the Commission would make public the cover page of a filed Form ATS–G material amendment upon filing and then make public the entirety of the material amendment following the expiration of the review period pursuant to Rule 304(a)(2)(ii). For updating and correcting amendments, which would be made public upon filing, the Commission believes that the information in the narrative could assist market participants in understanding the general nature of the change that the Government Securities ATS is implementing.

If the filing is a cessation of operations, the Commission is proposing that the Government Securities ATS provide the date that the ATS will cease to operate. The Commission is also proposing to include a checkbox where the ATS could indicate whether it wishes to withdraw a previously-filed Form ATS–G filing and provide the EDGAR accession number for the filing to be withdrawn. The instructions to Form ATS–G would state that a Government Securities ATS may withdraw an initial Form ATS–G or an amendment before the end of the applicable Commission review period. In addition, the Commission is proposing that a Government Securities ATS may withdraw a notice of cessation of operations at any time before the date that the ATS indicated it intended to cease operating.

2. Part I of Form ATS–G: Identifying Information

Part I of Form ATS–G, as proposed, would be substantively the same as that for Form ATS–N, as proposed to be amended,[203] except that unlike Form ATS–N, Form ATS–G would require an ATS to identify whether it trades U.S. Treasury Securities, Agency Securities, repos, or other securities. To parallel the Form ATS–N requirement, the Commission is proposing that Form ATS–G would require an ATS to identify the registered broker-dealer that operates the ATS. Part I, Item 1.a of Form ATS–G would require the ATS to state whether the filer is a broker-dealer registered with the Commission. The Commission is also proposing that the Government Securities ATS provide the name of the registered broker-dealer or government securities broker or government securities dealer for the Government Securities ATS (*i.e.,* the broker-dealer operator), as it is stated on Form BD, in Part I, Item 2 of Form ATS–G. Part I, Item 1.b of Form ATS–G would require the ATS to indicate whether the broker-dealer operator has been authorized by a national securities association to operate an ATS.[204] To comply with Regulation ATS, and thus qualify for the Rule 3a1–1(a)(2) exemption, an ATS must register as a broker-dealer and thus become a member of an SRO. As a member of the SRO, the ATS must comply with the rules of the SRO, including obtaining any required approvals by the SRO in connection with operating an ATS in accordance with applicable SRO rules.[205] The Commission believes that proposed Part I, Item 1.b would facilitate compliance with and Commission oversight of this requirement.

To the extent that a commercial or ''DBA'' (doing business as) name or names are used to identify the Government Securities ATS to the public, the Commission, or its SRO, or if a registered broker-dealer operates multiple Government Securities ATSs, Form ATS–G would require the full name(s) of the Government Securities ATS under which business is conducted, if different, in Part I, Item 3 of Form ATS–G. Part I, Item 4 of Form ATS–G would require the Government Securities ATS to provide the broker-dealer operator's SEC File Number and Central Registration Depository (''CRD'') Number. Part I, Item 5 of Form ATS–G would require the Government Securities ATS to select the types of securities the ATS trades (*i.e.,* U.S. Treasury Securities, Agency Securities, repos, or other). If the ATS selects ''other,'' it would be required to list the types of government securities that it trades.[206] Part I, Item 6 of Form ATS–G would require the Government Securities ATS to provide the full name of the national securities association of the broker-dealer operator, the effective date of the broker-dealer operator's membership with the national securities association, and its MPID. Pursuant to FINRA rules, each ATS is required to use a unique MPID in its reporting to FINRA, such that its volume reporting is distinguishable from other transaction volume reported by the broker-dealer operator of the ATS, including volume reported for other ATSs or trading desks operated by the broker-dealer operator.[207] The broker-dealer operator would provide the unique MPID for the Government Securities ATS and assess the functionalities related to trading under that MPID and describe them, as applicable, in response to the information requests on Form ATS–G. Providing the name of the Government Securities ATS or DBAs and its MPID would identify the ATS to the public and Commission. The Commission believes that the name, identity of the broker-dealer operator, any ''DBA'' name, and the ATS's MPID are basic information critical to market participants for identifying the ATS and should be disclosed.

Proposed Part I, Item 7 of Form ATS–G would require the Government Securities ATS to provide a URL address for the website of the ATS and proposed Part I, Item 8 of Form ATS–G would require the ATS to provide the physical street address, if any, of a secondary location for the ATS that may be used in the event that the primary physical location is not available.

Proposed Part I, Items 9 and 10 would require a Government Securities ATS to attach its most recently filed or amended Schedule A of the broker-dealer operator's Form BD disclosing information related to direct owners and

[201] The proposed cover page would provide that a filing may be an initial Form ATS–G, or a Form ATS–G material amendment, updating amendment, correcting amendment, or contingent amendment.

[202] *See* Instruction A.7.g of Form ATS–G. If a change subject to the amendment would equally apply to all subscribers and the broker-dealer operator, the Government Securities ATS would indicate that the change applies to all subscribers and the broker-dealer equally. If a change would apply differently among subscribers or types of subscribers, between subscribers and the broker-dealer operator, or between the broker-dealer operator and its affiliates (which may be subscribers to the ATS), the Government Securities ATS would state so and describe the differences in treatment. This is the same as how NMS Stock ATSs describe whether or not a change applies to all subscribers and the broker-dealer operator in amendments on Form ATS–N.

[203] The Commission is proposing changes to Form ATS–N, which are described *infra* Section V.D.

[204] The Commission is proposing herein to add this subpart to Form ATS–N. *See infra* Section V.D.

[205] *See* 15 U.S.C. 78o(b)(8). *See also* NMS Stock ATS Adopting Release, *supra* note 1, at 38773.

[206] The types of securities traded would be limited to government securities (15 U.S.C. 78c(a)(42)) and repos on government securities. *See* proposed Rule 300(l).

[207] *See* FINRA Rules 6160, 6170, 6480, and 6720.

executive officers, and its most recently filed or amended Schedule B of the broker-dealer operator's Form BD disclosing information related to indirect owners as Exhibits 1 and 2, respectively. In lieu of attaching those schedules, the Government Securities ATS can indicate, via a checkbox, that the information under those schedules is available on its website and is accurate as of the date of the filing of the Form ATS–G.[208] In addition, the Commission is proposing Part I, Item 11 of Form ATS–G to require the Government Securities ATS, for filings made pursuant to Rule 304(a)(2)(i) (*i.e.,* Form ATS–G amendments), to attach as Exhibit 3 a marked document to indicate changes to ''yes'' or ''no'' answers and additions or deletions from any item in Part I, Part II, and Part III, as applicable.

Request for Comment

49. A Legal Entity Identifier (''LEI'') is a 20-character reference code that uniquely identifies legally distinct entities that engage in financial transactions[209] and is used by numerous domestic and international regulatory regimes. Although several existing ATS broker-dealer operators currently have an LEI, not all broker-dealers have an LEI. An LEI can be obtained for a $65 initial cost and a $50 per year renewal cost.[210] Should the Commission require a Government Securities ATS to disclose the LEI of its broker-dealer operator, in addition to its CRD Number and the MPID for the Government Securities ATS, on Form ATS–G?

B. Part II of Form ATS–G: ATS-Related Activities of the Broker-Dealer Operator and Affiliates

The Commission believes that the interests of the broker-dealer operator or its affiliates sometimes compete against the interests of those that use the ATS's services. These competing interests, at times, may give rise to conflicts of interest for the broker-dealer operator and its affiliates or the potential for information leakage of subscribers' confidential trading information. Proposed Part II of Form ATS–G is designed to provide subscribers and market participants with information about these competing interests, and inform them about: (1) The operation of the Government Securities ATS—regardless of the corporate structure of the ATS—and of its broker-dealer operator, or any arrangements the broker-dealer operator may have made, whether contractual or otherwise, pertaining to the operation of its Government Securities ATS; and (2) ATS-related activities of the broker-dealer operator and its affiliates that may give rise to conflicts of interest for the broker-dealer operator and its affiliates or the potential for information leakage of subscribers' confidential trading information. The Commission believes that these disclosures would enable subscribers to protect their interests while participating on the ATS. At the same time, the Commission also believes that Form ATS–G should not require public disclosure of activities or affiliate relationships of the broker-dealer operator that do not relate to the Government Securities ATS and thus, do not present a potential conflict of interest.

The proposed definitions of ''affiliate'' and ''control,'' which are identical to those in Form ATS–N,[211] are intended to encompass all relevant affiliate relationships between the broker-dealer operator and other entities that the Commission believes would help market participants' evaluation of potential conflicts of interest.[212]

1. Broker-Dealer Operator and Its Affiliate Trading Activities on the Government Securities ATS

The Commission is proposing that Part II, Items 1(a) and 2(a) of Form ATS–G ask whether business units of the broker-dealer operator or its affiliates, respectively, are permitted to enter or direct the entry of orders and trading interest into the Government Securities ATS. If the person that operates and controls an ATS is also able to trade on that ATS, there may be an incentive to design the operations of the ATS to favor the trading activity of the operator of the ATS or affiliates of the operator. The operator of an ATS that also trades on the ATS it operates would likely have informational advantages over others trading on the ATS, such as a better understanding of the manner in which the system operates or who is trading on the ATS. In the most egregious case, the operator of the ATS might use the confidential trading information of other traders to advantage its own trading on or off of the ATS.[213] Part II, Items 1(a) and 2(a) of Form ATS–G disclosures are designed to inform market participants about whether the Government Securities ATS permits the broker-dealer operator or its affiliates to trade on the ATS. If the Government Securities ATS permits the broker-dealer operator or its affiliates to enter orders and trading interest on the ATS, whether on an agency or principal basis, the ATS would be required to only list the business units or affiliates that actually enter or direct the entry of orders and trading interest into the ATS. The Commission believes that if a business unit or affiliate of the broker-dealer operator enters or directs the entry of orders and trading interest into the Government Securities ATS, market participants would find it useful to know that they may be trading with those business units, affiliates, or client orders entered by those entities. The Commission believes that disclosure of whether a broker-dealer operator of a Government Securities ATS or its affiliates may trade on that ATS would

[208] Like Form ATS–N, Part I, Items 9 and 10 and Part III, Item 25 (*see infra* Section III.A.2 and Section III.C.25) are the only requests for information that would allow a Government Securities ATS to cross-reference to information on the Government Securities ATS's website instead of providing it in the form disclosures. Like Form ATS–N, Form ATS–G disclosures would be the vehicle for disseminating to the public information about the operations of the Government Securities ATS and the ATS-related activities of the broker-dealer operator and its affiliates under Rule 304, which are required to be kept current, accurate, and complete by the ATS. Accordingly, Government Securities ATSs would be required to provide information required by the form in the Form ATS–G disclosures and not cross-reference to other sources.

[209] *See* Securities Act Release No. 10425, 82 FR 50988 at 51005 (November 2, 2017) (stating that LEIs are intended to improve market transparency by providing clear identification of participants).

[210] Prices retrieved from Bloomberg Finance, L.P., *https://lei.bloomberg.com/docs/faq#what-fees-are-involved.* Bloomberg is one of twelve Legal Entity Identifier issuers that are accredited to issue LEIs specifically to U.S. entities.

[211] Proposed Form ATS–G would define ''affiliate'' as, with respect to a specified person, any person that, directly or indirectly, controls, is under common control with, or is controlled by, the specified person. ''Control'' would be defined to mean the power, directly or indirectly, to direct the management or policies of the broker-dealer of an alternative trading system, whether through ownership of securities, by contract, or otherwise. A person is presumed to control the broker-dealer of an alternative trading system if that person: (1) Is a director, general partner, or officer exercising executive responsibility (or having similar status or performing similar functions); (2) directly or indirectly has the right to vote 25 percent or more of a class of voting securities or has the power to sell or direct the sale of 25 percent or more of a class of voting securities of the broker-dealer of the alternative trading system; or (3) in the case of a partnership, has contributed, or has the right to receive upon dissolution, 25 percent or more of the capital of the broker-dealer of the alternative trading system. In this proposal, the Commission is proposing to update the definition of person for the purposes of Forms ATS–N and ATS–G. *See infra* Section V.D.

[212] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38818–19.

[213] For a further discussion about how a conflict of interest related to trading by the broker-dealer operator on its own ATS could be harmful to other subscribers, *see* NMS Stock ATS Adopting Release, *supra* note 1, at 38771, 38824–29.

be important to subscribers given the conflicts of interest that may arise from the unique position the broker-dealer operator occupies in relation to the ATS.

Part II, Items 1(a) and 2(a) of proposed Form ATS–G would require the Government Securities ATS to list the business unit or affiliate if, for example, a trading desk of the broker-dealer operator or an affiliate uses a direct connection to the ATS or algorithm to submit orders or trading interest into the ATS. Likewise, if an affiliated asset manager of the broker-dealer operator uses the services of a third-party broker-dealer to direct orders to the Government Securities ATS (*i.e.,* the asset manager instructs the third-party broker-dealer to send its orders to the ATS), the ATS would be required to list that affiliated asset manager under Item 2(a). However, if that affiliated asset manager submits orders to a third-party broker-dealer, and that third-party broker-dealer using its own discretion, directs the orders of the asset manager into the affiliated Government Securities ATS, the ATS would not be required to list the affiliated asset manager under Item 2(a); under such circumstances, the affiliate would not be ''directing'' orders to the ATS because the third-party broker-dealer is using its discretion to direct the affiliate's orders and thus, it would not be required to be listed under Item 2(a).

The proposed requests also specify the type of information that must be provided with regard to business units or affiliates of the broker-dealer operator. Specifically, Item 1(a) would require the Government Securities ATS to name and describe each type of business unit of the broker-dealer operator that enters or directs the entry of orders and trading interest into the ATS (*e.g.,* Government Securities ATS, type of trading desks, market maker, sales or client desk) and, for each business unit, to provide the applicable MPID and list the capacity of its orders and trading interest (*e.g.,* principal, agency, riskless principal). Item 2(a) would require the Government Securities ATS to name and describe each type of affiliate that enters or directs the entry of orders and trading interest into the ATS (*e.g.,* broker-dealers, investment companies, hedge funds, market makers, PTFs) and, for each of those affiliates, provide the applicable MPID and list the capacity of its orders and trading interest (*e.g.,* principal, agency, riskless principal). The Commission believes that market participants will find it useful to know both the types of broker-dealer operator business units and affiliates that can trade in the Government Securities ATS, and their trading activities.[214]

Part II, Items 1(c) and 2(c) of proposed Form ATS–G would require Government Securities ATSs to disclose the broker-dealer operator's or any of its affiliates' role as a liquidity provider on the ATS, if applicable. These Items would require the Government Securities ATS to disclose—in the form of a ''yes'' or ''no'' response—whether there are any formal or informal arrangements with any of the sources of orders or trading interest of the broker-dealer operator or affiliates identified in Item 1(a) and Item 2(a), respectively, to provide orders or other trading interest to the ATS (*e.g.,* undertaking to buy or sell continuously, or to meet specified thresholds of trading or quoting activity). If the Government Securities ATS answers ''yes,'' it must identify the business unit(s) or affiliate(s) and respond to the Item with information about liquidity providers on the ATS.[215] The Commission believes that highlighting whether the broker-dealer operator or affiliate acts as a liquidity provider on the Government Securities ATS would help market participants evaluate the potential for conflicts of interest or information leakage on the trading platform.

Finally, Part II, Item 1(d) and Item 2(d) of proposed Form ATS–G would require the Government Securities ATSs to disclose information about sending orders and trading interest to a trading venue operated or controlled by the broker-dealer operator or any of its affiliates, respectively. These Items would require the Government Securities ATS to disclose—in the form of a ''yes'' or ''no'' response—whether orders and trading interest in the ATS can be sent to a trading venue operated or controlled by the broker-dealer operator or any of its affiliates. If the Government Securities ATS answers ''yes,'' it must identify the trading venue and explain when and how the order or trading interest are sent from the ATS to the trading venue. NMS Stock ATSs are required to provide on Form ATS–N Part III, Item 16 information related to the routing of orders from the ATS if they indicated that the ATS sent trading interest to a trading center operated by the broker-dealer operator or any of its affiliates in Part II, Items 1(d) and 2(d). Because the routing of government securities among trading centers is not as prevalent as in the market for NMS stocks, the Commission is not proposing to require on Form ATS–G the same information about routing that would otherwise be covered under Part III, Item 16 of Form ATS–N. Instead, the Commission is requiring a Government Securities ATS to disclose information about the trading venue where orders and trading interest may be sent and when and how orders and trading interest are sent in Part II, Items 1(d) and 2(d) of Form ATS–G. The Commission believes that such information would help market participants evaluate whether the ATS sending orders to a trading venue operated or controlled by the broker-dealer operator or its affiliates poses a conflict of interest and is consistent with its trading objectives.

Request for Comment

50. What information about trading by the broker-dealer operator and its affiliates related to the Government Securities ATS is important to market participants?

51. Are there potential conflicts of interest for broker-dealer operators of Government Securities ATSs or their affiliates that may justify greater operational transparency for Government Securities ATSs?

52. Should the Commission require separate disclosures for different types of trading by the broker-dealer operator on the Government Securities ATS, such as trading by the broker-dealer operator for the purpose of correcting error trades executed on the ATS, as compared to other types of principal trading? If so, what types of principal trading should be addressed separately and why? What disclosures should the Commission require about principal trading and why?

53. Should the Commission limit or expand in any way the proposed disclosure requirements to require disclosure of arrangements regarding access by the broker-dealer operator or its affiliates to both other trading venues and affiliates of those other trading venues?

54. Form ATS–N requires, and Form ATS–G as proposed would require, that a Covered ATS name the affiliate(s) of the broker-dealer operator permitted to enter or direct the entry of orders and trading interest into the Covered ATS. The Covered ATS is required to describe the type of affiliates on the Covered Form. Should the Commission amend

[214] Although the narrative responses to Items 1(a) and 2(a) could typically be kept up-to-date via updating amendments to Form ATS–G, the Commission also notes that in most cases, if the ''yes'' or ''no'' response to Items 1(a) or 2(a) changes (*e.g.,* the Government Securities ATS changes its operations to allow affiliates to trade whereas they could not do so prior, or vice versa), the Government Securities ATS would be required to file a material amendment. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38826.

[215] This request is contained in Part III, Item 12. *See infra* Section III.C.12.

Form ATS–N, and not require in Form ATS–G, that the name(s) of affiliate(s) be disclosed?

55. Should the Commission require Government Securities ATSs to disclose the percentage of trading on the ATS attributable to each or all of the broker-dealer operator's business units, affiliates or both? Should Form ATS–G require a Government Securities ATS to disclose specific trade volume data for its trading with business units of the broker-dealer operator or its affiliates? If so, how should that volume be measured (*e.g.,* executed trades, dollar volume)? Should the Commission amend Form ATS–N to require such trading percentages or data for NMS Stock ATSs that execute orders with business units of the broker-dealer operator or its affiliates?

56. Would the disclosure of information about trading by the broker-dealer operator and its affiliates in the ATS be sufficient to address potential conflicts of interest? If disclosure alone is insufficient, are there other measures the Commission could take to mitigate potential conflicts of interest regarding trading? Should the Commission prohibit some or all trading by the broker-dealer operator and its affiliates in the ATS?

2. Order Interaction With Broker-Dealer Operator; Affiliates

Part II, Item 3 of proposed Form ATS–G would request information about the interaction of orders and trading interest between unaffiliated subscribers to the Government Securities ATS and orders and trading interest of the broker-dealer operator and its affiliates in the ATS. Part II, Item 3(a) of proposed Form ATS–G would require a Government Securities ATS to disclose whether a subscriber can opt out of interacting with orders and trading interest of the broker-dealer operator in the ATS, and Part II, Item 3(b) would require a Government Securities ATS to disclose whether a subscriber can opt out of interacting with the orders and trading interest of an affiliate of the broker-dealer operator in the ATS.[216] Part II, Item 3(c) of proposed Form ATS–G would require the Government Securities ATS to disclose whether the terms and conditions of the opt-out processes for the broker-dealer operator and affiliates required to be identified in Items 3(a) and (b) are the same for all subscribers. The Commission believes that proposed Part II, Item 3 would be important to unaffiliated market participants trading on an ATS because, given the potential for informational advantages by the broker-dealer operator or its affiliates,[217] some unaffiliated subscribers may not wish to interact with the order flow of the broker-dealer operator or its affiliates. This disclosure could also help subscribers understand whether and how they may avoid trading with the broker-dealer operator and its affiliates should they elect to use the services of the Government Securities ATS.

Request for Comment

57. Should proposed Form ATS–G request more or less information about how a market participant can limit its interaction on a Government Securities ATS with the broker-dealer operator or its affiliates? If commenters believe Form ATS–G should request more information, please provide specific information that would be useful along with an explanation of its utility.

3. Arrangements With Other Trading Venues

Part II, Item 4 of proposed Form ATS–G is designed to provide for the disclosure of formal or informal arrangements (*e.g.,* mutual, reciprocal, or preferential access arrangements)[218] between the broker-dealer operator or an affiliate of the broker-dealer operator and a trading venue (*e.g.,* ATS, OTC market maker, futures or options market)[219] to access the Government Securities ATS services (*e.g.,* arrangements to effect transactions or to submit, disseminate, or display orders and trading interest in the ATS).

Proposed Part II, Item 4 would require disclosure of an arrangement between the broker-operator for the Government Securities ATS or affiliate of the broker-dealer operator and a broker-dealer operator of an unaffiliated Government Securities ATS under which the broker-dealer operator would send orders or other trading interest to the unaffiliated Government Securities ATS for possible execution before sending them to any other destination. Item 4 also would require disclosure of the inverse arrangement pursuant to which any subscriber orders sent out of the unaffiliated Government Securities ATS would be sent first to the Government Securities ATS before any other trading venue. Item 4 would also require a summary of the terms and conditions of the arrangement such as, for example, whether the broker-dealer operator of the Government Securities ATS is providing monetary compensation or some other brokerage service to the unaffiliated Government Securities ATS. To the extent that a broker-dealer operator has an arrangement with another trading venue operated by the broker-dealer operator or an affiliate, or an unaffiliated trading venue, the Commission believes that market participants are likely to consider information about such arrangements relevant to their evaluation of a Government Securities ATS as a potential trading venue and such an arrangement may raise concerns about conflicts of interest or information leakage. The Commission is therefore proposing disclosure of such arrangements in Part II, Item 4 of proposed Form ATS–G.[220]

Request for Comment

58. What type of arrangements might a broker-dealer operator of a Government Securities ATS have with a trading venue for government securities or repos? Please explain and describe what information, if any, market participants may wish to know about such an arrangement.

4. Other Products and Services

Part II, Item 5(a) of proposed Form ATS–G is designed to disclose whether the broker-dealer operator offers subscribers any products or services for

[216] For example, if a broker-dealer operator uses algorithms to submit subscriber orders into the ATS, any steps that either the broker-dealer operator or the subscriber needs to take so that the ATS prevents those orders from trading with the broker-dealer operator or its affiliates would be required disclosures under Items 3(a) and 3(b), respectively.

[217] *See supra* Section III.B.1.

[218] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38831 n.769–70 and accompanying text. As the Commission discussed in the NMS Stock ATS Adopting Release, the disclosures required by Part II, Item 4 of proposed Form ATS–G are not so broad as to require the Government Securities ATS to list each unaffiliated subscriber that accesses its system. *See id.* at 38831.

[219] The Commission is using the term ''trading venue'' for proposed Form ATS–G instead of the term ''Trading Center,'' which is used in Form ATS–N, because ''Trading Center'' is a defined term for purposes of Regulation NMS (17 CFR 600(b)(78)). A trading venue for government securities can include, among other things, an ATS, an OTC market maker, a futures or options market, or any other broker- or dealer-operated platform for executing trading interest internally by trading as principal or crossing orders as agent.

[220] In the NMS Stock ATS Adopting Release, the Commission provided examples of when potential conflicts of interest and information leakage could occur as a result of preferential routing arrangements (*e.g.,* an affiliate is contractually obligated to route all unexecuted orders to ATS) or routing arrangements with affiliates (*e.g.,* all orders routed by the NMS Stock ATS must first be routed to an the affiliate(s)). Specifically, the former might result in information leakage should the arrangement provide that all orders not executed by the affiliate are to be sent to the NMS Stock ATS and the latter could provide incentive for the NMS Stock ATS to route orders to an affiliate instead of trying to execute the order in the ATS. The Commission believes that these issues could arise in the government securities markets, as well, so those examples are also applicable to this proposal. *See id.* at 38831 n.771.

the purpose of effecting transactions or submitting, disseminating, or displaying orders and trading interest in the Government Securities ATS (*e.g.,* algorithmic trading products that send orders to the ATS, order management or order execution systems, data feeds regarding orders and trading interest in, or executions occurring on, the ATS, order hedging or aggregation functionality), and if applicable, to indicate whether the terms and conditions of the services or products required to be identified in Part II, Item 5(a) are the same for all subscribers and the broker-dealer operator.[221]

Customers of a broker-dealer operator could be both subscribers to its ATS and customers of the broker-dealer operator and the broker-dealer operator may offer its customers trading products and services in addition to its ATS services. In certain cases, the product and service offered might be used by the customer in conjunction with the customer's use of the ATS. Broker-dealer operators of Government Securities ATSs may, directly or indirectly through an affiliate, offer products or services to subscribers for the purpose of, for example, submitting orders, or receiving information about displayed interest, in the ATS.[222] For example, a Government Securities ATS would be required to disclose any aggregation functionality that the broker-dealer operator or its affiliate(s) offers to subscribers, which, for example, could be used by subscribers to interface with the ATS to send or receive orders and trading interest to and from other markets, including U.S. Treasury Securities markets, over-the-counter spot markets, or futures markets. The Commission believes that subscribers to the Government Securities ATS would be interested in understanding the use of an aggregation functionality with the ATS and how it can help achieve their trading strategies. If the broker-dealer operator or its affiliate offered a product for effecting transactions or submitting, disseminating, or displaying orders and trading interest in the Government Securities ATS that was used in conjunction with related financial markets for non-government securities (*e.g.,* futures, currencies, swaps, corporate bonds), the ATS would summarize the terms and conditions for use of such a product in this item and explain the product's use under Part III, Item 16.

The Commission believes subscribers want to know the products or services that the broker-dealer operator or its affiliates may offer for the purpose of effecting transactions, or submitting, disseminating, or displaying orders and trading interest on the Government Securities ATS because such products or services may impact the subscribers' access to, or trading on, the ATS.[223] In some cases, a broker-dealer operator offering products or services in connection with a subscriber's use of the Government Securities ATS may result in the subscribers receiving more favorable terms from the broker-dealer operator with respect to their use of the ATS. For example, if a subscriber purchases a service offered by the broker-dealer operator of a Government Securities ATS, the broker-dealer operator might also provide that subscriber more favorable terms for its use of the ATS than other subscribers who do not purchase the service. Such favorable terms could include fee discounts or access to a faster connection line to the Government Securities ATS. Additionally, a broker-dealer operator of a Government Securities ATS may offer certain products and services only to certain subscribers or may offer products and services on different terms to different categories of subscribers. The Commission believes that subscribers would want to know, when assessing a Government Securities ATS as a potential trading venue, the range of services or products that the broker-dealer operator or its affiliates offers subscribers of the ATS, and any differences in treatment among subscribers, because such services or products may impact the subscribers' access to, or trading on, the ATS.

To the extent that a customer is a subscriber to the Government Securities ATS and is offered use of products and services by the broker-dealer operator or its affiliate for the purpose of effecting transactions or submitting, disseminating, or displaying orders and trading interest in the ATS, Part II, Item 5 of proposed Form ATS–G would require disclosures about those products or services. For example, if a broker-dealer operator offers its customers an order management system that can also be used by customer-subscribers to the Government Securities ATS to manage orders in the ATS (*e.g.,* adjust the pricing or size of an ATS order in relation to an order resting in or outside the ATS, modify order instructions to execute or cancel at a specified time or under certain market conditions), the ATS would be required to identify the order management system, provide a summary of the terms and conditions for its use, and identify the Part and Item number in Form ATS–G for where the order management system is explained. In addition, any services offered by the broker-dealer operator for subscribers to mitigate risk, such as limits on gross or net notional exposures by a subscriber, identification of duplicative orders in the ATS, or other checks offered related to order entry or authorizations to trade in the ATS, would be identified in this Item and explained further in Part III, Item 8 (Order Sizes). However, the proposed requests in Part II, Item 5 would not encompass trading products or services offered by the broker-dealer operator to customers that are not for the purpose of effecting transactions or submitting, disseminating, or displaying orders and trading interest in the Government Securities ATS.

To alleviate any concerns regarding the potential disclosure of commercially sensitive information in this disclosure request, the proposed disclosure request would require the Government Securities ATS to provide only a summary of the terms and conditions for the products and services disclosed and to explain how the product or service is used with the ATS in the applicable Item number in Part III of proposed Form ATS–G. The Commission believes that requiring only a summary narrative would normally not require the broker-dealer operator to disclose commercially sensitive information.

[221] For example, if a broker-dealer operator offers subscribers alternative algorithms to handle orders, including sending such orders to the Government Securities ATS, and there is a difference in the latency in which each of the alternatives transmits information, such differences in latency would need to be disclosed in Part II, Item 5 of proposed Form ATS–G.

[222] *See* NMS Stock ATS Proposing Release, *supra* note 62, at 81048. *See also* NMS Stock ATS Adopting Release, *supra* note 1, at 38832 n.779. For example, order hedging functionalities could encompass a product or service offered by the broker-dealer operator to a customer that the customer may use as a subscriber to the broker-dealer operator's ATS to hedge exposures of trading interest in or outside the ATS. A broker-dealer operator that offers such a functionality for use with the ATS would describe the terms and conditions for a subscriber to use the functionality in Part II, Item 5 and explain its use with regard to the ATS in Part III of Form ATS–G. For example, if the order hedging functionality affects order interaction in the ATS, the ATS would explain the functionality in Part III, Item 11(c). If the order hedging functionality involves futures and trading interest in the ATS, the Government Securities ATS would explain the related procedures under Part III, Item 16.

[223] Services for the purpose of effecting transactions, or submitting, disseminating, or displaying orders and trading interest on the Government Securities ATS that are offered by a third-party in contract with the broker-dealer operator or affiliates would also be responsive to this Item.

Request for Comment

59. What types of products and services do broker-dealer operators of Government Securities ATS or affiliates of the broker-dealer operator offer to subscribers and how are such products and services used in connection with the ATS?

60. What information about the products and services offered by broker-dealer operators would be helpful to market participants?

61. Should the Commission expand Part II, Item 5 of proposed Form ATS–G to require disclosure of products or services offered by the broker-dealer operator or its affiliates to subscribers, but not necessarily offered in connection with transacting on the Government Securities ATS?

5. Activities of Service Providers

a. Shared Employees

Part II, Item 6(a) of proposed Form ATS–G is designed to solicit disclosures relating to any employee of the ATS's broker-dealer operator or employee of its affiliate that provides services for both the operations of the Government Securities ATS and any other business unit or any affiliate of the broker-dealer operator (''shared employee'') that has access to subscriber confidential trading information. The Commission believes that disclosures about shared employees with access to subscriber confidential trading information would help market participants evaluate circumstances when there is the potential for information leakage. For example, the Commission believes that market participants would likely want to know if an employee of the broker-dealer operator (or employee of an affiliate of the broker-dealer operator) that is responsible for the operations of a system containing subscriber confidential trading information from the Government Securities ATS is also responsible for supporting, for instance, the principal trading activity of the broker-dealer operator, or another trading venue operated by the broker-dealer, or a trading venue that is an affiliate of the broker-dealer operator.

Request for Comment

62. Should the Commission expand the proposed disclosures in Part II, Item 6(a) to other employees, personnel, or independent contractors of the broker-dealer operator? If so, which employees, personnel, or independent contractors should be included and what information about such persons should be solicited?

b. Third-Party Service Providers

Part II, Item 6(b) of proposed Form ATS–G is designed to provide disclosures relating to any entity, other than the broker-dealer operator, that supports the services or functionalities of the Government Securities ATS. Information about the roles and responsibilities of service providers to the ATS is important because it could inform market participants about the potential for information leakage on the Government Securities ATS.[224] The Commission is not proposing that the third-party service provider requests encompass purely administrative items, such as human resources support, or basic overhead items, such as phone services and other utilities. The information solicited in this disclosure is meant to provide information about the extent to which a third party may be able to influence or control the operations of the ATS through involvement with its operations (such as operating the ATS's proprietary data feeds sent to subscribers). For example, any service provider for clearance and settlement of transactions on the ATS, consulting relating to the trading systems or functionality, regulatory compliance, and recordkeeping for the Government Securities ATS would be responsive to this request.[225]

Furthermore, the proposed requests under Part II, Items 6(c)–(d) would require the Government Securities ATS to disclose whether any service providers or their affiliates use the services of the ATS. If they do, the ATS would be required to identify the service providers, the service(s) used, and whether there is any disparate treatment between those service providers and other subscribers. Thus, a Government Securities ATS would only be required to obtain and disclose information about third-party vendors and their affiliates that actively use the services of the ATS; the ATS should be aware of all parties that use its services under its current recordkeeping obligations. The Commission believes that market participants, when analyzing potential conflicts of interest or information leakage, would find it very useful to understand whether potential counterparties with whom they are trading, and who also service the operation of the Government Securities ATS, have access to different or unique ATS-related services. Part II, Item 6(d) of proposed Form ATS–G would require the Government Securities ATS to identify and explain any differences in ATS services to a service provider and all other subscribers. Additionally, depending on the role and responsibilities of the third-party service provider, market participants may wish to consider evaluating the robustness of the Government Securities ATS's safeguards and procedures to protect confidential subscriber information.

This request for summary information is designed to provide market participants with a general understanding of the types of technology or hardware provided by the service provider as part of its responsibilities, and how that hardware or technology is used by the Government Securities ATS. The purpose of this disclosure is to provide information that subscribers can use to better understand whether the service provider might be able to access subscriber confidential trading information, so Government Securities ATSs should draft their disclosure with the goal of conveying such information. Simply stating that a third party provides technology or hardware to the ATS would not be responsive to the required summary of the service provider's role, but, on the other hand, the ATS would not have to provide information about the manufacturer of its hardware components.

Request for Comment

63. Are there any critical services or functionalities (*e.g.,* matching engine, market data) that, if provided by a third party, should be required to be described in a higher level of detail than the proposed ''summary'' level? If so, which services and functionalities?

6. Protection of Confidential Trading Information

Part II, Item 7(a) of proposed Form ATS–G would require a Government Securities ATS to describe its written safeguards and written procedures to protect the confidential trading information of subscribers to the ATS,

[224] Legacy Government Securities ATSs that operate pursuant to a Form ATS on file with the Commission are currently subject to the disclosure requirement of Exhibit E of Form ATS, which requires ATSs to disclose the name of any entity other than the ATS that will be involved in the operation of the ATS, including the execution, trading, clearing, and settling of transactions on behalf of the ATS; and to provide a description of the role and responsibilities of each entity. *See* Item 7 of Form ATS (describing the requirements for Exhibit E of Form ATS). Proposed Part II, Item 6(b) would expand upon this requirement.

[225] If a summary of the role and responsibilities of the service provider is disclosed in response to Part III of Form ATS–G, the Government Securities ATS need only list the applicable Item number in response to this Item. If there are services or functionalities that are not applicable to Part III, the ATS would identify the service provider, the services and functionalities, and also provide a summary of the role and responsibilities of the service provider in proposed Part II, Item 6(b).

including: (i) Written standards controlling employees of the ATS that trade for employees' accounts; and (ii) written oversight procedures to ensure that the safeguards and procedures described above are implemented and followed. The protection of confidential trading information is a bedrock component of the regulation of ATSs and is essential to ensuring the integrity of ATSs as execution venues. If such information is not protected, many of the advantages or purposes for which a subscriber may choose to send its orders to an ATS (*e.g.,* to trade anonymously and/or to mitigate the impact of trading in large positions) are eliminated. In cases where the confidential trading information of a subscriber is impermissibly shared with the personnel of the broker-dealer operator or any of its affiliates, such an abuse is also compounded by the conflicting interests of the broker-dealer operator. That is, in such a case, the broker-dealer operator has invited subscribers to trade on its ATS and may have abused that relationship to provide itself or its affiliates with a direct competitive advantage over that subscriber. Accordingly, the Commission believes that disclosures informing market participants about broker-dealer operators' written safeguards and written procedures to protect confidential trading information are necessary so market participants can independently evaluate the robustness of the safeguards and procedures and decide for themselves whether they wish to do business with a particular Government Securities ATS.

The Commission is proposing Part II, Items 7(b) and (c) to require a Government Securities ATS to disclose whether a subscriber can consent and withdraw consent, respectively, to the disclosure of its confidential trading information to any person (not including those employees of the ATS who are operating the system or responsible for its compliance with applicable rules). Subscribers should be able to give consent if they so choose to share their confidential trading information.[226] ATSs that transact in government securities vary in terms of the types of orders, indications of interests (''IOIs''), or other forms of trading interest that are confidential on their systems and what information about such trading interest may be shared. For example, an ATS might provide that no IOIs submitted by subscribers will be considered confidential, but may provide subscribers with the option to restrict the information in the IOI message to just the symbol and side (*i.e.,* buy or sell). For this example, Part II, Items 7(b) and 7(c) of proposed Form ATS–G would require the Government Securities ATS to describe the means by which a subscriber could control some of the information contained in the IOI message by providing consent or withdrawing such consent for the sharing of its confidential trading information.[227] For example, a subscriber can consent to its open trading interest being displayed to certain subscribers that the subscriber believes are less likely to misuse or exploit such information, or that have open trading interest on the contra side in the same symbol. If a Government Securities ATS allows subscribers to consent in this manner, the ATS would mark ''yes'' to Part II, Item 7(b). Continuing the example, if the subscriber can subsequently withdraw its consent to this display of its open trading interest, the Government Securities ATS would mark ''yes'' to Part II, Item 7(c).

Finally, the Commission is proposing Part II, Item 7(d) to require a Government Securities ATS to provide a summary of the roles and responsibilities of any persons that have access to confidential trading information, the confidential trading information that is accessible by them, and the basis for the access. In responding to this Item, the Government Securities ATS would initially need to describe what it considers to be confidential trading information. For example, the ATS would need to disclose whether only pre-trade order information would be considered confidential trading information, or whether post-trade information would also be treated as confidential trading information, and for what period of time. Furthermore, to explain the basis for the access, the Government Securities ATS would need to provide the basis for a person to have access to the confidential trading information and any limitations placed on that person's access.

Request for Comment—Part II

64. Should the Commission require the disclosure of the information in Part II of Form ATS–G? If so, what level of detail should be disclosed?

65. Would Part II of proposed Form ATS–G capture the information that is most relevant to understanding the Government Securities ATS and its relationship with the broker-dealer operator and the broker-dealer operator's affiliates? Please support your arguments.

66. Would the proposed disclosures in Part II require broker-dealer operators of Government Securities ATSs to reveal too much (or not enough) information about their structure and operations?

67. Is there other information about the activities of the broker-dealer operator and its affiliates that market participants might find relevant or useful in their assessment of use of the ATS? If so, describe such information and explain whether or not such information should be required to be provided under proposed Form ATS–G.

68. Should the proposed disclosures in Part II not be required to be disclosed on proposed Form ATS–G due to concerns regarding confidentiality, business reasons, trade secrets, burden, or any other concerns? If so, what information and why?

69. Are there ways to obtain the same information as would be required from Government Securities ATSs by Part II other than through disclosure on proposed Form ATS–G? If so, how else could this information be obtained and would such alternative means be preferable to the proposed disclosures in Part II?

70. Should Government Securities ATSs be required to publicly disclose in their entirety on Form ATS–G their written safeguards and written procedures to protect the confidential trading information of subscribers? Should the Commission require less information be disclosed about the written safeguards and procedures?

71. Would the information about written safeguards and written procedures to protect the confidential trading information of subscribers described in Form ATS–G be sufficient for subscribers to independently evaluate such safeguards and procedures and thus evaluate the ATS as a destination for their orders? Should the Commission prohibit the disclosure of confidential subscriber information in some circumstances?

C. Part III Form ATS–G: Manner of ATS Operations

Part III of proposed Form ATS–G is designed to provide public disclosures to help market participants understand, among other things, how subscribers' orders and trading interest are handled, matched, and executed on the Government Securities ATS. Part III of

[226] *See* Regulation ATS Adopting Release, *supra* note 35, at 70879.

[227] *See id.* The Commission believes that there may be some Government Securities ATSs that might not offer any means by which a subscriber could consent to the dissemination of its confidential trading information. A Government Securities ATS would be required to disclose this fact pursuant to Item 7(a). *See id.* at 70891 n.437.

Form ATS–G is modeled after Form ATS–N with few differences. Form ATS–G does not have an item corresponding to Part III, Item 16 (Routing) of Form ATS–N nor does it have an item corresponding to Part III, Item 24 (Order Display and Execution Access) of Form ATS–N as the associated rule is inapplicable to government securities. And, because of the close relationship between government securities markets and markets for other financial instruments (*e.g.,* futures), the Commission is proposing Part III, Item 16 of Form ATS–G to specifically highlight for market participants how the broker-dealer operator and subscribers may use a functionality or procedure to facilitate trading on, or source of pricing for, the Government Securities ATS in conjunction with a related market (*e.g.,* futures).[228] In Form ATS–G, the Commission has included ''yes'' or ''no'' questions, which the Commission believes would allow market participants to find information more efficiently and facilitate comparisons across Government Securities ATSs. The Commission also has included a requirement to identify and explain any differences in the treatment of subscribers and the broker-dealer operator that the Commission believes would help market participants discern any benefit or disadvantage they may receive in comparison to other market participants or the broker-dealer operator.[229] The Commission believes that the disclosure about differences in treatment of subscribers is important to market participants and would better allow them to decide whether submitting order flow to that Government Securities ATS aligns with their trading objectives.

1. Types of ATS Subscribers

Part III, Item 1 of proposed Form ATS–G is designed to provide information on the type(s) of subscribers that can use the Government Securities ATS services. The Item would provide market participants with information about the type of order flow in the Government Securities ATS based on the types of subscribers that use it. Government Securities ATSs may design their system for trading by retail investors, institutional investors, dealers, or any other type of market participant. The Commission is providing a list of market participants in Part III, Item 1 of proposed Form ATS–G that, in the Commission's experience, are commonly used.[230] The list includes: Retail investors, asset managers, brokers, dealers, investment companies, hedge funds, market makers, PTFs, insurance companies, pension funds, corporations, and banks. The list is non-exhaustive and a Government Securities ATS would be required to list any type of subscriber that can use the ATS's services.[231] In addition to disclosing its subscribers, a Government Securities ATS may use Part III, Item 1 to disclose any types of participants whose trading interest may reach the ATS. For example, for an ATS that only allows brokers or dealers as subscribers, the ATS could identify the types of customers for which the brokers or dealers send orders to the ATS.

Request for Comment

72. Should Form ATS–G include information about the types of subscribers to the ATS? Based on Commission experience, some ATSs only accept broker-dealers as subscribers to the ATS and various types of market participants send orders into the ATS through the broker-dealer subscriber. Should the Commission require the identification of the types of market participants whose orders may be sent to the ATS, whether directly or indirectly, by a broker-dealer subscriber to the Government Securities ATS? Should the Commission require the same information from NMS Stock ATSs by amending Form ATS–N? Would this information be useful to understanding the type of order flow in the ATS?

2. Eligibility for ATS Services

Part III, Item 2 of proposed Form ATS–G is designed to provide market participants with information about whether the Government Securities ATS requires subscribers to be registered broker-dealers or enter a written agreement to use the ATS services, and whether there are any other conditions that the ATS requires a person to satisfy before accessing the ATS services. This Item would require the conditions a person must satisfy ''*before* accessing the ATS services.'' On the other hand, Part III, Item 3 of proposed Form ATS–G (discussed *infra*), would require disclosures about any conditions that would exclude a subscriber, in whole or in part, from using the Government Securities ATS as a result of subscriber behavior while already actively participating in the ATS.[232]

The Commission believes that the disclosures required by Part III, Item 2 would allow market participants to understand the conditions that they would need to satisfy to participate on the Government Securities ATS. If the Government Securities ATS indicates that it does have conditions that a person must satisfy before accessing the ATS services, the request would require the ATS to list and provide a ''summary'' of those conditions. Some Government Securities ATSs may only have the eligibility requirement that a person be a client of the broker-dealer operator. In that case, any eligibility requirements to become a client of the broker-dealer operator would be responsive to this Item. For example, if a subscriber must be a customer of the broker-dealer operator, the Government Securities ATS would provide a summary of conditions the subscriber, as a customer, would need to satisfy (*e.g.,* know your customer) before its orders can be entered into the ATS. If the Government Securities ATS requires subscribers to be members of a third party for purposes of clearance and settlement, such as the Fixed Income Clearing Corporation's Government

[228] On Form ATS–N, an NMS Stock ATS that offers a functionality or procedure that subscribers could use on the ATS in conjunction with a related market (*e.g.,* futures, options) would disclose this information under Part II, Item 5 and Part III, Item 11.

[229] For example, in Part III, Item 5, if a Government Securities ATS designed its operations to allow only certain types of subscribers to enter orders into the ATS through direct means (*e.g.,* FIX protocol) and other types of subscribers to enter orders into the ATS through indirect means (*e.g.,* SOR or algorithm), the ATS would describe these means of entry in Part III, Items 5(a) and 5(c), respectively. If, for example, the Government Securities ATS were to treat a subscriber that enters orders directly into the ATS differently from other subscribers that also enter orders directly into the ATS with respect to means of order entry, the ATS would describe that different treatment in Part III, Item 5(b). Differences in treatment of subscribers and the broker-dealer operator are disclosed in the same way on Form ATS–N.

[230] As compared to Form ATS–N, the Commission is modifying the checkboxes listing types of subscribers to remove types that are not applicable to the government securities market and adding insurance companies, pension funds, and corporations to the list of checkboxes. The Commission is also proposing to add these checkboxes to Form ATS–N. *See infra* Section V.D. The Commission believes that adding these checkboxes will provide more granular information on the types of subscribers participating on an ATS in an easier-to-read format.

[231] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38820–21 (discussing the definition of ''subscriber'' and the persons encompassed thereunder).

[232] For example, if a Government Securities ATS has a practice of excluding subscribers that do not meet certain percentage thresholds for submitting firm-up orders in response to receiving an IOI or conditional order sent to them by the ATS, then this practice would be subject to disclosure under Part III, Item 3 of proposed Form ATS–G (''Exclusion from ATS Services'') and not Part III, Item 2 (''Eligibility for ATS Services'').

Securities Division, such information would be responsive.

Request for Comment

73. What eligibility requirements to access a Government Securities ATS are important to a potential subscriber or participant to the ATS and why?

3. Exclusion From ATS Services

Based on the Commission's experience, ATSs often have rules governing subscribers' participation on the ATS, and if a subscriber fails to comply with these rules, the ATS may limit or deny access to the ATS.[233] Part III, Item 3 of proposed Form ATS–G would require the Government Securities ATS to provide information about whether the ATS can exclude, in whole or in part, any subscriber from the ATS services, and if so, to list and provide a summary of the conditions for excluding (or limiting) a participant from using the ATS. The disclosures are designed to provide subscribers with information about when the Government Securities ATS can exclude, in whole or in part, a subscriber from the services of the ATSs and help them reasonably anticipate the types of activities that may cause them to be excluded (or limited) from using the services of the ATS. The Commission believes that allowing for a summary of conditions for excluding (or limiting) a participant would alert subscribers about the types of activities that may cause them to be excluded (or limited) from using the services of the Government Securities ATS while allowing the ATS to reasonably control the activities and quality of flow on its platform and not allowing subscribers to game a more detailed description of conditions for excluding.

Request for Comment

74. Is there any subscriber behavior for which ATSs commonly exclude a subscriber in whole or in part? What is that behavior(s) and what form of exclusion is commonly employed (*e.g.,* disqualification from ATS, limitation of services)?

4. Hours of Operations

Part III, Item 4 is intended to provide market participants with information about the days and hours of operations of the Government Securities ATS, including the times when orders or trading interest can be entered on the ATS, and any hours of operations outside of its regular trading hours, as established by the ATS. Notably, the Item would require a Government Securities ATS to provide the hours when it is operating, which would include functions such as accepting orders. Accordingly, the disclosure required is not limited to only those hours when the matching and execution of orders are occurring. The Commission believes that it is important for market participants and the Commission to understand when a Government Securities ATS operates and when orders can be entered, including when the ATS will accept orders outside of its regular trading hours. Making such information publicly available would enable market participants to more easily compare when trading interest can be entered on trading venues.

5. Means of Entry

Part III, Item 5 of proposed Form ATS–G is intended to disclose the means that can be used to directly enter orders and trading interest into the Government Securities ATS and any other means for entering orders and trading interest into the ATS (*e.g.,* smart order router, algorithm, order management system, sales desk, or aggregation functionality). The Government Securities ATS would be required to identify and explain the other means for entering orders and trading interest, indicate whether the means are provided through the broker-dealer operator itself, through a third-party contracting with the broker-dealer operator, or through an affiliate of the broker-dealer operator, and list and provide a summary of the terms and conditions for entering orders or trading interest into the ATS through these means.

Subscribers may submit orders or trading interest to the Government Securities ATS both directly and indirectly. A direct method of sending orders or trading interest to an ATS, for example, may include the use of a direct market access platform or FIX Protocol connection, which allows subscribers to enter orders or trading interest into the ATS without an intermediary. An example of an indirect method of submitting orders or trading interest to an ATS could include the use of a smart order router (''SOR''), algorithm or similar functionality, website, graphical user interface (''GUI''), aggregation interface, or front-end system. The means of order entry into an ATS (*e.g.,* direct or indirect) could impact the speed with which a subscriber's order is handled and potentially executed and could increase the risk of information leakage. The government securities markets are not interconnected markets like those for NMS stocks and therefore SOR technology may not be applied in the same manner by broker-dealer operators of Government Securities ATSs. The Commission believes, however, that SOR technology may be used to send or receive orders from a Government Securities ATS to reduce latency or send orders to markets with better prices for certain government securities, and to the extent it does, the ATS should be required to provide information about the SOR as required.

The Commission believes that the disclosures regarding the direct or indirect means of order entry would inform subscribers about the functionalities that their orders and trading interest pass through on their way to the ATS and help them assess any potential advantages that orders sent through the broker-dealer operator may have with respect to other subscribers on the Government Securities ATS. A Government Securities ATS would be required to identify the functionality that directly connects to the ATS (*e.g.,* algorithm) and, if present, any intermediate functionality that an ATS order passes through on its way to the functionality that directly connects to the ATS.[234] Conversely, if ATS orders submitted through an algorithm are sent to another intermediate functionality, and then submitted to the ATS by that functionality, such information would need to be disclosed pursuant to this Item.[235]

The proposed disclosure requirements would only require the Government Securities ATS to ''list and provide a summary of the terms and conditions for entering orders or trading interest into the ATS'' through these sources. Therefore, the Government Securities ATS would not need to provide a detailed description of the programming of the indirect means for entering order and trading interests that could put the ATS at a competitive disadvantage with competitors. However, if, for example, an ATS ''throttled'' the number of messages allowed for a given type of

[233] These limitations can result in some subscribers having different levels of functionality or more favorable terms of access than others. For example, in the Commission's experience, some ATSs exclude subscribers that frequently fail to respond with a firm-up order after receiving an IOI or request for quote.

[234] If an intermediate application or functionality has access to a subscriber's order information, the Government Securities ATS must take appropriate measures to protect the confidentiality of such information pursuant to Rule 301(b)(10) of Regulation ATS.

[235] If a broker-dealer operator permits subscribers to send orders to the ATS by excluding all other trading venues from where such orders could be sent, this procedure would in effect allow a subscriber to direct an order to the ATS and would be responsive to Part III, Item 5.

connection, that information would be responsive as a term or condition of that means of entry.

Among the advantages and disadvantages that market participants should be able to discern from the disclosure of Part III, Item 5(b) are any differences in the latency of the alternative means for entering orders and trading interest into the Government Securities ATS. The Commission understands that there might be different latencies associated with each alternative. For instance, in some cases, a direct connection to the Government Securities ATS may have reduced latencies as compared to indirect means where orders and trading interest pass through an intermediate functionality. A broker-dealer operator could also, for example, configure the Government Securities ATS to provide reduced latencies for certain means of order entry used by itself or its affiliates.[236] The Commission also believes that it is important for subscribers to understand a means of entry provided by an affiliate, even if it does not provide an advantage to a particular entity.

The Commission believes that disclosures about a broker-dealer operator's use of its or an affiliate's direct or indirect functionality to enter orders into the Government Securities ATS are important to market participants to allow them to assess the potential for information leakage. The indirect means of access (*e.g.,* SOR or algorithm) may obtain information about subscriber orders or trading interest that have been sent to the Government Securities ATS (and may now be resting on the ATS) and subscriber orders that have been sent out of the ATS. The high likelihood that an indirect means of accessing the Government Securities ATS could lead to leakage of subscribers' confidential trading information necessitates disclosure of certain information to subscribers about the use of such indirect means to send subscriber orders to or out of the ATS. In addition, there may be Government Securities ATSs where an intermediate functionality or entity is used by the ATS as the primary means to bring together the orders for securities of multiple buyers and sellers using established nondiscretionary methods (such as providing the means to enter, display or execute orders) and in this manner may be considered part of the ATS for purposes of Regulation ATS and Form ATS–G.[237]

Request for Comment

75. Are there any means for entering orders and trading interest into the Government Securities ATS where a higher level of detail should be required to explain their operation? Are there any aspects of those means of entry that are particularly important?

6. Connectivity and Co-Location

Part III, Item 6(a) of Form ATS–G would ask whether the Government Securities ATS offers co-location and related services, and if so, would require a summary of the terms and conditions for such services, including the speed and connection (*e.g.,* fiber, copper) options offered. Part III, Item 6(c) of Form ATS–G would require a Government Securities ATS to indicate whether it provides any other means besides co-location and related services described in the Item to increase the speed of communication with the ATS, and if so, to explain the means and offer a summary of the terms and conditions for its use. The Commission is also proposing to require in Part III, Item 6(e) the Government Securities ATS to indicate whether it offers any means to reduce the speed of communication with the ATS and if so, to provide a summary of the terms and conditions for its use.

Latency is an important feature of trading in certain government securities and market participants are interested in understanding the functionalities employed by Government Securities ATSs to influence it.[238] The Item would require a summary of the terms and conditions where a trading venue employs mechanisms to increase the latency or the length of time for orders, trading interest, or other information to travel from a user to the system. Subscribers of co-location services can experience faster or slower connection speeds to a Government Securities ATS depending on factors such as the distance of the customer servers from the matching engine, or the use or non-use of ''coiling'' to its matching engine to equalize connection speeds among subscribers, among others. Such differences in connection speed or latency would be required to be disclosed under Part III, Item 6(b). The Commission believes that the information disclosed in Item 6 would help market participants understand their connectivity options to the ATS and expedite the order entry process for subscribers.

Request for Comment

76. Are there any aspects of the means for increasing or reducing the speed of communication with Government Securities ATSs that the Commission should specifically require under this Item?

7. Order Types and Attributes

Part III, Item 7 would require a Government Securities ATS to identify and explain each order type offered by the ATS. To provide transparency to market participants and the Commission, the Item would require a complete and detailed description of the order types available on the Government Securities ATS, their characteristics, operations, and how they are handled. The Commission believes that all market participants should have full information about the operations of order types available on a Government Securities ATS for market participants to comprehensively understand how their orders and trading interest will be handled and executed on the ATS. Order types are a primary means by which users of a Government Securities ATS communicate their instructions for handling their trading interest to the ATS. Given the importance, diversity, and complexity of order types, the Commission is proposing to require Government Securities ATSs to disclose the information called for by Part III, Item 7 on proposed Form ATS–G.

The Commission believes that market participants should have sufficient information about all aspects of the operations of order types available on a Government Securities ATS to understand how to use order types to achieve their trading objectives, as well as to understand how order types used by other market participants could affect their trading interest. The Commission believes that a detailed description of the characteristics of the order types of a Government Securities ATS would assist subscribers in better understanding how their orders would function and interact with other orders

[236] The proposed rule would not require that the Government Securities ATS calculate and disclose precise latencies for each means of entry.

[237] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38832 and 38844.

[238] *See* October 15 Staff Report, *supra* note 14, at 36–37; Treasury Request for Information, *supra* note 10, at 3928. *See also* Letter from Dan Cleaves, Chief Executive Officer, BrokerTec Americas, and Jerald Irving, President, ICAP Securities USA LLC, to David R. Pearl, Office of the Executive Secretary, Treasury Department, dated April 22, 2016 (''BrokerTec/ICAP Letter''), at 3–4, *available at https://www.treasurydirect.gov/instit/statreg/gsareg/ICAPTreasuryRFILetter.pdf;* Letter from C. Thomas Richardson, Managing Director, Head of Electronic Trading Service, Wells Fargo Securities, and Cronin McTigue, Managing Director, Head of Liquid Products, Wells Fargo Securities, to Treasury Department, dated April 21, 2016, at 6–7, *available at https://www.treasurydirect.gov/instit/statreg/gsareg/RFIcommentWellsFargo.pdf.*

on the ATS. It also would allow market participants to see what order types could be used by other market participants, which could affect the probability, timing, and quality of their own executions. For example, if the time priority of a pegged order changes in response to changes in the reference price, that would affect the likelihood of execution for such an order.

Request for Comment

77. What are the most prevalent order types on Government Securities ATSs? Are there more important means than order types for subscribers to communicate the handling of their trading interest on Government Securities ATSs? Does Form ATS–G capture all of the means for subscribers to communicate the handling of their trading interest? Are there any aspects of order types on Government Securities ATSs that should be specifically addressed in the Item? If yes, please explain.

8. Order Sizes

Part III, Item 8 would require a Government Securities ATS to provide information about any requirements related to the permissible size of trading interest (*e.g.,* minimum or maximum size, odd-lot, mixed-lot, trading increments) and specify any trading interest size requirements and any related handling procedures.[239] This information would inform subscribers about the permissible size of orders and trading interest that a subscriber could enter on the ATS. For example, if a Government Securities ATS has minimum or maximum order sizes, or a minimum increment size requirement for order modifications, those requirements and related handling procedures would be responsive to the Item. Broker-dealer operators employ market access and risk management controls and procedures that prevent the entry of erroneous orders and orders that are above a subscriber's predetermined threshold. If order size requirements are imposed on subscribers as part of a risk management procedure, an explanation of those procedures as they relate to the ATS would be responsive to this Item. An explanation of how a Government Securities ATS's requirements and conditions related to the size of trading interest differ among subscribers and persons would also provide a market participant with information regarding how its trading interest would be handled vis-à-vis other market participants. The information that would be required by Item 8 would also be useful to the Commission's monitoring of developments in market structure.

Request for Comment

78. Are there any operations or procedures, either of an ATS or a broker-dealer operator, that could limit the entry, or size of, a subscriber's orders submitted to the ATS? If so, please describe these operations or procedures and explain why they are important to subscribers.

9. Indications of Interest

Part III, Item 9 of proposed Form ATS–G is designed to provide information about whether the Government Securities ATS sends or receives any messages indicating trading interest, and if so, to identify and explain the use of the messages, including information contained in messages, how and when messages are transmitted, the type of persons that receive the message, the possible responses to IOIs by recipients, and the conditions under which the messages might result in an execution in the ATS.[240]

Government Securities ATSs use IOIs to convey trading interest available on those trading venues. Understanding the manner in which Government Securities ATSs use messages that convey trading interest, such as IOIs and similar functionalities, could be useful to market participants for finding a contra-party as well as understanding potential information leakage. In the Commission's experience, the information that Government Securities ATS include in IOIs can vary, including different combinations of symbol, size, and/or price, and the Commission believes that this information would be relevant to market participants when understanding what information about their orders and trading interest is communicated to others and assessing potential information leakage. Identifying the type of persons that receive the message and possible responses, moreover, could help market participants understand when an IOI would result in a match, how market participants can use the ATS, who will see their trading interest, how their trading interest will be executed, and the potential for information leakage. If a Government Securities ATS employs a negotiation functionality that begins with IOIs to arrive at matches between subscribers, the ATS would describe the steps undertaken by the ATS from the initial IOI to the eventual match of trading interest.

Request for Comment

79. Are there aspects of IOIs as they are used in Government Securities ATSs that are not covered by this Item? What information about IOIs or the process for transmitting IOIs are important to subscribers?

10. Opening and Reopening

Part III, Item 10 of proposed Form ATS–G is designed to provide information about whether a Government Securities ATS uses any special procedures to match orders at the opening, or to set a single opening or reopening price to, for example, maximize liquidity and accurately reflect market conditions at the opening or reopening of trading. The Commission believes that market participants would likely want to know about any special opening or reopening processes employed by a Government Securities ATS, including which order types participate in the ATS's opening or reopening processes.

Information about when the Government Securities ATS will price and prioritize orders and trading interest during the opening or reopening of the ATS would provide market participants with the information they need to plan and execute their trading strategies during these periods. The Item would also, for example, require disclosure of any procedures to match orders to set a single opening or reopening price to maximize liquidity and accurately reflect market conditions at the opening or reopening of trading. For any orders allowed to be submitted before an ATS opens for trading, the Item would require an explanation of what priority rules would apply to those orders. The Commission believes most participants consider important the procedures for the pricing and priority of orders and trading interest, and the order types allowed because these rules and procedures can directly impact their execution price.

[239] The Commission is consolidating the information requested in Part III, Item 8(a)–8(f) of Form ATS–N into 2 subparts (Part III, Item 8(a) and 8(b)) in Form ATS–G to streamline the format of responses. The Commission believes the information requested is the same.

[240] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38847 for additional discussion of IOIs, actionable IOIs, conditional orders, and similar functionalities. The Commission removed the terms ''conditional orders'' and ''actionable IOIs'' that were included on the corresponding item on Form ATS–N. These terms appear to be less prevalent in the government securities market. However, the Commission believes the term ''IOI'' used herein would encompass both conditional orders and actionable IOIs.

11. Trading Services, Facilities and Rules

Part III, Item 11(a) would require a Government Securities ATS to provide a summary of the structure of the ATS marketplace and explain the means and facilities for bringing together the orders of multiple buyers and sellers on the ATS. Part III, Item 11(c) would require a Government Securities ATS to explain the established, non-discretionary rules and procedures of the ATS. Part III, Item 11 is designed to solicit disclosures about the facilities, functionalities, and mechanisms that the Government Securities ATS uses to match the orders and trading interest of counterparties and facilitate transactions on the ATS and to inform market participants and the Commission about the type of marketplace the ATS provides (*e.g.,* crossing system, auction market, limit order matching book, voice).

An ATS brings together orders when orders entered into the system for a given security have the opportunity to interact with other orders entered into the system for the same security.[241] An ATS can bring together orders through various methods. For instance, an organization, association, or group of persons brings together orders if it displays, or otherwise represents, trading interests entered on the system, such as a consolidated quote screen, to users.[242] The bringing together of orders can also occur if subscribers' orders are centrally collected for future processing and execution through, for example, a limit order matching book that allows subscribers to display buy and sell orders in particular securities and to obtain execution against matching orders contemporaneously entered or stored in the system.[243] As explained above, to qualify for the Exchange Act Rule 3a1–1(a)(2) exemption from the statutory definition of ''exchange,'' an ATS must, among other things, bring together the orders of multiple buyers and sellers.[244]

Government Securities ATSs may offer subscribers various types of trading mechanisms to bring together orders that would be disclosed under Part III, Item 11. For example, many ATSs bring together multiple buyers and sellers using limit order matching systems. Other ATSs use crossing mechanisms that allow participants to enter unpriced orders to buy and sell securities, with the ATS's system crossing orders at specified times at a price derived from another market.[245] Some ATSs use an auction mechanism (or similar workup functionality) that matches multiple buyers and sellers by first pausing execution in a certain security for a set amount of time, during which the ATS's system seeks out and/or concentrates liquidity for the auction; after the trading pause, orders will execute at either a single auction price or according to the priority rules for the auction's execution. In a workup, an ATS may have a private phase, where the two original contra parties submitting orders can negotiate, and a public phase where all subscribers can submit orders at the workup price. Some ATSs use a blotter scraping functionality, which may inform the ATS about trading interest residing on a participant's order management system but not yet entered into the ATS; the ATS or broker-dealer operator oftentimes can automatically generate orders from the trading interest and enter them into the ATS on behalf of the subscriber, in accordance with the relevant terms and conditions, when certain contra-side trading interest exists in the ATS. Certain ATSs may use a voice system to bring together orders as well, or a combination of voice and electronic systems. A Government Securities ATS could also offer services or functionalities to facilitate trading on, or source pricing for, the Government Securities ATS in conjunction with related markets for government securities that would be encompassed under this Item.[246]

The Commission believes that information about the trading facilities, functionalities, and mechanisms offered by a Government Securities ATS would help market participants evaluate whether the operations of the ATS comports with their trading strategies. Part III, Item 11(a) of proposed Form ATS–G would require Government Securities ATSs to provide a summary of the structure of the ATS marketplace, which would describe the type of market the ATS operates, such as a limit order book, auction market, or crossing system, in a more concise manner. This Item would require more detailed responses when explaining the means and facilities for bringing together the orders of multiple buyers and sellers on the Government Securities ATS. The Commission is also proposing to request information on whether the means and facilities are the same for all subscribers and the broker-dealer operator in Part III, 11(b) and is formatting the subpart request as a ''yes'' or ''no'' question.

Part III, Item 11(c) is designed to inform market participants about the rules and procedures used to determine how orders and trading interest may interact upon being entered into a Government Securities ATS.[247] The Commission previously explained in the Regulation ATS Adopting Release that use of established, non-discretionary methods could include operation of a trading facility or the setting of rules governing subscribers' trading.[248] For example, the Commission considers the use of an algorithm by an electronic trading system, which sets trading procedures and priorities, to be a trading facility that uses established, non-discretionary methods.[249] Similarly, the Commission has previously stated that rules imposing execution priorities, such as time and price priority rules, would be ''established, non-discretionary methods.''[250] As proposed, a Government Securities ATS would be required to address each aspect of the non-discretionary rules and procedures that are specifically listed as being included in Part III, Item 11(c).

The Commission is also proposing that a Government Securities ATS disclose pricing methodologies used for each type of security traded by the ATS under Part III, Item 11(c). For example, orders may be priced using spreads off of a benchmark price, or spreads between two different maturities of a security. An ATS may also restrict the allowable deviation from a benchmark price, or allow for indicative pricing of certain securities. If a transaction has more than one leg, the ATS may price both legs according to a price derived

[241] *See* Regulation ATS Adopting Release, *supra* note 35, at 70849.

[242] *See id.*

[243] *See id.*

[244] *See id.* As explained in the Regulation ATS Adopting Release, systems in which there is only a single seller, such as systems that permit issuers to sell their own securities to investors, would not be included within Rule 3b–16. *See id.* at 70849. The Commission emphasized in the Regulation ATS Adopting Release that the mere interpositioning of a designated counterparty as riskless principal for settlement purposes after the purchasing and selling counterparties to a trade have been matched would not, by itself, mean that the system does not have multiple buyers and sellers. *See id.*

[245] *See id.* at 70849 n.37.

[246] If a Government Securities ATS offers subscribers a functionality, for example, in conjunction with a non-government securities market, the Government Securities ATS would provide information about the use of the functionality with the ATS and non-government securities market in Part III, Item 16 of proposed Form ATS–G.

[247] As compared to Part III, Item 11(c) of Form ATS–N, the Commission has added examples of functionalities used in the government securities market for which the Government Securities ATS would be required to explain the non-discretionary rules and procedures, if applicable.

[248] *See* Regulation ATS Adopting Release, *supra* note 35, at 70851–52.

[249] *See id.* at 70851.

[250] *See id.* at 70852.

from one of the securities traded. In response to this request, a Government Securities ATS would be required to describe the ATS's procedures for determining all pricing methodologies and to the extent the pricing methodologies differ among subscribers and the broker-dealer operator, the ATS must disclose those differences.

Item 11 would require Government Securities ATSs to disclose the various terms and conditions under which orders interact and match. Some Government Securities ATSs may offer price-time priority to determine how to match orders (potentially with various exceptions), while others may offer midpoint-only matching with time priority. Some Government Securities ATSs might also take into account other factors to determine priority. For example, a Government Securities ATS may assign either a lower or higher priority to an order entered by a subscriber in a certain class (*e.g.,* orders of principal traders or retail investors) or sent from a particular source (*e.g.,* orders sent by an algorithm or similar functionality) when compared to an equally priced order entered by a different subscriber or via a different source. Furthermore, a Government Securities ATS might elect to apply different priority rules for matching IOIs than it does for matching orders. An ATS may also have rules concerning how the ATS would handle the order of a subscriber who seeks to execute at a size larger than what is available at the existing workup price. Also, if applicable, the Item would require an explanation of which party to a trade would receive any price improvement depending on the priority, order type, and prices of the matched orders and the percentage of price improvement the party would receive. A broker-dealer operator could also act as the counterparty for each side of a transaction that matches on its ATS. These disclosures would allow the Commission to better evaluate whether the entity that filed a proposed Form ATS–G meets the criteria of Exchange Act Rule 3b-16 and the definition of a Government Securities ATS.

A description of the ''established, non-discretionary rules and procedures'' of the Government Securities ATS is a principal requirement of Item 11(c), and the Commission is proposing to require that any differences among subscribers and the broker-dealer operator related to these methods be identified and explained in Part III, Item 11(d).

Request for Comment

80. Are there any specific means or facilities used to bring together multiple buyers and sellers on ATSs that trade government securities and repos that should be specifically included as an example in this Item? Are there any rules and procedures that govern trading of government securities and repos that should be specifically included as examples in this Item?

12. Liquidity Providers

Part III, Item 12 would request information about any formal or informal arrangements with any subscriber or the broker-dealer operator to provide orders or trading interest to the Government Securities ATS. The Item is designed to provide information about arrangements whereby a liquidity provider undertakes to buy or sell continuously, or to meet specified thresholds of trading or quoting activity. A Government Securities ATS may want to ensure that there is sufficient liquidity in a particular government security to incentivize market participants to send order flow in that government security to the ATS. To do this, the ATS may engage certain subscribers to provide liquidity to the Government Securities ATS and perform similar functions to that of a market maker on a national securities exchange.[251] The obligations required of liquidity providers and the benefits that they provide could vary across Government Securities ATSs. The Commission believes that information about liquidity providers would be useful to subscribers and market participants who, for example, may want their orders to only interact with agency orders (and not with those of a liquidity provider), or, conversely, may themselves want to become liquidity providers on the Government Securities ATS. The Commission believes that such arrangement could take many forms and the function of the liquidity provider on an ATS could depend on the structure and trading protocols of the ATS. Therefore, this Item could cover, for example, arrangements or agreements between the broker-dealer operator and another party to trade on the Government Securities ATS. The proposed Item does not cover agreements with a subscriber that has no obligation to buy or sell government securities or repos on the ATS.

Request for Comment

81. Are there any arrangements between Government Securities ATSs and market participants to provide orders or trading interest to the Government Securities ATS that may not be required by this Item but should be? If any, what is the nature of those arrangements and why are they important to disclose publicly on Form ATS–G?

13. Segmentation; Notice

Part III, Item 13 of proposed Form ATS–G would require a Government Securities ATS to disclose information about how orders and trading interest in the ATS can be segmented into categories, classifications, tiers, or levels. This Item would provide market participants with an understanding of the categories of order flow or types of market participants with which they may interact. In addition, the information provided would allow them to both assess the consistency of a segmented group and determine whether the manner in which the trading interest is segmented comports with their views of how certain trading interest should be categorized. Disclosure of the procedures and parameters used to segment categories would allow a market participant to determine whether its view of what constitutes certain trading interest it wants to seek or avoid is classified in the same way by the Government Securities ATS. For example, a subscriber may find it useful to understand the standards a Government Securities ATS uses to categorize high frequency trading firms so that it can compare the criteria used by the ATS with its view of what constitutes a high frequency trading firm, and thus be able to successfully trade against or avoid such trading interest. Similarly, information regarding the procedures applicable to trading among segmented categories would allow market participants to evaluate whether they can successfully trade against or avoid the segments of trading interest.

Some Government Securities ATSs segment order flow entered in the ATS according to various categories for purposes of order interaction. For example, a Government Securities ATS could elect to segment trading interest by type of participant (*e.g.,* buy-side or sell-side firms, PTFs, agency-only firms, firms above or below certain assets under management thresholds). When segmenting order flow in the ATS, a Government Securities ATS might look to the underlying source of the trading interest such as the trading interest of retail customers. Some Government Securities ATSs segment by the nature of the trading activity, which could include segmenting by patterns of

[251] These liquidity providers may quote in a particular government security on the ATS during trading hours and may receive a benefit for performing this function, such as discounts on fees, rebates, or the opportunity to execute with a particular type of segmented order flow.

behavior, time horizons of traders, or the passivity or aggressiveness of trading strategies. Government Securities ATSs might use some combination of these criteria or other criteria altogether. The ATS might use these segmented categories to design its order interaction rules, allowing only orders from certain categories to interact with each other.

The Commission recognizes the potential concern that describing the precise criteria used by the ATS to segment orders and trading interest could result in gaming by subscribers of those criteria and thus, the reduction of the effectiveness of segmentation as a control. On the other hand, the Commission believes that market participants are interested in understanding how their orders and trading interest are categorized on the ATS and the types of market participants that would interact with those orders and trading interest. The Commission believes that Part III, Item 13 of proposed Form ATS–G appropriately balances these competing interests by soliciting a *summary* of the parameters for each segmented category. By requiring Government Securities ATSs to provide a summary of these parameters on Form ATS–G, rather than a detailed analysis of the parameters and how they are calculated, this Item is designed to avoid responses that could allow the gaming or manipulation of segmentation criteria.

The Commission believes disclosing the origin of a customer order of a broker-dealer could be a form of segmentation because it can facilitate users restricting their trading to only certain types of market participants and it can contribute to information leakage and adverse selection of orders of institutional investors, who generally trade passively. Accordingly, the Commission is proposing to require a Government Securities ATS to disclose if it identifies orders or trading interest entered by a customer of a broker-dealer on the ATS as a customer order.

Request for Comment

82. What information about the segmentation of order flow by a Government Securities ATS would be important to persons that use the services of the ATS?

14. Counter-Party Selection

Part III, Item 14 of proposed Form ATS–G would require Government Securities ATSs to provide information about whether orders or trading interest can be designated to interact or not interact with certain orders or trading interest in the ATS. To analyze whether the ATS is an appropriate venue to accomplish their trading objectives, market participants have an interest in knowing whether—and how—they may designate their orders or trading interest to interact or avoid interacting with specific orders, trading interest, or persons on the ATS. Part III, Item 14 is designed to require disclosure of such information.

For instance, the disclosures proposed under this Item would allow a participant in the Government Securities ATS to know whether it can interact with certain categories of orders and trading interest on the ATS or can designate an order submitted to the ATS to interact only with orders of certain other types of ATS participants. For example, the ATS might allow subscribers to choose from categories of orders or categories of subscribers that the broker-dealer operator segments in the ATS. For example, buy-side or institutional subscribers might seek to trade only against other buy-side or institutional order flow, or might seek to avoid trading against PTFs or so-called high frequency trading firms. Also, it would also be responsive to this Item for an ATS to state whether a subscriber can restrict interacting with its own orders, whether such restrictions are by default or only upon subscriber request, and any applicable limitations on such restrictions. This Item would require description of any procedures allowing a subscriber to limit its counterparty on an order-by-order basis or a participant-by-participant basis, how it would go about doing so, and how such selection would affect the interaction and priority of trading interest. For example, an ATS would include in its response to this Item whether a participant can select a category of orders or category of subscribers for counterparty designation by marking its order to interact with them or whether the broker-dealer operator performs the action, and also, whether the broker-dealer operator implements the counterparty designation during the same trading day as the subscriber's selection or on a date thereafter.

Request for Comment

83. Should proposed Form ATS–G request more or less information about how orders or trading interest can be designated to interact or not interact with certain orders or trading interest in the Government Securities ATS? Are there important forms of counter-party selection that the Commission should address?

15. Display

Part III, Item 15 of proposed Form ATS–G would require a Government Securities ATS to disclose how and when orders and trading interest bound for or resting in the ATS may be displayed or made known to any person. The Commission believes that many market participants are sensitive to precisely how and when their trading interest is displayed or otherwise made known both inside and outside the Government Securities ATS as such information could result in other market participants trading ahead of their positions, and thus in inferior execution prices. These participants could use these disclosures to evaluate whether sending orders to a particular Government Securities ATS would achieve their trading strategies.

The display of subscriber orders and trading interest can occur in a number of ways. For instance, a Government Securities ATS may offer a direct data feed from the ATS that contains real-time order information.[252] Some ATSs have arrangements, whether formal or informal (oral or written) with third parties to display the Government Securities ATS's trading interest outside of the ATS, such as IOIs from the subscribers being displayed on vendor systems, or arrangements with third parties to transmit IOIs between subscribers. An ATS would be required to include this type of information in its response to this Item.

The Commission believes that subscribers that use the services of the Government Securities ATSs, including customers of the broker-dealer operator, have limited information about the extent to which their orders and trading interest sent to the ATS could be displayed outside the ATS. For instance, when a Government Securities ATS sends electronic messages outside of the ATS that expose the presence of orders or other trading interest on the ATS, it is displaying or making known orders or other trading interest on the ATS. An ATS would be required to disclose the circumstances under which the ATS sends these messages, the types of market participants that received them, and the information contained in the messages, including the exact

[252] In the case of a Government Securities ATS offering a direct data feed with information about orders or trading interest in the ATS, the ATS would be required to disclose under Part III, Item 15 what information the data feed provides about the orders and trading interest, the associated timing in receiving the feed (*e.g.,* real-time, delayed), how a subscriber would receive the feed (*e.g.,* connectivity), and if all subscribers are treated the same in receiving the feed, including whether all subscribers are eligible to receive it and any differences in latency receiving the feed.

content of the information, such as symbol, price, size, attribution, or any other information made known. In another example of display, subscribers' orders or trading interests directed to the Government Securities ATS could pass through the broker-dealer operator's non-ATS systems or functionalities before entering the ATS, such as an algorithm or a SOR. Such non-ATS systems and functionalities could be used to support the broker-dealer operator's other business units, including any trading venues.[253] Proposed Part III, Item 15(b) would also require the ATS to describe differences in latencies with the Government Securities ATS displaying subscribers' orders and trading interest due to a functionality of the ATS. For example, if a Government Securities ATS transmits and displays its proprietary data feed to certain subscribers faster than to other subscribers as a result of the alternative means offered by the ATS to connect, such information would be responsive.

In response to this Item, the Commission is proposing that a Government Securities ATS identify the recipient of displayed information by identifying the functionality of the broker-dealer operator (*e.g.,* SOR, algorithm) or the type of market participant,[254] or both, that receives the displayed information. For example, if orders bound for the Government Securities ATS pass through the broker-dealer operator's common gateway, or algorithm, the ATS would need to disclose these functionalities as the order was displayed to a functionality of the broker-dealer operator that would likely be outside the ATS. If orders resting in the Government Securities ATS are displayed to certain subscribers or one or more of the broker-dealer operator business units, the ATS would need to identify these types of subscribers and business units of the broker-dealer operator by type of market participant (*e.g.,* institutional investors, PTFs, market makers, affiliates, trading desks at the broker-dealer operator, market data vendors, clearing entities, and potential subscribers, among others). The Item would also require a Government Securities ATS that offers workups to match orders to disclose the information that is displayed to all subscribers or certain subscribers in public or private phases of the workup, as well as what characteristics of the orders are displayed.

The proposed Item would not require information about employees of the Government Securities ATS in non-trading related roles, such as technical, quality assurance, compliance or accounting roles, among others, that support the ATS's operations and to whom orders and trading interest are made known in the performance of their duties.[255]

Request for Comment

84. What information involving government securities and repos does an ATS display? Are there levels of displayed information that an ATS may offer to market participants? If so, what are the levels and are there any specific terms and conditions for a market participant to access that information? What functionalities does the ATS use to display information in government securities and repos? Please explain the purpose and operation of any such functionality.

85. For Government Securities ATSs that display trading interest both on the ATS and outside the ATS, what is the process for market participants to submit orders to interact with the trading interest that is displayed outside the ATS?

86. Are there any aspects in relation to the display of trading interest on the Government Securities ATS that should be specifically addressed in the Item? Are there any aspects of display that are unique to Government Securities ATSs?

16. Interaction With Related Markets

Part III, Item 16 of proposed Form ATS–G would require a Government Securities ATS to provide information about any functionality or procedure to facilitate trading on, or source pricing for, the Government Securities ATS that is offered by the broker-dealer operator or its affiliates[256] and used in conjunction with markets for financial instruments related to government securities. Markets for financial instruments related to government securities could include those non-government securities markets that trade futures, currencies, fixed income, and swaps, for example (''Related Markets''). If applicable, the Government Securities ATS would: (i) Identify the functionality, procedures, and source of pricing and the Related Market; (ii) state whether the functionality, procedure, and source of pricing is provided or operated by the broker-dealer operator or its affiliate, and whether the Related Market is provided or operated by the broker-dealer operator or its affiliate; (iii) explain the use of the functionality, procedures, and source of pricing with regard to the Related Market and the Government Securities ATS, including how and when the functionality, procedures, and source of pricing can be used, by whom, and with what markets; and (iv) state whether the functionality, procedures, and source of pricing identified are the same for all subscribers and the broker-dealer operator.

Item 16 requires the Government Securities ATS to disclose how the broker-dealer operator and subscribers may use a functionality or procedure with the Government Securities ATS and a Related Market. Such functionalities or procedures could include, for example, offering order types to facilitate transactions on the ATS and the Related Market, or procedures to allow subscribers to perform multi-leg transactions involving another market and the ATS. A Government Securities ATS could offer, for example, Exchange-for-Physical (''EFP'') transactions that can involve markets in addition to the ATS. An EFP transaction where ATS subscribers agree to exchange a financial product, such as a futures contract on a government security, for the underlying related government security, would be responsive to this Item. The Commission believes that it would be important to subscribers to understand functionality and procedures offered such as these, as they can impact subscribers' experience on the ATS.[257]

A Government Securities ATS would also be required to provide information about how the ATS uses market data from a Related Market, through an aggregator or otherwise, to provide the

[253] The broker-dealer operator typically controls the logic contained in these systems or functionality that determines where an order that the broker-dealer operator receives will be handled or sent.

[254] *See* Part III, Item 1 of proposed Form ATS–G (providing examples of types of market participants).

[255] The Government Securities ATS, as proposed, would be subject to the requirements of Rule 301(b)(10) and would be required to establish adequate safeguards and procedures to protect subscribers' confidential trading information, which must include: Limiting access to the confidential trading information of subscribers to those employees of the ATS who are operating the system or responsible for its compliance with these or any other applicable rules; and implementing standards controlling employees of the ATS trading for their own accounts. *See* 17 CFR 242.301(b)(10).

[256] Services to facilitate trading or source pricing for the Government Securities ATS in conjunction with non-government securities markets that are offered by a third-party in contract with the broker-dealer operator or affiliates would also be required to be disclosed under this Item.

[257] To the extent that a Government Securities ATS offers subscribers a functionality or procedure that the subscriber can use on the ATS in conjunction with a market for government securities (*e.g.,* trading venue for U.S. Treasury Securities or options), the Government Securities ATS should disclose information about that functionality and procedure in Part III, Item 11 of proposed Form ATS–G.

services it offers.[258] Among other things, for example, the Government Securities ATS would need to disclose in response to this Item its use of such market data to display, price, prioritize, execute, and remove trading interest on the ATS.[259] As part of this explanation, the Government Securities ATS would specify, if applicable, when the ATS may change between its use of different sources of market data to provide its services. In response to Part III, Item 16 of proposed Form ATS–G, the Government Securities ATS would explain how, for example, market data from a Related Market, is received by the ATS, compiled, and delivered to the matching engine. For example, among other possible arrangements, the Government Securities ATS could explain that market data from a Related Market is received by the broker-dealer operator and assembled there, and subsequently delivered to the matching engine, or that market data is sent directly to the matching engine, which normalizes the data for its use. For example, a Government Securities ATS would disclose whether it uses market data from the futures market to price and execute EFP transactions and describe how it uses that market data under this Item.

A broker-dealer operator's activities in financial instruments related to government securities or offerings of a Related Market, such as a futures exchange, along with its operation of an ATS, raise the potential for information leakage of a subscriber's confidential trading information, or the broker-dealer operator could provide certain advantages to subscribers that use a Related Market that it operates. As such, Item 16 would require information about whether the functionality, procedures, and source of pricing on the Government Securities ATS or the Related Markets are provided or operated by the broker-dealer operator or its affiliates. Finally, the Government Securities ATS would be required to indicate whether the functionality, procedure, and source of pricing are the same for all subscribers and the broker-dealer operator, and if not, to explain any differences.

Request for Comment

87. What are commenters' views on the relationship between markets for government securities and Related Markets and how investors may use these markets together with a Government Securities ATS to achieve their trading objectives?

88. What aspects of government securities markets and Related Markets, such as the futures markets, do market participants use for trading on a Government Securities ATS? What information about those markets might be useful to a subscriber and why?

89. Trading in NMS stocks can involve other markets for financial instruments that are not NMS stocks, such as options or futures on NMS stocks, and an NMS Stock ATS that offers a functionality or procedure that subscribers could use with the ATS and another market would be required to explain it under Part II, Item 5 and Part III, Item 11 on Form ATS–N. Should the Commission adopt amendments to Form ATS–N to include an item similar to proposed Item 16 in Form ATS–G to separate and highlight disclosures about such a functionality?

17. Closing

Part III, Item 17 of proposed Form ATS–G would require Government Securities ATSs to disclose information about differences between how orders and trading interest are treated on the ATS during any closing session(s) and during regular trading hours established by the ATS. The Item is designed to provide market participants with information about processes the Government Securities ATS uses to transition to the next trading day, including whether the ATS offers any particular order types during a closing session(s) or has different procedures for closing trading for a particular trading session and transitioning trading to the next trading day. The vast majority of requests in Part III of proposed Form ATS–G relate to trading during the Government Securities ATS's regular hours. Therefore, when discussing differences between trading during the Government Securities ATS's closing session(s) and during regular hours set by the ATS, the Government Securities ATS would be required to discuss differences as compared to relevant information disclosed in Part III Items, including, among others, order types (Item 7), order interaction, priority, matching, and execution procedures (Item 11), segmentation (Item 13), and display (Item 15). The Commission believes this information would be important for market participants to understand the closing procedures around a particular trading session, if any, to carry out their trading objectives.[260]

18. Trading Outside of Regular Trading Hours

Part III, Item 18(a) of proposed Form ATS–G would require a Government Securities ATS to provide information about its procedures for trading outside its regular trading hours, and subpart (b) would require the ATS indicate whether there are any differences between trading outside of its regular trading hours and trading during its regular hours. To the extent that there are differences, the Government Securities ATS must describe those differences. Similar to Item 17 (requesting differences between any closing session(s) and regular trading hours), a Government Securities ATS would be required to disclose differences between trading outside of its regular trading hours and during regular trading hours with respect to the relevant information disclosed in Part III Items, including, among others, order types (Item 7), order interaction, priority, matching, and execution procedures (Item 11), segmentation (Item 13), and display (Item 15). Many of the disclosures discussed elsewhere in Form ATS–G will relate to the ATS's regular trading hours so the ATS can simply discuss any differences between trading during its regular hours and trading outside its regular trading hours in Part III, Item 18(b), if applicable. The Commission believes that market participants would likely want to understand unique trading procedures that the Government Securities ATS offers outside its regular trading hours to assess whether participating in such trading would help accomplish their trading objectives.

19. Fees

Part III, Item 19 of proposed Form ATS–G would require a Government Securities ATS to provide information on any fees or charges for use of the ATS's services, including any fees or charges for use of the ATS's services that are bundled with the subscriber's use of non-ATS services or products offered by the broker-dealer operator or its affiliates, and any rebate or discount of fees or charges. The Commission believes that disclosures regarding fees on proposed Form ATS–G are necessary and important, and should not be voluntary for Government Securities

[258] If a Government Securities ATS uses market data from another market that trades government securities, that information would be disclosed under Part III, Item 23 of proposed Form ATS–G.

[259] Disclosure of any market data used by the Government Securities ATS for government securities, including market data for options and repos on government securities, would be required under Part III, Item 23 of proposed Form ATS–G.

[260] The Item would, for example, require disclosure of any procedures to match orders to set a single closing price to maximize liquidity and accurately reflect market conditions at the close of trading in the ATS.

ATSs. Fee disclosures on proposed Form ATS–G are designed to allow all market participants to analyze the fee structures across Government Securities ATSs in an expedited manner and decide which ATS offers them the best pricing according to the characteristics of their order flow, the type of participant they are (if relevant), or any other aspects of an ATS's fee structure that serves to provide incentives or disincentives for specific market participants or trading behaviors. Requiring disclosures of ATS fees is warranted as, in the Commission's experience, fees can be a primary factor for market participants in deciding where to send their orders and trading interest.

Part III, Item 19 would request that Government Securities ATSs include in their descriptions the structure of the fee, variables that impact the fee, and differentiation among types of subscribers, and the Commission provided examples of responsive information included in a parenthetical in the text of each subpart.[261] The Item also would require a range for each type of fee (*e.g.,* subscription, connectivity, and market data [262]) charged on the Government Securities ATS. With regard to the variables that impact the fees set, ATSs would be required to be specific and delineate how a given variable would likely impact the fee level (*e.g.,* higher or lower).

The Commission recognizes that the fee structures of Government Securities ATSs can vary and that not all Government Securities ATSs apply set tiers or categories of fees for subscribers; however, the Commission believes that a market participant should have sufficient information to understand the fees for using the services of the Government Securities ATS. Recognizing the various fees that can be charged by Government Securities ATSs, the Commission is specifying in the fee request the types of information that a Government Securities ATS must provide in response to the Commission's proposed request to describe its fees (*e.g.,* the structure of the fees, variables that impact each fee, differentiation among types of subscribers, and the range of fees). These disclosures are designed to provide market participants with more insight regarding the fees charged so that they can better understand how fees may apply to them and assess how such fees may impact their trading strategies. Although the fees charged for Government Securities ATS services may be individually negotiated between the broker-dealer operator and the subscriber, the disclosures about the type of fees charged by the Government Securities ATS are designed to help market participants discern how the ATS's fees are organized and compare that information across Government Securities ATSs, which could reduce the search costs of market participants in deciding where to send their orders and trading interest. The Commission believes that Government Securities ATSs should be required to disclose differences in the treatment among ''types of subscribers.'' This information would allow subscribers to observe whether a Government Securities ATS is offering preferential treatment for certain types of subscribers with respect to fees.

Part III, Item 19(b) of proposed Form ATS–G would require a description of any bundled fees, including a summary of the bundled services and products offered by the broker-dealer operator or its affiliates, the structure of the fee, variables that impact the fee (including, for example, whether the particular broker-dealer services selected would impact the fee), differentiation among types of subscribers, and range of fees. Part III, Item 19(b) is designed to allow market participants to better evaluate fees for bundled services that include access to the Government Securities ATS. Government Securities ATSs would be required to provide information, including the relevant services and products offered by the broker-dealer operator and its affiliates for each bundled fee offered, that will provide context to market participants with which to assess how bundled fees could apply to them as subscribers.[263]

Part III, Item 19(a) of proposed Form ATS–G covers charges to subscribers for their ''use of the Government Securities ATS services'' [264] and does not request information on fees charged for non-ATS services by a third party not in contract with the broker-dealer operator.[265] The disclosure requests under proposed Part III, Item 19 contain a stand-alone Item—Item 19(c)—which requests information about rebates and discounts of fees that are identified in subparts (a) and (b) of Item 19. Item 19(c) would require information about rebates and discounts that is similar to that which is required for fees (*e.g.,* the structure of the rebate or discount, variables that impact the rebate or discount, differentiation among types of subscribers, and range of rebate or discount).

Request for Comment

90. An ATS that is subject to the Fair Access Rule for a covered security is required to comply with fair access requirements under Rule 301(b)(5) of Regulation ATS, which, among other things, requires an ATS to establish written standards for granting access to trading on its system and not unreasonably prohibit or limit any person with respect to access to services offered by the ATS by applying the written standards in an unfair or discriminatory manner. An ATS that charges certain fees to one class of subscribers but different fees to other classes of subscribers for the same services could not, if it were subject to the Fair Access Rule, discriminate in this manner unless it adopted written reasonable standards and applied them in a fair and non-discriminatory manner. Should an ATS that is subject to the Fair Access Rule and is a meaningful source of orders and trading interest for NMS stocks or government securities be required to disclose the fees that the ATS charges for access to its services on Form ATS–N and proposed Form ATS–G? Would such a disclosure of the fees of an ATS that is subject to the Fair Access Rule provide additional transparency to subscribers and market participants and help ensure that the ATS does not unreasonably prohibit or limit any person with respect to access to the ATS's services by applying the written standards in an unfair or discriminatory manner?

91. In the alternative, should the Commission require NMS Stock ATSs and Government Securities ATSs that are subject to the Fair Access Rule and that exceed even higher volume thresholds to disclose their fee schedule

[261] The Commission is including non-exhaustive lists of examples of responsive information in parentheticals in the text of the Item. For instance, for descriptions of the structure of the fee, the Commission is providing as examples a fixed fee, volume-based and transaction-based fee structures. For the description of variables that may impact the fee, the Commission is providing as examples: The types of securities traded, block orders, and the form of connectivity to the ATS. For the description of the differentiation among types of subscribers for the fee, the Commission is providing as examples of the types of subscribers: Broker-dealers, institutional investors, and retail investors.

[262] For example, if a Government Securities ATS distributed a market data feed and charged a fee for it, the ATS would be required to provide the information responsive to Item 19 regarding that fee.

[263] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38858 (discussing responses to Item 19(b) depending on whether there is an explicit fee for the ATS as part of any bundled services).

[264] The NMS Stock ATS services generally include those services used for the purpose of effecting transactions in NMS Stock, or for submitting, disseminating or displaying orders on the ATS. *See* 17 CFR 242.300(b).

[265] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38858 (discussing what fees should be categorized as for use of the ATS's services).

on Form ATS–N and Form ATS–G? For example, should only an NMS Stock ATS and a Government Securities ATS that exceeds 10 percent, 20 percent, 30 percent, or 40 percent average weekly or daily trading volume in NMS stocks, U.S. Treasury Securities, or Agency Securities, respectively, be required to publicly disclose their fee schedule on Form ATS–N and Form ATS–G as applicable?

92. What fees should the Commission require an ATS subject to the Fair Access Rule to disclose on Form ATS–N or Form ATS–G?

20. Suspension of Trading

Part III, Item 20 of proposed Form ATS–G would require a Government Securities ATS to provide information about any procedures for suspending or stopping trading on the ATS, including the suspension of trading in a U.S. Treasury Security or an Agency Security. This Item is designed to, for example, inform market participants of whether, among other things, a Government Securities ATS will continue to accept orders and trading interest after a suspension or stoppage occurs, whether the ATS cancels, holds, or executes orders and trading interest that were resting in the ATS before the suspension or stoppage was initiated, and what type of notice the ATS provides to subscribers regarding a suspension or stoppage. Examples of system disruptions would include, but are not limited to, internal software problems that prevent the Government Securities ATS's system from opening or continuing trading,[266] a significant increase in volume that exceeds the ability of the trading system of the ATS to process incoming orders,[267] and the failure of the ability of the trading system of the ATS to receive external pricing information that is used in the system's pricing methodology. The Commission believes that information regarding a Government Securities ATS's procedures about how orders and trading interest might be handled by the ATS during a suspension or stoppage of trading would be useful to market participants because an ATS's procedures might require the cancelation of existing orders or preclude the acceptance or execution of orders or trading interest during a suspension, both of which would impact a subscriber's orders or its ability to trade on the ATS. This information would better inform a subscriber's trading decisions at the time of such an event and thus help that subscriber accomplish its trading objectives. If a Government Securities ATS establishes different procedures for suspending or stopping trading on the ATS depending on whether the source of the disruption is internal or external, a description of both procedures would be responsive to this request. In addition, this Item would require disclosure of procedures whereby a Government Securities ATS suspends trading in U.S. Treasury Securities or Agency Securities so that it does not cross the relevant volume thresholds and become subject to the Fair Access Rule under Regulation ATS, or Regulation SCI (as proposed herein).

The Commission also believes that information regarding the procedures for how a Government Securities ATS would handle orders during a suspension of trading or system disruption or malfunction would help the Commission better monitor the securities markets.

Request for Comment

93. Should proposed Form ATS–G request more or less information about any procedures for suspending or stopping trading on the Government Securities ATS?

21. Trade Reporting

Part III, Item 21 of proposed Form ATS–G would require a Government Securities ATS to provide information on any procedures and material arrangements for reporting transactions on the ATS. Trade reporting furthers the transparent, efficient, and fair operation of the securities markets.[268] FINRA member firms are required to report transactions in U.S. Treasury Securities and Agency Securities to TRACE.[269]

Part III, Item 21 would require a Government Securities ATS to disclose its trade reporting procedures for reporting transactions in government securities on the ATS to an SRO. For example, it would be responsive to Item 21 for a Government Securities ATS to disclose whether the ATS has a specific procedure for reporting transactions in a government security to the SRO at different times based on, for example, a subscriber's use of a particular order type, or the type of subscriber involved in the transaction. Government Securities ATSs would also be required to disclose ''material'' arrangements for reporting transactions on the ATS. The Commission recognizes that there could be arrangements relevant to trade reporting, such as the specific software used to report, that play a minor role in the ATS's trade reporting and need not be disclosed. On the other hand, if an ATS uses a third party to report transactions occurring on the ATS or has a backup facility that it uses for trade reporting, that information is likely to be responsive as a material arrangement. By proposing to require reporting only of material arrangements, the Commission hopes to reduce potential burdens on Government Securities ATSs while providing market participants with sufficient information to understand how their trade information will be reported. Also, the Commission believes the proposed disclosure of the trade reporting procedures would allow the Commission to more easily review the compliance of the Government Securities ATS with its applicable trade reporting obligations as a registered broker-dealer (as proposed herein).

22. Clearance and Settlement

Part III, Item 22 is designed to provide information on any procedures and material arrangements undertaken to facilitate the clearance and settlement of transactions on the Government Securities ATS. The integrity of the trading markets depends on the prompt and accurate clearance and settlement of securities transactions. For example, counterparties to a trade face counterparty credit risk, regardless of whether they choose to clear and settle bilaterally or through a central counterparty, and therefore knowledge of the clearing process promotes market integrity.[270] As a preliminary matter, ''clearance and settlement'' refers generally to the activities that occur following the execution of a trade. These post-trade processes are critical to ensuring that a buyer receives securities and a seller receives proceeds in accordance with the agreed-upon terms of the trade by settlement date. The disclosures required by this Item are intended to cover each of the steps in the post-trade process from the time of execution (including whether the Government Securities ATS is a counterparty to a transaction and

[266] *See* Regulation SCI Adopting Release, *supra* note 2, at 72254–55 n.28.

[267] *See id.* at 72255 n.29.

[268] *See* Regulation ATS Adopting Release, *supra* note 35, at 70887 (stating the market-wide transaction and quotation reporting plans operated by the registered national securities exchanges are responsible for the transparent, efficient, and fair operations of the securities markets).

[269] *See supra* notes 50–51 and accompanying text.

[270] *See* Treasury Market Practices Group (TMPG), *White Paper on Clearing and Settlement in the Secondary Market for U.S. Treasury Securities* (July 12, 2018), *available at https://www.newyorkfed.org/medialibrary/Microsites/tmpg/files/CS-DraftPaper-071218.pdf.* ''The TMPG found that many market participants do not understand the role of the [interdealer brokers] platform in terms of who their counterparty credit risk was to and the roles of various market participants in settlement and clearing.'' *Id.* at 27.

whether the obligations of a counterparty are ever assigned or novated), through trade matching and other clearing procedures (including whether the Government Securities ATS requires its participants to be a member of a registered clearing agency, whether participants have any particular clearing obligations, and whether transactions are—wholly or partially—submitted to a registered clearing agency or cleared bilaterally using clearing banks or clearing agents), until settlement of the transaction (including whether counterparties make use of custodians, settlement banks, or a registered clearing agency). If the Government Securities ATS has adopted clearing and settlement processes or imposes any obligations on its participants in the event of a disruption (for example, a settlement fail, counterparty default, or liquidity shortfall), this proposed Item should include a discussion of these processes and any resulting participant obligations.

The Item requires the disclosure of ''material'' arrangements to facilitate the clearance and settlement of transactions on the Government Securities ATS. For example, an arrangement under which a third party would have a role in clearance and settlement may constitute a material arrangement that could trigger the disclosure requirement under Part III, Item 22. Limiting the explanation required to material arrangements would reduce the burden on Government Securities ATSs while at the same time still allowing market participants to understand and more easily compare clearing arrangements required across Government Securities ATSs.

Part III, Item 22 is designed to help market participants understand the measures the Government Securities ATS takes to facilitate clearance and settlement of transactions. Market participants should know and be able to understand any requirements a Government Securities ATS places on its subscribers, or other persons whose orders are sent to the ATS, to have clearance and settlement systems and/or arrangements with a clearing firm. The Commission believes market participants would likely find the disclosures required by this Item to be useful in understanding the measures undertaken by a Government Securities ATS to facilitate clearance and settlement of subscriber orders on the ATS and allow them to more easily compare the clearance arrangements required across Government Securities ATSs as part of deciding where to send their trading interest. The Commission believes that these disclosures may assist the Commission in better understanding the clearance and settlement procedures of Government Securities ATSs and risks and trends in the market as part of its overall review of market structure.

Request for Comment

94. What aspects of the procedures and material arrangements undertaken to facilitate the clearance and settlement of transactions on Government Securities ATSs are important for ATSs to disclose on proposed Form ATS–G for the benefit of market participants?

23. Market Data

Part III, Item 23 of proposed Form ATS–G would require a Government Securities ATS to provide information about the sources of market data in government securities and repos used by the ATS and how the ATS uses that market data from these sources to provide the services that it offers. The Commission believes that market participants would likely find it useful to know the source and specific purpose of the market data that the Government Securities ATS might use as the market data received by the ATS might affect the price at which orders and trading interest are prioritized and executed in the ATS, including orders that are pegged to an outside reference price. A Government Securities ATS would also be required to provide information about how the ATS uses market data in government securities and repos to provide the services it offers.[271] Among other things, for example, proposed Part III, Item 23 would require the disclosure of the use of market data to display, price, prioritize, execute, and remove trading interest. As part of this explanation, the ATS would be required to specify, if applicable, when the ATS may change sources of market data to provide its services. A Government Securities ATS would also be required to explain how market data is received by the ATS, compiled, and delivered to the matching engine. For example, among other possible arrangements, the Government Securities ATS could explain in response to the Item that market data in government securities or repos is received by the broker-dealer operator and assembled there, and subsequently delivered to the matching engine, or that market data is sent directly to the matching engine, which normalizes the data for its use.

Request for Comment

95. What are the sources of market data in government securities and repos that are available to market participants as well as to Government Securities ATSs and how do market participants and ATSs use this information? What disclosures about an ATS's use of market data would be important to market participants?

24. Fair Access

Part III, Item 24 of proposed Form ATS–G would provide a mechanism under which a Government Securities ATS would notify market participants whether it has triggered the proposed fair access threshold and, if so, whether the ATS is subject to the Fair Access Rule. If subject to the Fair Access Rule, the Government Securities ATS would be required to describe the written standards for granting access to trading required to comply with Rule 301(b)(5)(ii) of Regulation ATS (as proposed to be applied herein).

If an ATS crosses the fair access thresholds, Rule 301(b)(5)(ii)(B) requires the ATS to ''not unreasonably prohibit or limit any person in respect to access to services offered by such alternative trading system by applying the [written] standards . . . in an unfair or discriminatory manner.''[272] The Commission believes that the proposed disclosures would facilitate its oversight of Government Securities ATSs and their compliance with Rule 301(b)(5) (as proposed herein). In addition, the proposed disclosures would allow market participants to assess whether fair access is in fact being applied by a Government Securities ATS that meet the fair access threshold, in part by making publicly available a description of the ATS's written standards for granting access.[273]

Request for Comment

96. Is there other information that market participants might find important or useful regarding the written standards for granting access to trading on an ATS that is subject to the Fair Access Rule? If so, describe such information and explain whether, and if so why, such information should be required to be provided under proposed Form ATS–G, Form ATS–N, or both.

[271] Market data reflecting options traded on government securities that is used by the ATS should be discussed in response to Part III, Item 16.

[272] *See* 17 CFR 242.301(b)(5)(ii)(B). The Commission is proposing that any change in a Government Securities ATS's response to Item 24 would be filed as a contingent amendment. *See supra* note 176 and accompanying text.

[273] The Commission is not including an item similar to Part III, Item 24 of Form ATS–N (Order Display and Execution Access) because Rule 301(b)(3) of Regulation ATS, which forms the basis for the item, only applies to an ATS's NMS stock activities.

25. Aggregate Platform-Wide Data; Trading Statistics

Part III, Item 25 of proposed Form ATS–G is designed to make public aggregate, platform-wide order flow and execution statistics that a Government Securities ATS already otherwise collects and publishes, or provides to one or more subscribers to the ATS. The Commission believes that a Government Securities ATS may choose to create and publish or provide to one or more subscribers or persons information concerning order flow and execution quality for different reasons. To the extent that a Government Securities ATS has made a determination to create and publish or provide to subscribers certain aggregate platform-wide order flow and execution quality statistics, the Commission believes that others may also find such information useful when evaluating the ATS as a possible venue for their orders. Proposed Part III, Item 25 would impose the same disclosure requirement as Part III, Item 26 of Form ATS–N for NMS Stock ATSs.[274]

Item 25 would not require a Government Securities ATS to amend its Form ATS–G every time it receives a data request. To comply with the requirements under Part III, Item 25, Form ATS–G only requires a Government Securities ATS that supplies aggregate platform-wide data to update its disclosures for this Item on a quarterly basis.[275] For instance, if a participant were to request updated or new aggregate platform-wide statistics in January, the Government Securities ATS would not be required to immediately file an updating amendment containing these statistics after complying with the participant's request. Rather, the ATS would need to file an updating amendment within 30 days following the end of the quarter. That updating amendment must contain the most recently distributed version of these statistics, as well as the most recently distributed version of all other aggregate platform-wide data that is provided during that quarter. The Commission notes that communications associated with the responsive statistics are not required to be publicly filed. In the prior example, for instance, if the statistics provided in the quarterly amendment are the ones provided in January (*i.e.,* those are the latest version of those aggregate platform-wide statistics the ATS distributed), the ATS would not (and should not) also attach to Form ATS–G the participant's email requesting the statistics.

Furthermore, Part III, Item 25 of proposed Form ATS–G would only require a Government Securities ATS to publicly disclose aggregate platform-wide data. As such, a Government Securities ATS would not be required to disclose individualized or custom reports containing data relating to that participant's specific usage of the ATS. For example, an individual participant's trade reports, order and execution quality statistics, and other statistics specific to a participant's trading on the ATS would not be covered by the disclosure request in Part III, Item 25. Whether a specific type of statistic should be categorized as an order and execution statistic or considered aggregate, platform-wide data will depend on the nature of the specific statistics being compiled by the Government Securities ATS. A Government Securities ATS would independently evaluate any statistics that it compiles and distributes to determine whether they are responsive to this disclosure request.

Part III, Item 25 would require the Government Securities ATS to attach both the responsive statistics and its explanation of the categories or metrics of those statistics as Exhibits 4 and 5, respectively. Also, in lieu of filing Exhibits 4 and 5, the Government Securities ATS could certify that the information requested under Exhibits 4 and 5 is available at the website provided in Part I, Item 7 of the form and is accurate as of the date of the filing.

Request for Comment

97. Does Part III of proposed Form ATS–G capture the information that is most relevant to understanding the operations of the Government Securities ATS? Are there any Items that commenters believe are unnecessary? If so, why?

98. Is there other information that market participants might find relevant or useful regarding the operations of Government Securities ATSs? If so, describe such information and explain whether, and if so why, such information should be required to be provided under proposed Form ATS–G.

99. Is there any information related to repos that Form ATS–G should require?

100. Is there any information related to options on government securities that Form ATS–G should require?

101. Is there any information that would be required by Part III of proposed Form ATS–G that a Government Securities ATS that should not be required to disclose due to concerns regarding confidentiality, business reasons, trade secrets, commercially sensitive information, burden, or any other concerns?

102. Should the Commission adopt a more limited or expansive definition of ''affiliate'' for purposes of Part III?[276]

103. Would the disclosures under Part III of proposed Form ATS–G help market participants better evaluate trading opportunities and decide where to send orders to reach their trading objectives?

104. Would the proposed disclosures in Part III of proposed Form ATS–G require a Government Securities ATS to reveal too much (or not enough) information about its structure and operations?

105. Are there ways to obtain the same information as would be required from Government Securities ATSs by Part III of proposed Form ATS–G other than through disclosure on proposed Form ATS–G? If so, how else could this information be obtained?

106. Could the proposed requirement to disclose the information that would be required by Part III of proposed Form ATS–G impact innovation on Government Securities ATSs?

107. Are there any aggregate platform-wide order flow and execution statistics of the Government Securities ATS that should not be required to be disclosed under Item 25?

D. Part IV of Proposed Form ATS–G

Part IV of proposed Form ATS–G would require a Government Securities ATS to provide certain basic information about the point of contact for the ATS, such as the point of contact's name, title, telephone number, and email address. Part IV would also require the Government Securities ATS to consent to service of any civil action brought by, or any notice of any proceeding before, the Commission or an SRO in connection with the ATS's activities. The Commission is proposing that Form ATS–G would be filed electronically and require an electronic signature. The signatory to each Form ATS–G filing would be required to represent that the information and

[274] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38861–63.

[275] If, for example, a Government Securities ATS publishes or provides a particular statistic on a daily basis, the ATS would include in Exhibit 4 of proposed Form ATS–G the statistic that was published or provided to one or more subscribers on the last trading day of the calendar quarter (*e.g.,* the statistic published or provided on June 30th or last trading day prior to June 30th). If a Government Securities ATS publishes or provides a particular statistic weekly, the ATS would be required to include in Exhibit 4 of proposed Form ATS–G the statistic that was published or provided to one or more subscribers at the end of the week prior to the end of the calendar quarter (*e.g.,* the statistic published for the last full week of June).

[276] *See supra* note 211 for the definition of affiliate under Form ATS–G.

statements contained on the submitted Form ATS–G, including exhibits, schedules, attached documents, and any other information filed, are current, true, and complete. Given that the Commission believes market participants would use information disclosed on Form ATS–G to evaluate potential venues, and that the Commission intends to use the information to monitor developments of Government Securities ATSs, the Commission believes it is important that Form ATS–G contain disclosures that are current, true, and complete, and therefore is proposing to require that the signatory to Form ATS–G make such an attestation.

IV. EDGAR Filing Requirements; Structured Data

The Commission is proposing that Form ATS–G be filed electronically in a structured format through EDGAR. By filing in EDGAR, Government Securities ATSs would be given the option of filing using a web-fillable Form ATS–G that will render into XML in EDGAR, or to file directly in XML using the XML schema for ATSs as published on the Commission's website. With both options, the Commission would receive the Form ATS–G disclosures in XML format. All Form ATS–G filings made public will be centrally located on EDGAR for the public to access in the same XML format in which the Commission received the Form ATS–G filing. Form ATS–G would be filed in the same format as current Form ATS–N.[277] The Commission believes, as discussed in the NMS Stock ATS Adopting Release, its XML schema and architecture for the web-fillable Form ATS–G would incorporate certain validations to ensure consistency and completeness among filings.[278] The Commission is also proposing that Form ATS and Form ATS–R be filed electronically through EDGAR[279] and both forms would be available only to the Commission staff with the exceptions discussed below.

Request for Comment

108. Are the proposed EDGAR filing requirements for Form ATS–G, Form ATS, and Form ATS–R appropriate? Should the Commission adopt an alternative means by which NMS Stock ATSs file Form ATS–N instead of EDGAR? As an alternative, should filers be required to submit Form ATS–G, Form ATS, and/or Form ATS–R to the Commission through another means, such as the Commission's SRO Rule Tracking System/Electronic Form Filing System (''SRTS/EFFS'') or email?

109. Should the Commission adopt the proposal that Form ATS–G be filed with the Commission in a structured format? If so, what standards of structuring should be used for information to be provided on proposed Form ATS–G? If not, what format should proposed Form ATS–G take? Please identify the format and explain.

110. Should the Commission require filers to submit Form ATS–G, Form ATS, and/or Form ATS–R in the Inline XBRL format?

V. Amendments to Regulation ATS, Form ATS, Form ATS–R, and Form ATS–N

A. Amendments to Rules 301(b)(5) and 301(b)(6) of Regulation ATS

The Commission is also proposing to remove an exclusion for compliance with the Fair Access Rule that is applicable to ATSs that trade equities[280] under Rule 301(b)(5) and the Capacity, Integrity, and Security Rule under Rule 301(b)(6). An ATS is excluded from complying with the requirements of the Fair Access Rule and the Capacity, Integrity, and Security Rule if the ATS: (a) Matches customer orders for a security with other customer orders; (b) such customers' orders are not displayed to any person, other than employees of the ATS; and (c) such orders are executed at a price for such security disseminated by an effective transaction reporting plan, or derived from such prices.[281] In adopting the exclusion, the Commission stated that ATSs of this nature, the so-called ''passive systems,'' did not contribute significantly to price discovery; however, the Commission also stated that they had the potential to and frequently do affect the markets from which their prices are derived, and thus, the Commission would continue to monitor these systems and reconsider whether the requirements should apply if concerns arise in the future.[282]

The Commission has reconsidered the exclusion for passive systems to compliance with the Fair Access Rule and believes it should be removed. In the Regulation ATS Adopting Release, the Commission explained that fair treatment by ATSs of subscribers is particularly important when an ATS captures a large percentage of trading volume in a security because investors lack access to viable alternatives to trading on the ATS.[283] Since the adoption of Regulation ATS, passive systems (as the term is used in the Regulation ATS Adopting Release) for NMS stocks have garnered a significant percentage of trading volume in securities and have come to play an important role in matching buyers and sellers of securities.[284] The Commission believes that eliminating the Rule 301(b)(5)(iii) exclusion would ensure that the Fair Access Rule is applied as intended and help ensure fair treatment of potential and current subscribers by any type of ATS that captures a large percentage of trading in a security or type of security.

The Commission is also proposing to amend Rule 301(b)(6) to remove the exclusion for compliance with the Capacity, Integrity, and Security Rule under Rule 301(b)(6)(iii).[285] As part of Regulation SCI, Rule 301(b)(6) of Regulation ATS was amended to no longer apply to ATSs that trade equities because Regulation SCI superseded and replaced the requirements of the Capacity, Integrity, and Security Rule with regard to ATSs that trade NMS stocks and non-NMS stocks.[286]

In addition, the Commission is proposing to amend Rules 301(b)(5) and 301(b)(6) to clarify the rule text. For purposes of determining whether an ATS crossed the average daily volume thresholds for compliance with the Fair Access Rule, Rule 301(b)(5)(i) does not specify whether the ATS's transaction volume in an NMS stock or an equity security that is not an NMS stock and for which transactions are reported to an SRO is calculated using the dollar or the share volume.[287] In the Regulation ATS Adopting Release, when discussing the Fair Access Rule, the Commission stated that for these two types of securities, the test should be based on the share volume.[288] Similarly, Rules 301(b)(5)(i)

[277] *See* NMS Stock ATS Adopting Release, *supra* note 1, at Section VII.

[278] *See id.*

[279] *See infra* Section V.C.

[280] When adopting the exclusion, the Commission contemplated that it would apply only to ATSs that trade equity securities, as one of the elements of the exclusion requires that the prices on the ATS be based on the SIP. The third prong of each exception states that if an ATS meets the requirement, among others, to execute customer orders ''at a price for such security disseminated by an effective transaction reporting plan, or derived from such prices,'' the ATS would not be subject to the Fair Access Rule or Capacity, Integrity, and Security Rule, as applicable. 17 CFR 242.301(b)(5)(iii)(c); 17 CFR 242.301(b)(6)(iii)(c).

[281] 17 CFR 242.301(b)(5)(iii); 17 CFR 242.301(b)(6)(iii).

[282] Regulation ATS Adopting Release, *supra* note 35, at 70853.

[283] *Id.* at 70872.

[284] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38770–71.

[285] 17 CFR 242.301(b)(6)(iii). *See supra* note 56 and accompanying text.

[286] *See* Regulation SCI Adopting Release, *supra* note 2, at 72252, 72267.

[287] 17 CFR 242.301(b)(5)(i)(A)–(B).

[288] *See* Regulation ATS Adopting Release, *supra* note 35, at 70873 (''Accordingly, if an [ATS]

and 301(b)(6)(i) do not specify whether, for purposes of determining compliance with the Fair Access Rule and the Capacity, Integrity, and Security Rule, the volume for municipal securities or corporate debt securities is calculated based on the dollar or the share volume.[289] In the Regulation ATS Adopting Release, the Commission intended the test applicable to debt securities to be the dollar volume.[290] To mitigate any potential confusion, the Commission is adding these terms to Rules 301(b)(5)(i) and 301(b)(6)(i) to align the rule text with the Regulation ATS Adopting Release.[291] Furthermore, the Commission is proposing to amend Rules 301(b)(5)(i)(C) and (D) to clarify that the average daily dollar volume in municipal securities and corporate debt securities is provided by the self-regulatory organization to which such transactions are reported. When Regulation ATS was adopted, transaction reporting plans for municipal securities and corporate debt securities were being developed.[292] Today, transactions in municipal securities are reported to the Municipal Securities Rulemaking Board (''MSRB'') and transactions in corporate debt securities are reported to FINRA. These two SROs provide the information that can be used by ATSs to determine whether the ATS is subject to the Fair Access Rule for these two categories of securities.[293] The Commission believes that this amendment will add clarity to the rule given the established transaction reporting regimes for municipal securities and corporate debt securities.

The Commission is also proposing to amend Rule 301(b)(5)(ii)(A) of Regulation ATS to add the word ''reasonable'' before the word ''written standards,'' to clarify that ATSs subject to the Fair Access Rule are required to have ''reasonable written standards'' for granting access to trading on its system. The Commission believes that the addition is consistent with its intent as expressed in the Regulation ATS Adopting Release. Specifically, in discussing the Fair Access Rule, the Commission stated that ''fair treatment . . . is particularly important'' when ATSs reach significant volume in a security, and the rule would serve to prohibit ''unreasonably'' discriminatory denials of access.[294] The Commission believes that adding the word ''reasonable'' to the rule text will help make clear that the written standards the ATS must apply in a fair and non-discriminatory manner (pursuant to Rule 301(b)(5)(ii)(B)) must be reasonable in the first instance.

B. Amendment to Rule 301(b)(2)(vii)

Rule 301(b)(2)(vii) provides that all reports filed pursuant to Rules 301(b)(2) and 301(b)(9) are ''deemed confidential'' and ''available only to the examination of Commission staff, state securities authorities, and the self-regulatory organizations.''[295] As a result, the Commission does not make Form ATS and Form ATS–R disclosures available to the public, including the types of securities that the ATS trades or intends to trade. Currently, the Commission makes public on a monthly basis on the Commission website information about ATSs that have a Form ATS on file with the Commission, which includes the name of the ATS, any name(s) under which business is conducted, and the location of each ATS. The list also identifies each ATS that filed a cessation of operations report in the prior month. While the Commission does not approve Form ATS filings, the list is designed to inform the public about ATSs that have noticed their operations with the Commission.

The Commission is proposing to amend Rule 301(b)(2) to clarify that being ''deemed confidential'' means receiving confidential treatment under a relevant Commission regulation subject to applicable law[296] and to eliminate confidential treatment for information about the type(s) of securities that the ATS trades as disclosed in the Exhibit B, subpart (a) of Form ATS and Form ATS–R. The Commission does not believe that ATSs will be harmed by these disclosures because a vast majority of ATSs currently publicize the types of securities in which they transact, for example, on the website for the ATS or the website of the ATS broker-dealer operator. The Commission publishes on its website a list of ATSs that have an active Form ATS on file with the Commission; however, information about types of securities traded is not provided on that list and the Commission frequently receives requests from the public and regulators for more detail in the Commission's publication about the types of securities traded by ATSs. The Commission believes that disclosing this information could help the public understand a fundamental aspect of an ATS. To allow for this narrow exception, the Commission is proposing to amend Rule 301(b)(2)(vii) of Regulation ATS to state that the content of reports filed under Rule 301(b)(2) and Rule 301(b)(9) ''(except for types of securities traded provided on Form ATS and Form ATS–R) will be accorded confidential treatment subject to applicable law.''

Request for Comment

111. Should the Commission eliminate the exclusion from compliance with the Fair Access Rule under Rule 301(b)(5)(iii) and with the Capacity, Integrity, and Security Rule under Rule 301(b)(6)(iii)?

112. Should the Commission amend Rule 301(b)(2)(vii) to make Form ATS, Form ATS–R, or both public? Should the Commission amend Rule 301(b)(2)(vii) to make any other disclosures provided on Form ATS or Form ATS–R public?

113. Should the Commission eliminate confidential treatment for information about the type(s) of securities that the ATS trades as disclosed on Form ATS and Form ATS–R?

C. Modernization and Electronic Filing of Form ATS and Form ATS–R

The Commission is proposing revisions to Rule 301(b)(2), Form ATS, and Form ATS–R to modernize Form ATS and Form ATS–R and to provide that they are filed electronically. Every ATS subject to Rule 301(b)(2) of Regulation ATS is required to file an initial operation report (''IOR''),[297]

accounted for twenty percent or more of the *share volume* in any equity security, it must comply with the fair access requirements in granting access to trading in that security.'') (emphasis added).

[289] 17 CFR 242.301(b)(5)(i)(C)–(D); 17 CFR 242.301(b)(6)(i)(A)–(B).

[290] *See* Regulation ATS Adopting Release, *supra* note 35, at 70873, 70875 (requiring compliance with the Fair Access Rule and the Capacity, Integrity, and Security Rule if an ATS accounted for more than 20 percent of the total ''share volume'' in a security with respect to equity securities, and for more than 20 percent of the ''volume'' in a security with respect to debt securities). While Form ATS–R requires an ATS to report total volume in terms of both units and dollars for equity securities, it requires an ATS to report the total settlement value only in dollar terms for debt securities, which include municipal securities and corporate debt securities. *See id.* at 70878.

[291] *See* proposed Rule 301(b)(5)(i)(A)–(D); proposed Rule 301(b)(6)(i)(A)–(B).

[292] *See* Regulation ATS Adopting Release, *supra* note 35, at 70873.

[293] *See* MSRB Rule G–14; FINRA Rule 6730. Electronic Municipal Market Access (''EMMA''), which is a service operated by the MSRB, and FINRA disseminate information on transactions in municipal securities and corporate debt securities, respectively. *See* EMMA Information Facility, *available at http://www.msrb.org/Rules-and-Interpretations/MSRB-Rules/Facilities/EMMA-Facility.aspx;* FINRA Rule 6750.

[294] *See* Regulation ATS Adopting Release, *supra* note 35, at 70872, 70874.

[295] *See* 17 CFR 242.301(b)(2)(vii).

[296] *See, e.g.,* 17 CFR 200.83, 240.24b–2.

[297] Form ATS, which provides the Commission with notice about of an ATS's operations and changes to such operations, is not approved by the Commission. *See* Regulation ATS Adopting

Continued

amendments to the IOR,[298] and cessation of operations report with the Commission on Form ATS.[299] ATSs are also required to file the information required by Form ATS–R [300] pursuant to Rule 301(b)(9) within 30 calendar days after the end of each calendar quarter in which the ATS has operated.[301]

First, the Commission is proposing an amendment to Rule 301(b)(2)(vi), which currently states that ''[e]very notice or amendment filed pursuant to this paragraph (b)(2) shall constitute a 'report' '' within the meaning of applicable provisions of the Exchange Act. The Commission proposes to add a reference to Rule 301(b)(9) to state that Form ATS–R, as is the case with Form ATS, constitutes a report within the meaning of applicable provisions of the Exchange Act.[302]

Next, the Commission is proposing to require that all Forms ATS and ATS–R are filed with the Commission electronically. Currently, ATSs are required to submit paper submissions of Forms ATS and ATS–R to the Commission.[303] The Commission proposes to amend Rule 301(b)(2)(vii) to require that an ATS must file a Form ATS or a Form ATS–R in accordance with the instructions therein. The Commission is proposing to revise the instructions to Form ATS and Form ATS–R to require that they be submitted electronically via EDGAR.[304] The Commission is also proposing to require in Rule 301(b)(2)(vii) that reports provided for in Rule 301(b)(2) and (b)(9) shall be filed on Form ATS and Form ATS–R, as applicable, and include all information as prescribed in Form ATS or Form ATS–R, as applicable, and the instructions thereto.[305] In addition, the Commission is proposing to require that any Form ATS or Form ATS–R shall be executed at, or prior to, the time Form ATS or Form ATS–R is filed and shall be retained by the ATS in accordance with Rule 303 of Regulation ATS and Rule 302 of Regulation S–T, and the instructions in Form ATS or Form ATS–R, as applicable.[306] The Commission believes that, among other benefits, the electronic filing of Forms ATS and ATS–R would increase efficiencies and decrease filing costs for ATSs (*i.e.,* ATSs would no longer be required to print and mail paper filings) and for the Commission's staff when undertaking a review of these forms. Currently, Form ATS–N must be filed in EDGAR, and under this proposal, Form ATS–G would be as well. EDGAR is currently configured to support the Commission's receipt and review of filings under Regulation ATS, and requiring electronic Form ATS and Form ATS–R filings to be submitted via EDGAR would be the most efficient way to facilitate their electronic filing.[307]

To facilitate electronic filing, the Commission is proposing to amend the text of General Instructions A.4 of Forms ATS and ATS–R to require that all filings be submitted via EDGAR and prepared, formatted, and submitted in accordance with Regulation S–T and the EDGAR Filer Manual.[308] The Commission also proposes to amend Forms ATS and ATS–R General Instruction A.5 to state that a filing that is defective may be rejected and not be accepted by the EDGAR system and that any filing so rejected shall be deemed not be filed. This is consistent with the requirements of Regulation S–T, which provides the rules for EDGAR submissions.[309] The Commission also notes that the instructions for current Form ATS contain similar language,[310] but the current instructions for Form ATS–R do not contain such language. The Commission believes that it would be appropriate to reject a filing as defective if, for example, a Form ATS or Form ATS–R is missing exhibits or does not comply with the electronic filing requirements. The Commission is also proposing to amend General Instruction A.6 (''Recordkeeping'') of both forms to reflect that records must be retained in accordance with the EDGAR Filer Manual and Rule 303 of Regulation ATS and to conform to the recordkeeping instructions on Form ATS–N and proposed Form ATS–G.[311]

In addition, the Commission is proposing to amend Form ATS to require an ATS filing an amendment on Form ATS to identify whether the Form ATS filing is a material amendment under Rule 301(b)(2)(ii), a periodic amendment under Rule 301(b)(2)(iii), or a correcting amendment under Rule 301(b)(2)(iv).[312] An ATS currently

Release, *supra* note 35, at 70864. Form ATS requires the ATS to submit the information specified in eleven exhibits (Exhibits A through I). Form ATS is used for three types of submissions: An IOR; an amendment to the IOR; and a cessation of operations report. An ATS designates the type of submission on Form ATS. Form ATS and the Form ATS instructions are available at *http://www.sec.gov/about/forms/formats.pdf.*

[298] *See* 17 CFR 242.301(b)(2). An ATS is required to file an amendment on Form ATS at least 20 calendar days prior to implementing a material change to the operation of the ATS, within 30 calendar days after the end of a quarter when information contained in an IOR filed on Form ATS becomes inaccurate, and promptly upon discovering that an IOR filed on Form ATS or an amendment on Form ATS was inaccurate when filed.

[299] *See* 17 CFR 242.301(b)(2)(vi).

[300] *See* Form ATS–R. *See also supra* note 126.

[301] *See* 17 CFR 242.301(b)(9)(i). An ATS must also file Form ATS–R more frequently upon request of the Commission. *See* Form ATS–R Instructions.

[302] This amendment would be consistent with Rule 301(b)(2)(vii), which states that ''[a]ll reports filed pursuant to this paragraph (b)(2) and paragraph (b)(9)'' of Rule 301 are, as proposed, accorded confidential treatment subject to applicable law. *See* 17 CFR 242.301(b)(2)(vii). The instructions to Form ATS and Form ATS–R require an ATS to submit one original and two copies of Form ATS and Form ATS–R to the Commission. *See* Form ATS and Form ATS–R Instructions. In addition, Rule 301(b)(2)(vii) requires that an ATS file copies of its Form ATS filings with the examining authority of the SRO with which it is registered (*e.g.,* FINRA) at the same time it files with the Commission, and upon request, the ATS must provide its SROs surveillance personnel with duplicate Form ATS–R filings. *See* 17 CFR 242.301(b)(2)(vii).

[303] Rule 301(b)(2)(vii) of Regulation ATS specifies that reports on Form ATS shall be considered filed upon receipt by the Division of Trading and Markets, at the Commission's principal office in Washington, DC. *See* 17 CFR 242.301(b)(2)(vii).

[304] *See infra* note 308 and accompanying text.

[305] Accordingly, the Commission is proposing to delete the provisions of Rule 301(b)(2)(vii) related to paper submission. Specifically, the Commission is deleting the sentence that the reports shall be considered filed ''upon receipt by the Division of Trading and Markets, at the Commission's principal office in Washington, DC.'' Additionally, although the Commission will continue to require that duplicates of filings on Form ATS be provided to the SRO that is the examining authority for each ATS, and that duplicates of the Form ATS–R be made available to the surveillance personnel of such SRO upon request, the Commission proposes to eliminate the reference to ''originals'' in Rule 301(b)(2)(vii) because paper reports will no longer be furnished to the Commission and there will therefore be no ''original'' version of the reports.

[306] The Commission notes that the proposed provisions would conform to similar provisions of Rule 304, which provide for the electronic filing of Form ATS–N. *See* 17 CFR 242.304(c).

[307] *See supra* Section IV.

[308] The Commission proposes to eliminate the language in the Form ATS instructions and Form ATS–R instructions requesting that an ATS type all information because an ATS would not otherwise have the option to handwrite any responses. The instructions for both forms would be amended to eliminate the option to use a ''reproduction'' of the forms. The Commission also believes it is redundant to state that the Form ATS or Form ATS–R must be the ''current version'' as the ATS is required to attest that the form is ''current.'' The Commission also proposes to delete the requirement to attach an execution page with original manual signatures for Form ATS because, as discussed above, the Form ATS and Form ATS–R would be signed electronically and thus there would be no need for an execution page. The Commission also proposes to delete the instruction that the name of the alternative trading system, CRD number, SEC file number, and report period dates be listed on each page, as this requirement will be unnecessary because the Form ATS or Form ATS–R will be submitted as a single submission. Because Form ATS and Form ATS–R would be submitted via EDGAR, the Commission is also proposing to delete references to submitting the ''original'' and ''copies'' of the form to the Commission at the Commission's mailing address.

[309] 17 CFR 232. This is also consistent with the requirements for current Form ATS–N.

[310] The Form ATS Instructions state that ''Form ATS shall not be considered filed, unless it complies with applicable requirements.''

[311] Rule 303 of Regulation ATS provides the record preservation requirements for ATSs. *See* 17 CFR 242.303.

[312] *See* Rule 301(b)(2)(ii)–(iv).

identifies an amendment to current Form ATS by marking the ''Amendment to Initial Operation Report'' box on Form ATS, and Form ATS currently does not ask the ATS to specify whether the amendment to Form ATS is a material, periodic, or correcting amendment.[313] The Commission believes that requiring an ATS to specify the type of amendment would better enable the Commission to determine whether an ATS is in compliance with Regulation ATS. The Commission also proposes requiring an ATS to provide the date that the ATS ceased to operate, which is not currently required on Form ATS. The Commission believes that having information about the date that the ATS ceased to operate would enable the Commission to determine more readily whether an ATS is, or was, in compliance with Regulation ATS.[314]

The Commission is also proposing to amend Form ATS and Form ATS–R to change the solicitation of information relating to the name of the broker-dealer operator and the registration and contact information of the broker-dealer operator. Because many broker-dealer operators of ATSs engage in brokerage and/or dealing activities in addition to operating an ATS and some broker-dealers operate multiple ATSs, the name of the broker-dealer operator of an ATS often differs from the commercial name under which the ATS conducts business. To identify the broker-dealer operator of an ATS and to assist the Commission in collecting and organizing its filings and assessing whether the ATS has met its requirement to register as a broker-dealer, Forms ATS and ATS–R would require the ATS to indicate the full name of the broker-dealer operator of the ATS, as it is stated on Form BD, in Item 1 of Form ATS and Form ATS–R. To further facilitate compliance with the requirements of Regulation ATS, as proposed, Form ATS and Form ATS–R would require the ATS to indicate whether the filer is a broker-dealer registered with the Commission and whether the broker-dealer operator has been authorized by a national securities association to operate an ATS. Such requirements would conform to the proposed requirements of Form ATS–N and Form ATS–G.[315] The Commission is proposing to conform Item 1 of Form ATS and Form ATS–R[316] to the requirements of Form ATS–N, which is currently filed electronically, and proposed Form ATS–G, which the Commission is proposing would be filed electronically.[317] The Commission believes these requests would help the Commission in identifying and corresponding with ATSs.[318]

The Commission is proposing to amend Form ATS–R to make it easier for the Commission staff to identify if the ATS has met its reporting obligations. First, the Commission is proposing to require an ATS to specify whether it is filing a quarterly report amendment under Rule 301(b)(9)(i) or a report for an ATS that has ceased to operate under Rule 301(b)(9)(ii) and, if the latter, to indicate the date the ATS ceased to operate. The Commission believes that requiring an ATS to indicate its type of Form ATS–R filing would enable the Commission to more effectively review Form ATS–R submissions and determine whether an ATS is in compliance with Regulation ATS. The Commission is also proposing to amend Form ATS–R to ask whether the ATS was subject to the fair access obligations under § 242.301(b)(5) during any portion of the period covered by the report by adding a corresponding box for the ATS to check ''yes'' or ''no.'' Currently, Form ATS–R requires an ATS that is subject to the Fair Access Rule to report a list of all persons for whom access to the ATS was granted, denied, or limited access during the period covered by the Form ATS–R.[319] The Commission believes that asking the ATS to indicate whether the ATS was subject to the Fair Access Rule during any portion of the period covered by the report would facilitate the Commission's review of Form ATS–R submissions.

The Commission is also proposing changes to the Form ATS–R categories of securities to modernize them and add more specificity with regard to all categories of securities. Form ATS–R currently requires ATSs to indicate the total unit volume and total dollar volume of government securities transactions in the period covered by the report. The Commission is proposing to require that ATSs specify the total unit volume and total dollar volume of transactions in ''U.S. Treasury Securities'' and ''Agency Securities'' under the heading ''Government securities.''[320] As currently, ATSs would also be required to indicate the total unit volume and total dollar volume in government securities overall. The Commission believes that this change will help the Commission facilitate compliance with the thresholds for the Fair Access Rule and Regulation SCI, which the Commission is proposing would be based on trading volume in U.S. Treasury Securities and Agency Securities.[321] In addition, the Commission is proposing to amend Form ATS–R to update the descriptions of certain categories of securities for which volume is required to be reported on Form ATS–R by an ATS. Specifically, the Commission is proposing to replace the names of the securities categories, ''Nasdaq National Market Securities'' and ''Nasdaq

[313] The Commission is also proposing to add cites to the relevant rule text next to the check boxes on Form ATS identifying whether the ATS is filing an IOR, amendment to Form ATS, or a cessation of operations report.

[314] *See* Rule 301(b)(2)(v) (requiring an ATS to promptly file a cessation of operations report on Form ATS in accordance with the instructions therein upon ceasing to operate as an alternative trading system).

[315] *See supra* note 203 and accompanying text.

[316] Form ATS and Form ATS–R currently ask for the ATS's main street address, mailing address, business telephone number and facsimile number, and the contact information for the ATS's contact person. The Commission is proposing to move the information requests for the name and title and telephone number of the contact employee to the signature block on the form, and to request an email address for such person. The proposed signature block would also ask for the primary street address and mailing address of the ATS. The current certifications required in Form ATS and Form ATS–R, including that the information filed is current, true, and complete, would remain unchanged. However, the Commission is proposing to delete the provision allowing for service of any civil action pursuant to confirmed telegram and instead, permit service of any civil action via email. The signature block on Form ATS and Form ATS–R would conform to the signature block in Form ATS–N, as proposed. *See infra* notes 323–324 and accompanying text.

[317] *See supra* Section IV.

[318] The Commission proposes to replace in Item 1 of Form ATS and Form ATS–R the requests for the ATS's main street address, mailing address, and business telephone number and facsimile number with a requirement that the ATS provide the primary, and if any, secondary physical street address of the ATS's matching system, as well as a URL address for its website if it has a website. The Commission believes that knowing the location of the matching system address and secondary matching system address could be useful to the Commission in the event of, for instance, a natural disaster that could impact market participants' ability to trade on the ATS and potential latency that could be experienced due to the location of the secondary site of the ATS. The Commission is also requesting the full name of the national securities association of the broker-dealer operator, the effective date of the broker-dealer operator's membership with the national securities association, and MPID of the ATS. In addition, because any current or former names of the ATS would be searchable on EDGAR and there will be multiple identifiers included on the form, including MPID, the Commission is proposing to delete the requirement that the ATS indicate if it is changing its name and list its former name.

[319] *See* Form ATS–R and Form ATS–R Instructions, No. 8.

[320] The Commission is proposing to add to the Form ATS–R instructions the definitions of U.S. Treasury Security and Agency Security, which would conform to the definitions the Commission is proposing in Rule 300(p) and Rule 300(q), respectively.

[321] *See supra* Section II.D and *infra* Section VI.

SmallCap Market Securities,'' reported in Items 4 and 6 of Form ATS–R, with ''Nasdaq Global Market Securities'' and ''Nasdaq Capital Market Securities,'' respectively. The Commission believes that replacing the description of categories of securities that no longer are in use with current categories of securities would reduce potential confusion for an ATS when completing Form ATS–R and would enable an ATS to reflect more accurately its trading activities during the applicable reporting period.

The Commission is also proposing to add new Item 4K to Form ATS–R, which requires ATSs to disclose the total dollar volume of transactions in repurchase agreements and reverse repurchase agreements. New Item 5C would require ATSs to list the types of securities subject to such repurchase or reverse repurchase agreements. In the Commission's experience, ATSs that trade repurchase or reverse repurchase agreements, which are currently disclosed as debt securities on Item 4N of Form ATS–R, currently provide on Form ATS–R a break-down of nominal trade value of each of these types of securities. The Commission believes that adding new Item 4K to Form ATS–R to require that ATSs provide the total dollar volume of transactions in repurchase or reverse repurchase agreements would require all ATSs that trade repurchase or reverse repurchase agreements to take a consistent approach in providing this information. The Commission is also proposing new Item 5C, which would require ATSs to list the types of securities subject to repurchase or reverse repurchase agreements reported in Item 4K of Form ATS–R. The Commission believes that this would provide information to the Commission about the types of securities that ATSs trade while imposing a minimal burden on filers.

Finally, the Commission is proposing to add new Item 5D, which would require an ATS to list the types of listed options reported in Item 4H of Form ATS–R. Item 4H of Form ATS–R currently requires ATSs to disclose the total unit volume and dollar volume of transactions in listed options. Under new Item 5D, an ATS might indicate, for example, that it trades equity options and options on government securities. The Commission believes that this would provide the Commission with more specific information about the types of options that each ATS trades.

Request for Comment

114. Would the proposed changes to Form ATS and Form ATS–R enhance the Commission's oversight of ATSs? Do commenters disagree with any of the proposed modifications? If so, what alternatives should the Commission implement?

115. Form ATS–R requires an ATS to quarterly report volume of transactions for certain securities, all subscribers that were participants on the ATS, and securities that were traded on the ATS. Should the Commission adopt amendments to Form ATS–R to add, change, or modify any of the requests for information on Form ATS–R? Are the current categories of securities and the proposed categories of securities for reporting transaction volume to the Commission appropriate?

116. Form ATS requires an ATS to report information to the Commission in Exhibits A through I. These requests solicit information about the ATS, including but not limited to, types of subscribers and differential access to services, types of securities traded, counsel, governance documents, service providers, manner of operations, including order entry, order execution procedures, clearance and settlement procedures, and trade reporting, procedures for reviewing system capacity, security, and contingency planning, procedures to safeguard subscriber funds and securities, and direct owners. Should the Commission adopt amendments to Form ATS to add, change, or modify any of the requests for information on Form ATS? If so, please identify the request and explain how it should be amended.

117. Should the Commission adopt amendments to Form ATS to require disclosures similar to disclosures required on Part II of Form ATS–N and proposed Form ATS–G, which request information about ATS-related activities of the broker-dealer operator and its affiliates?

118. Should the Commission adopt amendments to Form ATS to include questions similar to those in Part III of Form ATS–N and proposed Form ATS–G, which request information about the manner of the ATS's operations?

119. Are there any specific items on Form ATS–N or proposed Form ATS–G that the Commission should incorporate into Form ATS?

120. Should the Commission propose amendments to Regulation ATS to require ATSs that trade OTC equity securities to comply with Rule 304, including filing with the Commission a public form with requirements similar to Form ATS–N or proposed Form ATS–G?

121. Should the Commission require an ATS to disclose the LEI of its broker-dealer operator, in addition to its CRD Number and the proposed disclosure of the MPID for the ATS on Form ATS?

D. Changes to Form ATS–N

The Commission is proposing to delete the check box on the cover page of Form ATS–N that requires an NMS Stock ATS to select whether the NMS Stock ATS currently operates pursuant to a Form ATS. Rules 304 and 301(b)(2)(viii) required an NMS Stock ATS to file a Form ATS–N no later than February 8, 2019. After February 8, 2019, this check box became obsolete. The Commission is also proposing new Part I, Item 1.B, which would require the NMS Stock ATS to indicate whether the registered broker-dealer has been authorized by its national securities association to operate an ATS. The Commission believes this would facilitate compliance with and oversight of the requirement that an ATS complies with the rules of an SRO, including to obtain approval to operate an ATS.[322] In addition, to avoid confusion, the Commission is proposing to delete language in the signature block in Part IV of Form ATS–N that refers to the signatory as ''duly sworn.'' The Commission notes that Form ATS–N filings, which are submitted to EDGAR, are not required to be notarized;[323] instead, they are subject to the rules governing electronic signatures set forth in Rule 302 of Regulation S–T.[324]

The Commission is proposing to replace the current definition of ''Person'' in Form ATS–N, which is provided by the Investment Advisers Act of 1940 (''Advisers Act'')[325] with the different definition of ''Person'' as defined under the Exchange Act.[326] Because Regulation ATS is a Commission regulation under the Exchange Act, and NMS Stock ATSs are subject to various Exchange Act Rules,[327] the Commission believes that it is more appropriate to apply the definition of ''Person'' under the Exchange Act than the definition of ''Person'' under the Advisers Act, which is not applicable to ATSs. Although the definitions are not identical, the Commission believes the differences between the definitions are unlikely to result in differences to the disclosures

[322] *See supra* note 203 and accompanying text.

[323] Unlike Form ATS, Form ATS–N does not have a notarization block.

[324] 17 CFR 232.302.

[325] 15 U.S.C. 80a–2(a)(28) (defining ''Person'' as ''a natural person or a company'').

[326] 15 U.S.C. 78c(a)(9) (defining the term ''person'' as a natural person, company, government, or political subdivision, agency, or instrumentality of a government).

[327] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38768.

required by Form ATS–N.[328] To the extent ATSs might have found ambiguous the Commission's use of the Advisers Act definition in the context of an Exchange Act rule, the Commission believes that this proposed change will mitigate any such concerns. The Commission is also proposing to change the definition of ''NMS Stock ATS'' to conform to the proposed changes to the definition in Rule 300 and state that NMS Stock ATSs shall not trade securities other than NMS stocks.[329]

In Part III, Item 1, the Commission is proposing to remove the checkbox ''NMS Stock ATS'' under the list of types of subscriber to an NMS Stock ATS. A broker-dealer operator of an NMS Stock ATS seeking to access another NMS Stock ATS would involve the broker-dealer operator for the NMS Stock ATS becoming a subscriber to the ATS, not the ATS that the broker-dealer operates. In this scenario, an NMS Stock ATS that accepts a broker-dealer operator for another NMS Stock ATS would mark the checkbox for broker and/or dealer in Part III, Item 1 on Form ATS–N as appropriate. The Commission is also proposing to add insurance companies, pension funds, and corporations to the list of types of subscribers in Part III, Item 1 on Form ATS–N. The Commission believes that adding these checkboxes will provide more granular information on the types of subscribers participating on an NMS Stock ATS in an easier-to-read format.

In Part II, Item 4(b) of Form ATS–N, the Commission is proposing to delete the phrase ''if yes to Item 4(a).'' This phrase was included in Form ATS–N in error. The NMS Stock ATS would be required to respond to Part II, Item 4(b) regardless of its response to Part II, Item 4(a).

In Part II, Item 6(a) of Form ATS–N, the Commission is proposing to add language to the definition of ''shared employee'' to clarify that the Item solicits disclosures relating to both any employee of the broker-dealer operator and any employee of its affiliate that provides services to both the operations of the NMS Stock ATS and any other business unit or any affiliate of the broker-dealer operator. The proposed amendment is designed to clarify the existing requirements of the Item.

The Commission is proposing to add the term ''market data'' to the examples listed in Part III, Item 19 of the types of fees that NMS Stock ATSs must disclose. While most NMS Stock ATSs do not disseminate market data, the Commission believes that they can and a description of an NMS Stock ATS's market data fees is currently required by the Item.[330] The Commission believes that adding the example could assist NMS Stock ATSs in responding comprehensively to the Item. The Commission is also including the example in Form ATS–G as Government Securities ATSs are primarily lit venues that offer market data to subscribers. The Commission is also proposing to change the term ''Order Display and Fair Access Amendment'' throughout Form ATS–N to ''Contingent Amendment'' to conform to proposed changes to Rule 304.[331] Furthermore, the Commission is proposing several grammatical and technical changes to Form ATS–N to correct and clarify certain items on the form. These changes are listed in Section XIII *infra.*

Request for Comment

122. Should the Commission adopt alternative EDGAR filing requirements or formats for Form ATS–N (*e.g.,* filing in XBRL format)?

123. Would the use of the Exchange Act definition of ''Person'' instead of the Advisers Act definition of ''Person'' result in differences to the information required to be disclosed by Form ATS–N?

124. Should the Commission require a broker-dealer operator for an NMS Stock ATS to disclose its LEI, in addition to its CRD Number and MPID, which NMS Stock ATSs are currently required to provide, on Form ATS–N?

VI. Proposed Amendments to Regulation SCI for Government Securities ATS

The Commission proposes to amend Regulation SCI to expand the definition of ''SCI alternative trading system'' to include Government Securities ATSs that meet a specified volume threshold. A Government Securities ATS that meets the proposed amended definition of ''SCI alternative trading system'' would fall within the definition of ''SCI entity'' and, as a result, would be subject to the requirements of Regulation SCI. The Commission believes that the proposal to extend the requirements of Regulation SCI to Government Securities ATSs that trade a significant volume in U.S. Treasury Securities or Agency Securities would help to address the technological vulnerabilities, and improve the Commission's oversight, of the core technology of key entities in the markets for government securities.

The Commission adopted Regulation SCI in November 2014 to strengthen the technology infrastructure of the U.S. securities markets.[332] As discussed in the Regulation SCI Adopting Release, a number of factors contributed to the Commission's proposal and adoption of Regulation SCI. These factors included: The evolution of the markets becoming significantly more dependent upon sophisticated, complex, and interconnected technology; the successes and limitations of the Automation Review Policy (''ARP'') Inspection Program; a significant number of, and lessons learned from, recent systems issues at exchanges and other trading venues;[333] and increased concerns over the potential for ''single points of failure'' in the securities markets.[334] Regulation SCI is designed to strengthen the infrastructure of the U.S. securities markets, reduce the occurrence of systems issues in those markets, improve their resiliency when technological issues arise, and establish an updated and formalized regulatory framework, thereby helping to ensure more effective Commission oversight of such systems.[335]

The key market participants that are currently subject to Regulation SCI are called ''SCI entities'' and include certain SROs (including stock and options exchanges, registered clearing agencies, FINRA and the MSRB) (''SCI SROs''); alternative trading systems that trade NMS and non-NMS stocks exceeding specified volume thresholds (''SCI ATSs''); the exclusive SIPs (''plan processors''); and certain exempt clearing agencies.[336] Regulation SCI, among other things, requires these SCI entities to establish, maintain, and enforce written policies and procedures reasonably designed to ensure that their key automated systems have levels of capacity, integrity, resiliency, availability, and security adequate to maintain their operational capability and promote the maintenance of fair and orderly markets, and that such systems operate in accordance with the Exchange Act and the rules and

[328] The Exchange Act's inclusion of a ''government, or political subdivision, agency or instrumentality of a government'' under the definition of ''Person'' is unlikely to result in any changes to the disclosures required by the items in Form ATS–N that use the word ''Person'' as, in the Commission's experience, these entities are generally not involved in the operations of NMS Stock ATSs as subscribers or otherwise.

[329] *See supra* note 93 and accompanying text.

[330] Part III, Item 19 requires NMS Stock ATSs to identify and describe *any* (emphasis added) fees or charges for use of the Government Securities ATS services, including the type of fees.

[331] *See supra* note 176.

[332] *See* Regulation SCI Adopting Release, *supra* note 2, at 72252–56 for a discussion of the background of Regulation SCI.

[333] *See id.* at 72253–56.

[334] *See id.* at 72277–79.

[335] *Id.* at 72253, 72256.

[336] *See* 17 CFR 242.1000.

regulations thereunder and the entities' rules and governing documents, as applicable.[337] Broadly speaking, Regulation SCI also requires SCI entities to take appropriate corrective action when systems issues occur; provide certain notifications and reports to the Commission regarding systems problems and systems changes; inform members and participants about systems issues; conduct business continuity and disaster recovery testing and penetration testing; conduct annual reviews of their automated systems; and make and keep certain books and records.[338]

Regulation SCI applies primarily to the systems of, or operated on behalf of, SCI entities that directly support any one of six key securities market functions—trading, clearance and settlement, order routing, market data, market regulation, and market surveillance (''SCI systems'').[339] With respect to security, Regulation SCI also applies to systems that, if breached, would be reasonably likely to pose a security threat to SCI systems (''indirect SCI systems'').[340] In addition, certain systems whose function are critical to the operation of the markets, including those that represent single points of failure (defined as ''critical SCI systems''), are subject to certain heightened requirements.[341]

When adopting Regulation SCI, the Commission included within the scope of Regulation SCI those entities ''that play a significant role in the U.S. securities markets and/or have the potential to impact investors, the overall market, or the trading of individual securities.'' [342] The Commission identified by function the key market participants it believed were integral to ensuring the stability, integrity, and resiliency of securities market infrastructure.[343] As discussed below, SCI ATSs are currently among those entities that are subject to Regulation SCI, as they are heavily reliant on automated systems and represent a significant pool of liquidity for NMS and non-NMS stocks.[344] However, when the Commission adopted Regulation SCI, the Commission applied it to ATSs that trade NMS stocks and non-NMS stocks, but not to fixed income ATSs. Rather, in the context of the municipal and corporate debt markets, the Commission stated that fixed income markets rely much less on automation and electronic trading than markets that trade NMS stocks or non-NMS stocks.[345] The Commission also stated that the municipal and corporate debt markets tend to be less liquid than the equity markets, with slower execution times and less complex routing strategies.[346]

Although the Commission differentiated fixed income securities generally from equity securities when it adopted Regulation SCI, in light of the increasing automation of the government securities market and the operational similarities between many Government Securities ATSs and NMS Stock ATSs,[347] the Commission preliminarily believes that it would be appropriate to apply the requirements of Regulation SCI to Government Securities ATSs that meet certain volume thresholds. As the Commission previously stated, while technological developments provide many benefits to the U.S. securities markets, they also increased the risk of operational problems that have the potential to cause a widespread impact on the securities market and its participants.[348] The application of Regulation SCI to Government Securities ATSs that trade a significant volume of U.S. Treasury Securities or Agency Securities would further help to address those technological vulnerabilities, and improve the Commission's oversight, of the core technology used by key U.S. securities markets participants.

Accordingly, under this proposal, the definition of ''SCI ATSs'' would be expanded to include certain Government Securities ATSs that meet certain volume thresholds with respect to U.S. Treasury Securities and/or Agency Securities, as the Commission believes such ATSs similarly rely heavily on automated systems and represent a significant source of orders and trading interest in these asset classes.[349] Specifically, the definition of ''SCI ATS'' would be revised to include those ATSs which, during at least four of the preceding six calendar months: Had, with respect to U.S. Treasury Securities, five percent (5%) or more of the average weekly dollar volume traded in the United States as provided by the SRO to which such transactions are reported; or had, with respect to Agency Securities, five percent (5%) or more of the average daily dollar volume traded in the United States as provided by the SRO to which such transactions are reported. These proposed thresholds are the same as those being proposed for Government Securities ATSs with respect to the Fair Access Rule under Regulation ATS.[350]

The Commission believes that the proposed thresholds for applying Regulation SCI to Government Securities ATSs are appropriate measures to identify those ATSs that have the potential to significantly impact investors and the market should a systems issue occur.[351] Currently, the Commission believes that approximately three ATSs trading U.S. Treasury Securities and one ATS trading Agency Securities would be subject to Regulation SCI under the proposed five percent volume thresholds.[352] The ATS with the largest market volume in U.S. Treasury Securities has around 24 percent of

[337] *See* 17 CFR 242.1001; *infra* notes 365–374.

[338] *See* 17 CFR 242.1001–1007; *infra* notes 365–386.

[339] *See* 17 CFR 242.1000.

[340] *Id.*

[341] *Id. See also* Regulation SCI Adopting Release, *supra* note 2, at 72277. Paragraph (1) of the definition of ''critical SCI systems'' in Rule 1000 of Regulation SCI specifically enumerates certain systems to be within its scope, including those that directly support functionality relating to: (i) clearance and settlement systems of clearing agencies; (ii) openings, reopenings, and closings on the primary listing market; (iii) trading halts; (iv) initial public offerings; (v) the provision of consolidated market data; or (vi) exclusively-listed securities. *17 CFR 242.1000(1).*

[342] *See* Regulation SCI Adopting Release, *supra* note 2, at 72258.

[343] *See id.* at 72254.

[344] *See id.* at 72262–63. Rule 1000 of Regulation SCI defines SCI ATS to mean an ATS, which, during at least four of the preceding six calendar months, had: (1) With respect to NMS stocks: (i) five percent or more in any single NMS stock, and 0.25 percent or more in all NMS stocks, of the average daily dollar volume reported by an effective transaction reporting plan, or (ii) one percent or more, in all NMS stocks, of the average daily dollar volume reported by an effective transaction reporting plan; or (2) with respect to equity securities that are not NMS stocks and for which transactions are reported to an SRO, five percent or more of the average daily dollar volume as calculated by the SRO to which such transactions are reported. *See* 17 CFR 242.1000. Rule 1000 also states that an ATS that meets one of these thresholds is not required to comply with Regulation SCI until six months after satisfying the threshold for the first time. *See id.*

[345] *See* Regulation SCI Adopting Release, *supra* note 2, at 72270.

[346] *See id.*

[347] *See supra* Section I.A.

[348] *See* Regulation SCI Adopting Release, *supra* note 2, at 72253.

[349] *See* paragraphs (3) and (4) of the proposed definition of ''SCI ATS'' under Rule 1000 of Regulation SCI.

[350] *See supra* Section II.D. (Application of Fair Access to Government Securities ATSs).

[351] Under the proposal, Regulation SCI would not apply to Government Securities ATSs that trade repos, including repos on U.S. Treasury Securities and Agency Securities. Based on information available to the Commission, the Commission does not believe that ATSs today capture a significant market share for trading repos nor do they rely on the same level of automation as ATSs that trade U.S. Treasury Securities or Agency Securities. The Commission is requesting comment on this preliminary assessment and whether the Commission should amend Regulation SCI to require Government Securities ATSs that trade repos, including repos on U.S. Treasury Securities and Agency Securities, to be subject to the requirements of Regulation SCI.

[352] *See supra* Section II.D and *infra* Section X.B.1a.

market volume, while each of the second and third largest is slightly above five percent market share. The one ATS that would exceed the proposed threshold for Agency Securities accounts for roughly 13 percent of volume in Agency Securities.[353] If the proposed volume thresholds were 7.5 or 10 percent, however, only one ATS trading U.S. Treasury Securities and one ATS trading Agency Securities would be subject to Regulation SCI.[354] The Commission is requesting comment on whether these proposed volume thresholds should be set higher or lower for trading of U.S. Treasury Securities or Agency Securities by a Government Securities ATS.

The Commission believes that the proposed volume thresholds to apply Regulation SCI to a Government Securities ATS that trades U.S. Treasury Securities and Agency Securities are reasonable as compared to volume thresholds for applying Regulation SCI to ATSs that trade NMS stocks and ATSs that trade equity securities that are not NMS stocks. First, an ATS that trades NMS stocks is subject to Regulation SCI if its trading volume reaches: (i) Five percent or more in any single NMS stock and one-quarter percent or more in all NMS stocks of the average daily dollar volume reported by applicable transaction reporting plans; or (ii) one percent or more in all NMS stocks of the average daily dollar volume reported by applicable transaction reporting plans. With respect to non-NMS equity securities, an ATS is subject to Regulation SCI if its trading volume is five percent or more of the average daily dollar volume (across all non-NMS equity securities) as calculated by the SRO to which such transactions are reported. The proposed SCI volume thresholds for Government Securities ATSs would be similar to those for ATSs that trade non-NMS equity securities. The Commission believes that basing the thresholds on volume as provided by the SRO to which such transactions are reported is reasonable given that there is no transaction reporting plan for government securities and thus, the trading figures are based on dollar volume traded in the United States as provided by the SRO to which such transactions are reported.

In addition, the Commission believes that the proposed volume thresholds to apply Regulation SCI to a Government Securities ATS that trades U.S. Treasury Securities and Agency Securities are reasonable compared to volume thresholds that would subject an ATS to Rule 301(b)(6) under Regulation ATS (*i.e.,* the Capacity, Integrity, and Security Rule) for the ATS's trading of corporate bonds and municipal securities. While Regulation SCI is not applicable to ATSs that trade corporate bonds or municipal securities, an ATS that trades corporate bonds or municipal securities is subject to Rule 301(b)(6) if its trading volume reaches 20 percent or more of the average daily volume traded in the United States for either corporate bonds or municipal securities.[355] When the Commission adopted Regulation SCI, it decided not to apply Regulation SCI and its lower volume thresholds to the fixed income markets, concluding that a systems issue in fixed income markets would not have had as significant or widespread an impact as in the equities market.[356] Among other things, the Commission reasoned that the fixed income markets at the time relied much less on automation and electronic trading than the equities markets, and that the municipal securities and corporate bond fixed income markets tended to be less liquid than the equity markets, with slower execution times and less complex routing strategies.[357] As explained above, however, ATSs for government securities now operate with complexity similar to that of markets that trade NMS stocks in terms of automation and speed of trading, the use of limit order books, order types, algorithms, connectivity, data feeds, and the active participation of PTFs.[358] Government securities also make up more than half of the outstanding debt issuances in the U.S. bond market and play a critical role in the U.S. and global economies.[359] An ATS whose government securities volume falls between five percent and 20 percent of trading volume could significantly impact investors and the market should a systems issue occur, as discussed below in this section. By proposing to apply Regulation SCI to Government Securities ATSs with a threshold of below 20 percent the Commission seeks to impose the more stringent protections of Regulation SCI to these ATSs because of their importance to the U.S. securities markets. The Commission also recognizes that ATSs for corporate bonds and municipal securities are becoming increasingly electronic and as part of this release, the Commission is requesting comment on, among other things, whether the 20 percent volume threshold under Rule 301(b)(6) of Regulation ATS should be amended to capture ATSs that might be critical markets for those securities.

When adopting Regulation SCI, the Commission stated that it would ''monitor and evaluate the implementation of Regulation SCI, the risks posed by the systems of other market participants, and the continued evolution of the securities markets, such that it may consider, in the future, extending the types of requirements in Regulation SCI to additional categories of market participants.'' [360] The Commission believes that the continued evolution of the securities markets, including advancements in technology, have resulted in significant changes in how government securities trade.[361] In particular, the structure of the U.S. Treasury market has evolved in recent years and electronic trading has become an increasingly important feature of the interdealer market for U.S. Treasury Securities.[362] As stated by various sources, the secondary interdealer cash markets for on-the-run U.S. Treasury Securities have evolved such that those markets operate with complexity similar to that of markets that trade NMS stocks in terms of automation and speed of trading, the use of limit order books, order types, algorithms, and the active participation of PTFs on ATSs.[363]

Given this evolution in the U.S. Treasury market, the Commission now believes that there are Government Securities ATSs that operate with similar complexity as SCI ATSs that are currently subject to Regulation SCI, and that Government Securities ATSs with significant trading volume play an important role in the government securities markets and face similar technological vulnerabilities as existing SCI entities. The Commission believes that, without appropriate safeguards in place for these Government Securities ATSs, technological vulnerabilities could lead to the potential for failures, disruptions, delays, and intrusions, which could place government

[353] *See infra* Table X.1.

[354] *See id.*

[355] *See* 17 CFR 242.301(b)(6). The requirements of Rule 301(b)(6) are less rigorous than the requirements of Regulation SCI. Among other things, Rule 301(b)(6) requires an ATS to notify the Commission staff of material systems outages and significant systems changes and that the ATS establish adequate contingency and disaster recovery plans. *See id.* Currently, there are no ATSs that are subject to requirements of Rule 301(b)(6) of Regulation ATS.

[356] *See* Regulation SCI Adopting Release, *supra* note 2, at 72270.

[357] *See id.*

[358] *See supra* note 5.

[359] *See supra* notes 5–7 and accompanying text.

[360] *See* Regulation SCI Adopting Release, *supra* note 2, at 72270.

[361] *See supra* Section I.A.

[362] *See supra* note 14 and accompanying text.

[363] *See supra* notes 14–15 and accompanying text.

securities market participants at risk, and could possibly interfere with the maintenance of fair and orderly markets. For example, a systems issue could occur at a Government Securities ATS with significant trading volume (*e.g.,* a systems disruption or a cybersecurity incident that prevented the ATS from operating or being accessible to its subscribers), such that certain market participants or the government securities markets broadly could be significantly impacted until such time that the issue was resolved at the ATS. In addition, applying Regulation SCI to these Government Securities ATSs would help the Commission improve its oversight of the market for government securities, thereby continuing its efforts to address technological vulnerabilities of the core technology systems of key U.S. securities markets entities.

As proposed, those Government Securities ATSs trading U.S. Treasury Securities and/or Agency Securities that met the volume thresholds under the revised definition of SCI ATS would be subject to the requirements of Regulation SCI, as described below.[364] Rule 1001(a) of Regulation SCI requires SCI entities to have policies and procedures reasonably designed to ensure that their SCI systems and, for purposes of security standards, indirect SCI systems, have levels of capacity, integrity, resiliency, availability, and security adequate to maintain their operational capability and promote the maintenance of fair and orderly markets, and includes certain minimum requirements for those policies and procedures relating to capacity planning, stress tests, systems development and testing methodology, the identification of vulnerabilities, business continuity and disaster recovery plans (including geographic diversity and resumption goals), market data, and monitoring.[365] Rule 1001(a)(3) of Regulation SCI requires that SCI entities periodically review the effectiveness of these policies and procedures, and take prompt action to remedy any deficiencies.[366] Rule 1001(a)(4) of Regulation SCI provides that, for purposes of the provisions of Rule 1001(a), an SCI entity's policies and procedures will be deemed to be reasonably designed if they are consistent with current SCI industry standards, which shall be comprised of information technology practices that are widely available to information technology professionals in the financial sector and issued by an authoritative body that is a U.S. governmental entity or agency, association of U.S. governmental entities or agencies, or widely recognized organization;[367] however, Rule 1001(a)(4) of Regulation SCI also makes clear that compliance with such ''current SCI industry standards'' is not the exclusive means to comply with these requirements.

Rule 1001(b) of Regulation SCI requires that each SCI entity establish, maintain, and enforce written policies and procedures reasonably designed to ensure that its SCI systems operate in a manner that complies with the Exchange Act and the rules and regulations thereunder and the entity's rules and governing documents, as applicable, and specifies certain minimum requirements for such policies and procedures.[368] Rule 1001(b)(3) of Regulation SCI requires that SCI entities periodically review the effectiveness of these policies and procedures, and take prompt action to remedy any deficiencies.[369] Rule 1001(b)(4) of Regulation SCI provides individuals with a safe harbor from liability under Rule 1001(b) if certain conditions are met.[370]

Rule 1001(c) of Regulation SCI requires SCI entities to establish, maintain, and enforce reasonably designed written policies and procedures that include the criteria for identifying responsible SCI personnel, the designation and documentation of responsible SCI personnel, and escalation procedures to quickly inform responsible SCI personnel of potential SCI events.[371] Rule 1000 of Regulation SCI defines ''responsible SCI personnel'' to mean, for a particular SCI system or indirect SCI system impacted by an SCI event, such senior manager(s) of the SCI entity having responsibility for such system, and their designee(s).[372] Rule 1000 also defines ''SCI event'' to mean an event at an SCI entity that constitutes a system disruption, a systems compliance issue, or a systems intrusion.[373] Rule 1001(c)(2) of Regulation SCI requires that SCI entities periodically review the effectiveness of these policies and procedures, and take prompt action to remedy any deficiencies.[374]

Under Rule 1002 of Regulation SCI, SCI entities have certain obligations related to SCI events. Specifically, when any responsible SCI personnel has a reasonable basis to conclude that an SCI event has occurred, the SCI entity must begin to take appropriate corrective action which must include, at a minimum, mitigating potential harm to investors and market integrity resulting from the SCI event and devoting adequate resources to remedy the SCI event as soon as reasonably practicable.[375] Rule 1002(b) provides the framework for notifying the Commission of SCI events including, among other things, to: Immediately notify the Commission of the event; provide a written notification within 24 hours that includes a description of the SCI event and the system(s) affected, with other information required to the extent available at the time; provide regular updates regarding the SCI event until the event is resolved; and submit a final detailed written report regarding the SCI event.[376] Rule 1002(c) of Regulation SCI also requires that SCI entities disseminate information to their members or participants regarding SCI events.[377] These information

[364] The Commission is requesting comment on whether all of the obligations in Regulation SCI should apply to Government Securities ATSs that would be SCI ATSs, or whether only certain requirements should be imposed, such as those requiring written policies and procedures, notification of systems problems, business continuity and disaster recovery testing (including testing with subscribers of ATSs), and penetration testing.

[365] 17 CFR 242.1001(a)(1)–(2).

[366] 17 CFR 242.1001(a)(3).

[367] 17 CFR 242.1001(a)(4). The Commission notes that, concurrent with the Commission's adoption of Regulation SCI, Commission staff issued staff guidance on current SCI industry standards as referenced in Regulation SCI. The staff guidance listed examples of publications in nine domains describing processes, guidelines, frameworks, or standards an SCI entity could look to in developing reasonable policies and procedures to comply with Rule 1001(a) of Regulation SCI. *See* ''Staff Guidance on Current SCI Industry Standards,'' November 19, 2014, available at: *https://www.sec.gov/rules/final/2014/staff-guidance-current-sci-industry-standards.pdf.* The domains included: Application controls; capacity planning; computer operations and production environment controls; contingency planning; information security and networking; audit; outsourcing; physical security; and systems development methodology.

[368] 17 CFR 242.1001(b)(1)–(2).

[369] 17 CFR 242.1001(b)(3).

[370] 17 CFR 242.1001(b)(4).

[371] 17 CFR 242.1001(c).

[372] 17 CFR 242.1000.

[373] A ''systems disruption'' means an event in an SCI entity's SCI systems that disrupts, or significantly degrades, the normal operation of an SCI system. A ''systems compliance issue'' means ''an event at an SCI entity that has caused any SCI system of such entity to operate in a manner that does not comply with the Act and the rules and regulations thereunder or the entity's rules or governing documents, as applicable.'' A ''systems intrusion'' means any unauthorized entry into the SCI systems or indirect SCI systems of an SCI entity.'' *See* 17 CFR 242.1000.

[374] 17 CFR 242.1001(c)(2).

[375] *See* 17 CFR 242.1002(a).

[376] *See* 17 CFR 242.1002(b). For any SCI event that ''has had, or the SCI entity reasonably estimates would have, no or a de minimis impact on the SCI entity's operations or on market participants,'' Rule 1002(b)(5) provides an exception to the general Commission notification requirements under Rule 1002(b). Instead, an SCI entity must make, keep, and preserve records relating to all such SCI events, and submit a quarterly report to the Commission regarding any such events that are systems disruptions or systems intrusions.

[377] *See* 17 CFR 242.1002(c).

dissemination requirements are scaled based on the nature and severity of an event. Specifically, for ''major SCI events,'' SCI entities are required to promptly disseminate certain information about the event to all of its members or participants. For SCI events that are not ''major SCI events,'' SCI entities must, promptly after any responsible SCI personnel has a reasonable basis to conclude that an SCI event has occurred, disseminate certain information to those SCI entity members and participants reasonably estimated to have been affected by the event. In addition, dissemination of information to members or participants is permitted to be delayed for systems intrusions if such dissemination would likely compromise the security of the SCI entity's systems or an investigation of the intrusion.[378]

Rule 1003(a) of Regulation SCI requires SCI entities to provide reports to the Commission relating to system changes, including a report each quarter describing completed, ongoing, and planned material changes to their SCI systems and the security of indirect SCI systems, during the prior, current, and subsequent calendar quarters, including the dates or expected dates of commencement and completion.[379] Rule 1003(b) of Regulation SCI also requires that an SCI entity conduct an ''SCI review'' not less than once each calendar year.[380] ''SCI review'' is defined in Rule 1000 of Regulation SCI to mean a review, following established procedures and standards, that is performed by objective personnel having appropriate experience to conduct reviews of SCI systems and indirect SCI systems, and which review contains: A risk assessment with respect to such systems of an SCI entity; and an assessment of internal control design and effectiveness of its SCI systems and indirect SCI systems to include logical and physical security controls, development processes, and information technology governance, consistent with industry standards.[381] Under Rule 1003(b)(2)–(3), SCI entities are also required to submit a report of the SCI review to their senior management, and must also submit the report and any response by senior management to the report, to their board of directors as well as to the Commission.[382]

Rule 1004 of Regulation SCI sets forth the requirements for testing an SCI entity's business continuity and disaster recovery plans with its members or participants. This rule requires that, with respect to an SCI entity's business continuity and disaster recovery plan, including its backup systems, each SCI entity shall: (a) Establish standards for the designation of those members or participants that the SCI entity reasonably determines are, taken as a whole, the minimum necessary for the maintenance of fair and orderly markets in the event of the activation of such plans;[383] (b) designate members or participants pursuant to the standards established and require participation by such designated members or participants in scheduled functional and performance testing of the operation of such plans, in the manner and frequency specified by the SCI entity, provided that such frequency shall not be less than once every 12 months; and (c) coordinate the testing of such plans on an industry- or sector-wide basis with other SCI entities.

SCI entities are required by Rule 1005 of Regulation SCI to make, keep, and preserve certain records related to their compliance with Regulation SCI.[384] Rule 1006 of Regulation SCI provides for certain requirements relating to the electronic filing, on Form SCI, of any notification, review, description, analysis, or report to the Commission required to be submitted under Regulation SCI.[385] Finally, Rule 1007 of Regulation SCI contains requirements relating to a written undertaking when records required to be filed or kept by an SCI entity under Regulation SCI are prepared or maintained by a service bureau or other recordkeeping service on behalf of the SCI entity.[386]

Request for Comment

125. Should Regulation SCI apply to Government Securities ATSs that meet the proposed definition of SCI ATS? If so, are the proposed revisions to the definition of SCI ATS appropriate?

126. What are the risks associated with systems issues at a significant Government Securities ATS? What impact would a systems issue have on the trading of government securities and the maintenance of fair and orderly markets? Should all the requirements set forth in Regulation SCI apply to Government Securities ATSs that meet the proposed definition of SCI ATS?

127. Should Government Securities ATSs that meet the proposed volume thresholds for SCI ATSs be governed by the Capacity, Integrity, and Security Rule instead of being defined as SCI entities? Are there Government Securities ATSs that play a significant role in the secondary market for U.S. Treasury Securities but do not meet the proposed volume thresholds for SCI ATSs for which a different threshold should be established to mandate compliance with the Capacity, Integrity, and Security Rule? If yes, what additional regulatory requirements, if any, should be imposed on such ATSs? What would be the costs and benefits associated with applying Rule 301(b)(6) to Government Securities ATSs that are not SCI ATSs?

128. Should the Commission amend Regulation ATS to require Government Securities ATSs to comply with Rule 301(b)(6) but adopt a threshold that is lower or higher than 20 percent? For example, should the Commission amend Rule 301(b)(6) to subject Government Securities ATSs, or certain Government Securities ATSs, to the requirements of the rule if the Government Securities ATS reaches a 5 percent, 7.5 percent, 10 percent, or 15 percent volume threshold?

129. Do commenters believe that, even though certain Government Securities ATSs play a significant rule in the U.S. securities markets, regulatory requirements such as Regulation SCI and the Capacity, Integrity, and Security Rule are not necessary? If so, please specifically explain how the policy goals of Regulation SCI and the Capacity, Integrity, and Security Rule would continue to be achieved for such systems without relevant regulation.

130. Should the volume threshold to meet the definition of SCI ATS include trading in U.S. Treasury Securities and Agency Securities? Should Regulation SCI be applied to ATSs for any other type of government securities? Should Regulation SCI be applied to ATSs that trade repos or reverse repos on government securities, including repos or reverse repos on U.S. Treasury Securities, Agency Securities, or both?

[378] *See id.* In addition, the information dissemination requirements of Rule 1002(c) do not apply to SCI events to the extent they relate to market regulation or market surveillance systems, or to any SCI event that has had, or the SCI entity reasonably estimates would have, no or a de minimis impact on the SCI entity's operations or on market participants. *See* 17 CFR 242.1002(c)(4).

[379] *See* 17 CFR 242.1003(a).

[380] *See* 17 CFR 242.1003(b).

[381] *See* 17 CFR 242.1000. Rule 1003(b)(1) of Regulation SCI also states that penetration test reviews of an SCI entity's network, firewalls, and production systems must be conducted at a frequency of not less than once every three years, and assessments of SCI systems directly supporting market regulation or market surveillance must be conducted at a frequency based upon the risk assessment conducted as part of the SCI review, but in no case less than once every three years. *See* 17 CFR 242.1003(b)(1)(i)–(ii).

[382] *See* 17 CFR 242.1003(b)(2)–(3).

[383] *See* 17 CFR 242.1004.

[384] *See* 17 CFR 242.1005. Rule 1005(a) of Regulation SCI relates to recordkeeping provisions for SCI SROs, whereas Rule 1005(b) relates to the recordkeeping provision for SCI entities other than SCI SROs.

[385] *See* 17 CFR 242.1006.

[386] *See* 17 CFR 242.1007.

131. Should the proposed five percent threshold test for U.S. Treasury Securities be applied to all types of U.S. Treasury Securities or only to a subset(s) of U.S. Treasury Securities? For example, should the five percent volume test only be applied to transaction volume in on-the-run U.S. Treasury Securities? Should the five percent threshold only be applied to transaction volume in all Agency Securities or only to a subset(s) of Agency Securities?

132. Is the five percent threshold an appropriate threshold to capture ATSs that are significant markets for trading in U.S. Treasury Securities or Agency Securities? Would the five percent threshold capture ATSs that are not significant markets for U.S. Treasury Securities and Agency Securities? If commenters believe that there should be a percent threshold for a subset of U.S. Treasury Securities, such as on-the-run U.S. Treasury Securities or off-the-run U.S. Treasury Securities, what should that threshold be?

133. Should the Commission adopt a percent volume threshold that is lower than five percent for U.S. Treasury Securities, Agency Securities, or both? If so, what percentage threshold should the Commission adopt for Treasury Securities and Agency Securities? For example, should the Commission adopt a threshold that is four percent, three percent, two percent, or one percent for U.S. Treasury Securities? Should the Commission adopt a threshold that is four percent, three percent, two percent, or one percent for Agency Securities? Should there be no threshold for U.S. Treasury Securities? Should there be no threshold for Agency Securities? Please support your views.

134. Should the Commission adopt a percent volume threshold that is higher than five percent for U.S. Treasury Securities, Agency Securities, or both? For example, should the Commission adopt a threshold that is 7.5 percent, 10 percent, 15 percent, or 20 percent for U.S. Treasury Securities? Should the Commission adopt a threshold that is 7.5 percent, 10 percent, 15 percent, or 20 percent for Agency Securities?

135. Is it appropriate to use five percent of average weekly dollar volume traded in the United States as a threshold for application of Regulation SCI requirements to U.S. Treasury Securities? If the average weekly dollar volumes were to include transactions in the secondary cash market for U.S. Treasury Securities by non-FINRA members, which currently are not reported to, or collected by, the SRO that makes public average weekly dollar volume statistics, should the Regulation SCI threshold change? If so, what should be the appropriate threshold? Please support your views.

136. Is it appropriate to use five percent of average daily dollar volume traded in the United States as a threshold for the application of Regulation SCI requirements to Agency Securities?

137. Is the proposed four out of six month period an appropriate period to measure the volume thresholds for U.S. Treasury Securities, Agency Securities, or both? If not, what period of time would be appropriate?

138. Should the proposed Regulation SCI volume threshold measurement for Government Securities ATSs take into account whether Government Securities ATSs under common control share the same technology platform? For example, should two or more Government Securities ATSs under common control and operating on the same technology platform be viewed as a single entity required to aggregate volume for purposes of determining whether the threshold test has been satisfied?

139. Should only certain provisions of Regulation SCI apply to Government Securities ATSs that meet the proposed definition of SCI ATS? For example, should they only be subject to certain aspects of Regulation SCI? If so, which provisions should apply? Do commenters believe that different or unique requirements should apply to the systems of such Government Securities ATSs? What should they be and why?

140. In what instances, if at all, should the systems of Government Securities ATSs that meet the proposed definition of SCI ATS be defined as ''critical SCI systems''? Please describe.

141. Which subscribers or types of subscribers should Government Securities ATSs that meet the proposed definition of SCI ATS consider as ''designated members or participants'' that should be required to participate in the annual mandatory business continuity and disaster recovery testing? Please describe.

142. Should Government Securities ATSs that meet the proposed definition of SCI ATS not be defined as SCI entities but should be required to comply with provisions comparable to provisions of Regulation SCI?

143. What are the current practices of Government Securities ATSs with respect to the subject matter covered by Regulation SCI? To what extent do Government Securities ATSs have practices that are consistent with the requirements under Regulation SCI? To what extent do Government Securities ATSs' practices differ from the requirements under Regulation SCI? Please describe and be specific. Would the application of Regulation SCI or the Capacity, Integrity, and Security Rule weaken ATSs' existing capacity, integrity, and security programs?

144. Are there characteristics specific to the government securities market that would make applying Regulation SCI broadly or any specific provision of Regulation SCI to Government Securities ATSs unduly burdensome and inappropriate?

145. As commenters think about whether and how to apply Regulation SCI to Government Securities ATSs, are there any lessons commenters can draw from the market stress during Spring 2020, including, for example, lessons learned regarding business continuity or capacity planning?

VII. General Request for Comment

The Commission is requesting comments from all members of the public. The Commission particularly requests comment from the point of view of persons who operate ATSs that would meet the proposed definition of Government Securities ATS, subscribers to those systems, and investors. The Commission seeks comment on all aspects of the proposed rule amendments and proposed form, particularly the specific questions posed above. Commenters are requested to provide empirical data in support of any arguments or analyses. With respect to any comments, the Commission notes that they are of the greatest assistance to its rulemaking initiative if accompanied by supporting data and analysis of the issues addressed in those comments and by alternatives to the Commission's proposals where appropriate.

VIII. Concept Release on Electronic Corporate Bond and Municipal Securities Market

The SEC Fixed Income Market Structure Advisory Committee (''FIMSAC''), formed by the Commission in 2017, was established to provide the Commission ''with diverse perspectives on the structure and operations of the U.S. fixed income markets, as well as advice and recommendations on matters related to fixed income market structure.'' [387] In 2018, the Committee made a recommendation to the Commission concerning the regulation of corporate and municipal debt trading platforms.[388] The FIMSAC's core

[387] FIMSAC Charter art. 3 (November 15, 2017), *available at https://www.sec.gov/files/fimsac-charter.pdf.*

[388] *See* FIMSAC, Recommendation for the SEC to Review the Framework for the Oversight of Electronic Trading Platforms for Corporate and

concern was the lack of regulatory harmonization among fixed income electronic trading platforms, recognizing that some firms were regulated as ATSs, while some were regulated as broker-dealers or not at all. The FIMSAC stated that the varying regulatory treatment among fixed income electronic trading platforms is based on differences in trading protocols or business models. The FIMSAC concluded that these distinctions in regulatory oversight complicate efforts to improve the efficiency and resiliency of the fixed income electronic trading markets. Furthermore, the FIMSAC stated that without a unifying regulatory framework for all fixed income electronic trading platforms, market structures will likely fragment further as regulators adopt new regulations that apply to only one type of platform.

As such, the FIMSAC recommended, among other things, that the Commission form, together with FINRA and the MSRB, a joint working group to review the regulatory framework for oversight of fixed income electronic trading platforms.[389] Furthermore, when the Commission adopted the enhanced transparency rules for NMS Stock ATSs, the Commission stated that in light of the recent recommendations of the FIMSAC, and comments received on the proposal to amend Regulation ATS for NMS Stock ATSs, the Commission would review the regulatory framework for fixed income electronic trading platforms, including to consider whether the Commission should propose amendments to Regulation ATS (and any other applicable rules) to account for operational and regulatory differences among fixed income electronic trading platforms.[390]

While the trading protocols generally differ from those used in the interdealer secondary cash markets for on-the-run U.S. Treasury Securities, trading of corporate debt and municipal debt often does occur on ATSs and other electronic platforms. These electronic platforms might offer various protocols for bringing together buyers and sellers in fixed income securities, including auctions, central limit order books, negotiation functionalities, and request for quote platforms (''RFQ platforms''). The Commission is soliciting public comment to obtain information about fixed income electronic trading platforms, including their operations, services, fees, market data, and participants.[391] This information could help the Commission and other regulators evaluate potential regulatory gaps that may exist among these platforms with respect to access to markets, system integrity, surveillance, and transparency, among other things. The Commission expects that the comments it receives will ultimately inform regulatory policy. The Commission requests comment on the following:

146. Given the technological developments in the fixed income electronic trading markets and electronic trading of fixed income securities, do commenters believe that the current regulatory framework for fixed income electronic trading platforms best promotes the growth of fair and efficient markets for investors? If not, what regulatory approach(es) would best address the needs of the market and market participants? Does the current regulatory structure for national securities exchanges, broker-dealers, and ATSs cover the full range of fixed income electronic trading platforms operating today? If not, please explain any gaps in the regulatory structure and to which platforms it does not apply.

147. Exchange Act Rule 3b–16(a) sets forth a functional test of whether a system meets the definition of an exchange. Specifically, Rule 3b–16(a) provides that an organization, association, or group of persons meets the Exchange Act definition of ''exchange'' if it: (1) Brings together the orders for securities of multiple buyers and sellers; and (2) uses established, non-discretionary methods (whether by providing a trading facility or by setting rules) under which such orders interact with each other, and the buyers and sellers entering such orders agree to the terms of a trade. Is the Commission's approach under Exchange Act Rule 3b–16(a) appropriate for fixed income electronic trading platforms? If not, what elements of the definition of exchange under Rule 3b–16(a) do commenters believe that the Commission should consider changing and why? For example, should or should not the element of ''orders'' in Rule 3b–16(a) be included in the definition of exchange with regard to fixed income electronic trading platforms?

148. Are there particular elements of the definition of exchange under Exchange Act Rule 3b–16(a) that should or should not be changed with respect to fixed income electronic trading platforms, or more specifically, the corporate debt markets or municipal debt markets? What are commenters' views on the potential consequences of expanding or limiting the definition of exchange under Rule 3b–16(a) with regard to these trading platforms or markets? For instance, what are commenters' views on how changing Rule 3b–16(a) could benefit or harm investors and the market participants that use fixed income electronic trading platforms? Should the Commission, rather than amending Rule 3b–16(a), issue guidance on the elements of Rule 3b–16(a) regarding considerations relevant to the definition of exchange in the context of a fixed income platform? If so, what elements of Rule 3b–16(a) should the Commission issue guidance on and why? For example, should the Commission issue guidance on what is considered an ''order'' under Rule 3b–16(a)? Given the technological changes in the securities industry since Regulation ATS was adopted in 1998, should the Commission revise, or provide additional, examples in Regulation ATS of systems that fall within or outside the definition of exchange under Rule 3b–16?[392]

149. As noted above, fixed income electronic trading platforms offer a variety of different trading protocols and business models, and the FIMSAC expressed concern about varying regulatory treatment among these trading platforms. What do commenters believe are the key common characteristics of a fixed income

Municipal Bonds (July 16, 2018), *available at https://www.sec.gov/spotlight/fixed-income-advisory-committee/fimsac-electronic-trading-platforms-recommendation.pdf*. For purposes of this concept release, corporate debt securities (''corporate debt'') and municipal debt securities (''municipal debt'') are collectively referred to as ''fixed income securities,'' which do not include government securities.

[389] Specifically, the FIMSAC recommended that the SEC, FINRA, and MSRB form a joint working group to conduct a review of the regulatory framework for oversight of electronic trading platforms used in the corporate and municipal bond markets: (i) To ensure that the regulatory framework best promotes the growth of fair and effective fixed income electronic trading markets; (ii) to ensure that no regulatory gaps or inconsistencies in the application of such regulation exist that increase the potential for investor harm, systemic risk or unfair competition; (iii) to consider whether Regulation ATS (and any other applicable rules) should be amended to account for differences in protocols and market structures commonly used to trade fixed income as compared to equities; (iv) to ensure that regulation is not unfairly promoting or impeding specific trading protocols and business models over others; and (v) to consider whether any existing regulation impacting the fixed income electronic trading markets is unnecessary from a cost-benefit perspective. *See id.*

[390] *See* Regulation NMS Stock ATS Adopting Release, *supra* note 1, at 38783–84.

[391] While this concept release is focused on electronic trading platforms for corporate debt and municipal debt, to the extent commenters believe comments are relevant to electronic trading platforms for other types of debt securities, including government securities, that information would be helpful to the Commission.

[392] *See* Regulation ATS Adopting Release, *supra* note 35, at 70854–56.

electronic trading platform that should merit their common regulation under the securities laws?

150. As noted above, securities intermediaries generally are regulated either as exchanges or as brokers or dealers. What do commenters believe are the key regulatory standards that should apply to fixed income electronic trading platforms? Are there aspects of the current regulatory structure, other than regulatory treatment, that should not apply to these trading platforms? Are there other standards not addressed in the current regulation that should be considered? How could the current regulatory structure for these trading platforms be improved?

151. What do commenters believe are the key inconsistencies in the regulation of fixed income electronic trading platforms? Do these inconsistencies create risks to the integrity of the market for fixed income securities, and if so, how? Do these inconsistencies create burdens on competition among market participants, and if so, how?

152. Is the current regulatory framework for fixed income electronic trading platforms unfairly promoting or impeding specific trading platforms or trading protocols over others, and if so, how? How, if at all, is the current regulatory structure hindering automation of the markets?

153. The Commission, FINRA, and the MSRB all have important roles in the regulation of corporate and municipal debt markets. Do commenters believe that the combined regulation of these markets is effective? If not, how could collective regulation of these markets be improved?

154. Should the Commission consider a definition of exchange that is unique for fixed income electronic trading platforms? If so, what should that definition be and what aspects of the fixed income electronic trading markets should the definition address or not address? What are commenters' views on how such a definition would be advantageous or disadvantageous to market participants that use fixed income electronic trading platforms and investors? How would a definition of exchange tailored for fixed income electronic trading platforms promote fair and orderly markets? How could such a definition be crafted in a way that would account for potential changes in technology that could be applied to fixed income markets and trading in the future? Would a separate definition of exchange for fixed income electronic trading platforms conflict, or create investor confusion, with regard to a definition of exchange for other asset classes, such as government securities, NMS stock, or OTC equity securities?

155. Some electronic platform providers offer their customers a suite of different types of electronic trading protocols (*e.g.,* auctions, request for quotes, central limit order books) that are designed to find and match counterparties. These electronic platform providers might also offer voice protocols or a hybrid of voice and electronic protocols and pricing data and facilitate trade reporting and clearing services. Do electronic platform providers such as these provide fixed income market participants with a marketplace for buying and selling fixed income products? Should all the protocols and services offered by electronic platform providers be considered together for purposes of the definition of exchange under federal securities laws?

156. Are the current conditions to the exemption from the definition of an ''exchange'' under Regulation ATS appropriate for ATSs that trade corporate or municipal debt securities (''Fixed Income ATSs'')? For example, should Fixed Income ATSs that file a confidential Form ATS with the Commission be subject to the similar operational transparency rules as an NMS Stock ATS that files a public Form ATS–N with the Commission and disclose similar detailed information about the ATS's manner of operations and ATS-related activities of the broker-dealer operator and its affiliates? If yes, what types of disclosures should such a form solicit? What type of disclosures should such a form not solicit? How should the form compare to Form ATS–N?

157. Should the Commission continue to require Fixed Income ATSs to file a Form ATS but make Form ATS public? If so, how, if at all, should Form ATS be amended?

158. Rule 304 of Regulation ATS provides a process for the Commission to review Form ATS–N before it becomes effective and the NMS Stock ATS can operate pursuant to the exemption under Exchange Act Rule 3a1–1(a)(2). Rule 304 also provides the Commission with the opportunity to declare the Form ATS–N ineffective after notice and opportunity for hearing. Fixed Income ATSs operate pursuant to the same exemption provided under Exchange Act Rule 3a1–1(a)(2) as NMS Stock ATSs but are not subject to Rule 304. Should the Commission amend Regulation ATS to apply Rule 304 of Regulation ATS to Fixed Income ATSs?

159. Today, ATSs can only transact in securities; however, an ATS may, in addition to its Rule 3b–16 activity, conduct secondary transactions in securities in manners that may not meet a criteria of Exchange Act Rule 3b–16(a). Should the Commission amend Regulation ATS to require Fixed Income ATSs to only operate in a manner that meets the criteria of Rule 3b–16(a)? What would be the advantages and disadvantages to investors and the Commission should the Commission require this?

160. The Fair Access Rule applies when an ATS, during at least four of the preceding six months, had five percent or more of the average daily volume of municipal securities traded in the United States or had five percent or more of the average daily volume of corporate debt securities traded in the United States. Do commenters believe that the current fair access threshold under Rule 301(b)(5) of Regulation ATS for Fixed Income ATSs continues to be appropriate to capture ATSs with a significant percentage of the trading volume in corporate debt and municipal debt? If not, do commenters believe that access to Fixed Income ATSs is an important goal that the Commission should consider in regulating such platforms? If so, are there circumstances in which a Fixed Income ATS should be able to limit access to its system, or alternatively, should be required to grant access to its system? Are the current requirements of the Fair Access Rule appropriate for Fixed Income ATSs? Should the definition of exchange and Regulation ATS be amended so that the Fair Access Rule applies to transactions in fixed income securities occurring through various platforms offered by a broker-dealer and its affiliates in which the broker-dealer also operates a Fixed Income ATS? Should the Fair Access Rule apply to platforms that trade fixed income securities but are not Fixed Income ATSs?

161. The current Capacity, Integrity, and Security Rule under Rule 301(b)(6) of Regulation ATS applies when an ATS, during at least four of the preceding six months, had 20 percent or more of the average daily volume of municipal securities traded in the United States or had 20 percent or more of the average daily volume of corporate debt securities traded in the United States. Do commenters believe that the current Capacity, Integrity, and Security Rule continues to be appropriate to capture ATSs with a significant percentage of the trading volume in corporate debt and municipal debt? Should the Commission amend Rule 301(b)(6) to lower the current 20 percent threshold? If so, should the Commission adopt a threshold of, for example, 5

percent, 7.5 percent, 10 percent or 15 percent? Please support your views. Do commenters believe that the Capacity, Integrity, and Security Rule requirements are appropriate for Fixed Income ATSs? Should the requirements apply to all Fixed Income ATSs? Should the Capacity, Integrity, and Security Rule requirements apply to non-ATS platforms for corporate bonds and municipal securities operated by a broker-dealer that also operates a Fixed Income ATS? Should the Capacity, Integrity, and Security Rule apply to platforms that trade corporate bonds and municipal securities but are not Fixed Income ATSs?

162. ATSs that trade equity securities—both NMS stocks and non-NMS stocks—are no longer subject to the Capacity, Integrity, and Security Rule under Rule 301(b)(6) of Regulation ATS. Rather they are now subject to the requirements of Regulation SCI.[393] Should the Fixed Income ATSs be subject to Regulation SCI rather than the Capacity, Integrity, and Security Rule under Regulation ATS? If yes, should the same threshold tests for applying Regulation SCI to an ATS be applied to Fixed Income ATSs when determining if a given Fixed Income ATS is an ''SCI ATS?'' If not, what trading volume or other threshold should apply to Fixed Income ATS?

163. Do commenters believe that it is clear when a fixed income electronic trading platform meets the definition of a broker-dealer under the Exchange Act? Should the Commission provide guidance? Are there particular fact patterns that commenters believe would be helpful for the guidance to address?

164. Should broker-dealers offering customers protocols or facilities to buy and sell fixed income securities that would not meet the Exchange Act definition of ''exchange'' otherwise be subject to the same operational transparency rules as ATSs? If yes, should these broker-dealers be required to: (1) File a form with the Commission similar to the confidential Form ATS; or (2) file a form with the Commission similar to public Form ATS–N for NMS Stock ATSs? Alternatively, should these broker-dealers be subject to operational transparency requirements that are different than ATSs? If so, what form of operational transparency is appropriate? What type of information would be important for the broker-dealer to disclose to its customers about the platform that it operates? Do commenters have concerns that increased operational transparency requirements for these broker-dealers might cause an undue burden on competition for them? Do commenters think that increasing operational transparency for these broker-dealers would benefit competition in the market?

165. Do commenters believe that there are fixed income electronic trading platforms that are not registered as either a broker-dealer or a national securities exchange and that do not operate as an ATS but perform similar market functions as a broker-dealer, national securities exchange, or an ATS? If so, please explain what these systems are and how they may be different or the same as a broker-dealer, national securities exchange, or ATS that operates as a fixed income electronic trading platform. Do commenters believe that such platforms should or should not be required to register with the Commission? Do commenters believe that such platforms should or should not be required to operate pursuant to an exemption from the definition of an exchange, such as Regulation ATS? Should such platforms be required to register as something other than a broker-dealer or national securities exchange? Should such systems be subject to the same operational transparency requirements for broker-dealers, national securities exchanges, or ATSs? What aspects of these systems would be important to market participants who may use these platforms? Do commenters believe that there is sufficient oversight of these platforms by the Commission? If not, how should the Commission enhance oversight of these platforms?

166. As commenters think about whether and how to change the regulatory framework for fixed income electronic trading platforms, are there any lessons commenters can draw from the market stress during Spring 2020, including, for example, lessons learned regarding business continuity or capacity planning?

IX. Paperwork Reduction Act

Certain provisions of the proposed rule amendments contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[394] The Commission is submitting these collections of information to the Office of Management and Budget (''OMB'') for review in accordance with 44 U.S.C 3507(d) and 5 CFR 1320.11. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the agency displays a currently valid control number. The title of the new collection of information is ''Form ATS–G.'' The titles of the existing collections of information are:

Rule	Rule title	OMB control No.
Rule 304 of Regulation ATS	Regulation ATS Rule 304 and Form ATS–N	3235–0763
Rule 301 of Regulation ATS	Regulation ATS Rule 301 Amendments	3235–0509
Rule 302 of Regulation ATS	Rule 302 (17 CFR 242.302) Recordkeeping Requirements for Alternative Trading Systems.	3235–0510
Rule 303 of Regulation ATS	Rule 303 (17 CFR 242.303) Record Preservation Requirements for Alternative Trading Systems.	3235–0505
Rule 15b1–1 under the Exchange Act	Form BD and Rule 15b1–1 Application for Registration as a Broker-Dealer	3235–0012
Rule 10(b) of Regulation S–T	Form ID	3235–0328
Rules 1001 through 1007 of Regulation SCI.	Regulation SCI and Form SCI	3235–0703

A. Summary of Collection of Information

The proposed amendments to Regulation ATS include five new categories of obligations that would require a collection of information within the meaning of the PRA: (1) Requiring Currently Exempted Government Securities ATSs to comply with the applicable provisions of Rule 301(b) of Regulation ATS;[395] (2) applying the requirements of proposed

[393] *See supra* notes 286 and 345 and accompanying text.

[394] 44 U.S.C. 3501 *et seq.*

[395] 17 CFR 242.301. The applicable provisions are Rules 301(b)(1), 301(b)(8), 301(b)(9), and 301(b)(10).

Form ATS–G to Government Securities ATSs, including both Currently Exempted Government Securities ATSs and Legacy Government Securities ATSs that operate pursuant to a Form ATS on file with the Commission as of the Compliance Date; (3) amending Regulation ATS to apply the Fair Access Rule to Government Securities ATSs that have significantly large trading volume in U.S. Treasury Securities or Agency Securities; (4) amending Form ATS and Form ATS–R to provide that such forms be filed electronically; (5) applying the requirements of Regulation SCI to the trading of U.S. Treasury Securities and Agency Securities on Government Securities ATSs. The proposed new collections of information are summarized in the following table below:

	Legacy Filers [396]	Currently Exempted Government Securities ATSs	NMS Stock ATSs	ATSs that are not NMS Stock ATSs or Government Securities ATSs
Broker-dealer registration (Rule 301(b)(1))	*Existing requirement*	New requirement	*Existing requirement*	*Existing requirement.*
Fair Access Rule (Rule 301(b)(5))	New requirement	New requirement	*Existing requirement*	*Existing requirement for ATSs that trade certain securities.*
Recordkeeping requirements (Rule 301(b)(8)).	*Existing requirement*	New requirement	*Existing requirement*	*Existing requirement.*
Form ATS–R reporting (Rule 301(b)(9))	Revised requirements of Form ATS–R.	New requirement	Revised requirements of Form ATS–R.	Revised requirements of Form ATS–R.
Written safeguards and written procedures to ensure the confidential treatment of trading information (Rule 301(b)(10)).	*Existing requirement*	New requirement	*Existing requirement*	*Existing requirement.*
Recordkeeping requirements (Rule 302)	*Existing requirement*	New requirement	*Existing requirement*	*Existing requirement.*
Record preservation requirements (Rule 303)	*Existing requirement*	New requirement	*Existing requirement*	*Existing requirement.*
Form ATS/Form ATS–G/Form ATS–N filing requirements (Rules 301(b)(2) and 304).	New requirement under Rule 304.	New requirement under Rule 304.	Revised requirements of Form ATS–N, filed pursuant to Rule 304.	Revised requirements of Form ATS, filed pursuant to Rule 301(b)(2).
Regulation SCI	New requirement	New requirement	*Existing requirement*	*Existing requirement for ATSs that trade certain securities.*

1. Requirements Relating to Application of Rule 301(b) of Regulation ATS to Currently Exempted Government Securities ATSs

The Commission is proposing to amend Regulation ATS to remove the exemption from compliance for ATSs that solely trade government securities or repos and, therefore, require these ATSs to comply with the information collection requirements of Regulation ATS.[397]

2. Requirements Relating to Proposed Amendments to Rules 301(b)(2)(viii) and 304 of Regulation ATS, Including Proposed Form ATS–G, and Amendments to Rule 301(b)(9)

The Commission proposes that any ATS that meets the definition of Government Securities ATS would be required to complete Form ATS–G and file it with the Commission in a structured format via EDGAR.[398] The proposal would also require each Government Securities ATS to make public via posting on its website (i) a direct URL hyperlink to the Commission's website that contains Form ATS–G filings and (ii) the most recently disseminated Covered Form.[399]

Proposed Form ATS–G would require that the responding entity provide information about the type of filing on the cover page.[400] Part I of proposed Form ATS–G would require information about the broker-dealer operator.[401] Proposed Part II would require a Government Securities ATS to disclose information about the ATS-related activities of the broker-dealer operator and its affiliates.[402] Proposed Part III would require the Government Securities ATS to provide certain disclosures about the manner of operations of the ATS.[403] Proposed Part IV would require the Government Securities ATS to provide contact information and consent to service of any civil action brought by, or any notice of any proceeding before, the Commission or an SRO in connection with the ATS's activities.[404]

A Government Securities ATS would be required by Rule 301(b)(9) to file a Form ATS–R filing for the ATS to report its trading volume in government securities and repos.[405] An ATS that is not an NMS Stock ATS or Government Securities ATS would be subject to Rule 301(b)(2) and file a Form ATS, and, in accordance with Rule 301(b)(9), a Form ATS–R.[406]

3. Requirements Relating to Proposed Amendments to Rule 301(b)(5)

The Commission is proposing to amend Regulation ATS to require an ATS that has a significantly large percentage of volume of trading in U.S. Treasury Securities or Agency Securities to comply with the Fair Access Rule.[407] Under proposed Rule 301(b)(5), an ATS that reaches a certain volume of trading in U.S. Treasury Securities or Agency Securities would be required to, among others things, establish written standards for granting access to trading on their systems and apply these standards fairly, and is prohibited from unreasonably prohibiting or limiting any person with respect to trading in the stated securities. Government Securities ATSs that meet the fair access thresholds would also need to comply with Rule 303(a)(1)(iii),[408] which requires that, for a period of not less than three years, the first two years in an easily accessible place, an ATS preserve at least one copy of its

[396] *See* text accompanying *infra* note 422 for the definition of ''Legacy Filers.''

[397] These requirements are listed on the table above and described in detail in *supra* Sections II.C and II.E.

[398] *See generally supra* Sections II.F; II.H.

[399] *See supra* Section II.G.

[400] *See supra* Section III.A.1.

[401] *See supra* Section III.A.2.

[402] *See supra* Section III.B.

[403] *See supra* Section III.C.

[404] *See supra* Section III.D.

[405] *See supra* Section II.H.

[406] *See id.*

[407] 17 CFR 242.301(b)(5). *See supra* Section II.D.

[408] 17 CFR 242.303(a)(1)(iii).

standards for access to trading, all documents relevant to its decision to grant, deny, or limit access to any person, and all other documents made or received by the ATS in the course of complying with Rule 301(b)(5).[409]

4. Requirements Related to Proposed Amendments to Rule 301(b)(2), Form ATS, and Form ATS–R

Rule 301(b)(2) of Regulation ATS requires that every ATS subject to Regulation ATS file an initial operation report,[410] amendments to its initial operation report,[411] and a cessation of operations report on Form ATS.[412] ATSs are required to file quarterly transaction reports on Form ATS–R pursuant to Rule 301(b)(9).[413] The Commission proposes to require respondents to submit these reports electronically.[414] The Commission is also proposing changes to modernize Form ATS and Form ATS–R.[415]

5. Requirements Related to Amendments to Regulation SCI

The Commission is proposing to expand the definition of ''SCI ATS'' under Regulation SCI to include Government Securities ATSs that meet certain volume thresholds with respect to U.S. Treasury Securities and/or Agency Securities. Under the proposal, a Government Securities ATS that meets the proposed amended definition of ''SCI ATS'' would fall within the definition of ''SCI entity'' and, as a result, would be subject to the requirements of Regulation SCI.[416]

B. Proposed Use of Information

1. Proposed Amendments To Apply Rule 301(b) of Regulation ATS to Currently Exempted Government Securities ATSs

Records requested by Rule 301(b)(8), as well as Rules 302 and 303, and information provided pursuant to the proposed broker-dealer registration requirements under Section 15 or Section 15C(a)(1)(A) of the Exchange Act, including Form BD and SRO membership requirements, would allow the Commission and SROs to examine Currently Exempted Government Securities ATSs for compliance with the conditions of exemption provided under Exchange Act Rule 3a1–1(a) and Regulation ATS.[417] Information disclosed on Form ATS–R by Currently Exempted Government Securities ATSs under proposed Rule 301(b)(9) would permit the Commission to monitor the trading on these ATSs for compliance with the Exchange Act and applicable rules thereunder and enforce the Fair Access Rule. Information contained in the records required to be preserved pursuant to proposed Rules 301(b)(10) and 303(a)(1)(v) would be used by the Commission, state securities regulatory authorities, and SROs to better understand how each Currently Exempted Government Securities ATS protects subscribers' confidential trading information.

2. Proposed Amendments to Rule 301(b)(5) of Regulation ATS

The Commission will use the information related to the Fair Access Rule for Government Securities ATSs to monitor the growth and development of Government Securities ATSs. In addition, the Commission believes that this information will help the Commission oversee Government Securities ATSs to evaluate for compliance with the Fair Access Rule, which the Commission believes will ensure that qualified market participants have fair access to the nation's securities markets.

3. Proposed Amendments to Rule 301(b)(2), Form ATS, and Form ATS–R

The Commission uses the information provided pursuant to Rule 301 to monitor the growth and development of ATSs and oversee ATSs for the purpose of protecting investors. In particular, the information collected and reported to the Commission by ATSs enables the Commission to evaluate the operation of ATSs with regard to national market system goals, and to monitor the competitive effects of these systems to ascertain whether the regulatory framework remains appropriate with respect to such systems. Without the information required by Rule 301, the Commission would be limited in its ability to comply with its statutory obligations, including to provide for the protection of investors and to promote the maintenance of fair and orderly markets.

4. Proposed Application of Regulation SCI to Government Securities ATSs

The Commission would use information provided pursuant to Regulation SCI to, among other things, advance the goal of improving Commission review and oversight of U.S. securities market infrastructure and help promote the maintenance of fair and orderly markets.[418]

5. Proposed Rules 301(b)(2)(viii) and 304 of Regulation ATS, Including Proposed Form ATS–G, and Proposed Rule 301(b)(9)

The Commission believes that market participants would use the information publicly disclosed on proposed Form ATS–G to compare and evaluate information about different Government Securities ATSs. In addition, the Commission would use the information disclosed on proposed Form ATS–G and Form ATS–R to oversee the growth and development of Government Securities ATSs. The Commission believes that the information contained in the records required to be preserved by Rule 303(a)(2)(ii) would be used by examiners and other representatives of the Commission, state securities regulatory authorities, and SROs to evaluate whether Government Securities ATSs are in compliance with Regulation ATS as well as other applicable rules and regulations.

C. Respondents

The below table describes the applicable respondents for each category of ''collection of information'' requirements:

''Collection of information'' requirement	Applicable respondents
Applicable sections of Rule 301(b), Rule 302, and Rule 303	Currently Exempted Government Securities ATSs and any Government Securities ATSs that are established in the future.[419]
Rule 301(b)(2)(viii), Rule 304 and Form ATS–G, and Rule 301(b)(9)	All Government Securities ATSs.[420]

[409] *See supra* note 123.

[410] *See* 17 CFR 242.301(b)(2)(vi).

[411] *See* 17 CFR 242.301(b)(2)(ii).

[412] *See* 17 CFR 242.301(b)(2)(v).

[413] *See* 17 CFR 242.301(b)(9)(i). An ATS must also file Form ATS–R more frequently upon request of the Commission. *See* Form ATS–R Instructions.

[414] *See supra* Section IV.

[415] *See id.*

[416] For further details regarding the requirements of Regulation SCI, *see* Regulation SCI Adopting Release, *supra* note 2.

[417] *See supra* note 101 and accompanying text.

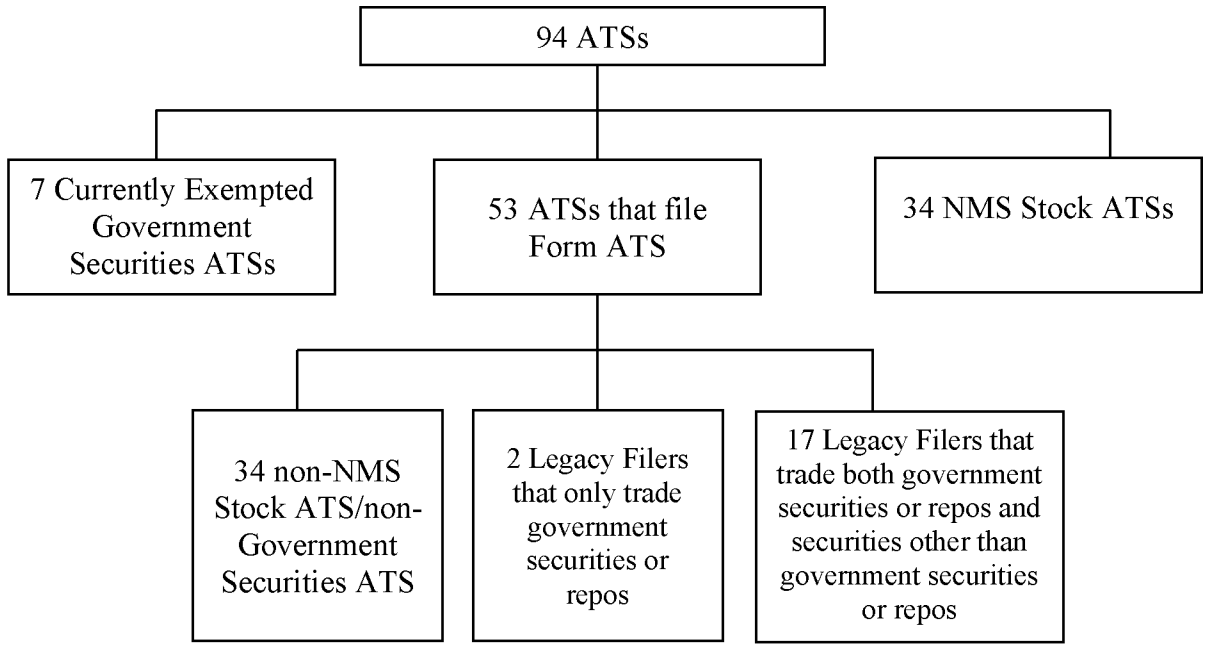
[418] *See* Regulation SCI Adopting Release, *supra* note 2, at Section V.B.

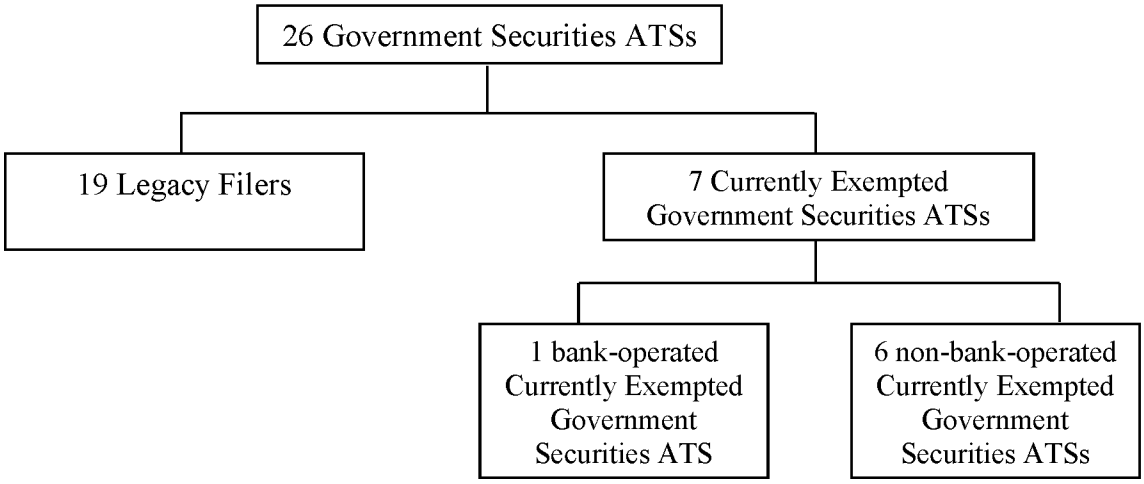
[419] The ''collection of information'' requirements relating to Rule 301(b), Rule 302, and Rule 303 have previously been established for Legacy Government Securities ATSs that have previously disclosed on their Form ATS their intention to trade government securities or repos. *See* FR Doc. 2014–02143, 79 FR 6236 (February 3, 2014) (Submission for OMB Review, Extension: Rule 301 and Forms ATS and ATS–R; SEC File No. 270–451; OMB Control No. 3235–0509) (''Rule 301 OMB Update'').

[420] The ''collection of information'' requirements relating to Rule 304 and Form ATS–G would replace the requirements of current Rule 301(b)(2).

"Collection of information" requirement	Applicable respondents
Form ATS	All ATSs that file a Form ATS.
Form ATS–R	All ATSs that file a Form ATS, Form ATS–N, or Form ATS–G.
Rule 301(b)(5) and Regulation SCI	All Government Securities ATSs that reach the volume thresholds.

The following chart summarizes the Commission's estimated number of respondents:





The Commission estimates that there are 7 Currently Exempted Government Securities ATSs that would be newly subject to the requirements of the exemption under Rule 3a1–1(a)(2) and required to comply with the applicable sections of Rule 301(b), Rule 302, and Rule 303.[421] Of these 7 Currently Exempted Government Securities ATSs, the Commission estimates that 1 is currently operated by a bank and would be newly subject to broker-dealer registration requirements under Section 15 or Section 15C(a)(1)(A) of the Exchange Act.

In addition, there are 19 ATSs operating pursuant to a Form ATS currently on file with the Commission that have noticed that they trade government securities or repos ("Legacy

[421] The Commission estimates that 5 ATSs that do not have a Form ATS on file with the Commission limit their trading activity to government securities and 2 ATSs limit their trading activity to repos.

Filers'').[422] Accordingly, the Commission estimates that 26 Government Securities ATSs would be required to comply with Regulation ATS, including Rule 304, Form ATS–G, and the proposed amendments related to Rule 301(b)(9).[423] Under the proposed amendments to Regulation ATS, 17 broker-dealers, each of which operates a Legacy Filer, would be required to file a Form ATS to disclose information about their activities in securities other than NMS stock, government securities, or repos, if any.[424] Consequently, these 17 broker-dealers would have to amend Forms ATS to remove discussion of those aspects of the ATS related to the trading of government securities and repos, and on an ongoing basis, file separate Forms ATS–R to report trading volume in government securities or repos.[425]

The Commission believes that of the 19 Legacy Filers, most would continue to operate notwithstanding the proposed amendments to Regulation ATS. For the purposes of this analysis of the paperwork burden associated with the proposed amendments to Regulation ATS, and to make a complete account of the impact on potential respondents, the Commission assumes that there will be 26 respondents. The Commission believes that this number is reasonable, as it assumes that most Legacy Filers would file a Form ATS–G with the Commission, and acknowledges that there may be some entities that may choose to commence operations as a Government Securities ATS and others that cease operations altogether. In the Commission's experience with implementation of Form ATS–N, a small number of NMS Stock ATSs either filed a cessation of operations report before they were required to file an initial Form ATS–N or did not file an initial Form ATS–N. These ATSs may have ceased operations and did not file a cessation of operations report or determined not to file initial Form ATS–N for a variety of business reasons, including to not comply with the new requirements of Form ATS–N. The Commission observes that from 2015 through the end of 2019, there was an average of 1 new ATS per year that disclosed that it trades or expects to trade government securities or repos on its initial operation report on Form ATS and 1 Government Securities ATS that ceased operations each year. Based on this information, the Commission estimates that 1 new entity will file to become a Government Securities ATS and 1 Government Securities ATS will cease operations in each of the next three years.

Currently, there are 53 ATSs that file Form ATS. As of July 1, 2020, 2 of these trade only government securities or repos and, as proposed, would only be required to file a Form ATS–G and amendments to Form ATS–G after the Compliance Date. Accordingly, the Commission estimates that 51 ATSs will continue to file Form ATS amendments. The Commission also estimates that 34 NMS Stock ATSs will continue to file Form ATS–N. In addition, the Commission estimates 94 ATSs will be required to file Form ATS–R, including 87 ATSs that currently file Form ATS–R and 7 Currently Exempted Government Securities ATSs.[426]

The Commission estimates that of the 26 Government Securities ATSs, 3 will meet the proposed volume thresholds and be subject to the Fair Access Rule and Regulation SCI.[427] The Commission believes that this number is reasonable based on the Commission's review of the Forms ATS–R of Legacy Filers.

D. Total Initial and Annual Reporting and Recordkeeping Burdens

1. Rule 301(b) of Regulation ATS to Currently Exempted Government Securities ATSs

a. Application of Rule 301(b)(1) to Currently Exempted Government Securities ATSs

The Commission recognizes that applying Rule 301(b)(1) to Currently Exempted Government Securities ATSs would impose a new burden on Currently Exempted Government Securities ATSs that are banks, as proposed Rule 301(b)(1) would require these ATSs to register as broker-dealers under Section 15 or Section 15C(a)(1)(A) of the Exchange Act. Based upon the existing burdens for completing and filing Form BD and amending Form BD when information originally reported on Form BD changes or becomes inaccurate, the Commission estimates that burdens for registering with the Commission as a broker-dealer under Section 15 or Section 15C(a)(1)(A)[428] would impose the following initial and annual burdens:

[422] Based on data compiled from Forms ATS submitted to the Commission as of July 1, 2020, 18 ATSs have disclosed on their Form ATS their intention to trade government securities, and 3 ATSs have disclosed their intention to trade repos. 2 of the 3 Government Securities ATSs that have noticed their intention to trade repos have also noticed their intention to trade government securities.

[423] These 26 ATSs include 19 Legacy Filers that operate pursuant to a Form ATS as of June 1, 2020 and 7 Currently Exempted Government Securities ATSs that would be newly subject to the requirements of the Exchange Act Rule 3a1–1(a)(2) exemption. As discussed below, the Commission recognizes that there may be new entities that will seek to become Government Securities ATSs, that would be required to comply with Regulation ATS, including proposed amendments to Rule 304, Rule 301(b)(9), and Form ATS–G.

[424] As of July 1, 2020, 2 of the 19 Legacy Filers trade only government securities or repos. Therefore, 2 broker-dealers that operate these Legacy Filers would not be subject to the proposed requirement to amend Form ATS and file separate Forms ATS–R.

[425] *See* proposed Rule 301(b)(9).

[426] The numbers of respondents are based on data compiled from Forms ATS and ATS–R filed with the Commission as of July 1, 2020. One broker-dealer operates both a Legacy Filer and an NMS Stock ATS. For purposes of estimating the burden applicable to this Legacy Filer and NMS Stock ATS, the Commission counts each ATS operated by a broker-dealer as a separate respondent because each such ATS has separate filing obligations. *See infra* Section IX.D.4.

[427] *See supra* Sections II.D and VI. The Commission believes that 3 Government Securities ATSs and 1 Government Securities ATS will meet the proposed volume threshold for U.S. Treasury Securities and Agency Securities, respectively. The Commission estimates that the Government Securities ATS that will meet the threshold for Agency Securities will also meet the threshold for U.S. Treasury Securities. Accordingly, the Commission estimates that, as proposed, 3 Government Securities ATSs will be subject to the Fair Access Rule and Regulation SCI. In addition, the Commission believes that 1 of the 3 Government Securities ATSs that would be subject to Regulation SCI is currently an SCI entity.

[428] The Commission believes that the burden to register as a government securities broker or dealer would be, for the purposes for this PRA analysis, the same as the burden to register as a broker-dealer because the information the ATS is required to provide in Form BD and amended Form BD is similar regardless of whether the ATS is registering under Section 15 or Section 15C(a)(1)(A). Sole government securities broker-dealers must indicate that they are registering as a government securities broker or dealer under Section 15C of the Exchange Act on Item 2.C of Form BD. Otherwise, the information required to be provided on Form BD is identical.

Burden	Initial burden	Annual burden
Filing and amending Form BD	*Per ATS:* 2.75 hours [429] *Industry:* 2.75 hours [430]	*Per ATS:* 1 hour[431] *Industry:* 1 hour [432]

b. Application of Rules 301(b)(8), 302, and 303 of Regulation ATS to Currently Exempted Government SecuritiesATSs

The Commission recognizes that applying Rule 301(b)(8) to Currently Exempted Government Securities ATSs would impose a new burden on Currently Exempted Government Securities ATSs, which are currently not required to comply with these requirements. Rule 301(b)(8) would require Currently Exempted Government Securities ATSs to comply with the requirements of Rules 302 and 303 of Regulation ATS. Based on the Commission's currently approved estimates for ATSs, including Legacy Filers,[433] the Commission estimates that the proposed application of Rules 301(b)(8), 302, and 303 to Currently Exempted Government Securities ATSs would impose the following annual burdens:

Burden	Annual burden
Recordkeeping requirements under Rule 302	*Per ATS:* 45 hours [434] *Industry:* 315 hours [435]
Record preservation requirements under Rule 303	*Per ATS:* 15 hours [436] *Industry:* 105 hours [437]
Total—Rule 301(b)(8)	*Per ATS:* 60 hours *Industry:* 420 hours

c. Application of Rule 301(b)(9) to Currently Exempted Government Securities ATSs

The Commission recognizes that the proposed application of Rule 301(b)(9) to Currently Exempted Government Securities ATSs would impose a burden on these respondents, as Currently Exempted Government Securities ATSs are currently not required to comply with these requirements. The Commission estimates that the proposed application of Rule 301(b)(9) to Currently Exempted Government Securities ATSs would impose the following annual burden:

Burden	Annual burden
Form ATS–R	*Per ATS:* 19 hours.[438] *Industry:* 133 hours.[439]

[429] *See* FR Doc. 2019–16601, 84 FR 38086 (August 5, 2019) (Submission for OMB Review, Extension: Rule 15b1–1/Form BD; SEC File No. 270–19; OMB Control No. 3235–0012).

[430] Compliance Manager at 2.75 hours × 1 bank-operated Currently Exempted Government Securities ATS = 2.75 burden hours. The Commission recognizes that the time necessary to complete Form BD would vary depending on the nature and complexity of the Currently Exempted Government Securities ATS.

[431] The Commission estimates that the additional annual burden hours necessary for a Currently Exempted Government Securities ATS to complete and file an amended Form BD would be approximately 0.33 hours. The Commission received an average of 10,959 Form BD amendments per year from fiscal year 2016 to 2019. As of 2019, there were 3,700 broker-dealers registered with the Commission. Based on this estimate, the Commission estimates that Currently Exempted Government Securities ATSs would file 3 amendments per year.

[432] Compliance Manager at 0.33 hours × 3 amendments × 1 Currently Exempted Government Securities ATS = 1 burden hour.

[433] As the requirements of Rules 301(b)(8), 302, and 303 would be identical for Currently Exempted Government Securities ATSs and Legacy Filers, the Commission believes that the hourly burden would be the same for Currently Exempted Government Securities ATSs as it is for Legacy Filers.

[434] Compliance Clerk at 45 hours = 45 burden hours. *See* FR Doc. 2019–19237, 84 FR 47028 (September 6, 2019) (Submission for OMB Review, Extension: Rule 302; SEC File No. 270–453; OMB Control No. 3235–0510).

[435] 45 hours × 7 Currently Exempted Government Securities ATSs = 315 burden hours.

[436] Compliance Clerk at 15 hours = 15 burden hours. *See* FR Doc. 2016–16040, 81 FR 44338, 44339 (Submission for OMB Review, Extension: Rule 303; SEC File No. 270–450; OMB Control No. 3235–0505).

[437] 15 hours × 7 Currently Exempted Government Securities ATSs = 105 burden hours.

[438] Attorney at 3 hours + Compliance Manager at 0.25 hours Clerk at 1.5 hours = 4.75 burden hours. *See infra* notes 525, 526, and 528. The annual burden per Currently Exempted Government Securities ATS would be 4.75 hours × 4 filings = 19 burden hours.

[439] The aggregate annual burden would be 4.75 hours × 4 filings × 7 Currently Exempted Government Securities ATSs = 133 burden hours.

The Commission's currently approved estimate for the average compliance burden for each Form ATS–R filing, including Form ATS–R filings by Legacy Filers, is 4 hours.[440] The Commission is proposing amendments to Form ATS–R, which would add an additional burden of 0.75 hours per filing,[441] and therefore the average compliance burden for each Form ATS–R filing would be 4.75 hours.

d. Application of Rules 301(b)(10) and 303(a)(1)(v) to Currently Exempted Government Securities ATSs

The Commission recognizes that Rules 301(b)(10) and 303(a)(1)(v) of Regulation ATS would impose certain new burdens on respondents as Currently Exempted Government Securities ATSs are not currently subject to these requirements. Based on the currently-approved burdens for Legacy Filers,[442] the Commission estimates that the proposed application of Rules 301(b)(10) and 303(a)(1)(v) to Currently Exempted Government Securities ATSs would impose the following initial and annual burdens:

Burden	Initial burden	Annual burden
Written safeguards and written procedures requirement under Rules 301(b)(10) and 303(a)(1)(v).	*Per ATS:* 10 hours.[443] ..... *Industry:* 70 hours[444]	*Per ATS:* 4 hours.[445] *Industry:* 28 hours[446]

[440] Attorney at 3 hours + Compliance Clerk at 1 hour = 4 burden hours. *See* Rule 301 OMB Update, *supra* note 419, at 6237.

[441] *See supra* Section V.C and *infra* Section IX.D.4 (discussing proposed changes to Form ATS–R applicable to all ATSs).

[442] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38868.

[443] The Commission estimates that a Currently Exempted Government Securities ATS's initial, one-time burden would be approximately 10 hours (Attorney at 9 hours + Compliance Clerk at 1 hour = 10 burden hours) based on the Commission's highest approximation of the additional burden per ATS, but that the burden could range between 5 and 10 hours (Attorney at 4–9 hours + Compliance Clerk at 1 hour = 5–10 burden hours). *See id.*

[444] (Attorney at 9 hours + Compliance Clerk at 1 hour) × 7 Currently Exempted Government Securities ATSs = 70 burden hours.

[445] Attorney at 2 hours + Compliance Clerk at 2 hours = 4 burden hours. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38868.

[446] 4 hours × 7 Currently Exempted Government Securities ATSs = 28 burden hours.

2. Proposed Amendments to Rules 301(b)(2)(viii) and 304 of Regulation ATS, Including Proposed Form ATS–G

a. Baseline Measurements

The Commission estimates that the proposed amendments to Rules 301(b)(2)(viii) and 304 would impose the following initial and annual baseline burdens to Legacy Filers, which are equivalent to the currently approved estimates for Form ATS and Form ATS–R:

Baseline burden	Initial baseline burden	Annual baseline burden
Initial operation report on Form ATS	*Per ATS:* 20 hours[447] *Industry:* 380 hours	N/A.
Form ATS amendments (twice per year)[448]	N/A	*Per ATS:* 12 hours.[449] *Industry:* 228 hours.
Cessation of operations report on Form ATS	N/A	*Per ATS:* 2 hours.[450] *Industry:* 2 hours.[451]
Form ATS–R	N/A	*Per ATS:* 16 hours.[452] *Industry:* 304 hours.
Total—baseline burden	*Per ATS:* 20 hours *Industry:* 380 hours	*Per ATS:* 30 hours. *Industry:* 534 hours.

Currently Exempted Government Securities ATSs are not currently required to comply with the requirements of Rule 301(b)(2). The Commission estimates that the proposed amendments to Rules 301(b)(2)(viii) and 304 would impose initial and annual baseline burdens equivalent to those for Legacy Filers described above.

b. Burdens

The Commission believes that although many of the disclosures required by proposed Form ATS–G are currently required by Form ATS, proposed Form ATS–G would require a Government Securities ATS to provide significantly more detail in those disclosures than currently is required by Form ATS, as well as additional disclosures not currently mandated by Form ATS.[453] In addition, because Currently Exempted Government Securities ATSs are not required to complete a Form ATS, the Commission estimates that Currently Exempted Government Securities ATSs will incur a burden equivalent to the current baseline burdens on Legacy Filers as a result of the proposal.[454]

i. Analysis of Estimated Additional Burden for Proposed Form ATS–G

Although Form ATS–G is tailored to describe operations relevant to Government Securities ATSs, the information requests on Form ATS–N and Form ATS–G are, for the most part, very similar. In the Commission's experience implementing Form ATS–N, the Commission believes that the estimates calculated in the NMS Stock ATS Adopting Release continue to be reasonable estimates of the burden hours imposed by Form ATS–N, and therefore, reasonable estimates of the burden hours imposed by Form ATS–G.[455] As discussed below, due to requests unique to Form ATS–G, the Commission estimates that Form ATS–G would require 5.75 more burden hours than Form ATS–N. Accordingly, the Commission estimates that the additional burden hours for filing a Form ATS–G would result in a total additional burden of 114.15 hours per Government Securities ATS above the current 20-burden hour baseline for an initial operation report on Form ATS.[456] The below chart compares the estimated burdens for Form ATS–G to the currently-approved estimates for Form ATS–N:[457]

Rule/item	ATS–G (hours)	ATS–N (hours)
Part I[458]	*0.75*	*0.5*
Part I Total	0.75	0.5
Part II, 1(a)	4.25	4.25
Part II, 1(b)	0.25	0.25
Part II, 1(c)	1	1
Part II, 1(d)[459]	*1.5*	*0.5*
Part II, 2(a)	6.25	6.25
Part II, 2(b)	0.25	0.25
Part II, 2(c)	1	1
Part II, 2(d)[461]	*1.5*	*0.5*
Part II, 3	1.5	1.5
Part II, 4	4	4
Part II, 5	3	3
Part II, 6	5	5
Part II, 7	1.5	1.5
Part II Total	31	29
Part III, 1	0.5	0.5
Part III, 2	1	1
Part III, 3	1	1
Part III, 4	0.5	0.5
Part III, 5	10.5	10.5
Part III, 6	2.5	2.5
Part III, 7	4	4
Part III, 8	1	1
Part III, 9	1	1
Part III, 10	1.25	1.25
Part III, 11	6	6
Part III, 12	1	1
Part III, 13	6	6
Part III, 14	2	2
Part III, 15[460]	*4.5*	*5*
Part III, 16[462]	*6*	*2*
Part III, 17	1.25	1.25
Part III, 18	1.25	1.25
Part III, 19	6	6
Part III, 20	2.5	2.5
Part III, 21 & 22	0.5	0.5
Part III, 23	5	5
Part III, 24 (only applies to select respondents)[463]	*10*	*5*
Part III, 25[464]	*7*	*5*
Part III, 26	*0*	*7*
Part III Total	82.25	78.75
Part IV Total	0	0
Total	114.15	108.4

[447] Attorney at 13 hours + Compliance Clerk at 7 hours = 20 burden hours. *See* Rule 301 OMB Update, *supra* note 419, at 6237.

[448] During the fiscal year of 2019, the Commission received 39 amendments from the 19 Legacy Filers. Accordingly, the Commission estimates that Legacy Filers amend their Form ATS on average twice per year.

[449] The Commission estimates the current average compliance burden for each amendment to Form ATS is: Attorney at 4.5 hours + Compliance Clerk at 1.5 hours = 6 burden hours. 2 Form ATS amendments filed annually × 6 hours per Form ATS amendment = 12 burden hours per ATS. *See id.*

[450] Attorney at 1.5 hours + Compliance Clerk at 0.5 hours = 2 burden hours. *See id.*

[451] 2 hours × approximately 1 cessation of operations report on Form ATS per year = 2 burden hours. *See supra* Section IX.D.

[452] Attorney at 3 hours + Compliance Clerk at 1 hour = 4 burden hours. *See* Rule 301 OMB Update, *supra* note 419, at 6237. 4 Form ATS–R filings annually × 4 hours per Form ATS–R filing = 16 burden hours.

[453] In establishing the estimates below with respect to proposed Form ATS–G, the Commission has considered its estimate of the burden for an SRO to amend a Form 19b–4. Specifically, the Commission estimated that 34 hours is the amount of time required to complete an average rule filing; 129 hours is the amount of time required to complete a complex rule filing; and 3 hours is the amount of time required to complete an average amendment to a rule filing. *See* Securities Exchange Act Release No. 50486 (October 4, 2004), 69 FR 60287, 60294 (October 8, 2004).

[454] *See supra* Section IX.D.2.a.

[455] *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38869–81.

[456] 108.4 additional burden hours for filing a Form ATS–N that the Commission estimated in the NMS Stock ATS Adopting Release + 5.75 hours added to the burden for requests unique to Form ATS–G = 114.15 additional burden hours. *See* NMS Stock ATS Adopting Release, *supra* note 1, at Section IX.D.2. The NMS Stock ATS Adopting Release stated that the Commission estimated that Form ATS–N would add an additional 107.4 hours to the baseline for each ATS. *See id.* at n.1228 and accompanying text. However, the actual total of the estimated burden hours of the items in Form ATS–N in the NMS Stock ATS Adopting Release is *108.4* (not 107.4). *See id.* at 38868–81. Therefore, the Commission is using the estimated total of 108.4 additional burden hours for Form ATS–N as basis for estimating the additional burden hours for Form ATS–G.

[457] *See id.* Items for which the burden hours differ between Form ATS–G and Form ATS–N are italicized.

[458] *See infra* note 465 and accompanying text.

[459] *See supra* note 466 and accompanying text.

[460] *See supra* note 467 and accompanying text.

[461] *See supra* note 466 and accompanying text.

[462] *See supra* note 468 and accompanying text.

[463] *See supra* note 470 and accompanying text. Other than as described below, the information required by Part III, Item 24 of Form ATS–G is similar to the information required by Part III, Item 25 of Form ATS–N.

Part I of proposed Form ATS–G is identical to Part I for Form ATS–N, as proposed, except that Part I, Item 5 of Form ATS–G requires a Government Securities ATS to select the types of securities the ATS trades (*i.e.,* U.S. Treasury Securities, Agency Securities, repos, or other). If the ATS selects ''other,'' it would be required to list the types of securities it trades. The Commission believes that the information required by the proposed disclosure under Part I, Item 5 is already required under Exhibit B of current Form ATS, which requires an ATS to provide, among other things, lists of securities and the types of securities the ATS trades or expects to trade. Consequently, the Commission believes that preparing this Item would not impose a significant additional burden above the baseline. The Commission estimates that, on average, preparing Part I, Item 5 for proposed Form ATS–G would add 0.25 hours above the baseline for each Government Securities ATS, resulting in an aggregate initial burden of 6.5 hours above the baseline for all Government Securities ATSs.[465]

Part II of proposed Form ATS–G is identical to Part II for Form ATS–N except for Part II, Items 1(d) and 2(d) of Form ATS–G. Part II, Items 1(d) and 2(d) of Form ATS–G would additionally require a Government Securities ATS to identify the trading venue operated or controlled by its broker-dealer operator or its affiliate, respectively, to which orders and trading interest in the ATS could be sent, and explain under what circumstances orders and trading interest are sent from the ATS to the trading venue. These requirements are similar to Part III, Item 16 of Form ATS–N, which requires an NMS Stock ATS to provide disclosures surrounding orders and trading interest in the ATS being routed to a destination outside the ATS. The Commission therefore estimates that, on average, preparing these narratives in Part II, Items 1(d) and 2(d) would each add one hour to the approved estimated burden hours to prepare Part II, Items 1 and 2 of Form ATS–N, resulting in an aggregate burden of 52 hours above the baseline for all Government Securities ATSs.[466]

Part III of proposed Form ATS–G requires a Government Securities ATS to provide information similar to that in which an NMS Stock ATS is currently required to provide under Part III of Form ATS–N with certain exceptions. Unlike Form ATS–N, Part III, Item 15 of proposed Form ATS–G does not ask whether the ATS is an Electronic Communication Network as defined in Regulation NMS. Accordingly, the Commission believes that Item 15 of proposed Form ATS–G would impose a lesser burden than the approved estimated burden for Item 15 of Form ATS–N. The Commission estimates that, on average, preparing Part III, Item 15 for Form ATS–G would add 4.5 hours to the baseline, resulting in an aggregate initial burden of 117 hours above the baseline for all Government Securities ATSs.[467]

Part III, Item 16 of Form ATS–N asks about order routing; the Commission is not including such a question in Form ATS–G. Instead, Part III, Item 16 of Form ATS–G would require a Government Securities ATS to disclose its functionalities or procedures to facilitate trading on or source pricing for the Government Securities ATS using related markets. As the broker-dealer operator controls all aspects of the operation of the Government Securities ATS, the Commission believes that the broker-dealer operator should already be aware of the ATS's trading and pricing practices. Therefore, preparing this Item would not impose a substantial burden on the respondents. The Commission estimates that, on average, preparing Part III, Item 16 for Form ATS–G would add a total of 6 hours to the baseline per respondent, resulting in an aggregate initial burden of 156 hours above the baseline for all Government Securities ATSs.[468]

As proposed, Form ATS–G would not, unlike Form ATS–N, include a question pertaining to order display and execution access.[469] However, similar to Part III, Item 25 of Form ATS–N, Part III, Item 24 of proposed Form ATS–G would require a Government Securities ATS to disclose whether the ATS has triggered the proposed fair access thresholds and, if applicable, describe the written standards for granting access to trading on the ATS to comply with Rule 301(b)(5)(ii)(A) of Regulation ATS. Historically, Government Securities ATSs have crossed these thresholds very rarely, with at most 3 Government Securities ATSs crossing either of the applicable thresholds in any given year, and the Commission believes this would continue to occur very infrequently. Consistent with the burden hours for completing Part III, Item 25 of Form ATS–N, the Commission estimates that preparing Part III, Item 24 in a proposed Form ATS–G would add 5 hours for each class of securities.[470] Because Part III, Item 24 of Form ATS–G requires the Government Securities ATS to provide the fair access disclosures for two categories of government securities—U.S. Treasury Securities and Agency Securities—the Commission estimates that preparing this Item would add an additional 5 hours per respondent and a total of 10 hours above the baseline for each respondent for which both thresholds are applicable.[471] The Commission believes that 3 ATSs crossed the proposed fair access threshold for U.S. Treasury Securities, and 1 ATS crossed the proposed fair access threshold for Agency Securities in four of the preceding six calendar months. Accordingly, the Commission estimates that the preparing Part III, Item 24 for proposed Form ATS–G would result in an aggregate initial burden of 20 hours above the baseline.[472]

In total, Government Securities ATSs would incur the following initial burden, on average, to prepare proposed Form ATS–G:

[464] The information required by Part III, Item 25 of Form ATS–G is identical to the information required by Part III, Item 26 of Form ATS–G.

[465] Compliance Clerk at 0.25 hours = 0.25 burden hours. 0.25 hours × 26 Government Securities ATSs = 6.5 burden hours.

[466] Attorney at 0.25 hours + Compliance Manager at 0.25 hours + Sr. Systems Analyst at 0.5 hours = 1 burden hour. The burden hours to answer ''yes'' or ''no'' questions whether orders and trading interest in the Government Securities ATS can be sent to a trading venue operated or controlled by the broker-dealer operator or its affiliate in proposed Part II, Items 1(d) and 2(d) of Form ATS–G, respectively, are accounted for in the approved estimated burden for preparing Part II of Form ATS–N. *See infra* note 475. The aggregate hours would be: 26 Government Securities ATSs × (1 hour (for Part II, Item 1(d)) + 1 hour (for Part II, Item 2(d))) = 52 burden hours.

[467] (Attorney at 0.9 hours + Compliance Manager at 1.8 hours + Sr. Systems Analyst at 1.8 hours) × 26 Government Securities ATSs = 117 burden hours. In contrast, the Commission estimated that Part III, Item 5 of Form ATS–N would require 5 hours per ATS to complete. *See* NMS Stock ATS Adopting Release, *supra* note 1, at n.1211.

[468] (Attorney at 2 hours + Compliance Manager at 2.5 hours + Sr. Systems Analyst at 1.5 hours) × 26 Government Securities ATSs = 156 burden hours. This is an additional 4 hours per ATS from the additional 2-hour burden for Part III, Item 16 estimated for Form ATS–N. *See* NMS Stock ATS Adopting Release, *supra* note 1, at n.1212.

[469] *See* Part III, Item 24 of Form ATS–N. In the NMS Stock ATS Adopting Release, the Commission estimated this Item would impose a 5-hour additional burden per ATS. *See* NMS Stock ATS Adopting Release, *supra* note 1, at n.1225.

[470] Attorney at 2 hours + Compliance Manager at 1 hour + Sr. Systems Analyst at 2 hours = 5 burden hours. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38880.

[471] (Attorney at 2 hours + Compliance Manager at 1 hour + Sr. Systems Analyst at 2 hours) × 2 categories of government securities = 10 burden hours.

[472] (5 hours × 3 Government Securities ATSs that crossed the fair access threshold for U.S. Treasury Securities) + (5 hours × 1 Government Securities ATS that crossed the fair access threshold for Agency Securities) = 20 burden hours.

Burden	Initial burden
Baseline for initial operation report on Form ATS	*Per ATS:* 20 hours. *Industry:* 520 hours.
Part I	*Per ATS:* 0.75 hours.[473] *Industry:* 19.5 hours.[474]
Part II	*Per ATS:* 31 hours.[475] *Industry:* 806 hours.[476]
Part III	*Per ATS:* 82.25 hours.[477] *Industry:* 1,898.5 hours.[478]
Access to EDGAR (applicable only to select respondents)	*Per ATS:* 0.15 hours. *Industry:* 0.15. hours.
Total—Form ATS–G	*Per ATS:* 134.15 hours. *Industry:* 3,244.15 hours.

ii. Estimated Burden Above the Current Baseline for a Form ATS–G, Form ATS–G Amendment, and Notice of Cessation on Form ATS–G

(a) Proposed Form ATS–G

Based on the above analysis, the Commission estimates that proposed Form ATS–G would, on average, require approximately 114.15 burden hours above the baseline per respondent. This would result in an estimated 134.15 burden hours in total per respondent, including the baseline.[479] Government Securities ATSs vary in terms of their structure and the manner in which they operate. Legacy Filers also vary with respect to the depth and extent of their disclosures on Form ATS. Consequently, the Commission believes that the estimated hour burdens herein regarding proposed Form ATS–G would likely vary among both Legacy Filers and Currently Exempted Government Securities ATSs, depending on such factors as the extent of their current disclosures on Form ATS (as applicable), the complexity and structure of their systems, and the extent of their other broker-dealer operator or affiliate activities.

(b) Form ATS–G Amendments

As previously stated, the Commission estimates that Legacy Filers submit 2 amendments to Form ATS, on average, each year.[480] In addition to the same three general categories of required amendments as Rule 301(b)(2) of Regulation ATS currently requires for Form ATS,[481] proposed Form ATS–G requires contingent amendments. Due to the greater detail and number of disclosures required by proposed Form ATS–G, the Commission believes that respondents may file more amendments to proposed Form ATS–G than Legacy Filers currently do on Form ATS. For example, proposed Form ATS–G requests information about the ATS-related activities of the broker-dealer operator and its affiliates in Part II of proposed Form ATS–G, which are not required disclosures under current Form ATS. To the extent information provided in response to these requests changes, a Government Securities ATS must file a Form ATS–G amendment. As with amendments to Form ATS, the burden on Government Securities ATS associated with updating From ATS–G to reflect current ATS functionality will vary depending on the frequency and scope of changes made by the ATS. Making complete and comprehensible disclosures of material changes to the Government Securities ATS's operations, such as the introduction of a new order type and its attributes or changes to segmentation procedures and parameters, would require more time and resources from a Government Securities ATS than providing complete and comprehensible disclosures of a simple change to the physical or website address of the ATS. Accordingly, the Commission is estimating that Government Securities ATSs will file 3 amendments to Form ATS–G per year. The Commission estimates that Government Securities ATSs would incur the following annual burdens to amend their Form ATS–G:

[473] Per respondent burden hours to prepare all items in Part I of Form ATS–G, except Part I, Item 5, would be identical to those of Part I for Form ATS–N. Therefore, the burden hours to prepare all items in Part I, except Part I, Item 5, would be: Compliance Clerk at 0.5 hours = 0.5 burden hours. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38869. In aggregate, burden hours per Government Securities ATS to prepare Part I of Form ATS–G would be: Compliance Clerk at 0.75 hours = 0.75 burden hours.

[474] Compliance Clerk at 0.75 hours × 26 Government Securities ATSs = 19.5 burden hours.

[475] Per respondent burden hours to prepare all items in Part II of Form ATS–G, excluding the narratives in Part II, Items 1(d) and 2(d), would be identical to those of Part II for Form ATS–N. Therefore, the burden hours to prepare all items in Part II of Form ATS–G, except Part II, Items 1(d) and 2(d), would be: Attorney at 15 hours + Compliance Manager at 11 hours + Sr. Marketing Manager at 2 hours = 28 burden hours. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38869–73. Per respondent burden hours to prepare Part II of Form ATS–G, including the burden hours to prepare the narratives for Items 1(d) and 2(d), *supra* note 466, would be: Attorney at 15.5 hours + Compliance Manager at 12.5 hours + Sr. Systems Analyst at 1 hour + Sr. Marketing Manager at 2 hours = 31 burden hours.

[476] 31 hours × 26 Government Securities ATSs = 806 burden hours.

[477] In aggregate, burden hours per Government Securities ATS to prepare Part III of Form ATS–G would be: Attorney at 23.5 hours + Compliance Manager at 28.2 hours + Sr. Systems Analyst at 30.55 hours = 82.25 burden hours. This estimate takes into account Part III, Items 24(a) and 24(b), which apply only to select respondents.

[478] (72.25 hours × 26 Government Securities ATSs subject to Part III (other than Items 24(a) and 24(b))) + (5 hours × 3 Government Securities ATSs subject to Part III, Item 24(a)) + (5 hours × 1 Government Securities ATS subject to Part III, Item 24(b)) = 1,898.5 burden hours.

[479] (Current Baseline at 20 hours) + (Part I at 0.75 hours) + (Part II at 31 hours) + (Part III at an average of 82.25 hours) + (Access to EDGAR at 0.15 hours, *see infra* Section IX.D.2.b.iv) = 134.15 burden hours. The aggregate totals by professionals, including the baseline, are estimated to be approximately 55 hours for an Attorney, 37.85 hours for a Compliance Manager, 31.55 hours for a Sr. Systems Analyst, 2 hours for a Sr. Marketing Manager, and 7.75 hours for a Compliance Clerk. This estimated burden for a Form ATS–G includes the hour burden associated with completing Part III, Item 24 of proposed Form ATS–G. The Commission believes that the majority of Government Securities ATSs would not be required to complete these items of the proposed form.

[480] *See supra* note 448.

[481] *See* 17 CFR 242.301(b)(2).

[482] Current ATSs file approximately 2 amendments per year, for a total burden of 12 hours. *See* note 449 and accompanying text. To calculate the total burden imposed by Form ATS–G amendment requirements, the Commission is estimating a baseline filing requirement for each Form ATS–G amendment equivalent to 6 hours per amendment × 3 Form ATS–G amendments = 18 total baseline burden hours.

[483] This would result in a total estimated hourly burden, including the baseline, of 9.4 hours for a Form ATS–G amendment. The annual burden per ATS would be: 9.4 hours × 3 amendments per year = 28.2 burden hours. The aggregate total by professional would be: 16.5 hours for an Attorney, 6 hours for a Compliance Manager, and 5.7 hours for a Compliance Clerk.

[484] 78 Form ATS–G amendments per year × 9.4 hours = 733.2 burden hours.

Burden	Annual burden
Baseline burden related to Form ATS amendment	*Per ATS:* 18 hours (6 hours × 3 Form ATS amendments).[482] *Industry:* 468 hours.
Form ATS–G amendment above the baseline	*Per ATS:* 9 hours (3 hours × 3 Form ATS–G amendments). *Industry:* 234 hours.
Preparing a brief summary and Exhibit 3	*Per ATS:* 1.2 hours (0.4 hours × 3 Form ATS–G amendments). *Industry:* 31.2 hours.
Total—Form ATS–G amendment	*Per ATS:* 28.2 hours.[483] *Industry:* 733.2 hours.[484]

As stated above, the Commission estimates that the hourly burden related to an amendment to Form ATS is 6 hours and that Currently Exempted Government Securities ATSs would have a baseline hourly burden of 6 hours to put them in the same position as Legacy Filers.[485] The Commission estimates that the average hourly burden above this baseline of 6 hours for each Form ATS–G amendment would be 3 hours to accommodate the more voluminous and detailed disclosures required by Form ATS–G as compared to Form ATS.[486] The Commission estimates that the 26 Government Securities ATSs will file 3 Form ATS–G amendments each year, for a total of 78 Form ATS–G amendments. In addition, a Government Securities ATS would also be required to provide a brief summary of the amendment at the top of Form ATS–G[487] and submit as Exhibit 3 one marked document that indicates changes to ''yes'' or ''no'' answers or additions to or deletions to Parts I, II, and III. The Commission estimates that drafting the summary and preparing the marked documents showing the amendments the Government Securities ATS is making would add an additional burden of 0.4 hours.[488]

(c) Notice of Cessation on Proposed Form ATS–G

As previously noted, from 2015 through 2019, there has been an average of 1 Legacy Government Securities ATS that ceased operations each year.[489] Although it is unclear how many Government Securities ATSs might cease operations each year going forward, for purposes of making a PRA burden estimate, the Commission is estimating that this average would generally remain the same for Government Securities ATSs using Form ATS–G because economic conditions, business reasons, and other factors may cause some Government Securities ATSs to cease operations. Accordingly, the Commission estimates that 1 Government Securities ATS may file a cessation of operation report on proposed Form ATS–G each year. The Commission believes that the burden for filing a cessation of operation report on proposed Form ATS–G would not be significantly greater than that for filing a cessation of operation report on current Form ATS. Both Form ATS and proposed Form ATS–G require that the ATS check the appropriate box indicating that the ATS is ceasing operations; however, proposed Form ATS–G also requires that the Government Securities ATS provide the date that the ATS expects to cease operating. The Commission therefore estimates that Government Securities ATSs that file a cessation of operation report would incur the following annual burden:

Burden	Annual burden
Cessation of operation report on Form ATS–G	*Per ATS:* 2 hours.[490] *Industry:* 2 hours.[491]

iii. Estimated Burden for Legacy Filers To File a Form ATS To Disclose Information Related to Trading Activity in Other Securities on an ATS

A broker-dealer that operates an ATS that currently trades government securities or repos and securities other than government securities or repos would incur: (1) The above baseline burdens related to filing a Form ATS–G and Form ATS–G amendments;[492] (2) the additional burden of filing an amendment to Form ATS to only disclose information related to trading activity in securities other than government securities or repos on an ATS[493] and amending the Form ATS on an ongoing basis;[494] and (3) the burden of completing and filing 2 Forms ATS–R—one disclosing trading volume in government securities or repos and one disclosing trading volume in securities other than government securities or repos.[495] As of July 1, 2020, of the 19 Legacy Filers, 17 ATSs trade, or have indicated that they expect to trade, in Exhibit B to their Form ATS, both government securities or repos and non-government securities on the ATS.[496]

[485] *See supra* note 449.

[486] Attorney at 1 hour + Compliance Manager at 2 hours = 3 burden hours. The Commission believes that information required under Form ATS–N amendment is similar to that required under proposed Form ATS–G amendment and, therefore, estimates that the burden for Form ATS–G amendment would be the same as the approved estimated burden for Form ATS–N amendment. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38881.

[487] *See* Exhibit 3 to Form ATS–G.

[488] Compliance Clerk at 0.4 hours = 0.4 burden hours. The Commission believes that most word processing software provides for this functionality. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38882.

[489] *See supra* Section IX.C.

[490] Attorney at 1.5 hours + Compliance Clerk at 0.5 hours = 2 burden hours. *See supra* note 450.

[491] 2 hours × 1 Government Securities ATS = 2 burden hours.

[492] *See supra* Section IX.D.2.b.ii.A and B.

[493] *See supra* note 151 and accompanying text.

[494] *See supra* Section IX.D.2.a and accompanying text for the baseline estimates for submitting an IOR for Form ATS and amendments to Form ATS.

[495] *See supra* Section IX.D.2.a and accompanying text for the baseline estimate for submitting a Form ATS–R.

[496] One of the 2 Legacy Filers also trade, or have indicated that it expects to trade, government securities in addition to repos and non-government securities. Therefore, 17 broker-dealers, each of which is a Legacy Filer, are subject to the burden in this section. The broker-dealer for 1 Legacy Filer

Continued

Broker-dealers that operate Legacy Filers would incur the following initial and annual burdens to disclose information related to trading activity in securities other than government securities or repos on the ATS:

Burden	Initial burden	Annual burden
Form ATS amendment to remove references to government securities and repos.	*Per Broker-Dealer:* 10 hours[497] ... *Industry:* 170 hours.	N/A.
Form ATS–G (excluding access to EDGAR)	*Per Broker-Dealer:* 134 hours ..... *Industry:* 2,278 hours.	N/A.
Form ATS amendment for non-Government Securities ATS	N/A	*Per Broker-Dealer:* 13 hours.[498] *Industry:* 221 hours.
Form ATS–G amendment	N/A	*Per Broker-Dealer:* 28.2 hours.[499] *Industry:* 479.4 hours.
Two Forms ATS–R (one for Government Securities ATS and one for non-Government Securities ATS).	N/A	*Per Broker-Dealer:* 21 hours.[500] *Industry:* 357 hours.
Total—burden for broker-dealers that operate Legacy Filers that trade securities other than government securities or repos.	*Per Broker-Dealer:* 144 hours ..... *Industry:* 2,448 hours[501]	*Per Broker-Dealer:* 62.2 hours. *Industry:* 1,057.4 hours.

iv. Access to EDGAR

Government Securities ATSs would be required to submit Form ATS–G filings through the Commission's EDGAR system. Based on the widespread use and availability of the internet, the Commission believes that filing Form ATS–G in an electronic format would be a less burdensome and more efficient filing process for Government Securities ATSs and the Commission, as it is likely to be less expensive and cumbersome than mailing and filing paper forms to the Commission.[502] For a Form ATS–G filer to gain access to submit filings on the EDGAR system, the filer must submit a Form ID as required by Rule 10(b) of Regulation S–T[503] and following the processes detailed in Volume I of the EDGAR Filer Manual. Once a Form ID has been successfully completed and processed, EDGAR will establish a Central Index Key (''CIK'') number, which permits each authorized user to create EDGAR access code, which will enable the Government Securities ATS to use EDGAR.

All registered broker-dealers have been assigned a CIK number and do not need to submit a Form ID to access EDGAR.[504] Because all Legacy Filers and Currently Exempted Government Securities ATSs other than those that are operated by banks are operated by either registered broker-dealers under Section 15 or government securities brokers or dealers under Section 15C(a)(1)(A), the Commission estimates that there will be no burden associated with gaining access to EDGAR for Legacy Filers and Currently Exempted Government Securities ATSs that are not operated by banks.[505]

Based on the number of initial filings and cessation of operations reports on current Form ATS for Legacy Filers, the Commission estimates that 1 to 2 new entities would file proposed Form ATS–G to become a Government Securities ATS in each of the next three years. The Commission estimates that among these new entities, 1 new entity per year will be operated by an entity that has not previously registered as a broker-dealer, a government securities broker, or a government securities dealer or that does not otherwise already have access to EDGAR. The Commission therefore estimates that an estimated 1 bank-operated Currently Exempted Government Securities ATS and 1 new entity would incur the following initial and annual burdens, respectively, by

currently also operates an NMS Stock ATS that files a Form ATS–N and a Form ATS–R to report transactions in NMS stocks. As proposed, this broker-dealer would be required to file 3 Forms ATS–R and maintain a Form ATS–G, Form ATS–N, and Form ATS for its transactions in government securities and repos, NMS stocks, and other securities, respectively. The burden related to the NMS Stock ATS filings was reflected in the NMS Stock ATS Adopting Release. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38882–83.

[497] In the NMS Stock ATS Adopting Release, the Commission estimated that the burden for an ATS to separately file a Form ATS for its non-NMS stock trading activity and Form ATS–N for its NMS stock trading activity will be 20 burden hours to amend its initial operation report on Form ATS for its non-NMS stock trading activity. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38882. In the Commission's experience implementing Form ATS–N, it found that the actual burden for a broker-dealer to amend the initial operation report on Form ATS to remove references to NMS stocks was much less than the estimated 20 hour burden. The Commission believes that this burden would be similar for broker-dealers operating Government Securities ATSs. Accordingly, the Commission is estimating that filing a Form ATS amendment to remove references to government securities or repos would be 10 hours. Attorney at 6.5 hours + Compliance Clerk at 3.5 hours = 10 burden hours. Such estimated hourly burden may be less than the estimated 10 burden hours, as the description of such ATS's trading activity in securities other than government securities or repos should already be contained in the existing Form ATS.

[498] 2 Form ATS amendments per year × 6.5 hours = 13 burden hours. The Commission estimates that, as proposed, the burden to file a Form ATS amendment is 6.5 hours, including the baseline burden and additional burden discussed in Section X.D.4. *See supra* note 449 and *infra* note 524.

[499] 3 Form ATS–G amendments per year × 9.4 hours = 28.2 burden hours.

[500] In addition, the Commission estimates that the total burden for a broker-dealer to complete Forms ATS–R for both its Government Securities ATS and non-Government Securities ATS would be 5.25 hours per quarter (Attorney at 3.5 hours + Compliance Manager at 0.25 hours + Compliance Clerk at 1.5 hours = 5.25 burden hours), which is 1.25 hours above the baseline burden of 4 hours for currently filing a Form ATS–R (Attorney at 0.5 hours + Compliance Manager at 0.25 hours + Compliance Clerk at 0.5 hours = 1.25 burden hours). *See infra* notes 525, 526, and 528. *See supra* note 452 and accompanying text for the baseline estimate for submitting a Form ATS–R. The Commission believes that broker-dealers required to file two Forms ATS–R would incur an additional burden of 0.5 hours above the baseline because they would be required to divide their trading statistics between two forms and file each form separately (Attorney at 0.5 hours = 0.5 burden hours). The Commission does not believe that those broker-dealers would incur any additional burden to collect the required information because they currently assemble that information when preparing the current Form ATS–R filings.

[501] (Form ATS amendment at 10 hours + Form ATS–G at 134 hours) × 17 broker-dealers = 2,448 aggregate burden hours. Broker-dealers that operate Legacy Filers do not have burden associated with gaining access to EDGAR, and therefore, burden for gaining access to EDGAR is not accounted for in the burden to complete Form ATS–G. *See infra* text accompanying note 505.

[502] All estimated burden hours with regard to completing Parts I through IV of proposed Form ATS–G include the estimated burden associated with the requirement that Government Securities ATSs file Form ATS–G in a structured XML format on EDGAR, including narrative responses that are block-text tagged, or use the web-fillable form.

[503] 17 CFR 232.10(b).

[504] A broker-dealer that has never used EDGAR to make electronic submissions may use its assigned CIK number to receive access codes that will allow that broker-dealer operator to submit Form ATS–G filings on EDGAR without needing to apply for a Form ID.

[505] The Commission further believes that 1 of the 19 Legacy Filers is operated by a broker-dealer that also operates an NMS Stock ATS, and therefore, the broker-dealer currently has access to and files through EDGAR.

submitting a Form ID to gain access to the EDGAR system:

Burden	Initial burden	Annual burden
Access to EDGAR	*Per ATS:* 0.15 hours [506] *Industry:* 0.15 hours [507]	*Per ATS:* 0.15 hours.[508] *Industry:* 0.15 hours.[509]

v. Public Posting on Covered ATS's Website

Proposed Rule 304(b)(3)(i) would require each Government Securities ATS to make public via posting on the ATS's website a direct URL hyperlink to the Commission's website that contains the documents enumerated in proposed Rule 304(b)(2).[510] Proposed Rule 304(b)(3)(ii) would require each Covered ATS to make public via posting on its website the most recently disseminated Covered Form. The Commission estimates that Government Securities ATSs and NMS Stock ATSs would incur the following initial and annual burdens to comply with the proposed requirements to program and configure their websites to post the required direct URL hyperlink and the most recently disseminated Covered Form pursuant to proposed Rule 304(b)(3):

Burden	Initial burden	Annual burden
Public posting of hyperlink to the Commission's website on Government Securities ATS's website.	*Per ATS:* 2 hours *Industry:* 52 hours [511]	N/A.
Public posting of the most recently disseminated Covered Form on Covered ATS's website.	*Per ATS:* 4 hours *Industry:* 240 hours [512]	*Per ATS:* 12 hours. *Industry:* 720 hours.[513]

vi. Recordkeeping Requirements

Rule 303(a)(2)(ii) requires an ATS to preserve copies of reports filed pursuant to Rule 301(b)(2) or 304, which includes all Form ATS filings, and, as proposed, all Form ATS–G filings, for the life of the enterprise and any successor enterprise. Because Legacy Filers that trade only government securities or repos would file Form ATS–G in lieu of Form ATS under this proposal, the Commission believes that Rule 303(a)(2)(ii) would not result in any burden for those ATSs that is not already accounted for under the baseline burden estimate for Rule 303.[514] For the 17 Legacy Filers that trade, or have indicated that they expect to trade in Exhibit B to their Form ATS, government securities or repos and securities other than government securities or repos, the Commission estimates that the annual burden above the baseline estimate for preserving records relating to compliance with Rule 303(a)(2)(ii) would be the following:

Burden	Annual burden
Record preservation requirement under Rule 303(a)(2)(ii)	*Per ATS:* 3 hours. *Industry:* 51 hours.[515]

[506] Compliance Manager at 0.15 hours = 0.15 burden hours. *See* FR Doc. 2019–04008, 84 FR 8126 (March 6, 2019) (Submission for OMB Review, Extension: Form ID; SEC File No. 270–291; OMB Control No. 3235–0328).

[507] Compliance Manager at 0.15 hours × 1 bank-operated Currently Exempted Government Securities ATS = 0.15 burden hours.

[508] *See supra* note 506.

[509] Compliance Manager at 0.15 hours × 1 new entity that has not previously registered as a broker-dealer, a government securities broker, or a government securities dealer or that does not otherwise already have access to EDGAR = 0.15 burden hours.

[510] NMS Stock ATSs are already required to comply with Rule 304(b)(3)(i).

[511] Sr. Systems Analyst at 2 hours × 26 Government Securities ATSs = 52 burden hours. The Commission estimates that this initial, one-time burden would be 2 hours, in part because many broker-dealer operators currently maintain a website for their Government Securities ATSs.

[512] The Commission estimates that Covered ATSs would each incur an initial burden of 4 hours to post its Covered Form on its website. The initial burden would be: Sr. Systems Analyst at 4 hours × (26 Government Securities ATSs + 34 NMS Stock ATSs) = 240 burden hours.

[513] The Commission estimates that the ongoing burden would be 4 hours for each amendment to Covered Form and that Covered ATSs would each file 3 amendments to Covered Form per year. *See supra* Section IX.D.2.b.ii.(b). *See also* NMS Stock ATS Adopting Release, *supra* note 1, at 38881. Therefore, the annual burden would be: Sr. Systems Analyst at 4 hours × 3 amendments × (26 Government Securities ATSs + 34 NMS Stock ATSs) = 720 burden hours.

[514] To comply with all of the record preservation requirements of Rule 303, the Commission currently estimates that ATSs spend approximately 1,380 hours per year. *See supra* note 436, 78 FR 43943. At an average cost per burden hour of $104.20, the resultant total related cost of compliance is $143,796 per year (1,380 burden hours × $104.20/hour). *See id.*

[515] Compliance Clerk at 3 hours × 17 Legacy Filers = 51 aggregate burden hours.

3. Proposed Amendments to Rule 301(b)(5) of Regulation ATS

The Commission recognizes that applying the Fair Access Rule to the trading of U.S. Treasury Securities and Agency Securities would impose certain burdens upon the respondents. Currently, Rule 301(b)(5) only applies to the trading of NMS stocks, equity securities that are not NMS stocks and for which transactions are reported to an SRO, municipal securities, and corporate debt securities, and therefore, it currently imposes no burden on Government Securities ATSs.[516] The Commission estimates that 3 Government Securities ATSs would meet the volume thresholds that trigger fair access obligations for U.S. Treasury Securities and Agency Securities, and that the average compliance burden of establishing written fair access standards for each entity would be 10 hours. As a result of the proposed amendments to Rule 301(b)(5), certain Government Securities ATSs would incur the following annual burden:[517]

Burden	Annual burden
Establishing written standards for granting access under Rule 301(b)(5)	*Per ATS:* 10 hours. *Industry:* 30 hours.[518]
Making and keeping records of grants and denials of access under Rule 301(b)(5)	*Per ATS:* 10 hours. *Industry:* 30 hours.[519]
Total—Rule 301(b)(5)	*Per ATS:* 20 hours. *Industry:* 60 hours.

4. Proposed Amendments to Rule 301(b)(2), Form ATS, and Form ATS–R

The Commission believes that the proposed amendments to Rule 301(b)(2), Form ATS, and Form ATS–R would impose the following initial and annual burden to applicable respondents described further below:[520]

[516] 17 CFR 242.301(b)(5).

[517] These estimated burdens are the same as the Commission's currently approved estimates for compliance with Rule 301(b)(5) because the requirements of the Fair Access Rule would be identical for Government Securities ATSs and ATSs that are currently subject to Rule 301(b)(5). *See* Rule 301 OMB Update, *supra* note 419, at 3238.

[518] Attorney at 10 hours × 3 responses = 30 burden hours.

[519] Attorney at 10 hours × 3 responses = 30 burden hours.

[520] The Commission notes that it is proposing changes to Form ATS–N to delete a question related to legacy status, and to include a checkbox asking if the registered broker-dealer is authorized by a national securities association to operate an ATS. *See supra* Section V.D. The Commission believes that because this information should be readily available to a filer and requires only marking a checkbox, this will have no impact on the estimated burden of Form ATS–N.

Burden	Initial burden	Annual burden
Electronic filing (access to EDGAR)	*Per ATS:* 0.15 hours *Industry:* 0.15 hours.	N/A.
Initial operation report on Form ATS:		
Current approved burden for initial Form ATS	*Per ATS:* 20 hours *Industry:* 1,020 hours.	N/A.
Changes to Part I on Form ATS	*Per ATS:* 0.5 hours *Industry:* 25.5 hours.	N/A.
Total for initial Form ATS, as proposed to be amended	*Per ATS:* 20.5 hours *Industry:* 1,045.5 hours.	N/A.
Amendment on Form ATS:		
Current approved burden for Form ATS amendment	N/A	*Per ATS:* 12 hours. *Industry:* 612 hours.
Changes to Part I on Form ATS	N/A	*Per ATS:* 1 hour. *Industry:* 51 hours.
Total for amendment to Form ATS, as proposed to be amended.	N/A	*Per ATS:* 13 hours. *Industry:* 663 hours.
Form ATS–R:		
Current approved burden for Form ATS–R (4 per year)	N/A	*Per ATS:* 16 hours. *Industry:* 1,504 hours.
Changes to Part I on Form ATS–R	N/A	*Per ATS:* 2 hours. *Industry:* 188 hours.
Indicating the type of filing and whether the ATS is subject to the fair access requirements on Form ATS–R.	N/A	*Per ATS:* 0.4 hours. *Industry:* 37.6 hours.
Providing additional detail (*e.g.,* trading volume and types of securities/options) on Form ATS–R.	N/A	*Per ATS:* 0.6 hours. *Industry:* 36 hours.
Total burden for filing Form ATS–R, as proposed to be amended.	N/A	*Per ATS:* 19 hours. *Industry:* 1,766 hours.

The Commission is proposing that Form ATS and Form ATS–R would be filed electronically. However, the Commission believes that electronic submission of Form ATS and Form ATS–R would impose no additional burden on existing ATSs. All ATSs that file a Form ATS or Form ATS–R are registered broker-dealers and therefore do not need to submit a Form ID to access EDGAR.

The Commission estimates that the burden associated with receiving access to EDGAR by submitting a Form ID is 0.15 burden hours per response. Based on the number of initial filings and cessation of operations reports on current Form ATS for by existing ATSs, the Commission estimates that 4 new entities would file a new Form ATS in each of the next three years. The Commission estimates that among these new entities, 1 new entity per year will be operated by an entity that has not previously registered as a broker-dealer, a government securities broker, or a government securities dealer or that does not otherwise already have access to EDGAR. The total estimated hourly burden and aggregate initial burden for new ATSs gaining access to EDGAR is therefore 0.15 hours.[521]

The Commission is also proposing changes to Part I of Form ATS and Form ATS–R. As stated above, Legacy Filers are subject to a baseline burden of 20 hours for filing Form ATS, a baseline burden of 6 hours for amending Form ATS per filing, and a baseline burden of 4 hours per quarter for filing Form ATS–R. The proposed changes contain substantially the same information as current Form ATS and Form ATS–R. However, the proposed changes would not include several information requests that appear on the current forms, and would include additional information requests, such as the website of the ATS, the MPID of the ATS, and information related to the national securities association of the broker-dealer operator. The Commission estimates that the changes to Part I on Form ATS–R and Form ATS will add an additional burden of 0.5 hours above the baseline burden [522] and an aggregate burden of 25.5 additional initial burden hours for ATSs filing Form ATS,[523] 51 additional annual burden hours for amending Form ATS,[524] and 188 additional annual burden hours for ATSs filing Form ATS–R.[525]

In addition, the Commission is proposing that ATSs provide additional detail on Form ATS–R. The Commission is proposing that ATSs differentiate trading volume in U.S. Treasury Securities and Agency Securities on Form ATS–R. The Commission believes that ATSs will be aware which of the securities they trade are U.S. Treasury Securities and which are Agency Securities, and that this requirement will impose no additional burden on Government Securities ATSs, but rather eliminate the need for ATSs to combine all of its trading in government securities in a single category. The Commission is also proposing that ATSs provide total dollar volume in transactions in repos. In the Commission's experience, ATSs currently provide this detail on Form ATS–R, but the Commission would include a new item requiring this disclosure. The Commission would require ATSs to provide a list of the types of securities subject to such repurchase and reverse repurchase agreements, as well as to provide a list of the types of listed options they trade. The Commission believes that ATSs are aware of this information and that this should impose very little burden on the

[521] Compliance Manager at 0.15 hours × 1 ATS = 0.15 burden hours.

[522] The Commission notes that the additional disclosures are substantially similar to those on Form ATS–N and the additional burden is the same as estimated in the NMS Stock ATS Adopting Release. *See* NMS Stock ATS Adopting Release, *supra* note 1, at 38869.

[523] Compliance Clerk at 0.5 hours × 51 ATSs filing Form ATS = 25.5 burden hours.

[524] Compliance Clerk at 0.5 hours × 2 average amendments filed on Form ATS per year × 51 ATSs filing Form ATS = 51 burden hours.

[525] Compliance Clerk at 0.5 hours × 4 filings annually × 94 ATSs filing Form ATS–R = 188 burden hours.

ATSs. The Commission estimates that checking these boxes would impose an additional burden of 0.15 hours for an aggregate additional annual burden of 36 hours.[526]

The Commission is also proposing changes to Form ATS–R to require an ATS to indicate the type of the filing (and if applicable the date of cessation) and whether the ATS is subject to fair access obligations.[527] The ATS would be aware of the type of filing it is making and whether it is subject to the fair access requirements, so this requirement will impose very little additional burden. The Commission estimates that checking these boxes would impose an additional burden of 0.1 hours for an aggregate additional annual burden of 37.6 hours.[528]

The Commission is also proposing changes to Form ATS to specify the type of amendment that the ATS is filing. The Commission believes this will create no additional burden as ATSs currently have to check what type of filing they are submitting. This proposed change would merely change which box the ATS would have to check. In the case of a cessation of operations filing, the Commission is proposing that the ATS would need to provide the date of cessation. The Commission believes that providing this information would impose minimal burden because this is information of which the ATS will be aware and will take little time to input on Form ATS.

5. Proposed Amendments to Regulation SCI

Currently, Regulation SCI imposes no burden on Government Securities ATSs. The Commission believes that the approved paperwork burden estimates per entity under Regulation SCI generally would be applicable to these Government Securities ATSs, because they would be subject to the same requirements and burdens as other SCI entities.[529] At the same time, the Commission believes that the burden estimates also should take into account the extent to which Government Securities ATSs may already be SCI entities or may be affiliated with SCI entities that already comply with the requirements of Regulation SCI. The Commission estimates that proposed amendments to Regulation SCI would impose the following initial and annual burdens to certain (1) Government Securities ATSs that are existing SCI entities or affiliated with SCI entities and (2) Government Securities ATSs that are not currently SCI entities or affiliated with existing SCI entities:

Burden	Initial burden	Annual burden
Compliance with Regulation SCI (existing SCI entities)	*Per ATS:* 1,017.15 hours *Industry:* 1,017.15 hours	*Per ATS:* 2,458.65 hours. *Industry:* 2,458.65 hours.
Compliance with Regulation SCI (not existing SCI entities)	*Per ATS:* 2,034.3 hours *Industry:* 4,068.6 hours	*Per ATS:* 2,458.65 hours. *Industry:* 4,917.3 hours.
Total—compliance with Regulation SCI	*Industry:* 5,085.75 hours[530]	*Industry:* 7,375.95 hours[531].

The Commission estimates that 3 Government Securities ATSs would be subject to these requirements, including 1 Government Securities ATS that is an existing SCI entity. In particular, the Commission believes that the 2 entities that are not currently SCI entities would have the same estimated initial paperwork burdens as those estimated for new SCI entities and the same ongoing paperwork burdens as all other SCI entities.[532] The Commission also believes that because 1 of these ATSs is an existing SCI entity or affiliated with an SCI entity that is already required to implement the requirements of Regulation SCI, this entity would not have initial burdens equivalent to those estimated for new SCI entities. At the same time, because this entity would be trading securities in a different segment of the securities market and is likely to have new or distinct SCI systems for government securities, the Commission believes that this ATS would have some initial burden that would be a percentage of that which entirely new SCI entities have. In particular, the Commission estimates that the initial burdens for a Government Securities ATS that is currently an SCI entity or affiliated with an SCI entity would be 50 percent of the estimated initial burdens for entirely new SCI entities. For example, the Commission believes that such ATS would need to develop and draft the policies and procedures required by Rule 1001(a) for new SCI systems utilized for the trading of government securities, but unlike completely new SCI entities, this entity would already have Rule 1001(a) policies and procedures in place for other types of SCI systems that it could utilize as a model and modify as needed for new SCI systems.[533] The Commission also believes that the estimated ongoing paperwork burden estimates for all SCI entities would be applicable to this entity as well.[534]

E. Collection of Information Is Mandatory

All collections of information pursuant to the proposed rules would be mandatory for entities that meet the definition of ATS.

[526] Compliance Manager at 0.15 hours × 4 filings annually × 60 non-NMS Stock ATSs that file Form ATS–R = 36 burden hours.

[527] *See supra* Section V.C.

[528] Compliance Manager at 0.1 hours × 4 filings annually × 94 ATSs that file Form ATS–R = 37.6 burden hours.

[529] *See* Proposed Collection; Comment Request; Extension: Regulation SCI, Form SCI; SEC File No. 270–653, OMB Control No. 3235–0703, 83 FR 34179 (''2018 SCI PRA Extension'').

[530] (1,017.15 initial burden hours for compliance with Regulation SCI × 1 Government Securities ATS affiliated with a current SCI entity) + (2,034.3 initial burden hours for compliance with Regulation SCI × 2 Government Securities ATSs not affiliated with current SCI entities) = 5,085.75 burden hours. In the Supporting Statement for the Paperwork Reduction Act Information Collection Submission for Regulation SCI, the Commission estimated that the total one-time initial burden for an SCI entity that is not an SRO or a plan processor to comply with Regulation SCI would be 2,034.3 hours. *See* Extension Without Change of a Currently Approved Collection: Regulation SCI and Form SCI; ICR Reference No. 201807–3235–001; OMB Control No. 3235–0703 (September 26, 2018) *available at: https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201807-3235-001* (''2018 SCI PRA Supporting Statement'').

[531] 2,458.65 ongoing burden hours for compliance with Regulation SCI × 3 Government Securities ATSs = 7,375.95 burden hours. In the Supporting Statement for the Paperwork Reduction Act Information Collection Submission for Regulation SCI, the Commission estimated that the total ongoing annual burden for an SCI entity that is not an SRO or a plan processor to comply with Regulation SCI would be 2458.65 hours. *See* 2018 SCI PRA Supporting Statement, *supra* note 530.

[532] *See* 2018 SCI PRA Extension, *supra* note 529.

[533] As an example, the estimate of an initial recordkeeping burden was 694 hours per new respondent to comply with the policies and procedures requirement of Rule 1001(a). *Id.* at 34180. The Commission estimates that, for a Government Securities ATS that is already an SCI entity or affiliated with an SCI entity, the initial burden for Rule 1001(a) would be 50 percent of this estimated amount, or 347 hours.

[534] The ongoing paperwork burden estimates in the 2018 SCI PRA Extension do not distinguish among different categories of SCI entities, but rather provide an average for all SCI entities.

F. Confidentiality of Responses to Collection of Information

With respect to the proposed amendments to Rules 301(b)(2)(viii) and 304 of Regulation ATS, including proposed Form ATS–G, the Commission would make publicly available on its website all effective Forms ATS–G, all properly filed Form ATS–G amendments to effective Forms ATS–G, and notices of cessation on Forms ATS–G.[535] The Commission would not make publicly available on its website Forms ATS–G that the Commission has declared ineffective, but these forms would be available for examination by the Commission and its staff, state securities authorities, and SRO(s) of which the Government Securities ATS's broker-dealer operator is a member. The other collections of information required by the proposed application of Rules 301(b) to Currently Exempted Government Securities ATSs and the proposed amendments to Rule 301(b)(2), Form ATS, Form ATS–R, the Fair Access Rule, and Regulation SCI would not be made public, but would be used for regulatory purposes by the Commission and the SRO(s) of which the ATS's broker-dealer operator is a member. In Part III, Item 24 of proposed Form ATS–G, however, Government Securities ATSs subject to the Fair Access Rule would be required to describe the written standards for granting access to trading on the ATS pursuant to Rule 301(b)(5)(ii)(A). To the extent that the Commission receives confidential information pursuant to this collection of information, such information would be kept confidential, subject to the provisions of applicable law.

G. Retention Period for Recordkeeping Requirements

All reports required to be made under Rules 301(b)(2)(viii), 301(b)(9), and 304 of Regulation ATS, including proposed Form ATS–G, will be required to be preserved during the life of the enterprise and any successor enterprise. As proposed, Currently Exempted Government Securities ATSs would also be required to preserve a copy of their written safeguards and written procedures to protect subscribers' confidential trading information under Rule 301(b)(10) of Regulation ATS for not less than three years, the first two years in an easily accessible place, pursuant to Rule 303(a)(1)(v) of Regulation ATS.[536] Currently Exempted Government Securities ATSs would be required to preserve for not less than three years, the first two years in an easily accessible place, a copy of all records required to be made pursuant to Rule 302, all notices provided by such ATSs to subscribers generally, and at least one copy of its standards for access to trading, all documents relevant to its decision to grant, deny, or limit access to any person, and all other documents made or received in the course of complying with Rule 301(b)(5).[537] An SCI entity must keep all documents relating to compliance with Regulation SCI for a period of not less than five years, the first two years in a place that is readily accessible by the Commission or its representatives for inspection and examination.[538]

H. Request for Comments

Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments to:

167. Evaluate whether the proposed collection of information is necessary for the proper performance of the Commission's functions, including whether the information shall have practical utility;

168. Evaluate the accuracy of the Commission's estimates of the burden of the proposed collection of information;

169. Determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected;

170. Evaluate whether there are ways to minimize the burden of collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology; and

171. Evaluate whether the proposed amendments would have any effects on any other collection of information not previously identified in this section.

Persons submitting comments on the collection of information requirements should direct them to the Office of Management and Budget, Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, DC 20503, and should also send a copy of their comments to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090, with reference to File Number S7–12–20. Requests for materials submitted to OMB by the Commission with regard to this collection of information should be in writing, with reference to File Number S7–12–20 and be submitted to the Securities and Exchange Commission, Office of FOIA/PA Services, 100 F Street NE, Washington, DC 20549–2736. As OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

X. Economic Analysis

The Commission is sensitive to the economic consequences and effects, including the costs and benefits, of its rules. The following economic analysis identifies and considers the costs and benefits—including the effects on efficiency, competition, and capital formation—that may result from, among other things, (i) the proposed amendments to Regulation ATS to require Government Securities ATSs to publicly disclose on Form ATS–G their manner of operations and the ATS-related activities of the broker-dealer operator and its affiliates, (ii) the proposed amendments to Regulation ATS to apply the Fair Access Rule to Government Securities ATSs that meet certain volume thresholds in U.S. Treasury Securities or Agency Securities, and (iii) the proposal to amend Regulation SCI to apply its requirements to ATSs that meet certain volume thresholds in U.S. Treasury Securities or Agency Securities.[539]

This discussion of the economic effects of the proposed amendments to Regulation ATS and Regulation SCI (collectively referred to as ''proposed amendments'') begins with a baseline analysis of the market for government securities and the current regulations that apply to ATSs that trade government securities or repos. The economic analysis then discusses the likely economic effects of the proposed amendments, including the costs and benefits as well as their effects on efficiency, competition, and capital formation. The economic analysis also includes a discussion of the potential

[535] *See supra* Section II.G.

[536] Legacy Filers are currently subject to the recordkeeping requirements of Rule 301(b)(10). *See supra* Section IX.A.

[537] *See supra* Section II.C.

[538] *See* 17 CFR 242.1005(b)(2).

[539] Exchange Act Section 3(f) requires the Commission, when it is engaged in rulemaking pursuant to the Exchange Act and is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f). In addition, Exchange Act Section 23(a)(2) requires the Commission, when making rules pursuant to the Exchange Act, to consider among other matters the impact that any such rule would have on competition and not to adopt any rule that would impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. *See* 15 U.S.C. 78w(a)(2).

costs and benefits of reasonable alternatives to the proposed amendments. The Commission requests comment on all aspects of the economic effects of the proposed amendments and of reasonable alternatives.

A. Introduction

Government Securities ATSs have grown to levels of sophistication similar to those of NMS Stock ATSs, but Regulation ATS currently only applies in a limited manner—if at all—to Government Securities ATSs.[540] The Commission believes that removing the exemption for Currently Exempted Government Securities ATSs and amending Regulation ATS for Government Securities ATSs would: (1) Extend the investor protections of Regulation ATS to subscribers of Currently Exempted Government Securities ATSs; (2) enhance the regulatory oversight of Government Securities ATSs and allow the Commission to better monitor trading and their role in the government securities and repo market; (3) enhance the operational transparency of Government Securities ATSs through public disclosures on Form ATS–G and; and (4) help ensure the fair treatment of potential and current subscribers to Government Securities ATSs with significant volume in U.S. Treasury Securities and Agency Securities.

The Commission believes that the proposed amendments to Regulation SCI for Government Securities ATSs would help address technological vulnerabilities and reduce the chance of a system issue disrupting trading on a significant government securities platform.[541] The proposed amendments would also help improve system up-time and would reduce the frequency, severity, and duration of systems issues that directly inhibit execution facilities or order matching, which could help prevent interruptions in the price discovery process and liquidity flows and, thus may help prevent periods with pricing inefficiencies from occurring.

The Commission believes that the proposed amendments would enhance the operational transparency and the Commission's oversight of ATSs that trade U.S. Treasury Securities. As described in the October 15 Staff Report, on July 13, 2015, the market for U.S. Treasury securities and futures experienced an unprecedented round-trip in prices between 9:33 a.m. and 9:45 a.m., resulting in a 37 basis point trading range for the day.[542] The market continued to function with high volatility and trading volumes, but liquidity conditions became significantly strained. After this event, the Treasury Department issued a Request for Information on the evolution of the U.S. Treasury market structure.[543] In response to the Treasury Request for Information, many entities called for greater transparency and public access to data regarding the functioning of U.S. Treasury markets.[544] Enhancing operational transparency and public disclosures is expected to improve market efficiency, which should help address concerns raised by the ''flash rally.'' Enhancing the Commission's ability to monitor transactions volume at a detailed level would permit more focused surveillance to address potential concerns about market function.

The Commission recognizes that Government Securities ATSs would incur implementation and ongoing compliance costs as a result of the proposed amendments, which require Government Securities ATSs to establish and update policies and procedures, gather information for new disclosures, update systems to comply with recordkeeping requirements, and make other adjustments to comply with the requirements of the proposed amendments.[545] The Commission recognizes that the proposed amendments could have effects on competition for order flow in the market for government securities and repo execution services, the efficiency with which market participants achieve their trading objectives, and capital formation.[546] The Commission believes that the enhancement in operational transparency of Government Securities ATSs could promote competition for order flow and incentivize Government Securities ATSs to innovate.[547] The Commission also believes that the proposed amendments could lower search costs and increase trading venue options for market participants resulting in lower trading costs and better efficiency with which they achieve their trading objectives.[548] Furthermore, the Commission believes that extending Regulation SCI to include Government Securities ATSs with significant volume in U.S. Treasury Securities and Agency Securities would reduce the frequency, severity, and duration of such effects resulting from systems issues, thereby enhancing price efficiency of government securities and promoting capital formation.[549]

B. Baseline

The baseline against which economic costs and benefits, as well as the impact of the proposed amendments on efficiency, competition, and capital formation, are measured is the current market and regulatory framework for the market for government securities and repo execution services. The baseline describes how ATSs play an important role in the current state of competition in the market for trading government securities. Competition among ATSs is influenced by current reporting requirements for Government Securities ATSs, including operational and transaction reporting requirements, which creates a potentially uneven competitive landscape. Similarly, the limited public information about Government Securities ATSs' operations results in information asymmetries. Current regulation of Government Securities ATSs' treatment of subscriber confidential trading information could lead to potential abuse of such information.

The Fair Access Rule of Regulation ATS does not currently apply to ATSs that trade government securities, and there is no mechanism to prevent Government Securities ATSs from unreasonably denying or limiting subscribers' access to an ATS that is a significant market for government securities, which could increase their trading costs.[550] Furthermore, Regulation SCI does not currently apply to the government securities activities of

[540] *See supra* Section I.B for a discussion of the current regulatory framework for Government Securities ATSs.

[541] *See infra* Section X.C.1.b.

[542] *See* October 15 Staff Report, *supra* note 14.

[543] *See* Treasury Request for Information, *supra* note 10.

[544] *See* Press Release, U.S. Securities and Exchange Commission, Statement on Trade Reporting in the U.S. Treasury Market (May 16, 2016), *available at https://www.sec.gov/news/pressrelease/2016-90.html. See also* Michael J. Fleming, *Advent of Trade Reporting for U.S. Treasury Securities* (January 17, 2017), Federal Reserve Bank of New York, Liberty Street Economics, *available at https://libertystreeteconomics.newyorkfed.org/2017/01/advent-of-trade-reporting-for-us-treasury-securities.html.*

[545] *See infra* Section X.C.2.

[546] *See infra* Section X.C.3.

[547] *See supra* note 546.

[548] *See id.*

[549] *See infra* Section X.C.3.c for a discussion about the price discovery and price efficiency of U.S. Treasury Securities, risk-free rate benchmarks, pricing of risky securities, and capital formation. *See also* October 15 Staff Report, *supra* note 14, for a discussion about price discovery being especially important in the secondary market for on-the-run U.S. Treasury Securities because the transaction prices are used as risk-free rate benchmarks to price other securities transactions.

[550] *See supra* Sections I.B and II.D discussing the Fair Access Rule requirements. *See infra* Section X.B.5 discussing why market forces alone may not be sufficient to prevent a Government Securities ATS from unreasonably denying access to some market participants.

an ATS. The Commission believes that, without appropriate safeguards in place for these Government Securities ATSs, technological vulnerabilities could lead to the potential for failures, disruptions, delays, and intrusions, which could place government securities market participants at risk, harm price discovery, and reduce price efficiency.[551] In Section X.B.7, we discuss the current regulatory framework and competition for order flow in the market for government securities and their implications on market efficiency.

The economic analysis that follows is based only on transactions reported to TRACE.[552] Due to the lack of data on activities of ATSs operated by non-FINRA members, the quantitative analysis of transactional activity does not include ATSs that are not FINRA members.[553] Furthermore, the economic analysis does not include repo transactions and activities of options on government securities because there is a lack of available data.[554]

The parties that would be affected by the proposed amendments include: Existing Government Securities ATSs, which comprise Legacy Filers and Currently Exempted Government Securities ATSs; potential new Government Securities ATSs; broker-dealers that operate or are affiliated with Government Securities ATSs; non-ATS trading venues that compete for order flow in the electronic market with Government Securities ATSs and the broker-dealers that operate these non-ATS trading venues. The proposed amendments would also affect current and potential subscribers of Government Securities ATSs including: Primary dealers in government securities, non-primary broker-dealers in government securities, PTFs that trade on Government Securities ATSs, and institutional investors that directly trade in the electronic market for government securities; and institutional investors that transact in the dealer-to-customer market.[555]

1. Current State of Competition in the Market for Trading Government Securities

Government Securities ATSs play a significant competitive role in the market for government securities execution services as Government Securities ATSs account for approximately 43 percent and 13 percent of overall trading volume in the U.S. Treasury and Agency Securities market, respectively.[556] Government Securities ATSs compete on fees and technological features for subscribers and, ultimately, customer order flow through interdealer transactions. Government Securities ATSs account for 57 percent of overall trading volume in the on-the-run U.S. Treasury Securities market.[557] In the off-the-run Treasury Securities market, Government Securities ATSs account for 20 percent of trading volume.[558]

Government securities represent a large proportion of the entire U.S. fixed income market in terms of outstanding debt and daily trading volume.[559] According to the United States Treasury, as of the end of 2019, the total amount outstanding of marketable Treasury Securities is approximately $17 trillion.[560] Furthermore, the Financial Accounts of the United States Z.1 released by the Federal Reserve Board show that the amount outstanding of Agency- and GSE-Backed Securities is about $9.4 trillion, collectively accounting for approximately 60 percent of the $47.386 trillion U.S. fixed income market.[561] According to data published by SIFMA, over the last six months of 2019, the average daily trading volume in government securities was about $835 billion, or roughly 95 percent of all fixed income trading volume in the U.S.[562]

The most actively traded government securities are U.S. Treasury Securities. U.S. Treasury Securities serve many important roles, including as a means of financing the U.S. federal government, as instruments for monetary policy implementation, as hedging and collateral instruments, as a liquid asset used to satisfy regulatory requirements, and as risk-free benchmarks for pricing other financial instruments. In December 2019, the average daily trading in U.S. government securities totaled $754.3 billion, which is further broken down as follows: $523.2 billion in U.S. Treasury Securities; $227.1 billion in Agency Mortgage-Backed Securities (MBSs); and $4.0 billion in other Agency Securities.[563]

Overall, trading in the market for government securities is characterized by many competing trading venues with various trading functionalities, order types, and trading venue fees. However, the Commission believes that lack of public disclosure about the operations and potential conflicts of interest of Government Securities ATSs could hinder competition among these ATSs and between the Government Securities ATSs and non-ATS trading venues in the market for government securities and repo execution services. Although the Commission recognizes that non-ATS trading venues compete with Government Securities ATSs in the market for government securities and repo execution services, non-ATS trading venues, unlike ATSs, cannot offer certain execution protocols, such as crossing mechanisms, auctions, and central limit order books, which generally meet the definition of an exchange.[564]

Government Securities ATSs compete with other Government Securities ATSs, non-ATS interdealer broker trading platforms, and dealers that operate various trading protocols for order flow in the market for government securities and repo execution services. Trading of government securities occurs on a diverse set of trading venues—such as

[551] *See supra* Section VI.

[552] Transaction data is based on available information that is currently reported to FINRA.

[553] *See infra* Section X.B.2.b.

[554] Based on information provided to the Commission on Form ATS filings as of July 1, 2020, three ATSs have noticed their intention to trade repos on government securities while no ATS has noticed its intention to trade options on government securities.

[555] PTFs refers to principal trading firms. *See supra* Section I.A.

[556] Based on the regulatory version of TRACE for U.S. Treasury and Agency Securities from 7/1/2019 to 12/31/2019.

[557] On-the-run Treasury Securities have much more trading activity than off-the-run Treasury Securities. *See supra* note 10.

[558] Based on the regulatory version of TRACE for U.S. Treasury Securities from 7/1/2019 to 12/31/2019.

[559] *See supra* note 6.

[560] *See* Monthly Statement of the Public Debt of the United States, dated December 31, 2019, *available at https://www.treasurydirect.gov/govt/reports/pd/mspd/2019/opds122019.pdf.*

[561] *See* Federal Reserve Board L.208 Debt Securities, *available at https://www.federalreserve.gov/releases/z1/20200611/html/l208.htm.*

[562] *See* SIFMA Fixed Income Trading Volume, *available at https://www.sifma.org/resources/research/us-fixed-income-trading-volume/.* The stated figures include Treasury Securities, Agency MBS, and Federal Agency Securities. The six-month average is the mean of the average daily trading volume for these instruments over the period from July to December 2019.

[563] Based on the regulatory version of TRACE for U.S. Treasury Securities and TRACE for Agency Securities. Trading volume is reported as par volume in dollars. Par volume is the volume measured in the face value ($100) of bond in dollars. *See also* FINRA TRACE Fact Book, *available at https://www.finra.org/filing-reporting/trace/trace-fact-book.*

[564] *See supra* Section I.B. ATS and non-ATS trading venues both offer execution services. Orders matched on non-ATS trading venues generally result from a broker-dealer exercising discretionary activity while an ATS, which is an exchange, matches the orders of multiple buyers and sellers in securities using established non-discretionary methods.

ATSs and non-ATS interdealer brokers—and directly between market participants, including bilateral dealer-to-dealer (interdealer) and dealer-to-customer transactions. Participants in the government securities market include dealers, PTFs, hedge funds, and large institutional investors. In the dealer-to-dealer market, trading platforms offer a variety of trading protocols, for example, central limit order books, quote streaming, and request for quotes.

Government Securities ATSs play an important role in the U.S. Treasury Securities market.[565] Government Securities ATSs facilitate significant liquidity provision for U.S. Treasury and Agency Securities markets, particularly those that operate in the secondary interdealer markets for on-the-run U.S. Treasury Securities.[566] The majority of trading in on-the-run markets occurs on Government Securities ATSs.[567] Although Government Securities ATSs trade a significant share of volume in off-the-run U.S. Treasury Securities, their share of trading volume in the off-the-run U.S. Treasury Securities is smaller than their share of on-the-run U.S. Treasury Securities trading.[568] Traditionally, participation in the interdealer trading market is open to only bank- and non-bank dealers; however, the interdealer trading market now includes non-dealer participants, most notably PTFs in the on-the-run U.S. Treasury Securities market.[569]

In the dealer-to-customer market, customers (*e.g.,* investment companies, pension funds, insurance companies, corporations, or retail investors) [570] trade with dealers either through traditional voice-assisted brokers or through electronic systems.[571] Customers submit orders either over the phone via an electronic voice system or on trading platforms that facilitate matching buy and sell orders through single or multi-dealer electronic systems, such as RFQ platforms.[572] The Commission understands that in the dealer-to-customer market for government securities, dealers do not usually redirect customer order flow to Government Securities ATSs.[573] Instead, the dealers cross or fill the orders internally and they trade on ATSs to manage their inventory levels. Due to a lack of available data, the extent to which dealers internalize customer orders is unclear.

Competition among dealers for customer order flow happens in multiple ways. One of the clearest ways that dealers compete with each other is via their quotes. One comment letter submitted in response to the Treasury Request for Information said that dealers in the U.S. Treasury Securities market also compete along other dimensions such as by offering: Better customer service, better allocations on the issuance of other securities, access to research, and favorable financing terms.[574]

Some Government Securities ATSs are operated by, or affiliated with, multi-service broker-dealers that also fill customer orders for dealer-to-customer trades. These broker-dealer operators or their affiliates may compete for customer order flow along with subscribers to their own Government Securities ATSs.

Competition among Government Securities ATSs and between Government Securities ATSs and non-ATS trading venues could affect market participants' trading costs in the government securities market. Trading costs may include bid-ask spreads,[575] search costs in the selection of trading venues, and trading venue fees. When deciding which trading venue most suits their trading purposes, market participants may consider various ATS operational facets, such as order handling, order types, order segmentation, trading functionalities, and any potential conflicts of interest that may arise from the ATS-related activities of the broker-dealer operator or its affiliates. Trading venue fees could be a primary factor for market participants in deciding to which trading venue to send their orders.[576] The Commission recognizes that the fee structures of ATSs can vary and may depend on, among other things, the types of subscribers and services.[577] In the selection of trading venues, market participants may consider which ATS fee structure offers the best pricing according to order flow and market participant characteristics.[578]

TABLE X.1—ATS MARKET SHARE ANALYSIS

	Treasury securities	Agency securities	Number of unique ATSs
Num. of Gov. Sec. ATS	19	6	19
Gov. Sec. ATS volume share	43.1%	13.1%	
Above 10% Market Share:			
Num. of Gov. Sec. ATS	1	1	2

[565] *See infra* Section X.B.1.a for a discussion of the on-the-run U.S. Treasury Securities market and *infra* Section X.B.1.b for a discussion of the off-the-run U.S. Treasury Securities market. *See supra* notes 9 and 10 for the definition of the on-the-run and the off-the-run U.S. Treasury Securities, respectively.

[566] *See supra* Section I.B.

[567] *See infra* Section X.B.1.a for a discussion of the on-the-run U.S. Treasury Securities market.

[568] *See infra* Section X.B.1.b for a discussion of the off-the-run U.S. Treasury Securities market.

[569] *See infra* Section X.B.1.a for a discussion about PTF participation in the on-the-run U.S. Treasury Securities market.

[570] *See* Treasury Request for Information, *supra* note 10, at 3928.

[571] *See* October 15 Staff Report, *supra* note 14, at 11, 55.

[572] *See id.* at 36, n.31; Treasury Request for Information, *supra* note 10, at 3928.

[573] In Tables X.2, X.3, and X.4, dealer transactions on Government Securities ATSs represent a significant portion of overall Government Securities ATS trading volume, whereas customer transactions account for a small portion of overall Government Securities ATS trading volume. The Commission understands that some portion of dealer transactions on Government Securities ATSs represents customer orders because dealers may fill customer orders internally and trade on ATSs to manage their inventory levels.

[574] *See* Letter from Jim Greco, CEO, Direct Match, to David R. Pearl, Office of the Executive Secretary, U.S. Department of the Treasury, dated April 22, 2016, at 5, *available at https://www.treasurydirect.gov/instit/statreg/gsareg/RFIcommentletterDirectMatch.pdf* (''Direct Match Letter'').

[575] The estimated average daily relative quoted spread for interdealer transactions for on-the-run U.S. Treasury Securities is small, approximately 0.8 bps for 2-year Treasury Securities and 2.4 bps for 10-year Treasury Securities. The estimated average daily relative quoted spread for interdealer transactions for off-the-run U.S. Treasury Securities, approximately 1.7 bps for 2-year Treasury Securities and 5.4 bps for 10-year Treasury Securities, is larger compared to that of on-the-run Treasury Securities. Though, spreads have narrowed in the past couple of years with a change to a smaller minimum trading increment of ⅛ of 1/32 of $1. The average daily relative quoted spread is computed as the daily average of the difference between the intraday offer and bid prices divided by the corresponding price mid-quote. *See also* Paolo Pasquariello & Clara Vega, *The On-the-Run Liquidity Phenomenon,* 92 J. Fin. Econ. 1 (2009); Tobias Adria, Michael Fleming, & Or Shachar, *Market Liquidity after the Financial Crisis* (June, 28, 2017), Federal Reserve Bank of New York, Liberty Street Economics, *available at https://libertystreeteconomics.newyorkfed.org/2017/06/market-liquidity-after-the-financial-crisis.html.*

[576] *See supra* Section III.C.19.

[577] *See id.*

[578] *See id.*

TABLE X.1—ATS MARKET SHARE ANALYSIS—Continued

	Treasury securities	Agency securities	Number of unique ATSs
Gov. Sec. ATS volume share	24.1%	12.7%	
Above 5% Market Share:			
Num. of Gov. Sec. ATS	3	1	3
Gov. Sec. ATS volume share	35.0%	12.7%	
Above 4% Market Share:			
Num. of Gov. Sec. ATS	3	1	3
Gov. Sec. ATS volume share	35.0%	12.7%	
Above 3% Market Share:			
Num. of Gov. Sec. ATS	4	1	4
Gov. Sec. ATS volume share	38.1%	12.7%	
Above 2% Market Share:			
Num. of Gov. Sec. ATS	5	1	5
Gov. Sec. ATS volume share	40.5%	12.7%	

Each panel reports the volume share (%) for Government Securities ATSs and the number of Government Securities ATSs above the specified market share level. Treasury Securities include nominal bonds, TIPS and STRIPS. Agency Securities include Agency Debentures, Agency Collateralized Mortgage Obligations, and Agency Pass-Through Mortgage Backed Securities.[579] Trading volume is measured in dollar volume in par value. Data is based on the regulatory version of TRACE for U.S. Treasury Securities and TRACE for Agency Securities from July 1, 2019 to December 31, 2019.

The Commission estimates that 19 Legacy Filers [580] and 7 Currently Exempted Government Securities ATSs [581] would be subject to the proposed amendments to Regulation ATS. However, only 19 of these 26 Government Securities ATSs reported transactions on government securities to TRACE over the six-month period between July and December 2019.

Of the 19 Government Securities ATSs that report transactions to TRACE, the volume is concentrated in only a few ATSs, and predominantly in one ATS. Table X.1 reports the number of Government Securities ATSs and the trading volume share of Government Securities ATSs for multiple volume share levels, using government securities transactions reported to TRACE during the six-month period between July and December 2019. Over the six-month period in 2019, 19 Government Securities ATSs accounted for approximately 43 percent of overall U.S. Treasury Securities trading volume. In the market for U.S. Treasury Securities, 3 Government Securities ATSs each have at least five percent of overall U.S. Treasury Securities trading volume. The Government Securities ATS with the largest market volume in U.S. Treasury Securities has approximately 24 percent of total U.S. Treasury Securities trading volume, whereas each of the Government Securities ATSs with the second and third largest market volume has a trading volume that is slightly above five percent of total U.S. Treasury Securities. In the market for Agency Securities, 6 Government Securities ATSs accounted for 13 percent of overall Agency Securities trading volume. One Government Securities ATS has at least five percent of overall Agency Securities trading volume.

In the subsections below, Section X.B.1.a and Section X.B.1.b discuss competition among trading venues and market participants in the on-the-run and off-the-run U.S. Treasury Securities market, respectively. Section X.B.1.c discusses competition among trading venues and market participants in the Agency Securities market.

a. On-the-Run U.S. Treasury Securities

In the on-the-run U.S. Treasury Securities market, Government Securities ATSs compete with other Government Securities ATSs and non-ATS trading venues for PTF, dealer, and ultimately, customer order flows.[582] While there are multiple avenues to trade on-the-run government securities, the majority of trading goes through Government Securities ATSs. Table X.2 reports the trading volume shares for Government Securities ATSs, non-ATS interdealer brokers, and bilateral secondary market transactions over the six month period between July and December 2019. As shown in Table X.2, 19 Government Securities ATSs and 24 non-ATS interdealer brokers reported on-the-run U.S. Treasury Securities transactions to TRACE during the six month period in 2019. Government Securities ATSs accounted for approximately 57 percent of total trading volume and approximately 67 percent of total interdealer trading volume in the on-the-run U.S. Treasury Securities market over the six month period in 2019.[583] A substantial amount of trading is concentrated on the largest Government Securities ATS in terms of trading volume, accounting for approximately 64 percent of the total Government Securities ATS trading volume and approximately 37 percent of the total trading volume for on-the-run U.S. Treasury Securities. This largest Government Securities ATS in terms of trading volume serves as the primary location for price discovery in the cash market for on-the-run U.S. Treasury Securities. This ATS's transaction prices, along with prices in the U.S. Treasury Securities futures market, are used by many market participants to determine risk-free benchmarks for pricing other financial products.[584]

[579] Agency Pass-through Mortgage Backed Securities include those traded in specified pool transactions and those to be announced.

[580] Based on data compiled from Form ATS filed with the Commission as of July 1, 2020, the Commission has 19 Form ATSs on file from Legacy Filers.

[581] The Commission believes that 7 Currently Exempted Government Securities ATSs transact exclusively in government securities or repos, and are not required to file a Form ATS. *See also supra* Section IX.C for the estimated number or respondents to the ''collection of information'' requirements.

[582] In Table X.2, the reported trading volume share of Government Securities ATSs in the secondary market trading for on-the-run U.S. Treasury Securities is small. Government Securities ATSs compete for customer order flow through interdealer transactions on ATSs. The Commission understands that dealers fill customer trades internally and trade on Government Securities ATSs to manage their inventory levels. *See supra* note 9.

[583] (ATS dealer volume/(dealer volume from ATS + dealer volume from non-ATS interdealer brokers + bilateral dealer-to-dealer volume) × 100) = ATS share of dealer volume (%).

[584] *See* October 15 Staff Report, *supra* note 14, at 15, 17–18, 45.

TABLE X.2—ON-THE-RUN U.S. TREASURY SECURITIES TRADING VOLUME

	Number of venues	Volume	Volume share (%)
ATSs	19	995,669	57.4
Customer trades	12	74,094	4.3
Dealer trades	18	377,166	21.7
PTF trades	13	544,409	31.4
Non-ATS Interdealer Brokers	24	72,963	4.2
Customer trades	22	31,389	1.8
Dealer trades	23	41,574	2.4
Bilateral dealer-to-dealer trades	422	145,734	8.4
Bilateral dealer-to-customer trades	348	520,818	30.0

This table reports trading volume and volume share for ATSs, Non-ATS interdealer brokers, bilateral dealer-to-dealer transactions, and bilateral dealer-to-customer transactions for on-the-run U.S. Treasury Securities. On-the-run U.S. Treasury Securities are the most recently issued nominal coupon securities. Nominal coupon securities pay a fixed semi-annual coupon and are currently issued at original maturities of 2, 3, 5, 7, 10, 20, and 30 years. Treasury Bills and Floating Rate Notes are excluded. For bilateral transactions, the number of venues denotes the number of distinct MPIDs.[585] *Volume* is the average weekly dollar volume in par value (in millions of dollars) over the 6-month period, from July 1, 2019 to December 31, 2019.[586] *Number of Venues* is the number of different trading venues in each category and the number of MPIDs for bilateral transactions. *Market Share (%)* is the measure of the dollar volume as a percent of total dollar volume.[587] The volume of ATSs and non-ATS interdealer brokers are broken out by *Customer trades, Dealer trades,* and *PTF trades* within each group.[588] Data is based on the regulatory version of TRACE for U.S. Treasury Securities from July 1, 2019 to December 31, 2019.

In addition to competing for subscribers through the fees they charge, Government Securities ATSs also compete with each other via the technological features and order options they offer to subscribers. As highlighted in the October 15 Staff Report,[589] Government Securities ATSs in the secondary electronic cash market for on-the-run U.S. Treasury Securities have evolved such that they operate with a complexity in terms of automation and speed of trading that is similar to that observed on NMS Stock ATSs. Four Government Securities ATSs operate as anonymous central limit order book systems and offer features to allow participants to interact with specific counterparty groups on the ATS, such as low latency and high-speed connectivity via direct market data feeds and co-location services, a variety of order types and algorithms to pursue aggressive and passive trading strategies, and order flow segmentation. Unlike NMS Stock ATSs, whose broker-dealer operators connect to national securities exchanges to route orders, broker-dealer operators of Government Securities ATSs usually do not offer to route subscribers' orders to other trading venues.

Historically, Government Securities ATSs in the market for on-the-run U.S. Treasury Securities only allowed bank and non-bank dealers to trade. Dealers had primarily traded directly with customers in the dealer-to-customer market and traded with other broker-dealers on Government Securities ATSs as a source of orders and trading interest or to balance their inventory risk. However, beginning in 2003, Government Securities ATSs started allowing firms that were neither banks nor dealers, such as hedge funds, insurance companies and PTFs to trade directly in interdealer transactions on Government Securities ATSs.[590] This change has allowed some traders who were previously restricted to the dealer-to-customer trading venues to access Government Securities ATSs, where they can trade anonymously.

With the growth of high-speed electronic trading, the presence of PTFs has greatly increased in the secondary cash market for on-the-run U.S. Treasury Securities. In 2008, PTFs accounted for 25 percent of the trading volume on ATSs.[591] Based on Table X.2, over the six month period in 2019, PTFs traded on 13 Government Securities ATSs accounting for approximately 55 percent[592] of total Government Securities ATS trading volume. PTFs have also become the primary liquidity providers.[593] As of the end of 2019, there are over 100 PTFs operating on ATSs that trade U.S. Treasury Securities, primarily on four Government Securities ATSs.[594] Similar to HFTs in the equity markets, PTFs trading on the electronic market for U.S. Treasury Securities often employ automated algorithmic trading strategies that rely on speed and allow the PTFs to quickly execute trades, or cancel or modify quotes in response to perceived market events.[595] Furthermore, most PTFs trading U.S. Treasury Securities on electronic trading venues also restrict their activities to principal trading and do not hold positions long term.[596]

In the secondary markets for on-the-run U.S. Treasury Securities, dealer transactions account for a significant portion of overall Government Securities ATS trading volume. In Table X.2, dealers account for approximately 38 percent[597] of overall Government Securities ATS trading volume. The Commission understands that some portion of dealer transactions on Government Securities ATSs represents customer orders because dealers may fill customer trades internally and trade on Government Securities ATSs to manage their inventory levels.

[585] Dealers are counted using the number of distinct MPIDs. *See also supra* Section III.A.2.

[586] FINRA reports volume as par volume, where par volume is the volume measured by the face value of the bond, in dollars. *See also* FINRA TRACE Fact Book, *available at https://www.finra.org/filing-reporting/trace/trace-fact-book.*

[587] Total dollar volume (in par value) is calculated as the sum of dollar volume for ATSs, non-ATS interdealer brokers, bilateral dealer-to-dealer transactions, and bilateral dealer-to-customer transactions.

[588] We identify ATS trades and non-ATS interdealer broker trades using MPID in the regulatory version of TRACE for U.S. Treasury Securities. The regulatory version of TRACE for U.S. Treasury Securities includes an identifier for customer and interdealer trades. Furthermore, we use MPID for non-FINRA member subscriber counterparties in the regulatory version of TRACE for U.S. Treasury Securities to identify PTF trades on ATSs.

[589] *See* October 15 Staff Report, *supra* note 14, at 35–36.

[590] *See* Direct Match Letter, *supra* note 574, at 6–7.

[591] *See* Alexandra Scaggs & Susanne Barton, *Treasuries Wilder Than Ever as Ultrafast Bond Traders Rise Up,* Bloomberg, October 12, 2015, *https://www.bloomberg.com/news/articles/2015-10-12/treasuries-wilder-than-ever-as-ultra-fast-bond-traders-rise-up* (citing the Tabb Group Report).

[592] (ATS PTF volume/ATS volume) × 100 = PTF share of ATS volume (%).

[593] TRACE for Treasury data. *See also* October 15 Staff Report, *supra* note 14, at 21, 23, 38–39.

[594] FINRA PTF participant list as of 12/31/2019.

[595] *See* October 15 Staff Report, *supra* note 14, at 32, 35–36, 39.

[596] *See id.* at 38.

[597] (ATS dealer volume/ATS volume) × 100 = dealer volume share of ATS volume (%).

b. Off-the-Run U.S. Treasury Securities

Government Securities ATSs play a significant role in secondary market trading for off-the-run U.S. Treasury Securities.[598] Government Securities ATSs account for approximately 51 percent [599] and 20 percent of the total interdealer trading volume and the total trading volume, respectively, in the off-the-run U.S. Treasury Securities market. However, Government Securities ATSs' share of trading volume in the off-the-run U.S. Treasury Securities market is smaller than that of Government Securities ATSs in the on-the-run U.S. Treasury Securities market. As U.S. Treasury Securities transition from on-the-run status to off-the-run, their trading activity shifts away from electronic venues, such as Government Securities ATSs, and toward the bilateral secondary trading market.

In the off-the-run U.S. Treasury Securities market, Government Securities ATSs compete with other Government Securities ATSs and non-ATS trading venues for PTF, dealer, and ultimately, customer order flows.[600] Table X.3 reports the trading volume shares for Government Securities ATSs, non-ATS interdealer brokers, and bilateral secondary market transactions in the off-the-run Treasury Securities market over the six month period between July and December 2019. Based on Table X.3, 19 Government Securities ATSs and 24 non-ATS interdealer brokers reported off-the-run U.S. Treasury Securities transactions to TRACE during the six month period in 2019. Although Government Securities ATSs' share of trading volume in the off-the-run U.S. Treasury Securities market is smaller than that of Government Securities ATSs in the on-the-run U.S. Treasury Securities market, Government Securities ATSs still play a significant role in the trading of off-the-run U.S. Treasury Securities, accounting for approximately 20 percent of the overall trading volume and 51 percent [601] of overall interdealer trading volume. Furthermore, in the secondary trading market for off-the-run U.S. Treasury Securities, dealers account for approximately 80 percent [602] of Government Securities ATS trading volume whereas PTFs account for approximately 7 percent [603] of Government Securities ATS trading volume. The Commission understands that some portion of dealer transactions on Government Securities ATSs represents customer orders because dealers may fill customer trades internally and trade on Government Securities ATSs to manage their inventory levels.

TABLE X.3—OFF-THE-RUN U.S. TREASURY SECURITIES TRADING VOLUME

	Number of venues	Volume	Volume share (%)
ATSs	*19*	*121,601*	*20.2*
Customer trades	11	15,813	2.6
Dealer trades	16	96,994	16.1
PTF trades	11	8,794	1.5
Non-ATS Interdealer Brokers	*24*	*35,932*	*6.0*
Customer trades	22	7,160	1.2
Dealer trades	23	28,773	4.8
Bilateral dealer-to-dealer trades	*684*	*62,899*	*10.5*
Bilateral dealer-to-customer trades	*628*	*381,009*	*63.3*

This table reports trading volume and volume share for ATSs, Non-ATS interdealer brokers, bilateral dealer-to-dealer transactions, and bilateral dealer-to-customer transactions for off-the-run U.S. Treasury Securities. Off-the-run or ''seasoned'' U.S. Treasury Securities include TIPS, STRIPS, and nominal coupon securities issues that preceded the current on-the-run nominal coupon securities. *Number of Venues* is the number of different trading venues in each category and the number of MPIDs for bilateral transactions.[604] *Volume* is the average weekly dollar volume in par value (in millions of dollars) over the 6-month period, from July 1, 2019 to December 31, 2019.[605] *Market Share (%)* is the measure of the dollar volume as a percent of the total dollar volume.[606] The volume of ATSs and non-ATS interdealer brokers are broken out by *Customer trades, Dealer trades,* and *PTF trades* within each group.[607] Data is based on the regulatory version of TRACE for U.S. Treasury Securities from July 1, 2019 to December 31, 2019.

c. Agency Securities

Government Securities ATSs play a significant role in secondary market trading for Agency Securities.[608] However, Government Securities ATSs' share of trading volume in Agency Securities market is smaller than that of Government Securities ATSs in the U.S. Treasury Securities market. Government Securities ATSs account for approximately 45 percent [609] and 13 percent of the total interdealer trading volume and the total trading volume, respectively, in the Agency Securities market.

In the Agency Securities market, Government Securities ATSs compete with other Government Securities ATSs and non-ATS trading venues for dealer and ultimately, customer order flows.[610] Table X.4 reports the trading volume shares for Government Securities ATSs, non-ATS interdealer brokers, and bilateral secondary market transactions in the Agency Securities market over the six month period between July and

[598] *See supra* note 10.

[599] (ATS dealer volume/(dealer volume from ATS + dealer volume from non-ATS interdealer brokers + bilateral dealer-to-dealer volume) × 100) = ATS share of dealer volume (%).

[600] In Table X.3, the reported trading volume share of Government Securities ATSs in the secondary market trading for off-the-run U.S. Treasury Securities is small. *See also supra* note 582.

[601] (ATS dealer volume/(dealer volume from ATS + dealer volume from non-ATS interdealer brokers + bilateral dealer-to-dealer volume) × 100) = ATS share of dealer volume (%).

[602] (ATS dealer volume/ATS volume) × 100 = dealer volume share of ATS volume (%).

[603] (ATS PTF volume/ATS volume) × 100 = PTF share of ATS volume (%).

[604] *See supra* note 585.

[605] *See supra* note 586.

[606] *See supra* note 587.

[607] We identify ATS trades and non-ATS interdealer broker trades using MPID in the regulatory version of TRACE for U.S. Treasury Securities. The regulatory version of TRACE for U.S. Treasury Securities includes an identifier for customer and interdealer trades. Furthermore, we use MPID for non-FINRA member subscriber counterparties in the regulatory version of TRACE for U.S. Treasury Securities to identify PTF trades on ATSs.

[608] Agency Securities are those issued by U.S. Government sponsored enterprises (''GSEs'') such as Federal Home Loan Banks (''FHLBs''), the Federal National Mortgage Association (''Fannie Mae''), and the Federal Home Loan Mortgage Corporation (''Freddie Mac''). *See supra* Section I.A.

[609] (ATS dealer volume/(dealer volume from ATS + dealer volume from non-ATS interdealer brokers + bilateral dealer-to-dealer volume) × 100) = ATS share of dealer volume (%).

[610] The trading volume share of Government Securities ATSs in the secondary market trading for Agency Securities is small. *See infra* Table X.4. *See also supra* note 582.

December 2019. As shown in Table X.4, 6 Government Securities ATSs and 10 non-ATS interdealer brokers reported Agency Securities transactions to TRACE during the six month period in 2019. Although Government Securities ATSs' share of trading volume in the Agency Securities market is smaller than that of Government Securities ATSs in the U.S. Treasury Securities market, Government Securities ATSs still play a significant role in trading of Agency Securities, accounting for approximately 13 percent of the overall trading volume and 45 percent [611] of overall interdealer trading volume. In the secondary market trading of Agency Securities, dealers account for approximately 87 percent [612] of overall Government Securities ATS trading volume. The Commission understands that some portion of dealer transactions on Government Securities ATSs represents customer orders because dealers may fill customer trades internally and trade on Government Securities ATSs to manage their inventory levels.

TABLE X.4—AGENCY SECURITIES TRADING VOLUME

	Number of venues	Volume	Volume share (%)
ATSs	6	35,063	13.1
Customer trades	5	4,462	1.7
Dealer trades	6	30,601	11.4
Non-ATS Interdealer Brokers	10	10,967	4.1
Customer trades	9	1,169	0.4
Dealer trades	10	9,798	3.7
Bilateral dealer-to-dealer trades	552	27,229	10.2
Bilateral dealer-to-customer trades	551	194,143	72.6

This table reports trading volume and volume share for ATSs, Non-ATS interdealer brokers, bilateral dealer-to-dealer transactions, and bilateral dealer-to-customer transactions for U.S. Agency Securities. Agency Securities include Agency Debentures, Agency Collateralized Mortgage Obligations, and Agency Pass-Through Mortgage Backed Securities.[613] *Number of Venues* is the number of different trading venues in each category and the number of MPIDs for bilateral transactions.[614] *Volume* is the average daily dollar volume in par value (in millions of dollars) over the 6-month period, from July 1, 2019 to December 31, 2019.[615] *Market Share (%)* is the measure of the dollar volume as a percent of the total dollar volume.[616] The volume of ATSs and non-ATS interdealer brokers are broken out by *Customer trades* and *Dealer trades* within each group.[617] Data is based on the regulatory version of TRACE for Agency Securities from July 1, 2019 to December 31, 2019.

2. Reporting Requirements for Government Securities ATSs

a. Operational Reporting Requirements

All 19 Legacy Filers are subject to the requirements of Regulation ATS, whereas the seven Currently Exempted Government Securities ATSs are not. These differences in reporting requirements can lead to an uneven competitive landscape for Government Securities ATSs. For instance, Currently Exempted Government Securities ATSs are not required to file Form ATS or Form ATS–R with the Commission or comply with certain recordkeeping requirements.[618] In contrast, ATSs that trade government securities or repos as well as non-government securities—such as corporate or municipal fixed income securities—must either register as a national securities exchange or comply with Regulation ATS pursuant to the exemption provided under Exchange Act Rule 3a1–1(a)(2).[619] These Legacy Filers must also comply with certain reporting requirements, such as updating the Form ATS pursuant to Rule 301(b)(2) of Regulation ATS, and recordkeeping requirements pursuant to Rule 301(b)(8).[620]

The Commission recognizes that all of the 19 Legacy Filers currently incur reporting costs to comply with Regulation ATS.[621] These costs include filing Form ATS as both an initial operation report and, whenever there is a material change in operations, as a confidential filing with the Commission. The Commission may use this information in monitoring, examinations and enforcement. These reporting requirements for Legacy Filers (which do not apply to the Currently Exempted Government Securities ATSs) may contribute to an uneven competitive landscape. Furthermore, all but one of the Currently Exempted Government Securities ATSs and all of the Legacy Filers are registered broker-dealers that incur costs of registering with the Commission as well as SRO membership and face operational regulatory reporting requirements. The Commission estimates that one of the Currently Exempted Government Securities ATSs is bank-operated.[622] This bank-operated Currently Exempted Government Securities ATS is not required to register as a broker-dealer with the Commission and thus, does not have to file Form BD with the Commission or be subject to FINRA rules. As a result, the bank-operated Currently Exempted Government Securities ATS incurs different regulatory compliance costs, which may contribute to the uneven competitive landscape.

b. Transaction Reporting Requirements

Currently Exempted Government Securities ATSs are not required to report their transaction volume in government securities to the Commission on a quarterly basis via Form ATS–R. However, Legacy Filers are required to confidentially report their transaction dollar volume in government securities to the Commission on a quarterly basis via Form ATS–R within 30 days after the end of each calendar quarter. Trading volume on Currently Exempted Government Securities ATSs is not reported to the Commission. However, all transactions in government securities

[611] (ATS dealer volume/(dealer volume from ATS + dealer volume from non-ATS interdealer brokers + bilateral dealer-to-dealer volume) × 100) = ATS share of dealer volume (%).

[612] (ATS dealer volume/ATS volume) × 100 = dealer volume share of ATS volume (%).

[613] *See supra* note 579.

[614] *See supra* note 585.

[615] *See supra* note 586.

[616] *See supra* note 587.

[617] We identify ATS trades and non-ATS interdealer broker trades using MPID in the regulatory version of TRACE for Agency Securities. The regulatory version of TRACE for Agency Securities includes an identifier for customer and interdealer trades.

[618] *See supra* Section I.B (discussing regulatory framework for Government Securities ATSs).

[619] *See id.* NMS Stock ATSs also must file Form ATS–N. *See also supra* Section V.D.

[620] *See id.*

[621] *See supra* Sections IX.C and IX.D.1.b.

[622] *See supra* Section IX.C.

by ATSs operated by FINRA-members are reported to TRACE.[623]

However, the transaction reporting requirements to TRACE do not apply to transactions executed by non-FINRA members, such as some primary dealer banks, and the information on those U.S. Treasury Securities transactions is not disseminated publicly via TRACE. The estimated one bank-operated Currently Exempted Government Securities ATS does not currently report government securities transactions to TRACE. Nevertheless, starting in March 2020, FINRA has published aggregated market volume in U.S. Treasury Securities on a weekly basis.[624] Monthly volume reports for other TRACE-Eligible Securities, including Agency Securities, are also available from FINRA since 2013.[625] These two publicly available aggregate market statistics for trading in U.S. Treasury Securities and Agency Securities, respectively, can provide a common source of information to determine the market share of Government Securities ATSs in the relevant market.

In addition to TRACE reporting, which applies to broker-dealers who are FINRA members, government securities primary dealers are required to report their positions and cumulative transaction volumes in government securities to the Federal Reserve Bank of New York on a weekly basis via Form FR2004.[626] Based on comment letters received in response to the Treasury Request for Information, certain Government Securities ATSs also make real-time U.S. Treasury Securities transactions data on their platforms available to subscribers and to other market participants through subscriptions to third party data vendors.[627]

3. Information Asymmetries Due to Limited Public Information About Operations of Government Securities ATSs

Market participants do not receive a complete snapshot of the operations and activities of all ATSs that trade government securities because a Currently Exempted Government Securities ATS is not required to file a Form ATS or Form ATS–G and a Legacy Filer is not required to publicly disclose its Form ATS or to file a publicly available Form ATS–G.[628] This disparity in requirements could lead to information asymmetries amongst different classes of subscribers.

Certain Government Securities ATSs may make voluntary disclosures regarding their operations, creating disparate levels of transparency. For example, subscribers to a particular Government Securities ATS may have greater access to information about the ATS, including the ATS's subscriber manual and other subscriber quotes, than other market participants. There could also be differences in the information available to different classes of subscribers to a Government Securities ATS. Because there is no required disclosure of order execution statistics for government securities trading, different classes of subscribers to a Government Securities ATS could receive differing levels of information regarding execution quality on the ATS. This could lead to potential inefficiencies as market participants with limited access to information struggle to compete with those who have greater access to information, and this could also be the case with respect to other information about the operations of Government Securities ATSs. In all cases, subscribers who have greater access to information offered by the Government Securities ATS may be able to make better choices about their trading decisions relative to subscribers who have limited access to information about the operations of the ATS.

4. Government Securities ATSs Treatment of Subscriber Confidential Trading Information

Because Currently Exempted Government Securities ATSs are not required to comply with Regulation ATS, they are not subject to Rule 301(b)(10) and Rule 303(a)(1), which means that they are not required to establish written safeguards and written procedures to protect subscribers' confidential trading information pursuant to Regulation ATS.[629] To the extent that a Currently Exempted Government Securities ATS does not have these procedures, or has them but such procedures are not adequate, the integrity of a subscriber's confidential trading information could be at risk of unauthorized disclosure and subject to potential misuse. ATSs are not required to file their written safeguards and written procedures with the Commission. Therefore, absent an examination by the Commission staff regarding the adequacy of the written safeguards and written procedures, the Commission is not able to determine the specific Government Securities ATSs that currently have adequate written safeguards and written procedures to protect subscribers' confidential trading information. At the same time, based on the experience of the Commission, the Commission believes that some Government Securities ATSs currently have, and maintain in writing, safeguards and procedures to protect subscribers' confidential trading information, as well as the oversight procedures to ensure such safeguards and procedures are followed.

5. Fair Access Rule

The Fair Access Rule of Regulation ATS does not currently apply to ATSs that trade government securities because government securities are not a category of securities covered under the rule. As a result, there is no legal mechanism to prevent Government Securities ATSs from unreasonably denying or limiting subscribers' access to an ATS that is a significant market for government securities.[630] Access to a Government Securities ATS may not be critical when market participants are able to substitute the execution services of one ATS with those of another. However, when a Government Securities ATS has a significant share of trading volume in government securities, unfairly discriminatory actions may hurt investors lacking access to the system because viable alternatives to trading on such a system may be limited. Furthermore, market forces alone may not be sufficient to prevent a Government Securities ATS from unreasonably denying access to some market participants. In the absence of the Fair Access Rule, for example, a Government Securities ATS with a significant volume in government securities may only allow certain types

[623] *See supra* notes 50–51 and accompanying text discussing TRACE reporting requirements for Government Securities ATSs.

[624] The weekly TRACE Treasury aggregate trading statistics are *available at https://www.finra.org/filing-reporting/trace/data/trace-treasury-aggregates.*

[625] These reports are *available at https://www.finra.org/filing-reporting/trace/content-licensing/volume-reports.* FINRA also publishes more detailed breakdowns of trading volume in MBSs into agency and non-agency categories. These reports are *available at http://tps.finra.org/idc-index.html.*

[626] The data is aggregated and published weekly in the Federal Reserve Bank of New York's press release, ''Weekly Release of Primary Dealer Transactions.''

[627] *See* BrokerTec/ICAP Letter, *supra* note 238, at 7.

[628] *See* 17 CFR 242.301(b)(2)(vii).

[629] In contrast, Legacy Filers are currently subject to Rule 301(b)(10) and Rule 303(a)(1) of Regulation ATS. *See supra* Section IX.A.

[630] *See supra* Sections I.B and II.D discussing the Fair Access Rule requirements.

of market participants to access the ATS and exclude others without establishing reasonable written standards.[631] In this case, the ATS may cater to the preferences of subscribers that favor the exclusion, while failing to internalize the negative externality that this may impose on the excluded market participants who could have more limited trading venue options, resulting in higher trading costs and the reduction in efficiency with which they achieve trading objectives. This failure to internalize an externality could lead to market failure.

6. Regulation SCI

The provisions of Regulation SCI and Rule 301(b)(6) of Regulation ATS do not apply to the government securities activities of an ATS and therefore Currently Exempted Government Securities ATSs and Legacy Filers are not subject to either.[632] Among the three ATSs that trade government securities and satisfy the proposed volume thresholds for government securities that would trigger application of Regulation SCI, one Government Securities ATS is operated by a broker-dealer that also operates an NMS Stock ATS that is an SCI entity because the NMS Stock ATS meets Regulation SCI volume thresholds for NMS stocks. As an existing SCI entity, this NMS Stock ATS has the policies and procedures in place for systems related to trading of NMS stocks as required by Regulation SCI. The Commission believes that the broker-dealer operator for the Government Securities ATS of the existing SCI entity could have already capitalized on operational synergies from operating both an NMS Stock ATS and a Government Securities ATS, and could have implemented some of the same policies and procedures of the NMS Stock ATS required by Regulation SCI, modified as needed for systems related to trading of government securities and repos.

More generally, although most Government Securities ATSs are not subject to the requirements of Regulation SCI with respect to their government securities activities, a comment letter received in response to the Treasury Request for Information stated that many Government Securities ATSs adopted system testing and control procedures that followed the recommended best practices of the Treasury Market Practices Group.[633] The Treasury Market Practices Group promotes a robust control environment for government securities trading, using internal controls and risk management.[634] However, these best practices are meant only as useful operational guideposts rather than binding rules, and each trading venue can choose if it wants to comply and how to comply, which could provide weak safeguards to protect against the risks of system failures. In contrast, Regulation SCI establishes a formalized regulatory framework to ensure more effective Commission oversight.

While the Commission recognizes that Government Securities ATSs have some incentives to maintain robust systems in order to remain competitive, the Commission believes that market forces alone are insufficient to significantly reduce systems issues in the market for trading and execution services in government securities. In particular, the Commission believes that Government Securities ATSs do not fully internalize the costs associated with systems issues, because systems issues pose significant negative externalities on the market. That is, systems issues have ramifications on the market for government securities beyond the impact on the Government Securities ATS responsible for the systems issues. If a trading system of a Government Securities ATS with significant trading volume fails, this failure not only forces the ATS to forgo revenue but also can diminish trading in government securities during the disruption. In particular, the failure of such trading system can increase trading costs of market participants that have optimized their trading strategy under the assumption that all Government Securities ATSs with significant volume are fully operational.

The Commission also believes that some Government Securities ATSs that trade a large volume of government securities play a significant role in the government securities market, particularly those that trade on-the-run U.S. Treasury Securities, because the prices from these transactions serve as risk-free rate benchmarks for pricing other financial products. Without appropriate safeguards in place for Government Securities ATSs, technological vulnerabilities continue to exist and could lead to the potential for costly failures, disruptions, delays, intrusions, and the reduction in systems up-time, which could harm the price discovery process and price efficiency of government securities.[635]

Furthermore, based on the staff's experience receiving reports of systems issues concerning NMS Stock SCI ATSs, the Commission believes that the frequency and the duration of systems issues have decreased and systems up-time has improved over time since the adoption of Regulation SCI. Because Government Securities ATSs operate with similar complexity as NMS Stock SCI ATSs,[636] the Commission believes that extending Regulation SCI to Government Securities ATSs with significant volume would also help reduce the frequency and the duration of systems issues and improve systems up-time for those Government Securities ATSs.[637]

7. Implications for Efficiency

The intensity of competition among trading venues, the availability of information regarding Government Securities ATS operational facets, the number of trading venue options available to market participants, and the risk of potential market disruptions due to systems issues could affect market participants' trading costs and the efficiency with which market participants achieve their trading or investment objectives. The Commission believes that there is currently limited publicly available information regarding the operations of Government Securities ATSs and that some subscribers to these ATSs may be privy to more detailed

[631] An ATS subject to the Fair Access Rule could not offer a service or level of service to only one subscriber or class of subscribers unless the ATS has established written standards that do not unreasonably prohibit or limit access of permissioned subscribers to the service or level of service.

[632] *See supra* Section I.B discussing Rule 301(b)(6) and its current application to ATSs.

[633] *See* Letter from Mike Zolik, Nate Kalich, and Larry Magargal, Ronin Capital LLC, to David R. Pearl, Office of the Executive Secretary, U.S. Department of the Treasury, dated March 19, 2016, at 31–33, *available at https://www.treasurydirect.gov/instit/statreg/gsareg/RoninCapital.pdf.*

[634] See Treasury Market Practices Group, *Best Practices For Treasury, Agency Debt, and Agency Mortgage-Backed Securities Markets* (July 2019), available at *https://www.newyorkfed.org/medialibrary/Microsites/tmpg/files/TMPG_BestPractices_071119.pdf.*

[635] *See infra* Section X.C.3.c. On January 11, 2019, the largest trading platform in on-the-run U.S. Treasury Securities, experienced a system outage approximately from 2 p.m. to 3:30 p.m. ET. While the outage resulted in a modest reduction in market volume, had it occurred at a time other than late on a Friday afternoon when trading activity is normally already low, the outage could have resulted in more adverse consequences on the overall market. *See also* Elizabeth Stanton, Nick Baker, & Matthew Leising, *Treasuries Hit by One-Hour Outage on Biggest Electronic Platform,* Bloomberg, January 13, 2019, *https://www.bloomberg.com/news/articles/2019-01-11/brokertec-inter-dealer-treasury-broker-suffers-outage.*

[636] *See supra* Section VI.

[637] *See infra* Section X.C.1.b discussing the benefits of the proposed amendments to Regulation SCI. *Infra* Section X.C.2.b discusses the costs of these proposed amendments, while *infra* Section X.C.3 discusses the effects of these amendments on efficiency, competition, and capital formation.

information about how their orders are executed, sent, and/or prioritized compared to other subscribers.[638] Market participants in the government securities market with limited information regarding ATS operational facets, such as order handling, fee structure, and any potential conflicts of interest that may arise from the ATS-related activities of the broker-dealer operator or its affiliates, could face difficulty in comparing Government Securities ATSs when deciding which venue most suits their trading purposes and could incur higher search costs in the selection of trading venues. This would result in higher trading costs for market participants and reduce the efficiency with which market participants achieve their trading objectives.

Government Securities ATSs and non-ATS trading venues compete for order flows in the government securities market.[639] The Commission believes that the limited publicly available information regarding Government Securities ATS operational characteristics, such as fee structure, order types, and trading functionalities, reduces the incentives of ATSs and non-ATS trading venues to compete more vigorously, innovate systems technology, improve execution quality, and lower fees. This could also reduce the efficiency with which market participants achieve their trading objectives. Currently, government securities are not subject to the Fair Access Rule.[640] To the extent that there are market participants who are unreasonably denied access to an ATS with a significant volume in U.S. Treasury Securities or Agency Securities, this could limit trading venue options for these market participants, resulting in higher trading costs and the reduction in efficiency with which they achieve their trading objectives.

The provisions of Regulation SCI do not apply to systems related to the trading of government securities.[641] Market disruptions due to systems issues at an ATS with a significant volume in U.S. Treasury Securities or Agency Securities could interrupt the price discovery process and liquidity flows in the market for government securities, which would result in periods of pricing inefficiencies for government securities and risky securities. Diminished price discovery in the secondary market for on-the-run U.S. Treasury Securities could also reduce price efficiency of risky securities because the transaction prices of on-the-run U.S. Treasury Securities are used as risk-free rate benchmarks to price risky securities transactions.[642] Price efficiency of risky securities is important because prices that accurately convey information about fundamental value improve the efficiency with which capital is allocated across projects and entities.

C. Economic Effects and Effects on Efficiency, Competition, and Capital Formation

The Commission has considered the economic effects of the proposed amendments to extend Regulation ATS and Regulation SCI to include Government Securities ATSs.[643] The Commission believes these proposed amendments would (i) help prevent the potential for abuse of ATS subscriber confidential trading information;[644] (ii) improve the ability of the Commission or an SRO to detect and investigate potential irregularities that might occur in the market for government securities and repo execution services;[645] (iii) increase the Commission's knowledge regarding the operations of and potential conflicts of interest on Government Securities ATSs and help identify whether they operate in a manner consistent with the federal securities laws;[646] (iv) help market participants make better-informed decisions about where to send their orders in order to achieve their trading or investment objectives, which could lower trading costs and enhance order execution quality;[647] (v) allow some market participants to access and increase options in the selection of trading venues, which could lower their trading costs;[648] and (vi) help reduce market disruptions due to systems issues[649] and prevent interruptions in the price discovery process and liquidity flows.[650]

Government Securities ATSs would incur implementation and ongoing compliance costs to comply with the proposed Regulation ATS and Regulation SCI amendments. Market participants in the government securities and repo market could face higher trading costs (*e.g.,* higher fees) from Government Securities ATSs to the extent that compliance costs of Regulation ATS and SCI amendments are passed on to them.

The compliance costs of the proposed amendments include, among other things, costs associated with establishing and updating policies and procedures to protect subscriber confidential information, updating systems to comply with recordkeeping requirements, gathering information for new disclosures, filing Form ATS–G, and establishing fair access standards.[651] The Commission also believes that Currently Exempted Government Securities ATSs would incur costs to comply with Regulation ATS in addition to those incurred by Legacy Filers.[652] Government Securities ATSs that meet the specified volume thresholds would also incur compliance costs as SCI entities,[653] such as costs associated with documentation, mandatory reporting and dissemination of SCI events, reporting of material systems changes, recordkeeping, and implementing the policies and procedures related to systems capacity, integrity, resiliency, availability, security, and compliance. Regulation SCI also imposes some indirect requirements on other market participants interacting with SCI entities (*e.g.,* third-party vendors providing SCI systems to SCI entities and members of SCI entities participating in testing of business continuity and disaster recovery plans).[654]

In addition to compliance costs, some market participants could incur indirect

[638] *See supra* Section X.B.3.

[639] *See supra* Sections X.B.1.a, X.B.1.b, and X.B.1.c for discussion on competition in the on-the-run U.S. Treasury Securities, off-the-run U.S. Treasury Securities, and Agency Securities, respectively.

[640] *See supra* Section X.B.5 for a discussion about the Fair Access Rule.

[641] *See supra* Section X.B.6 for a discussion about Regulation SCI practices.

[642] As noted in the October 15 Staff Report, *supra* note 14, price discovery is especially important in the secondary market for on-the-run U.S. Treasury Securities because the transaction prices are used as risk-free rate benchmarks to price other securities transactions.

[643] Government Securities ATSs account for significant portion of interdealer and overall volume in the government securities market. *See supra* Section X.B.1 for Tables X.1, X.2, X.3, and X.4. *See also supra* Section X.A for a discussion about the need for greater transparency and public data availability regarding the functioning of U.S. Treasury markets.

[644] *See infra* Section X.C.1.a.i. *See also supra* Section X.A for a discussion about the need for greater transparency and public data availability regarding the functioning of U.S. Treasury markets.

[645] *See* supra note 644.

[646] *See infra* Section X.C.1.a.ii. *See also supra* Section X.A for a discussion about the need for greater transparency and public data availability regarding the functioning of U.S. Treasury markets.

[647] *See supra* note 644.

[648] *See infra* Section X.C.1.a.iii.

[649] *See infra* Section X.C.1.b.

[650] *See infra* Sections X.C.1.b and X.C.3.c.

[651] *See infra* Section X.C.2.a for a discussion of compliance costs associated with the proposed amendments to Regulation ATS.

[652] *See infra* Section X.C.2.a.i for a discussion of compliance costs for Currently Exempted Government Securities ATSs.

[653] *See infra* Section X.C.2.b for a discussion of compliance costs associated with the proposed amendments to Regulation SCI.

[654] *See supra* note 653.

costs from the proposed amendments. A Government Securities ATS could incur indirect costs if its competitive position in the market were adversely affected as a result of the public disclosure requirement of Form ATS–G. However, such costs to one ATS would constitute transfers to other ATSs rather than a net social cost, and the Commission believes that the risk of such transfers is likely to be low.[655] Furthermore, as discussed in Section X.C.2.a.ii, some subscribers of a Government Securities ATS could incur indirect costs if the subscribers were to lose their informational advantage regarding the operational facets of the ATS over other subscribers as a result of the public disclosure requirement of Form ATS–G.

The Commission believes that the amendments could foster competition for order flow in the market for government securities and repo execution services, help market participants make better informed decisions about where to send their orders to achieve their trading or investment objectives, enhance execution quality, and improve efficiency and capital allocation. Moreover, the Commission believes that the risk of the proposed amendments adversely affecting competition in the market for government securities and repo execution services, the incentive for Government Securities ATSs to innovate, and the efficiency with which market participants achieve trading objectives, is likely to be low.[656]

In addition to the economic effects discussed below, the proposed amendment to Exchange Act Rule 3a1–1(b) would require a Government Securities ATS to register as a national securities exchange if the ATS meets certain volume thresholds and the Commission finds that the exemption would not be necessary or appropriate in the public interest or consistent with the protection of investors.[657] The Commission believes that the proposed amendment to Exchange Act Rule 3a1–1(b) would enhance the Commission's ability to regulate certain large volume ATSs upon registration as a national securities exchange, which would improve the Commission's market surveillance and help protect investors.[658] A Government Securities ATS that the Commission required to register as a national securities exchange would incur costs corresponding with a registered national securities exchange, including costs related to the requirement to be so organized to, and have the capacity to carry out the purposes of the Exchange Act including its own ability to enforce member compliance with securities laws.[659]

The Commission has attempted, where possible, to quantify the benefits and costs anticipated to result from the proposed amendments to Regulation ATS and Regulation SCI.

However, as explained in more detail below, because the Commission does not have, and in certain cases does not believe it can reasonably obtain data that may inform the Commission on certain economic effects, the Commission is unable to quantify certain economic effects. Further, even in cases where the Commission has some data, it may not be practicable to perform a quantitative analysis due to the number and type of assumptions necessary to quantify certain economic effects, which likely would render any such quantification unreliable. Therefore, certain parts of the discussion below are qualitative in nature and focus on the direction of the various effects of the proposed amendments. The inability to quantify certain benefits and costs, however, does not mean that the overall benefits and costs of the final rules are insignificant.

1. Benefits

The Commission assessed the anticipated economic benefits from the various components of the proposed amendments to Regulation ATS and SCI. The Commission believes that the proposed amendments to Regulation ATS would help improve the oversight of Government Securities ATSs[660] by the Commission and SROs. The extension of Regulation ATS to include Currently Exempted Government Securities ATSs would help protect investors and help the Commission better oversee these ATSs. In addition, the public disclosure of operational facets of Government Securities ATSs via Form ATS–G under Rule 304 of Regulation ATS could lower search costs in the selection of trading venues and result in lower trading costs for market participants. Requiring Form ATS–G to be filed on EDGAR in a structured format would improve the usability, accessibility, and reliability of Form ATS–G disclosures for market participants and for the Commission and SROs; EDGAR filing requirements for Forms ATS and ATS–R, along with other amendments related to Forms ATS, ATS–R, and ATS–N, would similarly enhance Commission and SRO oversight of Form ATS, ATS–R, and ATS–N filers, thereby protecting investors and helping ensure the adequacy and reliability of information on the market. To the extent that there are market participants excluded from trading on Government Securities ATSs, the Commission believes that the extension of the Fair Access Rule for government securities could increase trading venue options and lower trading costs for those market participants. Finally, the Commission believes the proposed amendments to Regulation SCI would help prevent interruptions in the price discovery process and liquidity flows, and thus would help prevent periods with pricing inefficiencies from occurring.[661]

a. Extension of Regulation ATS to Currently Exempted Government Securities ATSs and Amendment to Regulation ATS for All Government Securities ATSs

The proposed extension of Regulation ATS would extend Regulation ATS to include Currently Exempted Government Securities ATSs; extend Rule 304 of Regulation ATS to include all Government Securities ATSs and amend Rule 304; and apply the Fair Access Rule. Each of these changes would produce a number of benefits.

i. Extension of Regulation ATS To Include Currently Exempted Government Securities ATSs

The Commission believes that the proposed amendments to require Currently Exempted Government Securities ATSs to comply with certain provisions of Regulation ATS would help protect investors and enhance the oversight of Currently Exempted Government Securities ATSs by the Commission and SROs.

The Commission believes that requiring Currently Exempted Government Securities ATSs to adopt written safeguards and written procedures to protect subscribers' confidential trading information and to

[655] *See infra* Section X.C.2.a.ii for a discussion about transfer cost and why the Commission believes the risk of incurring such transfer cost is likely to be low.

[656] *See infra* Section X.C.3.

[657] The Commission estimates that currently, there is no Government Securities ATS that meets the volume thresholds specified in the provisions of Exchange Act Rule 3a1–1(b). *See supra* Section II.A.

[658] *See* Regulation ATS Adopting Release, *supra* note 35, at 70903–07 for a discussion of benefits and costs for registering as a national securities exchange.

[659] *See supra* note 658.

[660] Government Securities ATSs account for significant portion of interdealer and overall volume in the government securities market. *See supra* note 641.

[661] *See infra* Section X.C.1.b. *See also supra* Section X.B.6.

separate ATS functions from other broker-dealer functions would help prevent the potential for abuse of subscriber confidential trading information. The trading information of subscribers to Currently Exempted Government Securities ATSs could be subject to the same potential abuse as at other ATSs, such as sharing confidential subscriber trading information with other customers or the operator of the ATS using the confidential trading information of other subscribers to advantage its own trading on the ATS. The Commission, however, lacks information on the extent to which the confidential trading information of subscribers to Currently Exempted Government Securities ATSs is currently being abused.[662] Nonetheless, the Commission believes that the establishment of written safeguards and written procedures to separate Currently Exempted Government Securities ATS system functions from other broker-dealer functions, including principal trading, and to limit access to subscribers' confidential trading information to those employees of the ATS who are operating the system or are responsible for its compliance with applicable rules would help protect investors by reducing the chance that a subscriber's confidential information is accessed or shared inappropriately.

The Commission believes that requiring Currently Exempted Government Securities ATSs to comply with the recordkeeping and reporting requirements of Regulation ATS would improve the Commission's ability to monitor Currently Exempted Government Securities ATSs and improve its oversight of the market for government securities execution services. Each quarter, a Currently Exempted Government Securities ATS would be required to file a confidential Form ATS–R with the Commission, which would include transaction volume statistics, the identity of participants on the ATS, and the securities traded on the ATS. This information would allow the Commission to better monitor the types of investors that trade on these ATSs and the role they play in the government securities and repo market.[663]

The requirement for a Currently Exempted Government Securities ATS to keep and preserve records of subscribers to the ATS, daily summaries of trading in the ATS, and time-sequenced records of order information in the ATS would help create a meaningful audit trail of activities on the ATS. The preserved records of customer orders and transactions are expected to improve the ability of the Commission or an SRO to detect and investigate potential irregularities that might occur in the market for government securities and repos, which would help promote a fair and orderly market for government securities.

The Commission believes that the extension of Regulation ATS to include bank-operated Currently Exempted Government Securities ATSs would improve transaction transparency, which would enhance the Commission's or SRO's market surveillance and help protect investors.[664] In addition, the improvement in transaction transparency could facilitate price discovery and price formation. Under the proposal, bank-operated Currently Exempted Government Securities ATSs would be required to register as broker-dealers and become members of an SRO and report transactions in government securities to TRACE,[665] which FINRA would publicly disseminate. This would result in the transaction reporting and public dissemination of government securities transactions executed by bank-operated Currently Exempted Government Securities ATSs, which are currently not reported to TRACE. The Commission believes that the improvement in transaction transparency could facilitate market surveillance by the Commission and FINRA and help protect investors and enhance price discovery and price formation.[666] The Commission believes that the magnitude of benefits from the increase in transaction transparency depends on the portion of transactions executed by the bank-operated Currently Exempted Government Securities ATSs, which are currently not reported to TRACE.[667] However, the Commission is unable to estimate the magnitude of this benefit because the Commission does not have transaction data executed by the estimated one bank-operated Currently Exempted Government Securities ATS that exists, which would not be subject to transaction reporting obligations.

ii. Extension of Rule 304 of Regulation ATS To Include All Government Securities ATSs and Amendments to Rule 304

The Commission believes that the proposed extension of Rule 304 to Currently Exempted Government Securities ATSs and Legacy Filers would enhance the regulatory oversight of and the operational transparency of Government Securities ATSs, which account for significant trading volume of government securities,[668] and also could lower search costs, reduce trading costs, and improve the quality of order execution for market participants. Furthermore, the Commission believes that requiring Covered ATSs [669] to post their Forms ATS–N and Forms ATS–G on their websites would help facilitate public access to the forms for market participants who may use Form ATS–N or Form ATS–G to obtain information regarding operational facets of an ATS or to compare ATSs in the selection of trading venues.[670]

First, the Commission believes that the information disclosed in Form ATS–G, and the ability of the Commission to declare Form ATS–G ineffective, would improve the quality of information the Commission receives and significantly enhance the Commission's knowledge of the operations of Government Securities ATSs, the activities of its broker-dealer operator and its affiliates, and its safeguards and procedures to protect the confidential trading information of subscribers. Based in part on the Commission's experience with Form ATS–N for NMS Stock ATSs, the Commission believes that extending Rule 304 to include all Government Securities ATSs would result in better regulatory oversight of these ATSs and help protect investors.[671] Second, the Commission believes that the proposed public disclosure of Form ATS–G would enhance the operational transparency of all Government Securities ATSs.[672] Similar to Form ATS–N for NMS Stock ATSs, the Commission believes that Form ATS–G would provide market participants in the government securities markets with more uniform

[662] Although the Commission currently lacks this information, we describe above a potential scenario where the confidential trading information of a subscriber could be impermissibly shared with the personnel of the broker-dealer operator or any of its affiliates, and the broker-dealer operator, in turn, could potentially abuse that relationship to provide itself or its affiliates with a direct competitive advantage over that subscriber. *See supra* Section III.B.6.

[663] *See supra* Section X.A for a discussion about the need for greater transparency and public data availability regarding the functioning of U.S. Treasury markets.

[664] *See supra* note 662.

[665] *See supra* note 50.

[666] *See supra* note 662.

[667] *See supra* Section IX.D.1.

[668] *See supra* note 643.

[669] Covered ATSs as defined in the proposed rule currently would include 26 Government Securities ATSs and 34 NMS Stock ATSs if the proposed rule were in effect today. *See supra* note 95. *See also supra* Section II.B.

[670] *See* Rule 304(b)(3)(ii).

[671] *See supra* note 663.

[672] *See id.*

information regarding how orders are handled and any potential conflicts of interest that may arise from the ATS-related activities of the broker-dealer operator or its affiliates. The Commission believes that there is currently limited publicly available information regarding the operations of Government Securities ATSs and that some subscribers of a Government Securities ATS may be privy to more detailed information about how their orders are executed, sent and/or prioritized than other subscribers. The Commission believes that the proposed public disclosure of Form ATS–G would help equalize information distribution among market participants, lower search costs, and assist market participants in selecting a Government Securities ATSs for their orders, which could lower their trading costs and improve the quality of their order execution.

The Commission believes that the increase in amount, and the improvement in quality, of information regarding Government Securities ATSs via Form ATS–G filings would help improve the regulatory oversight of the ATSs and help protect investors. Form ATS–G would improve the amount and quality of information the Commission receives regarding Government Securities ATSs because Form ATS–G would require Government Securities ATSs to disclose more detailed information regarding their operations than Form ATS does for Legacy Filers. For Currently Exempted Government Securities ATSs, the Commission would receive this detailed information about how those systems operate for the first time. For example, compared to Form ATS, Form ATS–G requires detailed information regarding the types of orders offered, how they interact and match, and how customer order flow is segmented. Form ATS–G would require Government Securities ATSs to report on the activities of the broker-dealer operator and its affiliates in connection with the ATS, which Form ATS does not require. The Commission's recent experience with Form ATS–N informs this belief. Since February 2019, the Commission has reviewed initial Form ATS–N filings and amendments thereto and engaged in direct conversation with all NMS Stock ATSs about their Form ATS–N filings. When new NMS Stock ATSs seek to begin operations, the initial Form ATS–N provides the Commission with detailed information about how the ATS will operate. With this knowledge, the Commission is better able to oversee compliance and evaluate how NMS Stock ATSs as a group are evolving. The Commission believes that similar information disclosed in proposed Form ATS–G would also help make the examination process of Government Securities ATSs more effective and efficient, improving the ability of the Commission and the ATS's SRO to examine for compliance with the federal securities laws.

The Commission believes that the Commission's process to declare Form ATS–G ineffective that is set forth in the proposed amendments would help ensure the quality of information disclosed in Form ATS–G, which would improve the efficiency in the regulatory oversight of Government Securities ATS, with attendant benefits to market participants who utilize Form ATS–G. The Commission's review of Form ATS–G would not be merit-based; instead, it would focus on the completeness and comprehensibility of the disclosures.[673] The proposed amendments would provide a process for the Commission to declare a Form ATS–G ineffective if the form contained material deficiencies with respect to, among other things, its accuracy, currency, or completeness.[674] The Commission believes that the process would incentivize Government Securities ATSs to file accurate, current, and complete public disclosures about their operations and accordingly would improve the quality of information disclosed by the ATSs as compared to the information currently filed on Form ATS by Legacy Filers. In the Commission's experience, working with NMS Stock ATSs on their Form ATS–N filings has helped ensure that such disclosures are complete and comprehensible. Many NMS Stock ATSs have opted to seek the Commission staff's input about pending material amendments prior to filing, which has contributed to clearer and more effective disclosures.

The Commission believes that the public disclosure of Form ATS–G could lower search costs, reduce trading costs, and improve the quality of order execution for market participants.[675] Specifically, the Commission believes that requiring detailed public disclosures about the operations of Government Securities ATSs would, among other things, better standardize the type of information market participants receive about those operations including how orders are handled, fee structures, or any potential conflicts of interest that may arise from the activities of the broker-dealer operator or its affiliates. Based on the Commission's experience with its review of initial Form ATS–N filings, the Commission believes that Form ATS–G would result in more standardized public information about Government Securities ATSs. As a result, search costs for market participants could be lower, as consistent disclosure requirements for all Government Securities ATSs as part of the proposed amendments to Regulation ATS should facilitate market participants' comparison of Government Securities ATSs when deciding which venue best suits their trading purposes. The Commission believes the enhanced operational transparency resulting from the public disclosures of Form ATS–G would aid market participants when evaluating potential trading venues, which could lower their trading costs and improve the quality of their order execution. Furthermore, based on the Commission's experience, fees can be a primary factor for market participants in deciding where to send their orders.[676] Fee disclosures on proposed Form ATS–G would help market participants compare and analyze the fee structures across Government Securities ATSs in an expedited manner and decide which ATS offers them the best pricing according to the characteristics of their order flow and the type of participant they are, which would lower their search costs and trading costs.

However, the Commission is unable to quantify these benefits to market participants because the Commission lacks data on the amount of information that is currently available to different market participants regarding Government Securities ATS operations and the activities of its broker-dealer operators and their affiliates. The magnitude of the anticipated benefits discussed above would also depend on a number of factors, including the extent to which market participants would change their behavior as a result of

[673] *See supra* note 166. To emphasize that the Commission is not conducting a merit-based review of Form ATS–G disclosures filed with the Commission, the Commission is proposing to include a legend on the Form ATS–G cover page stating that the Commission has not passed upon the merits or accuracy of the disclosures in the filing. *See supra* Section III.A.1.

[674] A Government Securities ATS would not qualify for the exemption from the definition of ''exchange'' unless its Form ATS–G becomes effective.

[675] The proposed Rule 304(b)(3)(i) would require Government Securities ATSs to make Form ATS–G public via posting on their websites a direct URL hyperlink to the Commission's website that contains their Form ATS–G filing. The proposed Rule 304(b)(3)(ii) would require all Covered ATSs (26 Government Securities ATSs and 34 NMS Stock ATSs) to make the most recently disseminated Covered Forms (Form ATS–G and Form ATS–N) public via posting the forms on their websites. *See supra* Section II.B for the definition of the terms ''Covered ATS'' and ''Covered Form.'' *See also supra* note 95.

[676] *See supra* Section III.C.19.

receiving the public disclosure of more comprehensive and uniform information of this type in Form ATS–G. It is inherently difficult to predict how different market participants will use the information contained in Form ATS–G in evaluating and choosing the Government Securities ATSs that best serve their trading objectives.

With respect to the filing location and format of Form ATS–G, the Commission believes requiring all Government Securities ATSs to file Form ATS–G on the EDGAR system in a structured, machine-readable custom eXtensible Markup Language (''custom XML'') format would benefit market participants by improving the usability, accessibility, and reliability of the Form ATS–G disclosures.[677] By requiring a structured format and a publicly accessible filing location for Form ATS–G, the Commission would enable market participants to download the disclosed information directly into their databases and analyze the information using various tools and applications. This would make it easier for market participants to aggregate the information and compare multiple Government Securities ATSs to help select the venue that best suits their trading purposes, thereby potentially avoiding the cost of paying a third party data vendor to extract and structure the disclosed information on their behalf.

The Commission also believes requiring all Government Securities ATSs to submit Form ATS–G in a custom XML format would facilitate more effective and thorough review and analysis of Government Securities ATSs by the Commission, which should yield greater insights into the operations of Government Securities ATSs and the activities of their operators and affiliates. Additionally, Commission staff would be better able to assemble and review a larger pool of data regarding Government Securities ATSs. The Commission believes that both of these outcomes would benefit market participants by facilitating the Commission's examination process and thus would help protect investors and ensure the sufficiency of information in the market related to Government Securities ATSs.

Requiring all Government Securities ATSs to file Form ATS–G on EDGAR would benefit market participants by ensuring that the Form ATS–G disclosures are in a centralized, publicly accessible filing location with validation capabilities. Providing a centralized filing location would prevent market participants from incurring additional costs to locate and retrieve different Forms ATS–G from different filing locations. Similarly, because EDGAR is a publicly accessible system, an EDGAR requirement would prevent market participants from incurring additional costs that would arise if an operator or other party were to place any barriers to access Form ATS–G (such as a website registration requirement). Because EDGAR provides basic validation capabilities, an EDGAR requirement would reduce the incidence of non-discretionary errors on Forms ATS–G, thereby improving the quality of Form ATS–G disclosures.

iii. Application of Fair Access Rule to Government Securities ATSs

The Commission believes that the proposed application of the Fair Access Rule could increase trading venue options available to market participants who are currently excluded, which could lower their trading costs, to the extent that there are market participants currently excluded from trading on Government Securities ATSs that meet the specified volume thresholds. The Commission believes that requiring Government Securities ATSs that meet the volume thresholds to establish and objectively apply fair access standards could help prevent certain market participants from being denied access to an ATS that trades a significant portion of the market for U.S. Treasury Securities and Agency Securities, to the extent there are any such market participants. Denials of access are of particular concern when an ATS captures a significant percentage of trading volume in a particular type of securities. The Commission also believes that Form ATS–R information regarding fair access grants, denials, and limitations of access to Government Securities ATSs would improve the Commission's ability to oversee those ATSs to evaluate for compliance with the Fair Access Rule.

Under the proposal, if a Government Securities ATS meets the fair access volume thresholds, the ATS would be required to apply the same access standards to all persons in a subscriber group. As a result, for example, there would be a mechanism to prevent a Government Securities ATS that met the volume threshold from unreasonably denying access to one hedge fund while granting access to another similar hedge fund. The Commission believes that to the extent there are any market participants currently excluded from trading on Government Securities ATSs, the proposed change would address any unreasonable exclusion practices by Government Securities ATSs that have a significant market share, which would increase trading platform options and lower trading costs for previously excluded market participants.

b. Extension of Regulation SCI to Government Securities ATSs

The Commission believes the proposed amendments to Regulation SCI would promote the establishment of more robust systems that are less likely to experience a system disruption by requiring Government Securities ATSs that meet the definition of SCI entity to establish and enforce written policies and procedures to ensure that their SCI systems have adequate levels of capacity, integrity, resiliency, availability, and security to maintain the SCI entity's operational capability.[678] The Commission believes that the proposed extension of Regulation SCI could help strengthen the infrastructure and improve the resiliency of the automated systems of Government Securities ATSs that are important to the government securities markets. The Commission expects requiring Government Securities ATSs that meet certain volume thresholds to comply with Regulation SCI could help prevent system issues from occurring and reduce the severity and duration of any effects when such issues do occur. The Commission believes that this would help facilitate the price discovery process and liquidity flows in government securities market. Price discovery in the secondary market for on-the-run U.S. Treasury Securities is important because the transaction prices of on-the-run U.S. Treasury Securities are used as risk-free rate benchmarks to price other securities transactions.[679]

The Commission also believes that the requirement for a Government Securities ATS that would be an SCI ATS to establish procedures to disseminate information about SCI events to responsible SCI personnel, ATS participants, and the Commission would help reduce the duration and severity of any system distributions that do occur.[680] The procedures would improve the ability of such an ATS to quickly provide the affected parties with critical information in the event that it experiences a system disruption. This

[677] *See supra* Section IV. The custom XML format requirement would be specified in the EDGAR Filer Manual and in the Instructions to Form ATS–G. *See* Instruction A.5 to proposed Form ATS–G.

[678] *See supra* Section VI.

[679] As noted in the October 15 Staff Report, *supra* note 14, price discovery is especially important in the secondary market for on-the-run U.S. Treasury Securities because the transaction prices are used as risk-free rate benchmarks to price other securities transactions.

[680] *See supra* note 678.

could allow the affected parties to respond more quickly and appropriately to the incident, which could help shorten the duration and reduce the effects of a system event. Additionally, the Commission believes that the requirement for a Government Securities ATS that meets the definition of SCI ATS to conduct testing of its business continuity and disaster recovery plans with its designated participants and other industry SCI entities would help detect and improve the coordination of responses to system issues that could affect multiple trading venues and participants in the government securities and repo market.[681] This testing should help prevent these system disruptions from occurring and help reduce the severity of their effects, if they do occur.

As discussed in Section X.B.6, one Government Securities ATS operated by a broker-dealer operator of an NMS Stock ATS that is a SCI entity could already have utilized some of the policies and procedures of the NMS Stock ATS required by Regulation SCI and modified them as needed for systems related to trading of U.S. Treasury Securities and Agency Securities.[682] However, the Commission believes that imposing the requirements of Regulation SCI on systems related to trading of U.S. Treasury Securities and Agency Securities could further strengthen these policies and procedures, which would help improve the robustness of SCI systems and SCI indirect systems.

c. Amendments to Rule 301(b)(2), Form ATS, Form ATS–R, and Form ATS–N

The Commission believes that the proposed amendments to modernize Form ATS and Form ATS–R would enhance the efficiency of the Commission in overseeing ATSs as well as the efficiency of filing Forms ATS and ATS–R for ATSs. Such amendments would apply to all ATSs that file Form ATS and/or Form ATS–R. Requiring an ATS to specify the type of amendment on Form ATS and to provide the cessation date, which is not currently required, would better enable the Commission to determine whether an ATS is in compliance with Regulation ATS.

The Commission believes that the proposed amendments to Form ATS–R would help facilitate the Commission's review and provide the Commission with more specificity for all categories of securities that ATSs trade. The Commission believes that requiring the ATS to indicate whether it was subject to the Fair Access Rule during any portion of the period covered by the report would facilitate the Commission's review of Form ATS–R submissions. The Commission believes that this change would help the Commission facilitate compliance with the trading volume-based thresholds for the Fair Access Rule and Regulation SCI.[683] The Commission believes that updating the descriptions of certain categories of securities for which volume is required to be reported on Form ATS–R by an ATS would reduce potential confusion for an ATS when completing Form ATS–R and would enable an ATS to reflect more accurately its trading activities during the applicable reporting period.[684] Furthermore, adding new Item 4K of Form ATS–R would result in consistent reporting of the total dollar volume of transactions in repurchase or reverse repurchase agreements that ATSs trade. New Item 5C of Form ATS–R would provide the Commission with information regarding the types of securities subject to repurchase or reverse repurchase agreements reported in Item 4K of Form ATS–R. The Commission believes that adding new Item 5D would provide the Commission with more specific information about the types of options (equity options and options on government securities) that each ATS trades, which would help enhance the regulatory oversight of ATSs.

The Commission is also proposing to require Forms ATS and ATS–R, which are currently required to be sent to the Commission in paper form, to be filed on EDGAR.[685] All ATSs subject to Regulation ATS are required to file a Form ATS–R, and, as proposed, all ATSs that do not trade NMS stocks or government securities would file a Form ATS. As discussed above, requiring forms to be filed on EDGAR would provide a centralized filing location with validation capabilities for submitted filings.[686] The Commission believes that an EDGAR requirement would also increase filing efficiencies for ATSs by removing the need to print and mail paper versions of Forms ATS and ATS–R.

The Commission is also proposing several revisions to Form ATS–N, including: deletion of a checkbox requiring NMS Stock ATSs to indicate whether they currently operate pursuant to a Form ATS; addition of a requirement to indicate whether the registered broker-dealer has been authorized by its national securities association to operate an ATS; deletion of signature block language that refers to the signatory as ''duly sworn''; and changes to the Form's definitions of ''Person'' (to reflect the Exchange Act definition, not the Advisers Act definition) and ''NMS Stock ATS'' (to reflect the proposed changes to Rule 300).[687] Certain of these proposed changes represent technical clarifications that are unlikely to materially impact the disclosures on Form ATS–N, but would facilitate the preparation and filing of Form ATS–N. With respect to the proposed requirement for Form ATS–N filers to indicate whether the registered broker-dealer has been authorized by its SRO to operate an ATS, the Commission believes this would benefit market participants by facilitating the Commission's oversight of an NMS Stock ATS operator's compliance with SRO rules (including the need to obtain approval to operate an ATS), thereby likely decreasing the incidence of non-compliance with those rules.

2. Costs

Government Securities ATSs would incur both initial implementation and ongoing compliance costs due to the proposed amendments to Regulation ATS and Regulation SCI. In addition, market participants in the government securities and repo market could face higher trading costs (*e.g.,* higher fees) from Government Securities ATSs, to the extent that compliance costs from Regulation ATS and Regulation SCI amendments are passed on to market participants. The Commission estimates that Government Securities ATSs would incur the following approximate aggregate PRA compliance costs and FINRA membership related costs associated with the proposed amendments to Regulation ATS.[688]

[681] *See id.*

[682] *See supra* Section X.B.6 for a discussion of Government Securities ATSs of existing SCI entities.

[683] *See supra* Sections II.D and VI.

[684] *See supra* Section V.C for a discussion of the proposal to replace the names of the securities categories, ''Nasdaq National Market Securities'' and ''Nasdaq SmallCap Market Securities,'' reported in Items 4 and 6 of Form ATS–R, with ''Nasdaq Global Market Securities'' and ''Nasdaq Capital Market Securities,'' respectively.

[685] *See supra* note 308.

[686] *See supra* Section X.C.1.a.ii.

[687] *See supra* Section V.D.

[688] The Commission is unable to estimate costs associated with FINRA rules, such as FINRA examination and surveillance, trade reporting obligations, and certain investor protection rules, for the bank-operated Currently Exempted Government Securities ATS. *See infra* Section X.C.2.a.i for a discussion about compliance costs associated with FINRA rules for the bank-operated Currently Exempted Government Securities ATS. Furthermore, to comply with the Fair Access Rule,

TABLE X.5—REGULATION ATS

Regulation ATS	Aggregate initial costs	Aggregate annual costs
i. Regulation ATS for Currently Exempted Government Securities ATSs [689]	[690] $344,000	[691] $156,000
ii. Rule 304 for all Government Securities ATSs [692]	[693] 1,194,000	[694] 514,000
iii. Rule 301(b)(2) and Forms ATS and ATS–R [695]	[696] 1,800	[697] 46,000
iv. Fair Access Rule [698]		[699] 25,000

The Commission also believes that Government Securities ATSs with significant volume in U.S. Treasury Securities or Agency Securities would incur the following approximate aggregate PRA and non-PRA compliance costs associated with Regulation SCI:

TABLE X.6—REGULATION SCI

Regulation SCI [700]	Aggregate initial costs	Aggregate annual costs
PRA costs [701]	$1,631,000	$2,413,000.
Non-PRA costs [702]	960,000 ~ $7.2 million	640,800 ~ $4.8 million.

In addition to compliance costs, some market participants could experience indirect costs from the proposal. For example, a Government Securities ATS could incur indirect costs if its competitive position in the market were adversely affected as a result of the public disclosure requirement of Form ATS–G. However, such costs to one ATS would constitute transfers to other ATSs rather than a net social cost, and the Commission believes that the risk of such transfers is likely to be low.[703]

a. Extension of Regulation ATS to Currently Exempted Government Securities ATSs and Amendment to Regulation ATS for All Government Securities ATSs

The proposed extension of Regulation ATS would generate a number of costs for Currently Exempted Government Securities ATSs and Legacy Filers associated with extending Regulation ATS to include Currently Exempted Government Securities ATSs; extending Rule 304 of Regulation ATS to include all Government Securities ATSs and amending Rule 304; and applying the Fair Access Rule.[704]

i. Extension of Regulation ATS To Include Currently Exempted Government Securities ATSs

The Commission estimates that, together, 7 Currently Exempted Government Securities ATSs would incur the aggregate initial PRA costs of approximately $27,000 [705] and the

the Commission recognizes that Government Securities ATSs could incur non-PRA compliance costs (*e.g.,* costs associated with changing fee structures and adapting the operating model to grant access to market participants), for which the Commission is unable to provide cost estimates. *See infra* Section X.C.2.a.iii for a discussion about non-PRA compliance costs associated with the Fair Access Rule for Government Securities ATSs.

[689] The Commission estimates 7 Currently Exempted Government Securities ATSs would be subject to the proposed amendments to Regulation ATS. *See also supra* Section IX.C.

[690] This cost includes the approximate initial cost of $275,000 for registering as a broker-dealer with the Commission and becoming a FINRA member for 1 estimated bank-operated Currently Exempted Government Securities ATS to comply with Rule 301(b)(1). *See also infra* Section X.C.2.a.i for a discussion of the initial cost of registering as a broker-dealer with the Commission via Form BD and becoming a FINRA member for a bank-operated Currently Exempted Government Securities ATS to comply with Rule 301(b)(1).

[691] This cost includes the approximate ongoing annual cost of $50,000 for registering as a broker-dealer with the Commission and maintaining FINRA membership for 1 estimated bank-operated Currently Exempted Government Securities ATS to comply with Rule 301(b)(1). *See also infra* Section X.C.2.a.i for a discussion of the ongoing annual cost of registering as a broker-dealer with the Commission via Form BD and becoming a FINRA member for a bank-operated Currently Exempted Government Securities ATS to comply with Rule 301(b)(1).

[692] The Commission estimates 26 Government Securities ATSs would be subject to the proposed amendments to Regulation ATS. *See also supra* Section IX.C.

[693] This cost does not include the aggregate initial PRA costs associated with Rule 304(b)(3)(ii) for 34 NMS Stock ATSs. *See infra* Section X.C.2.a.ii for a discussion about the aggregate initial PRA costs to comply with the proposed amendments to Rule 304 of Regulation ATS. *See also infra* notes 726 and 728.

[694] This cost does not include the aggregate ongoing annual PRA costs associated with Rule 304(b)(3)(ii) for 34 NMS Stock ATSs. *See infra* Section X.C.2.a.ii for a discussion about the aggregate ongoing annual PRA costs to comply with the proposed amendments to Rule 304 of Regulation ATS. *See also infra* notes 727 and 729.

[695] The Commission estimates 1 bank-operated Currently Exempted Government Securities ATS would initially be required to file a Form ID to gain access to EDGAR as a result of the proposed amendments. *See also supra* Section IX.D.2.b.iv. In addition, the Commission notes that it is proposing changes to Form ATS–N to delete a question related to legacy status, and to include a checkbox asking if the registered broker-dealer is authorized by a national securities association to operate an ATS; the Commission believes that because this information should be readily available to a filer and requires only marking a checkbox, this would not impose additional monetary costs above the baseline for Form ATS–N filers. *See also supra* note 520.

[696] *See infra* Section X.C.2.c for a discussion about the aggregate initial PRA costs to comply with the proposed amendments to Rule 301(b)(2), Form ATS, and Form ATS–R.

[697] *See infra* Section X.C.2.c for a discussion about the aggregate ongoing annual PRA costs to comply with the proposed amendments to Rule 301(b)(2), Form ATS, and Form ATS–R.

[698] The Commission estimates 3 Government Securities ATSs would be subject to the Fair Access Rule. *See also supra* Section IX.D.3.

[699] *See infra* Section X.C.2.a.iii for a discussion about the aggregate ongoing annual PRA costs to comply with the Fair Access Rule.

[700] The Commission estimates 3 Government Securities ATSs would be subject to Regulation SCI. *See also supra* Section IX.D.5. The costs tabulated in this table do not include costs for market participants interacting with SCI entities (*e.g.,* third-party vendors providing SCI systems and/or indirect SCI systems to SCI entities, members or participants of SCI entities participating in testing of business continuity and disaster recovery plans). *See also infra* Section X.C.2.b.

[701] These cost estimates are based on the 2018 SCI PRA Extension. *See* 2018 SCI PRA Extension, *supra* note 529. *See also supra* Section IX.D.5 discussing PRA burden estimates related to compliance with Regulation SCI.

[702] *See infra* note 767. *See also infra* Section X.2.b and Regulation SCI Adopting Release, *supra* note 2, at 72416.

[703] *See infra* Section X.C.2.a.ii for a discussion about transfer costs and why the Commission believes the risk of incurring such transfer costs is likely to be low.

[704] *See supra* Section X.C.2 for a discussion and table regarding the summary of PRA compliance costs associated with the proposed amendments to Regulations ATS.

[705] $27,146 (estimated aggregate initial cost of compliance with Rule 301(b)(10) for 7 Currently Exempted Government Securities ATSs). *See infra* note 719. The Commission estimates the wage rate associated with these burden hours based on salary information for the securities industry compiled by SIFMA. The estimated wage figure for attorneys, for

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aggregate ongoing annual PRA costs of approximately $77,000 [706] to comply with the applicable rules of Regulation ATS (other than the costs to comply with Rule 304, which are discussed below).[707] In addition, the Commission estimates that 1 bank-operated Currently Exempted Government Securities ATS would incur the additional initial costs of approximately $275,000 [708] and the ongoing annual costs of approximately $50,000 [709] to register as a broker-dealer with the Commission via Form BD and become a member of FINRA under the proposed Rule 301(b)(1).[710]

Currently Exempted Government Securities ATSs would incur ongoing annual PRA costs to comply with recordkeeping requirements of Rules 302 and 303 of Regulation ATS.[711] Currently Exempted Government Securities ATSs would also incur ongoing annual PRA costs associated with filing information required by Form ATS–R with the Commission each quarter to comply with Rule 301(b)(9). The requirements to establish written safeguards and procedures to protect the confidential trading information of ATS subscribers under Rules 301(b)(10) and 303(a)(1)(v) would impose one-time initial PRA costs on Currently Exempted Government Securities ATSs. In addition, Currently Exempted Government Securities ATSs would incur ongoing annual PRA costs to update and preserve the written safeguards.

Table X.7 tabulates initial and ongoing annual PRA costs associated with Rules 302, 303, 301(b)(9), 301(b)(10), and 303(a)(1)(v):

Burden	Initial PRA costs	Annual PRA costs
Recordkeeping under Rule 302	N/A	*Per ATS:* $3,195,[712] *Industry:* $22,365.[713]
Recordkeeping under Rule 303	N/A	*Per ATS:* $1,065,[714] *Industry:* $7,455.[715]
Filing Form ATS–R under Rule 301(b)(9)	N/A	*Per ATS:* $5,817,[716] *Industry:* $40,719.[717]
Written safeguards and procedures under Rules 301(b)(10) and 303(a)(1)(v).	*Per ATS:* $3,878,[718] *Industry:* $27,146 [719]	*Per ATS:* $988,[720] *Industry:* $6,916.[721]

The Commission believes that Currently Exempted Government Securities ATSs that are banks (*i.e.,* bank-operated Currently Exempted Government Securities ATSs) would incur additional compliance costs related to registering with the Commission as broker-dealers, which entails becoming members of an SRO, such as FINRA, compared to those not operated by banks. In addition, as members of FINRA, bank-operated Currently Exempted Government Securities ATSs would incur costs related to FINRA examination and surveillance, trade reporting obligations, and certain investor protection rules.[722] It is the Commission's understanding that bank-operated Currently Exempted Government Securities ATSs may adopt a structure where the ATS is operated by a bank affiliate that is a registered broker-dealer, rather than by the bank itself.[723] In this case, the bank affiliates operating ATSs would be required to register as broker-dealers with the Commission via Form BD and become members of an SRO under the proposed Rule 301(b)(1). The Commission estimates that 1 bank-operated Currently Exempted Government Securities ATS would register as a broker-dealer with the Commission via Form BD and

example, is based on published rates for attorneys, modified to account for a 1,800 hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead yielding an effective hourly rate for 2013 of $380 for attorneys. *See* Securities Industry and Financial Markets Association, Management & Professional Earnings in the Securities Industry—2013, *available at https://www.sifma.org/resources/research/managementand-professional-earnings-in-the-securitiesindustry-2013/.* These estimates are adjusted for an inflation rate of 11.34 percent based on the Bureau of Labor Statistics data on CPI–U between October 2013 and May 2020. Therefore, the current inflation adjusted effective hourly wage rates for attorneys are estimated at $423 ($380 × 1.1134). We discuss other costs of compliance with the proposed rules below.

[706] $22,365 (estimated aggregate ongoing cost of compliance with Rule 302 for 7 Currently Exempted Government Securities ATSs) + $7,455 (estimated aggregate ongoing cost of compliance with Rule 303 for 7 Currently Exempted Government Securities ATSs) + $40,719 (estimated aggregate ongoing cost of compliance with Rule 301(b)(9) for 7 Currently Exempted Government Securities ATSs) + $6,916 (estimated aggregate ongoing cost of compliance with Rule 301(b)(10) for 7 Currently Exempted Government Securities ATSs) = $77,455. For an explanation of each of these costs, *see infra* notes713, 715, 717, and 721. Costs of compliance with Rule 301(b)(5), as applicable, are discussed below. *See infra* note 757.

[707] These aggregated compliance costs associated with the PRA include the costs to comply with Rule 301(b)(1), Rule 301(b)(2), Rule 301(b)(9), Rule 301(b)(10), Rule 302, and Rule 303(a)(1)(v). These aggregated compliance costs associated with the PRA do not include the compliance costs associated with Rule 301(b)(2)(viii), Rule 304 of Regulation ATS, the Fair Access Rule, and Regulation SCI.

[708] The Commission estimates that 1 bank-operated Currently Exempted Government Securities ATS would incur the aggregate initial cost for registering as a broker-dealer with the Commission via Form BD and becoming a FINRA member under Rule 301(b)(1) of approximately $275,000. *See also infra* note 724.

[709] The Commission estimates that 1 bank-operated Currently Exempted Government Securities ATS would incur the aggregate ongoing cost associated with Form BD and maintaining FINRA membership under Rule 301(b)(1) of approximately $50,000. *See also infra* note 725.

[710] *See supra* note 429 and accompanying text for hourly burden. The initial PRA costs would be: Compliance Manager at $315 × 2.75 hours × 1 estimated bank-operated Currently Exempted Government Securities ATS = $866.25. *See supra* note 430. The ongoing annual PRA costs would be: (Compliance Manager at $315 × 0.33 hours) × 3 amendments × 1 estimated bank-operated Currently Exempted Government Securities ATS = $311.85. *See supra* note 432.

[711] Rule 301(b)(8) would require Currently Exempted Government Securities ATSs to comply with the requirements of Rules 302 and 303 of Regulation ATS. Legacy Filers already comply with Rules 302 and 303 of Regulation ATS. *See also supra* Section IX.D.1.b.

[712] Compliance Clerk at $71 × 45 hours = $3,195. *See supra* note 434. This burden is equal to the Commission's estimate of the annual costs that a Legacy Filer currently bears for fulfilling the requirements of Rule 302.

[713] $3,195 × 7 Currently Exempted Government Securities ATSs = $22,365.

[714] Compliance Clerk at $71 × 15 hours = $1,065. *See supra* note 436. This burden is equal to the Commission's estimate of the annual costs that a Legacy Filer currently bears for fulfilling the requirements of Rule 303.

[715] $1,065 × 7 Currently Exempted Government Securities ATSs = $7,455.

[716] (Attorney at $423 × 12 hours) + (Compliance Manager at $315 × 1 hour) + (Compliance Clerk at $71 × 6 hours) = $5,817. *See supra* note 438. This burden is equal to the burden that Legacy Filers bear for complying with Rule 301(b)(9). *See supra* Section IX.D.1.c.

[717] $5,817 × 7 Currently Exempted Government Securities ATSs = $40,719.

[718] (Attorney at $423 × 9 hours) + (Compliance Clerk at $71 × 1 hour) = $3,878. *See supra* note 443.

[719] $3,878 × 7 Currently Exempted Government Securities ATSs = $27,146.

[720] (Attorney at $423 × 2 hours) + (Compliance Clerk at $71 × 2 hours) = $988. *See supra* note 445. This burden is equal to the Commission's estimate of the annual costs that a Legacy Filer currently bears to comply with the rule under the proposal.

[721] $988 × 7 Currently Exempted Government Securities ATSs = $6,916.

[722] *See supra* notes 108–110.

[723] *See supra* Section II.C for a discussion of bank-operated Currently Exempted Government Securities ATS. Because a bank-operated Government Securities ATS could comply with the proposed requirements by, for example, restructuring so that an existing affiliate operates the ATS, the Commission does not consider costs that would be associated with creating a new bank-affiliated entity to be part of the incremental costs of the proposal.

become a member of an SRO under the proposed Rule 301(b)(1).

The Commission estimates an initial cost of approximately $275,000 to register as a broker-dealer with the Commission via Form BD and become a member of FINRA.[724] Additionally, the Commission estimates an ongoing annual cost of approximately $50,000 to maintain the broker-dealer registration with the Commission and FINRA membership.[725] The Commission believes that these costs related to broker-dealer registration and FINRA membership are relevant primarily to bank-operated Currently Exempted Government Securities ATSs. However, these estimates are uncertain because the Commission does not have information on the estimated 1 bank-operated Currently Exempted Government Securities ATS, such as the number of registering persons, profitability, the degree of reliance on outside legal or consulting costs necessary for effectively completing the application to be a member of FINRA, and the current sample size of one may be too small to be a reliable indicator of industry costs. For example, the initial registration costs for FINRA membership is higher for entities with a larger number of associated persons being registered. The ongoing costs to remain a FINRA member vary based on the profitability and the size (*i.e.,* the number of registered persons and the number of branch offices) of the entity. Furthermore, the Commission is unable to provide estimated costs related to FINRA examination and surveillance, trade reporting obligations, and certain investor protection rules because these costs are based on compliance with FINRA rules. The costs associated with FINRA examination and surveillance, trade reporting obligations, and certain investor protection rules may depend on various factors, such as the costs of updating systems for trade reporting requirements and the costs of complying with FINRA rules (including drafting policies and procedures as may be required for the bank-operated Currently Exempted Government Securities ATS), for which the Commission does not have information. The Commission invites comments on costs that a bank-operated Government Securities ATS could incur in relation to FINRA membership, FINRA examination and surveillance, trade reporting, and certain investor protection rules.

ii. Extension of Rule 304 of Regulation ATS To Include All Government Securities ATSs and Amendments to Rule 304

The Commission estimates that all 26 Government Securities ATSs would incur the aggregate initial PRA costs of approximately $1,143,000[726] to complete Form ATS–G and to make Form ATS–G public. The Commission estimates that all 26 Government Securities ATSs would incur the aggregate ongoing annual PRA costs of approximately $331,000[727] to amend their Forms ATS–G. In addition, the Commission estimates that some Legacy Filers would incur PRA costs associated with amending Form ATS and filing Form ATS–R. As discussed below, the Commission estimates that 17 Legacy Filers would incur the aggregated initial PRA costs of approximately $51,000[728] for amending Form ATS and the aggregated ongoing annual PRA costs of approximately $183,000[729] for amending Form ATS and Form ATS–R. Furthermore, the Commission estimates that 34 NMS Stock ATSs would incur the aggregated initial and ongoing annual PRA costs of approximately $39,000[730] and $118,000,[731] respectively, to make the most recently disseminated Forms ATS–N public via posting on the ATSs' websites. The Commission also believes that some subscribers of Government Securities ATSs could incur indirect costs resulting from the public disclosure requirement of Form ATS–G.

The proposed amendments to Regulation ATS would impose PRA costs on all Government Securities ATSs in that they would require Government Securities ATSs to adhere to heightened disclosure and reporting requirements regarding their operations. The Commission expects the PRA costs of the proposed amendments to be incremental relative to the PRA costs associated with the existing requirements. Specifically, the Commission believes that the incremental PRA costs would consist largely of providing new disclosures and updating records and retention policies necessary to comply with the proposed amendments. The Commission estimates that all 26 Government Securities ATSs would need to comply with the proposed amendments to Regulation ATS relating to Rules 301(b)(2)(viii) and 304, which require the filing of proposed Form ATS–G. Some of the information requests on Form ATS–G would be applicable to only Government Securities ATSs that meet the applicable volume thresholds.[732] This would result in the aggregate initial PRA cost of $1,097,773 for all Government Securities ATSs to complete Form ATS–G and comply with proposed Rules 301(b)(2)(viii) and 304 of Regulation ATS.[733]

[724] *See* Exchange Act Release No. 33–9974 (October 30, 2015), 80 FR 71388, 71509 (November 16, 2015) (''Regulation Crowdfunding Adopting Release''). In addition to the initial costs to become a member of FINRA, this cost includes the paperwork related initial costs of $866.25 for filing Form BD with the Commission. *See also supra* note 708.

[725] In addition to the ongoing annual costs to maintain a membership with FINRA, this cost includes the costs of paperwork related ongoing annual costs of $311.85 to amend Form BD with the Commission. *See supra* note 709. *See also* Regulation Crowdfunding Adopting Release, *supra* note 724, at 71509.

[726] $1,097,773 (estimated aggregate initial cost associated with completing Form ATS–G required by Rule 301(b)(2)(viii) and Rule 304 for 26 Government Securities ATSs) + $15,028 (estimated aggregate initial cost associated with making public posting on ATS's website of direct URL hyperlink to the Commission's website that contains Form ATS–G, as required by Rule 304(b)(3)(i) for 26 Government Securities ATSs) + $30,056 (estimated aggregate initial cost associated with making public posting on ATS's website of the most recently disseminated Form ATS–G, as required by Rule 304(b)(3)(ii) for 26 Government Securities ATSs) = $1,142,857. *See also infra* notes 733, 747, and 749.

[727] $241,129 (estimated aggregate ongoing cost associated with amending Form ATS–G required by Rule 301(b)(2)(viii) and Rule 304 for 26 Government Securities ATSs) + $90,168 (estimated aggregate ongoing cost associated with making public posting on ATS's website of the most recently disseminated Form ATS–G, as required by Rule 304(b)(3)(ii) for 26 Government Securities ATSs) = $331,297. *See also infra* notes 735 and 749.

[728] $50,966 (estimated aggregate initial cost associated with amending Form ATS, as required by Rule 301(b)(2)(viii) for 17 Legacy Filers). *See also infra* note 742.

[729] $69,547 (estimated aggregate ongoing cost associated with amending Form ATS required by Rule 301(b)(2)(viii) for 17 Legacy Filers) + $113,271 (estimated aggregate ongoing cost associated with amending Form ATS–R, as required by Rule 301(b)(9) for 17 Legacy Filers) = $182,818. *See also infra* notes 733 and 744.

[730] $39,304 (estimated aggregate initial cost associated with making public posting on ATS's website of the most recently disseminated Form ATS–N, as required by Rule 304(b)(3)(ii) for 34 NMS Stock ATSs). *See also infra* note 749.

[731] $117,912 (estimated aggregate ongoing cost associated with making public posting on ATS's website of the most recently disseminated Form ATS–N, as required by Rule 304(b)(3)(ii) for 34 NMS Stock ATSs). *See also infra* note 749.

[732] *See supra* Section IX.D.2.b.i.

[733] Aggregate costs to complete Part I of Form ATS–G: (Compliance Clerk at $71 × 0.75 hours) × 26 Government Securities ATSs = $1,384.50 (*see supra* note 473). Aggregate costs to complete Part II of Form ATS–G: ((Attorney at $423 × 18.5 hours) + (Compliance Manager at $315 × 9.5 hours) + (Sr. Systems Analyst at $289 × 1 hour) + (Sr. Marketing Manager at $311 × 2 hours)) × 26 Government Securities ATSs = $304,954 (*see supra* note 475). Aggregate costs to complete Part III items applicable to all respondents: ((Attorney at $423 × 19.5 hours) + (Compliance Manager at $315 × 26.2 hours) + (Sr. Systems Analyst at $289 × 26.55 hours) × 26 Government Securities ATSs = $628,535 (*see supra* note 477). Aggregate costs to complete Part III, Item 24(a): ((Attorney at $423 × 2 hours) + (Compliance Manager at $315 × 1 hour) + (Sr. Systems Analyst

Continued

In addition to the initial PRA costs mentioned above, Government Securities ATSs would also incur ongoing PRA costs to comply with the proposed amendments to Rule 3a1–1(a) and Regulation ATS. For instance, Government Securities ATSs would incur ongoing PRA costs associated with amending their Form ATS–G prior to material changes in their operations, or to correct any information that has become inaccurate. Regardless of the reason for filing a Form ATS–G amendment, the Commission estimates that a Government Securities ATS would incur approximately $9,274 to prepare and file its Form ATS–G amendments.[734] This would result in the aggregate ongoing annual PRA cost of $241,129 for all Government Securities ATSs to amend their Forms ATS–G and comply with proposed Rules 301(b)(2)(viii) and 304 of Regulation ATS.[735]

Requiring Form ATS–G to be filed on EDGAR would impose only a minimal cost, at most, on Government Securities ATSs. The Commission believes requiring proposed Form ATS–G to be filed on EDGAR would impose the aggregate initial PRA cost of approximately $47 for 1 bank-operated Currently Exempted Government Securities ATS,[736] and the aggregate ongoing annual PRA costs of approximately $47 for 1 new Government Securities ATS per year that may be operated by an entity without prior access to EDGAR.[737] Because all Legacy Filers are operated by registered broker-dealers, there would be no burden associated with gaining access to EDGAR for Legacy Filers.[738] The Commission estimates that 1 Currently Exempted Government Securities ATS is operated by a bank, not a registered broker-dealer; as such, there would be a total cost of approximately $47 associated with gaining access to EDGAR (assuming the bank operator is not subject to other EDGAR filing requirements).[739]

Requiring Form ATS–G to be filed in a custom XML format would not impose any incremental costs on filers as compared to an unstructured format such as HTML. All Government Securities ATSs would be given the option of filing Form ATS–G using a web-fillable form that will render into XML in EDGAR, or to file directly in XML using the custom XML schema for ATSs as published on the Commission's website.[740] Given the availability of the web-fillable form, the XML requirement would not impose upon any Government Securities ATS the need to license XML-based filing preparation software or establish XML-based filing processes.

Some existing broker-dealers that operate ATSs that transact in securities other than government securities or repos in addition to operating the Government Securities ATSs might incur additional costs to comply with the proposed amendments. Pursuant to the proposed amendments to Regulation ATS, a Government Securities ATS could not trade securities other than government securities or repos.[741] Accordingly, broker-dealers that operate an ATS that currently trades government securities and repos and securities other than government securities or repos, would incur additional PRA costs compared to a Currently Exempted Government Securities ATS, which only trades government securities or repos, because the former would be required to file both an initial Form ATS–G and amend their Form ATS. The Commission estimates that 17 Legacy Filers would need to file an initial Form ATS–G in regard to their trading activity in government securities or repos and an amendment to a Form ATS to remove references to government securities or repos and that the aggregate initial PRA cost for those ATSs to file would be $823,288[742] and that the aggregate ongoing annual PRA cost to file an amendment to Form ATS and initial Form ATS–G would be $227,208.[743] Furthermore, the broker-dealers operating these Government Securities ATSs would also be required to file a pair of Forms ATS–R four times annually. The Commission estimates that the aggregate ongoing annual PRA cost of filing two Forms ATS–R for broker-dealers that operate one ATS that trades government securities or repos and a second ATS that trades securities other than government securities and repos would be $113,271.[744]

A Government Securities ATS would incur costs associated with programming and website configuration to make Form ATS–G public via posting on its website a direct URL hyperlink to the Commission's website that contains its Form ATS–G filing, as required by Rule 304(b)(3)(i).[745] The Commission estimates that the initial one-time PRA cost would be approximately $578[746] per Government Securities ATS and the aggregate PRA cost for all Government Securities ATSs would be approximately $15,028.[747] Furthermore, all Covered ATSs (26 Government Securities ATSs and 34 NMS Stock ATSs) would incur costs associated with programming and website

at $289 × 2 hours)) × 3 ATSs subject to the requirement = $5,217. Aggregate costs to complete Part III, Item 24(b): (Attorney at $423 × 2 hours) + (Compliance Manager at $315 × 1 hour) + (Sr. Systems Analyst at $289 × 2 hours)) × 1 ATS subject to the requirement = $1,739. ($1,385 (Part I) + $304,954 (Part II) + $628,535 (Part III items applicable to all filers) + $5,217 (Part III, Item 24(a)) + $1,739 (Part III, Item 24(b)) + $155,896 (baseline) + $47 (access to EDGAR) = $1,097,773 total aggregate costs.

[734] *See supra* note 483. (Attorney at $423 × 16.5 hours) + (Compliance Manager at $315 × 6 hours) + (Compliance Clerk at $71 × 5.7 hours) = $9,274.2.

[735] 28.2 total hours (*see supra* note 484) × 26 Government Securities ATSs = 733.2 hours. $9,274.20 × 26 Government Securities ATSs = $241,129.

[736] (Compliance Manager at $315 × 0.15 hours) × 1 bank-operated Currently Exempted Government Securities ATS = $47.25. *See supra* note 509. This cost is reflected in the aggregate initial costs discussed earlier in this section.

[737] (Compliance Manager at $315 × 0.15 hours) × 1 new Government Securities ATS = $47.25. *See supra* note 509. This cost is reflected in the aggregate ongoing annual costs discussed earlier in this section.

[738] *See supra* Section IX.C.

[739] (Compliance Manager at $315 × 0.15 hours) × 1 bank-operated Currently Exempted Government Securities ATS = $47.25. *See supra* notes 515 and 516.

[740] *See supra* Section IV. This reflects the current filing methods for Form ATS–N.

[741] *See* proposed Rule 300(l).

[742] The Commission estimates that the total hourly burden for a broker-dealer to separately file an amended Form ATS for the non-Government Securities ATS and initial Form ATS–G for the Government Securities ATS would be 10 burden hours to amend its initial operation report on Form ATS for its trading activity related to securities other than NMS stock and government securities or repos, and approximately 134 burden hours to file its initial Form ATS–G. *See also supra* notes 497 and 501. ((Attorney at $423 × 61.5 hours) + (Compliance Manager at $315 × 37.7 hours) + (Sr. Systems Analyst at $289 × 31.55 hours) + (Sr. Marketing Manager at $311 × 2 hours) + (Compliance Clerk at $71 × 11.25 hours)) × 17 Legacy Filers that would continue to file a Form ATS = $823,288. Of $823,288, the cost of $50,966 is attributable to the aggregate initial costs for amending Form ATS to remove references to government securities or repos for 17 Legacy Filers.

[743] The Commission estimates that a broker-dealer operator that operates an ATS that currently trades government securities or repos and securities other than government securities or repos would face an annual burden of 13 hours to file amendments to Form ATS and 28.2 hours to file amendments to Form ATS–G. *See also supra* notes 498 and 499. ((Attorney at $423 × 25.5 hours) + (Compliance Manager at $315 × 6 hours) + (Compliance Clerk at $71 × 9.7 hours)) × 17 Legacy Filers that would continue to file a Form ATS = $227,208. Of $227,208, the cost of $69,547 is attributable to the aggregate ongoing costs to amend Form ATS for 17 Legacy Filers.

[744] The Commission estimates that a broker-dealer would face a total burden of 5.25 hours to prepare two Form ATS–Rs. *See supra* note 500. ((Attorney at $423 × 14 hours) + (Compliance Manager at $315 × 1 hour) + (Compliance Clerk at $71 × 6 hours)) × 17 Legacy Filers that would continue to file a Form ATS = $113,271.

[745] NMS Stock ATSs are already required to comply with Rule 304(b)(3)(i). *See supra* Section IX.D.2.b.v.

[746] *See supra* Section IX.D.2.b.v.

[747] (Sr. Systems Analyst at $289 × 2 hours) × 26 Government Securities ATSs = $15,028.

configuration to make the most recently disseminated Forms ATS–G and Forms ATS–N public via posting on their websites, as required by Rule 304(b)(3)(ii).[748] The Commission estimates that the initial PRA cost would be $1,156 per Covered ATS and $69,360 for all Covered ATSs and that the ongoing annual PRA cost would be $3,468 per Covered ATS and $208,080 for all Covered ATSs.[749]

Under the proposal, when a Government Securities ATS ceases operations, it would be required to file a cessation of operations on Form ATS–G. Currently Exempted Government Securities ATSs are not required to notify the Commission when they cease operations. If a Currently Exempted Government Securities ATS were to cease operations, the Commission estimates that each Currently Exempted Government Securities ATS would incur a one-time PRA cost of $670 to prepare and file a cessation of operations on Form ATS–G with the Commission.[750] The Commission also estimates that one new Government Securities ATS would file a Form ATS–G per year[751] and make the Form ATS–G public by posting a direct URL hyperlink on its website to the Commission's website,[752] resulting in the PRA cost of $47,264.[753]

Regardless of their size and transaction volume, all Government Securities ATSs would need to ensure that their disclosures meet the requirements of proposed Form ATS–G and that they correctly file their Form ATS–G. Government Securities ATSs may develop internal processes to ensure correct and complete reporting on Form ATS–G, which would result in a fixed setup PRA cost. These PRA costs may fall disproportionately on smaller Government Securities ATSs in terms of PRA costs relative to transaction volume (as opposed to larger Government Securities ATSs in terms of PRA costs relative to transaction volume), because all Government Securities ATSs would be likely to incur these fixed PRA costs. However, smaller Government Securities ATSs that are not operated by multi-service broker-dealer operators and that generally do not engage in other brokerage or dealing activities in addition to their ATSs would likely incur lower PRA costs because certain sections of proposed Form ATS–G would not be applicable to these Government Securities ATSs.

The PRA costs could also vary across Government Securities ATSs depending on the complexity of the ATS and the services that it offers. For example, some Government Securities ATSs may not segment subscriber order flow or offer counter-party selection protocols. These ATSs would not be required to complete Part III, Items 13 and 14 of proposed Form ATS–G. As a result, such Government Securities ATSs could incur lower PRA costs because these ATSs would apply lesser burden hours to complete their Form ATS–G.

In addition to the PRA compliance costs discussed above, the Commission believes that the proposed ability for the Commission to be able to declare a Form ATS–G or Form ATS–G amendment ineffective would generate direct costs for Government Securities ATSs.[754] If the Commission declares a Government Securities ATS's Form ATS–G or Form ATS–G amendment ineffective, then the ATS might have to cease operations, roll back a change in operations, or delay the start of operations until it is able to address the deficiencies in the previously filed form by filing a new Form ATS–G or Form ATS–G amendment. An ineffective Form ATS–G filing could also impose indirect costs on the overall market for government securities execution services resulting from a potential reduction in competition or the removal of a sole provider of a niche service within the market.[755]

However, the Commission believes that there would not be a substantial burden imposed in connection with resubmitting Form ATS–G or a Form ATS–G amendment for these entities or from an ineffective declaration in general. Because Government Securities ATSs and market participants would not incur these costs unless the Commission declares a Form ATS–G or amendment ineffective, Government Securities ATSs would be incentivized to comply with the requirements of Form ATS–G, as well as federal securities laws, including the other requirements of Regulation ATS, to avoid an ineffectiveness declaration. The Commission believes that these incentives would encourage Government Securities ATSs to initially submit a more accurate and complete Form ATS–G and amendments, which would reduce the likelihood that they are declared ineffective.

Additionally, currently operating Government Securities ATSs would not have to bear the costs of immediately ceasing operations under the proposal without having an effective Form ATS–G on file with the Commission because Legacy Filers would be able to continue operations pursuant to a previously filed initial operation report on Form ATS and Currently Exempted Government Securities ATSs would also be able to continue operations pending the Commission's review of its initial Form ATS–G. However, if after notice and opportunity for hearing, the Commission declares an initial Form ATS–G filed by a Legacy Filer or Currently Exempted Government Securities ATS ineffective, the ATS would be required to cease operations. The Government Securities ATS would then have the opportunity to address deficiencies in the previously filed form by filing a new initial Form ATS–G.

The proposed amendments could generate indirect costs for some subscribers by causing Government Securities ATSs to stop sharing information that they might currently offer to only some subscribers, but the Commission believes that this risk could be low because ATSs could have a commercial incentive to continue disclosing it. Form ATS–G would require Government Securities ATSs to publicly disclose any platform-wide order execution metrics that they share with any subscriber. In order to avoid publicly disclosing this information, an ATS could stop sharing the information with subscribers. The trading costs of subscribers that currently use this information to help make trading decisions could increase if the information is no longer available to them. The Commission believes that the risk of ATSs disclosing less information than they currently do depends on several factors, such as the commercial purpose for releasing such information. If the subscribers that receive such information demand the information as

[748] *See supra* Section IX.D.2.b.v.

[749] For all Covered ATSs, the aggregate initial cost would be: (Sr. Systems Analyst at $289 × 4 hours) × (26 Government Securities ATSs + 34 NMS Stock ATSs) = $30,056 (estimated aggregate initial costs for 26 Government Securities ATSs) + $39,304 (estimated aggregate initial costs for 34 NMS Stock ATSs) = $69,360. *See supra* note 512. For all Covered ATSs, the aggregate ongoing cost would be: (Sr. Systems Analyst at $289 × 12 hours) × (26 Government Securities ATSs + 34 NMS Stock ATSs) = $90,168 (estimated aggregate ongoing costs for 26 Government Securities ATSs) + $117,912 (estimated aggregate ongoing costs for 34 NMS Stock ATSs) = $208,080. *See supra* note 513.

[750] Currently Exempted Government Securities ATSs are currently not required to notify the Commission when they cease operations. (Attorney at $423 × 1.5 hours) + (Compliance Clerk at $71 × 0.5 hours) = $670. *See supra* note 490.

[751] *See supra* Section IX.C.

[752] *See supra* Section IX.D.2.b.v.

[753] (Attorney at $423 × 55 hours) + (Compliance Manager at $315 × 39.85 hours) + (Sr. Systems Analyst at $289 × 35.55 hours) + (Sr. Marketing Manager at $311 × 2 hours) + (Compliance Clerk at $71 × 7.75 hours) = $47,264.

[754] *See* Rule 304(a)(1)(iv)(B).

[755] *See infra* Section X.C.3.a.i.b for a discussion about the impact of a declaration of ineffectiveness on competition in the market for government securities and repo execution services.

a condition of subscribing, ATSs would have a commercial incentive to continue disclosing it.

The Commission also believes that the public disclosure of Form ATS–G could generate indirect costs, in the form of transfers, for some subscribers to Government Securities ATSs that might currently have more information regarding some ATS features, such as order priority and matching procedures, than other subscribers. The public disclosure of these features might reduce informed subscribers' information advantage over other subscribers on the Government Securities ATS and increase their trading costs. In this regard, the Commission recognizes that the benefit of the proposal enjoyed by some subscribers in receiving the proposed information may be seen as a cost by those subscribers who currently receive such information.

Some Government Securities ATSs could experience indirect costs from the public disclosure of Form ATS–G though the Commission believes these costs actually amount to transfers. To the extent that a Government Securities ATS in part relies on certain operational characteristics (*e.g.,* order types, trading functionalities) to attract customer order flow and generate trading revenues, it is possible that the public disclosure of these characteristics in Form ATS–G could make it easier for other trading venues to adopt the operational characteristics, which could lower trading volume and reduce revenue of the disclosing ATS. Such costs to the disclosing ATS would constitute transfers to competing ATSs rather than a net social cost. However, the Commission believes that the risk of such transfers may be low because it is not likely the responsive information to the proposed Form ATS–G would include information regarding operational facets such that the public disclosure of the information would adversely affect the competitive position of the disclosing ATS in the market for government securities and repo execution services.[756]

iii. Application of Fair Access Rule to Government Securities ATSs

The Commission estimates that three Government Securities ATSs would incur the aggregate ongoing annual PRA costs of approximately $25,000 [757] to comply with the proposed Fair Access Rule. In addition, the Commission believes that the proposed application of the Fair Access Rule to U.S. Treasury Securities and Agency Securities could impose non-PRA compliance costs on Government Securities ATSs and market participants could incur indirect costs resulting from Government Securities ATSs being subject to the Fair Access Rule.[758]

Government Securities ATSs that meet certain volume thresholds for U.S. Treasury Securities, Agency Securities, or both would incur costs to establish written standards for granting access to their systems.[759] The Commission estimates that three Government Securities ATSs would meet the volume thresholds that trigger the Fair Access Rule and that the average ongoing annual PRA cost of establishing written fair access standards for each entity would be $4,230.[760] Accordingly, the Commission estimates that the aggregate ongoing annual PRA cost for Government Securities ATSs to establish written fair access standards would be approximately $12,690.[761]

Government Securities ATSs that meet the fair access volume thresholds would incur costs to make and keep records of (1) all grants of access including, for all subscribers, the reasons for granting such access; and (2) all denials or limitations of access and reasons, for each applicant, for denying or limiting access. They would also incur costs to disclose on Exhibit C of Form ATS–R a list of all persons granted, denied, or granted limited access to the system during the relevant period.[762] The Commission estimates that the average ongoing annual reporting PRA cost for each Government Securities ATS that is subject to these requirements would be $4,230.[763] Thus, the Commission estimates that the aggregate ongoing annual PRA cost for three Government Securities ATSs to keep these records would be $12,690.[764]

The Commission believes the proposed extension of the Fair Access Rule to U.S. Treasury Securities and Agency Securities could impose non-PRA compliance costs on Government Securities ATSs. Under the proposal, Government Securities ATSs that meet the specified volume thresholds could no longer treat subscribers differently with respect to access to the services of the ATS without a reasonable basis. For example, a Government Securities ATS could not offer one class of subscriber a service (*e.g.,* an order interaction procedure, order type, or connectivity method) without offering the service to all subscribers unless the Government Securities ATS had a reasonable basis for the differential treatment. In addition, a Government Securities ATS could not charge fees that may unreasonably prohibit certain market participants from accessing the services of the ATS. To the extent that Government Securities ATSs must change fee structures or access and adapt their operating model due to the Fair Access Rule, those Government Securities ATSs would incur costs related to changing business operations.

The Commission, however, is unable to quantify the potential non-PRA compliance costs discussed above. In particular, the Commission lacks data on the extent to which Government Securities ATSs that meet the fair access volume thresholds currently grant access to the ATS services to all subscribers on the same terms, and on the specific types of services and subscribers in question. In addition, the Commission lacks similar data for other trading venues in the market for government securities that may offer differential access to services. Thus, the Commission is not able to estimate the costs associated with changing fee structures and adapting operating models. In turn, the Commission is not able to estimate the loss of revenues that Government Securities ATSs that meet the fair access volume thresholds could

[756] *See supra* note 196 and accompanying text.

[757] ((Attorney at $423 × 10 hours) × 3 Government Securities ATSs) + ((Attorney at $423 × 10 hours) × 3 Government Securities ATSs) = $25,380. *See supra* notes 518 and 519.

[758] In addition to the costs discussed here and in the following section about the extension of Regulation SCI to Government Securities ATSs, ATSs may incur costs to subscribe to, and program their internal systems to process, TRACE trade reports for Agency Securities. FINRA currently publishes the weekly aggregate volume data for U.S. Treasury Securities on which ATSs would base their fair access calculations for U.S. Treasury Securities. *See supra* Section II.D. But ATSs would need to subscribe to TRACE to obtain the trade reports necessary to calculate the threshold for Agency Securities. *See id.* The Commission believes that the vast majority—and likely, all—broker-dealer operators of Government Securities ATSs that trade Agency Securities currently subscribe to TRACE, however, the Commission is requesting comment on the extent to which Government Securities ATSs (both Currently Exempted Government Securities ATSs and those subject to current Regulation ATS) have access to TRACE trade reports for Agency Securities. *See supra* note 146.

[759] *See supra* Section IX.D.3 for a discussion of this proposal.

[760] Attorney at $423 × 10 hours = $4,230. *See supra* note 518. This cost is equal to the Commission's estimate for compliance with Rule 301(b)(5) because the requirements of the Fair Access Rule would be identical for Government Securities ATSs and ATSs that are currently subject to Rule 301(b)(5). *See* Rule 301 OMB Update, *supra* note 419, at 3238.

[761] $4,230 × 3 Government Securities ATSs = $12,690.

[762] The burdens associated with filing Form ATS–R are discussed above in Section IX.D.3.

[763] Attorney at $423 × 10 hours = $4,230. *See supra* note 519.

[764] 3 responses × 10 hours = 30 hours. $4,230 × 3 Government Securities ATSs = $12,690.

incur as a result of the proposed extension of the Fair Access Rule.

The Commission believes that market participants could incur indirect costs related to Government Securities ATSs being subject to the Fair Access Rule. Government Securities ATSs that are close to satisfying the volume thresholds for certain government securities could limit the trading in those government securities on their ATSs over some period to stay below the volume thresholds and avoid being subject to the Fair Access Rule. The order flow that was being executed on those Government Securities ATSs might be absorbed and redistributed amongst other Government Securities ATSs. If a Government Securities ATS that is the sole provider of a niche service limits the trading in certain government securities to avoid being subject to the Fair Access Rule, it could require some market participants to seek execution on other trading venues, which could result in higher trading costs.

b. Extension of Regulation SCI to Government Securities ATSs

The Commission estimates that three Government Securities ATSs (two Currently Exempted Government Securities ATSs and one Legacy Filer) that meet the specified volume thresholds would incur both PRA and non-PRA direct and indirect compliance costs as SCI entities. The Commission estimates that two Currently Exempted Government Securities ATSs would incur the aggregate initial PRA costs of approximately $1,305,000 and the aggregate ongoing annual PRA costs of approximately $1,609,000 to comply with Regulation SCI.[765] Furthermore, the Commission estimates that one Legacy Filer would incur the initial PRA costs of approximately $326,000 and the ongoing annual PRA costs of approximately $804,000 to comply with Regulation SCI.[766] The Commission also estimates that three Government Securities ATSs would incur the aggregate initial non-PRA costs of between approximately $960,000 and $7.2 million, and the aggregate ongoing annual non-PRA costs of between approximately $640,800 and $4.8 million to comply with Regulation SCI.[767] In addition, as discussed below, the Commission believes that the proposed amendments to Regulation SCI would impose indirect compliance costs on market participants interacting with SCI entities.

Under the proposal, the definition of SCI ATSs would be expanded to include Government Securities ATSs that meet certain volume thresholds for U.S. Treasury Securities and/or Agency Securities would be subject to the requirements of Regulation SCI. Because Regulation SCI imposes some indirect requirements on other market participants interacting with SCI entities (*e.g.,* third-party vendors providing SCI systems and/or indirect SCI systems [768] to SCI entities, members or participants of SCI entities participating in testing of business continuity and disaster recovery plans), those market participants would also incur indirect costs from Government Securities ATSs being defined as SCI entities. Also, market participants (including broker-dealers and institutional investors who use Government Securities ATSs) in the government securities and repo market may face increased trading costs (in the form of higher fees) from SCI entities, to the extent that increased compliance costs are passed on to market participants.

The Commission believes that the 2018 estimates of initial PRA burdens for new SCI entities and ongoing PRA burdens for all SCI entities under Regulation SCI are largely applicable to Government Securities ATSs.[769] The Commission believes that Government Securities ATSs could be divided into two groups: [770] Government Securities ATSs that are existing SCI entities; and Government Securities ATSs that are entirely new SCI entities currently not subject to Regulation SCI. For the first group (Government Securities ATSs that are existing SCI entities), the Commission believes that such entities would incur approximately 50 percent of the Commission's initial PRA burden estimates for an entirely new SCI entities. Furthermore, for the second group (Government Securities ATSs that are new SCI entities currently not subject to Regulation SCI), the Commission believes that such entities would incur the same estimated initial PRA burdens as those estimated for new SCI entities in the 2018 SCI PRA Extension. The Commission also believes that the same ongoing PRA burdens for all SCI entities estimated in the 2018 SCI PRA Extension are applicable to Government Securities ATSs in both the first and the second group.

Among the three Government Securities ATSs that satisfy the volume thresholds, the Commission believes that one Government Securities ATS (referred as the first group above) would incur approximately 50 percent of initial PRA burden estimates for an entirely new SCI entity included in the 2018 SCI PRA Extension, and two Government Securities ATSs (referred as the second group above) would incur the same estimated initial PRA burdens as those estimated for new SCI entities included in the 2018 PRA Extension. In addition, the Commission believes that all three Government Securities ATSs would incur the same ongoing PRA burdens as all other SCI entities included in the 2018 SCI PRA Extension.

Government Securities ATSs would also incur non-PRA direct compliance costs as SCI entities. The Regulation SCI Adopting Release in 2014 estimated that an SCI entity would incur an initial cost of between approximately $320,000 and $2.4 million. Additionally, an SCI entity would incur an ongoing annual cost of between approximately $213,600 and $1.6 million. The Commission believes that these non-PRA costs are largely applicable to Government Securities ATSs. However, the Commission is uncertain about the actual level of costs Government Securities ATSs would incur because these costs may differ from the types of SCI entities considered in the Regulation SCI Adopting Release, which did not include fixed income ATSs.[771] The Commission is also uncertain about the actual level of costs Government Securities ATSs would incur because the actual costs could differ based on various factors, such as

[765] These cost estimates are based on the 2018 SCI PRA Extension. *See* 2018 SCI PRA Extension, *supra* note 529. *See also supra* Section IX.D.5 discussing PRA burden estimates related to compliance with Regulation SCI.

[766] *See supra* note 765.

[767] Based on the Regulation SCI Adopting Release in 2014, the Commission estimates that a Government Securities ATS would incur an initial cost of between approximately $320,000 and $2.4 million. Thus, 3 Government Securities ATSs would incur the aggregate initial cost of between approximately $960,000 and $7.2 million. Additionally, a Government Securities ATS would incur an ongoing annual cost of between approximately $213,600 and $1.6 million. Thus, three Government Securities ATSs would incur the aggregate ongoing annual cost of between approximately $640,800 and $4.8 million. *See also* Regulation SCI Adopting Release, *supra* note 2, at 72416.

[768] The term ''indirect SCI systems'' is defined to mean ''any systems of, or operated by or on behalf of, an SCI entity that, if breached, would be reasonably likely to pose a security threat to SCI systems.'' *See* Regulation SCI Adopting Release, *supra* note 2.

[769] *See* 2018 SCI PRA Extension, *supra* note 529.

[770] We divide Government Securities ATSs into two groups in discussing PRA costs because Government Securities ATSs operated by a broker-dealer operator of an NMS Stock ATS that is a SCI entity would have lower initial PRA costs. *See also* 2018 SCI PRA Extension, *supra* note 529.

[771] *See* Regulation SCI Adopting Release, *supra* note 2. In the Regulation SCI Adopting Release, fixed income ATSs are excluded from the regulation.

complexity of SCI entities' systems and the degree to which SCI entities employ third-party systems. The Commission believes that Government Securities ATSs with relatively simpler systems would incur lower compliance costs compared to those with more complex systems.[772] Also, any SCI systems operated by a third-party on behalf of an SCI entity would be subject to the requirements of Regulation SCI. The Commission believes that Government Securities ATSs with higher dependency on SCI systems operated by third-party vendors could incur higher compliance costs compared to those with lower dependency on third-party systems.[773]

Additionally, the Commission believes that some Government Securities ATSs' participants required to participate in the testing of business continuity and disaster recovery plans would incur Regulation SCI-related connectivity costs of approximately $10,000 apiece.[774] To the extent that larger members or participants of SCI Government Securities ATSs already maintain connections to backup facilities including for testing purposes, the compliance costs associated with the business continuity and disaster recovery plans testing requirements in Rule 1004 for those larger member or participants could be limited.

The Commission believes that market participants could incur indirect costs related to compliance requirements for Government Securities ATSs as SCI entities. Government Securities ATSs that are close to satisfying the volume thresholds for certain government securities could limit the trading in those government securities on their ATSs over some period to stay below the volume thresholds and avoid being subject to Regulation SCI. The order flow that was being executed on those Government Securities ATSs might be absorbed and redistributed amongst other Government Securities ATSs. If a Government Securities ATS that is the sole provider of a niche service limits the trading in certain government securities to avoid being subject to Regulation SCI, it could require some market participants to seek execution on other trading venues, which could result in higher trading costs.

The Commission believes that the costs to comply with Regulation SCI discussed above would also fall on third-party vendors employed by Government Securities ATSs to provide services used in their SCI systems. The costs for third-party vendors imposed by Regulation SCI could depend on the extent to which Government Securities ATSs use third-party systems that fall under the definition of SCI systems and the portion of third-party vendors operating SCI systems on behalf of larger Government Securities ATSs already comply with the requirements of Regulation SCI. It is possible that some third-party vendors operating SCI systems on behalf of larger Government Securities ATSs that already complies with the requirements of Regulation SCI because they also operate the SCI systems for other SCI (*e.g.,* SCI ATSs, SCI SROs). The additional compliance costs from the proposed amendments of Regulation SCI for these third-party vendors would be minimal. However, at this time, it is difficult to estimate the cost for third-party vendors because the Commission does not know the extent to which Government Securities ATSs use third-party systems that fall under the definition of SCI systems.

c. Amendments to Rule 301(b)(2), Form ATS, Form ATS–R, and Form ATS–N

The proposal to amend Rule 301(b)(2) and Forms ATS and ATS–R would impose initial and ongoing annual PRA costs on all ATSs including Government Securities ATSs.[775] For the proposed amendments to Part I of Form ATS, the Commission estimates that Form ATS filers would incur aggregate PRA costs of approximately $1,800 for initial Form ATS filings, as well as aggregate annual PRA costs of approximately $3,600 for Form ATS amendments.[776] In addition, the proposed Form ATS–R amendment that would require filers to indicate the type of filing (and if applicable the date of cessation) and whether the ATS is subject to fair access obligations would impose aggregate annual PRA costs of approximately $11,800.[777] Furthermore, the proposed Form ATS–R amendment that would require additional details on Form ATS–R, such as total dollar volume in transactions in repos, would impose aggregate annual PRA costs of approximately $11,300.[778]

The proposal to require Forms ATS and ATS–R to be filed on EDGAR is not expected to impose any incremental costs on any Government Securities ATS. As discussed above, because all ATSs that are currently subject to Form ATS and ATS–R filing requirements (including Legacy Filers) are operated by registered broker-dealers, those ATSs would not incur any burden to gain access to EDGAR. Any new ATS entities that are not operated by a registered broker-dealer (including bank-operated Currently Exempted Government Securities ATSs) and do not otherwise have access to EDGAR would need to submit a Form ID and thus incur the estimated 0.15 hour burden in order to file Form ATS–G, and would consequently already have access to EDGAR when filing a Form ATS–R.[779] Beyond the cost of gaining access to EDGAR, the Commission does not expect that the EDGAR filing requirement would impose any incremental costs on any Form ATS and ATS–R filer (including Government Securities ATSs) with respect to ongoing filing requirements (such as quarterly reports on Form ATS–R or amendments to a Form ATS).

The proposed changes to Form ATS–N include a new requirement for NMS Stock ATSs to indicate via checkbox whether the broker-dealer operator of the NMS Stock ATS is authorized by a national securities association to operate an ATS. The Commission believes that because this information should be readily available to a filer and requires only marking a checkbox, the requirement would not impose any material additional costs relative to the current baseline.[780]

3. Efficiency, Competition, and Capital Formation

The Commission considered the effects of the amendments on efficiency, competition, and capital formation. The Commission believes that the amendments could foster competition for order flow in the market for government securities and repo

[772] *See id.* The Regulation SCI Adopting Release explains that compliance costs would depend on the complexity of SCI entities' systems and they would be higher for SCI entities with more complex systems.

[773] *See id.* The Regulation SCI Adopting Release discusses that compliance costs could in part depend on the extent to which an SCI entity utilize third-party systems because ensuring compliance of systems operated by a third-party with Regulation SCI may be more costly than ensuring compliance of internal systems with Regulation SCI.

[774] *See id.* The Regulation SCI Adopting Release estimated connectivity costs as part of business continuity and disaster recovery plans to be approximately $10,000 per SCI entity member or participant.

[775] *See supra* Section IX.D. The estimated aggregate ongoing annual PRA cost associated with filing Form ATS–R for 7 Currently Exempted Government Securities ATSs is reflected in the cost associated with Rule 301(b)(9) in *supra* note 706. The estimated aggregate ongoing annual PRA cost associated with filing Form ATS and Form ATS–R for 17 Legacy Filers is reflected in the cost associated with Rule 301(b)(2)(viii) and Rule 301(b)(9) in *supra* note 729. *See also supra* Section V.C.

[776] *See supra* notes 522 and 523. Compliance Clerk at $71 × 25.5 hours = $1810.50; Compliance Clerk at $71 × 51 hours = $3,621.

[777] *See supra* note 531. Compliance Manager at $315 × 37.6 hours = $11,844.

[778] *See supra* note 529. Compliance Manager at $315 × 36 hours = $11,340.

[779] *See supra* Sections IX.D.4 and X.C.2.a.ii.

[780] *See supra* Section V.D and note 520.

execution services, enhance the efficiency with which market participants achieve their trading objectives or investment objectives, and promote price efficiency and capital formation.

The Commission believes that the proposed amendments to Regulation ATS could promote competition in the markets for government securities and repo execution services. The Commission believes that the proposal to extend Regulation ATS to include Currently Exempted Government Securities ATSs would enable ATSs wishing to effect transactions in government securities or repos to compete for order flow on a more level competitive landscape with the same regulatory requirements.[781] The Commission also believes that the public disclosure of Form ATS–G could promote competition for order flow in the market for government securities and repo execution services via lowering fees and improving order handling procedures. Furthermore, greater competition for order flow could in turn incentivize Government Securities ATSs to innovate, including, in particular, in technology related to execution services to compete on execution services to attract more subscribers and order flow.

The Commission believes that the proposed amendments to Regulation ATS could enhance the efficiency with which market participants achieve their trading objectives. The Commission believes the proposed amendments to Regulation ATS would increase transparency regarding the operations of Government Securities ATSs and the activities of its broker-dealer operator and its affiliates and lower search costs for market participants in the selection of trading venues in the market for government securities and repos. Furthermore, the fair access requirements could increase trading venue options for market participants resulting in lower trading costs and better efficiency with which they achieve their trading objectives.

The Commission believes that extending Regulation SCI to include Government Securities ATSs with significant volume could promote price efficiency and capital formation. Extending Regulation SCI to include Government Securities ATSs could reduce the frequency, severity, and duration of such effects resulting from systems issues, thereby facilitating price discovery process in government securities and promote capital formation.[782]

As discussed in more detail below, the Commission believes that the risk of the proposed amendments adversely affecting competition in the market for government securities and repo execution services, the incentive for Government Securities ATSs to innovate, and the efficiency with which market participants achieve trading objectives, is likely to be low.

a. Competition

The Commission believes that the proposed amendments of Regulation ATS and Regulation SCI could affect competition for order flow and the decision of ATSs to enter or exit the market for government securities and repo execution services.[783]

i. Regulation ATS

The Commission believes that the proposed amendments to Regulation ATS could foster competition for order flow in the market for government securities and repo execution services. The proposed extension of Regulation ATS to include Currently Exempted Government Securities ATSs would enable ATSs wishing to effect transactions in government securities or repos to compete for order flow on a more level competitive landscape. The Commission believes that the public disclosure of Form ATS–G could promote competition and incentivize Government Securities ATSs to innovate. Furthermore, the Commission does not believe that allowing the Commission to declare Form ATS–G ineffective and PRA compliance costs imposed on Government Securities ATSs would result in significant adverse impact on competition in the market for government securities and repo execution services.

(a) Competitive Landscape

The Commission believes that the proposed extension of Regulation ATS to include Currently Exempted Government Securities ATSs would help eliminate a Government Securities ATS's competitive advantage or competitive disadvantage that may arise due to uneven regulatory requirements in the market for government securities and repo execution services. For example, Legacy Filers could be at a competitive disadvantage to Currently Exempted Government Securities ATSs, which do not currently incur compliance costs associated with the requirements of Regulation ATS.[784] Furthermore, due to reporting requirements of Regulation ATSs, it could be more difficult or costly for a Legacy Filer to implement significant operational changes to compete with Currently Exempted Government Securities ATSs if the Legacy Filer's competitive advantage is driven by operational facets that would be reported on Form ATS. The proposed extension of Regulation ATS would subject Currently Exempted Government Securities ATSs, bank-operated Currently Exempted Government Securities ATSs, and Legacy Filers to the same regulatory requirements.

(b) Declaration of Ineffectiveness

The proposal to allow the Commission to declare Form ATS–G and amendments to Form ATS–G ineffective could lead some Currently Exempted Government Securities ATSs and Legacy Filers to exit the market for government securities and repo execution services. However, based on the Commission's experience with NMS Stock ATSs that filed an initial Form ATS–N, the Commission believes this would be an unlikely result.[785] If the Commission declares an initial Form ATS–G or amendment ineffective, the Government Securities ATS would either have to cease operations[786] or, in the case of an amendment, roll back any changes it made and operate pursuant to its previous Form ATS–G that is effective until it is able to address the deficiencies and file a new Form ATS–

[781] *See supra* Section X.B.2 for discussion about the current regulatory requirements for bank-operated Currently Exempted Government Securities ATSs, Currently Exempted Government Securities ATSs, and Legacy Filers.

[782] *See infra* Section X.C.3.c for a discussion about the price discovery and price efficiency of U.S. Treasury Securities, risk-free rate benchmarks, pricing of risky securities, and capital formation. *See also* October 15 Staff Report, *supra* note 14, for a discussion about price discovery being especially important in the secondary market for on-the-run U.S. Treasury Securities because the transaction prices are used as risk-free rate benchmarks to price other securities transactions.

[783] *See supra* Section X.C.1.a for a discussion about benefits from the requirements of Regulation ATS and Section X.C.2.a for a discussion about costs of the requirements of Regulation ATS.

[784] Presently, Currently Exempted Government Securities ATSs, bank-operated Currently Exempted Government Securities ATSs, and Legacy Filers compete for order flow in the market for government securities and repo execution services on an uneven competitive landscape with different regulatory requirements. *See supra* Section X.B.2 for a discussion about the differences in regulatory requirements between Legacy Filers and Currently Exempted Government Securities ATSs under the current regulatory framework. *See also supra* Section I.B.

[785] Unlike the current rules applicable to NMS Stock ATSs under Rule 304 of Regulation ATS with respect to ineffectiveness, the Commission does not have a process to declare a Form ATS ineffective because of the quality of the disclosures and cause the ATS cease operating pursuant the exemption. *See* Rule 304(a)(1)(iv)(B).

[786] *See* Rule 304(a)(1)(iv)(B).

G that becomes effective.[787] Some broker-dealer operators of Legacy Filers may find that the costs of addressing deficiencies in Form ATS–G outweigh the benefits of continuing to operate the ATS, particularly if the ATS does not constitute a significant source of profit for a broker-dealer operator. The ability of the Commission to declare Form ATS–G ineffective could also raise barriers to entry for new Government Securities ATSs, as it could create uncertainty as to whether the Commission would declare its initial Form ATS–G effective or ineffective and as to the cost of avoiding an ineffective declaration. If a new Government Securities ATS's initial Form ATS–G is declared ineffective, it would require time and additional expenditures to address the deficiencies delaying the commencing of operations, which may deter some potential ATSs from operating in this space.

(c) Public Disclosure

The increase in transparency due to the public disclosure of Form ATS–G could foster greater competition for order flow in the market for government securities and repo execution services. The increase in competition could lower trading venue fees, improve the efficiency of order handling procedures, and promote innovation. For instance, because the public disclosure of Form ATS–G would make it easier for market participants to compare fees across Government Securities ATSs, market participants could choose to send their orders to ATSs that offer lower fees, and Government Securities ATSs may lower their fees to attract subscribers and compete for order flow. If non-ATS trading venues compete with Government Securities ATSs for trade execution services, the increased operational transparency of Government Securities ATSs could also incentivize non-ATS trading venues to reduce their fees to compete with Government Securities ATSs for order flow.

Because the public disclosure of Form ATS–G would make it easier for market participants to compare order handling procedures and execution statistics—if they are made available—across trading platforms,[788] market participants may be more likely to send their orders to ATSs that offer better execution services. Greater competition for order flow could in turn incentivize Government Securities ATSs to innovate, including, in particular, technology related to execution services to improve the quality of trade execution services and to compete on execution services to attract more subscribers and order flow.

The public disclosure of a Government Securities ATS's previously non-public information regarding innovative operational facets could adversely impact competition for order flow in the market for government securities and repo execution services and could also lower the incentives for Government Securities ATSs to innovate. However, the Commission believes that the risk of this is likely to be low. If the competitive advantage of a Government Securities ATS in the market is driven by certain operational innovations, the disclosure of this information could result in other competing Government Securities ATSs with similar operational platforms implementing similar methodologies, which could cause market participants to direct more order flow to those other Government Securities ATSs. This could potentially reduce the incentives for Government Securities ATSs to innovate if publicly disclosing new innovations results in the disclosing ATS earning less revenue from new innovations it develops. Furthermore, some Government Securities ATSs may choose to exit the market if their profitability declines. Fewer opportunities to profit from innovation could also raise barriers to entry for new Government Securities ATSs. However, the Commission believes that the risk of this may be low because it is not likely the responsive information to the proposed Form ATS–G would include information regarding operational facets such that the public disclosure of the information would adversely affect the competitive position of the disclosing Government Securities ATS in the market for government securities and repo execution services.[789]

(d) Compliance Costs

The Commission believes that the direct compliance costs associated with the amendments to Regulation ATS are generally represented by PRA costs.[790] The Commission does not believe that initial and ongoing PRA compliance costs associated with the amendments to Regulation ATS would have a significant adverse impact on competition in the market for government securities and repo execution services. If Government Securities ATSs find that PRA costs outweigh the benefits of operating a Government Securities ATS, these costs could act as a deterrent or a barrier to entry for potential ATSs wishing to effect transactions in government securities or could cause some Government Securities ATSs to exit the market for government securities or repo execution services. However, the Commission does not believe that the PRA costs imposed by the proposed amendments to Regulation ATS would be significant enough to make this a likely possibility.[791]

The Commission believes that the PRA compliance costs could have different effects on the rates at which small and large Government Securities ATSs may exit the market. The Commission believes that most of the estimated PRA costs are fixed costs, which all Government Securities ATSs may incur, regardless of the amount of trading activity that takes place on them. The PRA costs would represent a larger fraction of revenue generated for a small Government Securities ATS relative to that for a large Government Securities ATS.[792] This could adversely affect small Government Securities ATSs in competing against larger Government Securities ATSs and could lead to small ATSs exiting the market for government securities and repo execution services. However, smaller Government Securities ATSs that are not operated by multi-service broker-dealer operators are likely to incur lower PRA costs because certain sections of proposed Form ATS–G would not be applicable to these Government Securities ATSs.[793] The PRA costs could also vary across Government Securities ATSs depending on the complexity of the ATS and the services that it offers.[794] For example, some Government Securities ATSs may not segment subscriber order flow or offer counter-party selection protocols. These ATSs would not be required to complete Part III, Items 13 and 14 of proposed Form ATS–G. As a result,

[787] *See id.*

[788] *See supra* Section X.C.1.a.ii for a discussion about benefits from public disclosure via Form ATS–G.

[789] *See supra* note 196 and accompanying text.

[790] *See supra* Section X.C.2 for a discussion about compliance costs associated with the amendments to Regulation ATS. The effect of compliance costs associated with the extension of Regulation ATS to include the Currently Exempted Government Securities ATSs on competition is discussed in Section X.C.3.a.i.a. The effect of indirect costs associated with the declaration of ineffectiveness for Form ATS–G and the public disclosure of Form ATS–G on competition is discussed in Section X.C.3.a.i.b and X.C.3.a.i.c, respectively.

[791] *See supra* Sections X.C.2.a and X.C.2.c for discussions on the PRA costs associated with the amendments to Regulation ATS.

[792] *See supra* Section X.C.2.a.ii for a discussion about the impact of PRA costs for small Government Securities ATSs.

[793] *See supra* note 792.

[794] *See supra* Section X.C.2.a.ii for a discussion about PRA costs and the complexity of the ATS and the services that it offers.

such Government Securities ATSs could incur lower PRA costs because these ATSs would complete their Form ATS–G with fewer burden hours. To the extent that small Government Securities ATSs engage in providing simpler services, these small Government Securities ATSs are likely to incur lower compliance costs. Furthermore, to the extent that the Government Securities ATSs that decide to cease operating as ATSs due to this fixed PRA compliance cost only transact small dollar volume, the Commission does not believe that there would be a significant impact on the overall competitive structure for the remaining Government Securities ATSs. The order flow that was being executed on those small Government Securities ATSs may be absorbed and redistributed amongst those larger remaining Government Securities ATSs. On the other hand, if the PRA costs cause a small Government Securities ATS that is the sole provider of a niche service to cease operating as an ATS, it could require some market participants to seek execution on other trading venues that may not minimize their trading costs to the same extent.

ii. Regulation SCI

The Commission does not believe that the requirements imposed by Regulation SCI would have significant adverse effect on competition for order flow in the market for government securities and repo execution services and the efficiency with which market participants achieve their trading objectives.

The Commission does not believe that the compliance costs imposed by the proposed amendments of Regulation SCI would have significant adverse effect on competition among SCI Government Securities ATSs, non-SCI Government Securities ATSs, and non-ATS trading venues due to mitigating factors. The compliance costs imposed by the proposed amendments of Regulation SCI could have some impact on competition in the market for government securities and repo execution services. Specifically, because non-SCI Government Securities ATSs do not have to incur the compliance costs associated with Regulation SCI, non-SCI Government Securities ATSs and non-ATS trading venues may gain a competitive advantage in the market for government securities and repo execution services over SCI Government Securities ATSs with which they compete. To the extent that SCI Government Securities ATSs pass on the compliance costs to their subscribers in the form of higher fees, SCI Government Securities ATSs could lose order flow or their subscribers to other non-SCI Government Securities ATSs and non-ATS trading venues with lower fees. The Commission believes that the adverse competitive effect, however, would be mitigated to some extent because an SCI Government Securities ATS likely would have more robust systems, fewer disruptive systems issues, and better up-time compared to non-SCI Government Securities ATSs.[795] Furthermore, any adverse competitive effect could be minor to the extent that an SCI Government Securities ATS is large and has a more stable and established subscriber base than other ATSs and non-ATS trading venues. Although non-ATS trading venues may compete with SCI Government Securities ATSs in the market for government securities and repo execution services, non-ATS trading venues cannot offer the same services as ATSs without becoming ATSs, regardless of whether Regulation SCI applies to the ATS.[796]

The costs imposed by the amendments to Regulation SCI could also affect barriers to entry for new Government Securities ATSs and thus could adversely affect competition. Specifically, the Commission acknowledges that Regulation SCI would increase the costs for those that meet the volume thresholds. This would increase the expected compliance costs of market entrants who expect to eventually be SCI Government Securities ATSs. To the extent that an increase in these costs reduces the number of potential new entrants, the potential competition from new entrants would be lower.

The compliance costs associated with participating in business continuity and disaster recovery plan testing may affect competition among subscribers of SCI Government Securities ATSs and also could raise barriers to entry for new subscribers. Because some subscribers would incur compliance costs associated with Rule 1004 and others would not, it could adversely impact the ability for those subscribers of SCI Government Securities ATSs to compete. However, it is difficult to gauge the extent of impact on competition because the Commission does not have sufficient information, for example, on whether certain subscribers of SCI Government Securities ATSs currently maintain connections to backup facilities including for testing purposes. If larger subscribers of SCI Government Securities ATSs already maintain connections to backup facilities including for testing purposes, the adverse impact on competition would be mitigated to some extent because the compliance costs associated with the business continuity and disaster recovery plans testing requirements in Rule 1004 would be limited for those larger subscribers. The Commission believes that new subscribers are less likely to be designated immediately to participate in business continuity and disaster recovery plan testing than are existing larger subscribers because new subscribers may not initially satisfy the ATS's designation standards as they establish their businesses.

As discussed in Section X.C.2.b, it is difficult to estimate the costs of the proposed amendments of Regulation SCI for third-party vendors that operate SCI systems or indirect SCI systems[797] on behalf of SCI Government Securities ATSs. To the extent that the proposed amendments of Regulation SCI impose compliance costs on third-party vendors that operate SCI systems or indirect SCI systems on behalf of SCI Government Securities ATSs, the compliance costs could affect the competition among third-party vendors in the market for SCI systems or indirect SCI systems. To the extent that the costs associated with Regulation SCI for third-party vendors outweigh the benefits of continuing to operate SCI systems or indirect SCI systems on behalf of SCI Government Securities ATSs, these third-party vendors could exit the market for SCI systems or indirect systems. In this respect, Regulation SCI could adversely impact such vendors and reduce the ability for some third-party vendors to compete in the market for SCI systems and indirect SCI systems, with attendant costs to SCI Government Securities ATSs. To the extent that this happens, SCI Government Securities ATSs would incur costs from having to find a new vendor, form a new business relationship, and adapt their systems to those of the new vendor. SCI Government Securities ATSs may also elect to perform the relevant functions internally. To the extent that the current third-party vendors are the most efficient means of performing certain functions for SCI Government Securities ATSs, and to the extent that any third-party vendor exits the market, finding new vendors or performing the functions internally would represent a

[795] *See supra* Section X.B.6.

[796] *See supra* Section X.B.1 for a discussion about the differences in execution services between ATSs and non-ATS trading venues. *See also supra* note 564.

[797] *See supra* note 767 and accompanying text for the definition of indirect SCI systems.

reduction in efficiency for SCI Government Securities ATSs.

b. Market Participants' Trading Efficiency

The Commission believes that the proposed amendments of Regulation ATS including the Fair Access Rule and Regulation SCI could affect the efficiency with which market participants achieve trading objectives, and in the subsections below, we discuss both positive and potential negative effects.

i. Positive Effects on Market Participants' Trading Efficiency

The enhancement in Government Securities ATS operational transparency via public disclosure of Form ATS–G would help market participants select the trading venue that best meets their trading needs (*e.g.,* order types, trading functionalities) and lower search costs in the selection of trading venues, which would help market participants achieve their trading objectives more efficiently. Market participants may consider various factors, such as order types, trading functionalities, and fees, in deciding where to send their orders to achieve their trading objectives. The public disclosure of Form ATS–G would enable market participants to compare Government Securities ATSs in an expedited manner and find an ATS that would help them achieve their trading objectives more efficiently.

The Commission believes that the public disclosure of Form ATS–G that contains the information related to operational characteristics of Government Securities ATSs could foster greater competition for order flow in the market for government securities and repo execution services and result in lower trading costs and better execution quality for market participants, which would help achieve their trading objectives more efficiently. For example, because the public disclosure of Form ATS–G would make it easier for market participants to compare fees and order handling procedures and execution statistics—if they are made available—across Government Securities ATSs,[798] market participants would be more likely to send their orders to ATSs that offer lower fees or better execution services. To the extent that non-ATS trading venues compete with Government Securities ATSs for trade execution services, the increased operational transparency of these ATSs could also incentivize non-ATS trading venues to reduce their fees or improve the efficiency of order handling procedures to compete with Government Securities ATSs for order flow. This would lower market participants' trading costs and enhance order execution quality, which would help achieve their trading objectives more efficiently.

The Commission believes that the proposed application of Fair Access Rule could help market participants achieve their trading objectives more efficiently. Market participants who may have been denied access to a Government Securities ATS that would now be subject to the Fair Access Rule may be able to access the ATS as a result of the proposal because the previous reasons for denial of access by the ATS no longer comport with the reasonable standards under the Fair Access Rule. To the extent that there are market participants excluded from trading on Government Securities ATSs, this could increase trading venue options for those market participants and result in lower trading costs or better execution for their orders, which would help achieve their trading objectives more efficiently.

ii. Negative Effects on Market Participants' Trading Efficiency

The Commission does not believe that the compliance costs imposed by the proposed amendments of Regulation SCI would have a significant adverse effect on the efficiency with which market participants achieve their trading objectives. It is possible that SCI Government Securities ATSs would pass on the compliance costs to their subscribers in the form of higher venue fees. However, the adverse effect of higher fees on the efficiency with which market participants achieve their trading objectives could be mitigated to some extent because an SCI Government Securities ATS likely would have more robust systems, fewer disruptive systems issues, and better up-time compared to non-SCI Government Securities ATSs.

Through exits and entries, the number of ATSs competing in the market for government securities and repos could change and this could impact market participants' trading costs and thus the efficiency with which market participants achieve their trading objectives. The Commission does not believe that requirements and costs imposed by the proposed amendments to Regulation ATS and Regulation SCI would result in Government Securities ATSs exiting and adversely impact the efficiency with which market participants achieve their trading objectives.[799] The Commission recognizes that the public disclosure of Form ATS–G required by Regulation ATS and the costs associated with Regulation SCI could dissuade potential entrants from entering the market.[800] To the extent that these effects reduce the number of potential new entrants, the potential competition from new entrants would be lower and this could adversely affect market participants' trading costs and thus the efficiency with which market participants achieve their trading objectives.

The Commission believes that the proposed amendments of the Fair Access Rule and Regulation SCI could adversely affect the efficiency with which market participants achieve their trading objectives. Government Securities ATSs that are close to satisfying the volume threshold for certain government securities could limit the trading in those securities over some period to stay below the volume thresholds and avoid being subject to the Fair Access Rule and Regulation SCI. The order flow that was being executed on those Government Securities ATSs might be absorbed and redistributed amongst other Government Securities ATSs. If a Government Securities ATS that is the sole provider of a niche service limits the trading in certain government securities to avoid being subject to the Fair Access Rule and Regulation SCI, it could require some market participants to seek execution on other trading venues, which could result in higher trading costs and reduce the efficiency with which they achieve their trading objectives.

c. Price Efficiency and Capital Formation

The Commission believes that the proposed extension of Regulation SCI to include systems that trade government securities and repos could promote price efficiency and capital formation by reducing the potential for systems disruptions on ATSs that capture a significant portion of the trading volume in the market for U.S. Treasury or Agency Securities. Although the Commission acknowledges that extending Regulation SCI to Government Securities ATSs would not eliminate all systems issues,[801] the Commission believes that extending Regulation SCI would help prevent market disruptions due to systems issues, which could help prevent

[798] *See supra* Section X.C.1.a.ii for a discussion about benefits from public disclosure via Form ATS–G.

[799] *See supra* Section X.C.3.a.

[800] *See supra* Sections X.C.3.a.i.c and X.C.3.a.ii.

[801] *See supra* Section X.B.6 for a discussion about market disruption and system up-time.

interruptions in the price discovery process and liquidity flows and thus could help prevent periods with pricing inefficiencies from occurring in the government securities market. Specifically, the Commission believes that extending Regulation SCI would help improve systems up-time [802] for SCI Government Securities ATSs and would also promote more robust systems that directly support execution facilities, order matching, and the dissemination of market data.[803] This would help facilitate the price discovery process and liquidity flows in the secondary market for on-the-run U.S. Treasury Securities and could also enhance price efficiency of risky securities because the transaction prices of on-the-run U.S. Treasury Securities are used as risk-free rate benchmarks to price risky securities transactions.[804] Price efficiency of risky securities is important because prices that accurately convey information about fundamental value improve the efficiency in allocating capital across projects and entities, which helps promote capital formation.

On the other hand, the Commission believes that the proposed amendments of the Fair Access Rule and Regulation SCI could adversely affect capital formation. Government Securities ATSs that are close to satisfying the volume threshold for certain government securities could limit the trading in those securities over some period to stay below the volume thresholds and avoid being subject to the Fair Access Rule and Regulation SCI. To the extent that Government Securities ATSs limit the trading in certain government securities to avoid being subject to the Fair Access Rule and Regulation SCI, this could limit or reduce liquidity provision and liquidity flows in those government securities, which would adversely affect the price discovery process and price efficiency in those government securities harming capital formation.[805]

D. Reasonable Alternatives

The Commission considered several alternatives to the proposal: (1) Require Currently Exempted Government Securities ATSs to file Form ATS, but not publicly disclose Form ATS; (2) require Government Securities ATSs to file proposed Form ATS–G, but treat the information as confidential; (3) require differing levels of public disclosure by Government Securities ATSs depending on their trading volume; (4) extend the transparency requirements of Regulation ATS to all non-ATS trading government securities; (5) alter the volume thresholds for the Fair Access Rule and Regulation SCI; (6) apply Rule 301(b)(6) of Regulation ATS to Government Securities ATSs; (7) require Forms ATS–G, ATS, and ATS–R to be submitted in the Inline XBRL format; and (8) require Forms ATS–G, ATS, and ATS–R to be filed on EFFS/SRTS or on individual ATS websites.

1. Require Currently Exempted Government Securities ATSs To File a Non-Public Form ATS

One alternative could require Currently Exempted Government Securities ATSs to file Form ATS and subsequent amendments with the Commission, instead of filing Form ATS–G. This alternative would allow Legacy Filers to continue to file current Form ATS. However, Form ATS would be deemed confidential for all Government Securities ATSs and would not have to be publicly disclosed. Under this alternative, compliance costs would be lower because Legacy Filers would not bear the additional costs of preparing and amending Form ATS–G. Furthermore, Currently Exempted Government Securities ATSs would not incur additional costs associated with amending Form ATS–G to address any deficiencies to avoid an ineffectiveness determination because Rule 304 of Regulation ATS does not apply to Form ATS filings. However, this alternative would reduce regulators' insight into Government Securities ATSs compared to the proposal because Form ATS would require the disclosure of less information about the operations of Government Securities ATSs and the activities of their broker-dealer operators and their affiliates, as compared to Form ATS–G.

The lack of public disclosure of Form ATS under the alternative could result in market participants making less informed decisions regarding where to send their orders and thus result in lower execution quality than they would obtain under the proposal. Additionally, this alternative could result in higher search costs for subscribers to identify potential trading venues for their orders. Because Government Securities ATSs would not have to publicly disclose their fees or details about their operations, there would be less competition among Government Securities ATSs and between Government Securities ATSs and non-ATS trading venues compared to the proposal. To the extent that there is less competition for order flow in the market for government securities and repo execution services, there could be less incentive to innovate for Government Securities ATSs.

2. Require Proposed Form ATS–G Be Filed but Treat the Information as Confidential

Another alternative approach the Commission could take would be to require Government Securities ATSs to file the proposed Form ATS–G with the Commission, but not make Form ATS–G public. The proposed Form ATS–G would include detailed disclosures about the operational facet of a Government Securities ATS and the activities of its broker-dealer operator and its affiliates, and the Commission would have the ability to declare Form ATS–G filings ineffective. Although this alternative would allow the Commission to review the disclosures of Government Securities ATSs, this alternative would make Government Securities ATSs' operations less transparent for market participants, which could result in market participants making less informed decisions regarding where to send their orders and thus result in lower execution quality than they would obtain under the proposal. Because Form ATS–G would not be publicly disclosed under this alternative, there would be less competition among Government Securities ATSs and between Government Securities ATSs and non-ATS trading venues, as compared to the proposal. To the extent that a Government Securities ATS's competitive advantage in attracting order flow and generating trading revenues is in part driven by certain operational characteristics, the confidentiality of Form ATS–G could help maintain that Government Securities ATS's competitive advantage in the market for government securities and repo execution services compared to the proposal. However, the Commission believes that it is not likely the responsive information to the proposed Form ATS–G would include information regarding operational facets such that the public disclosure of the information would adversely affect the competitive position of the disclosing Government Securities ATS in the market for government securities and repo execution services.[806]

[802] Systems up-time is a measure of the time that a computer system is running and available.

[803] Based on the Commission's understanding, Government Securities ATSs disseminate their Treasury trades via private feeds and third-party vendors. These prices also serve as benchmarks for pricing other financial products.

[804] *See* October 15 Staff Report, *supra* note 14.

[805] *See id.*

[806] *See supra* note 789 and accompanying text. *See also supra* note 196 and accompanying text.

3. Initiate Differing Levels of Public Disclosure Depending on Government Securities ATS Dollar Volume

The Commission could require different levels of disclosure among Government Securities ATSs based on dollar volume in government securities. In particular, this alternative would subject Government Securities ATSs with lower dollar volumes to lower levels of disclosure on the proposed Form ATS–G. This alternative could provide smaller Government Securities ATSs with a competitive advantage over larger ones because smaller Government Securities ATSs would incur lower compliance costs relative to the proposal, which could translate into lower entry barriers relative to such barriers under the proposal. Because these small Government Securities ATSs would not have to disclose as much information pertaining to their operational facets to their competitors, they would have a competitive advantage over more established Government Securities ATSs and non-ATS government securities trading venues. This approach therefore would promote competition in the market. It also would promote innovation because these small Government Securities ATSs would not be deterred from innovating by the possibility of having to disclose certain operational facets. This approach could also benefit market participants who execute on these ATSs by improving the execution quality of their trades. However, this alternative could incentivize small Government Securities ATSs to limit the trading in government securities on their ATSs to stay small and not trigger additional disclosure requirements. To the extent that this happens, it could limit market participants' options for trading venues, which could result in higher trading costs or worse execution quality. Lower execution quality or higher trading costs for market participants would reduce the efficiency with which they achieve their trading objectives as compared to the proposal.

4. Extend the Transparency Requirements of Regulation ATS to All Non-ATS Trading Venues for Government Securities

As another alternative, the Commission could extend the transparency requirements (*i.e.,* filing Form ATS–G) of Regulation ATS to non-ATS trading venues for government securities. Under this alternative, investors would receive information about the operations and the activities of the broker-dealer operators and affiliates of all non-ATS trading venues for government securities. While the disclosure requirements of individual venues would be similar to what is required under the proposal, investors would be able to access detailed information on non-ATS trading venues that use a variety of protocols.[807] This could help market participants make better-informed decisions about where to send their orders to achieve their trading or investment objectives as compared to under the proposal. However, non-ATS trading venues, unlike ATSs, cannot offer certain execution protocols, such as crossing mechanisms, auctions, and central limit order books, which generally meet the definition of an exchange.[808] Thus, non-ATS trading venues may not be as technologically advanced and may not have the same level of automation, speed, and complexity as ATSs that would be required to comply with Regulation ATS under the proposal. Thus, the public disclosure of information from such non-ATS trading venues concerning their trading protocols could be less valuable to market participants.

Under this alternative, non-ATS trading venues effecting transactions in government securities would incur the compliance costs discussed in Section X.C.2.a to comply with Regulation ATS. Additionally, the public disclosure of details regarding the operational facets of non-ATS trading venues could adversely impact competition for order flow and raise barriers to entry in the market for government securities and repo execution services, and could also lower the incentives for non-ATS trading venues to innovate. However, the Commission believes that the risk of this is likely to be low.[809]

5. Alter the Volume Thresholds for the Fair Access Rule and Regulation SCI

Another alternative for the Commission is to alter the volume thresholds for the Fair Access Rule and Regulation SCI.[810] A higher volume threshold for the Fair Access Rule would result in a smaller number of Government Securities ATSs that are subject to the Fair Access Rule than under the proposal.[811] With fewer Government Securities ATSs subject to the Fair Access Rule, some market participants may not be able to trade on as many Government Securities ATSs as they could have under the proposal. This could result in higher trading costs or worse execution quality for those market participants than under the proposal. With a higher volume threshold for the Fair Access Rule, fewer Government Securities ATSs would incur compliance costs discussed in Section X.C.2.a.iii to comply with the Fair Access Rule than under the proposal. This could lower barriers to entry in the market for government securities execution services and increase competition compared to the proposal, resulting in lower trading costs or better execution quality for investors.

A lower volume threshold for the Fair Access Rule would allow market participants to access a greater number of Government Securities ATSs and provide them with more options in the selection of trading venues than under the proposal.[812] Thus, compared to the proposal, investors could better access the trading venue that best meets their trading objectives resulting in lower trading costs or better execution for their orders, which would help achieve their trading objectives more efficiently. With a lower volume threshold for the Fair Access Rule, ATSs would incur greater compliance costs discussed in Section X.C.2.a.iii to comply with the Fair Access Rule than under the proposal. The Commission also believes that there would be a greater likelihood of small Government Securities ATSs exiting the market and thus decreasing competition for government securities execution services, which could

[807] *See supra* Section X.B.1.

[808] *See supra* Section X.B.1 for a discussion about the differences in execution services between ATSs and non-ATS trading venues. *See also supra* note 564.

[809] *See supra* Section X.C.3.a.i.c for a discussion about the risk that the responsive information to the proposed Form ATS–G would include information regarding operational facets such that the public disclosure of the information would adversely affect the competitive position of the disclosing ATS and why the Commission believes that this risk likely to be low. *See also supra* note 196 and accompanying text.

[810] The Commission estimates that 3 ATSs trading U.S. Treasury Securities and 1 ATS trading Agency Securities would be subject to the Fair Access Rule under the proposal. Furthermore, the Commission estimates that 3 Government Securities ATSs would meet the volume thresholds for Regulation SCI under the proposal. *See also supra* Sections II.D and IX.C.

[811] If the proposed volume thresholds were 10 percent, the Commission estimates only 1 ATS trading U.S. Treasury Securities and 1 ATS trading Agency Securities would be subject to the Fair Access Rule. *See* Table X.1 in *supra* Section X.B.1. *See also supra* Section II.D.

[812] If the proposed volume thresholds were three percent, the Commission estimates 4 ATSs trading U.S. Treasury Securities and 1 ATS trading Agency Securities would be subject to the Fair Access Rule. *See also supra* Section II.D. Furthermore, if the proposed volume thresholds were two percent, the Commission estimates 5 ATSs trading U.S. Treasury Securities and 1 ATS trading Agency Securities would be subject to the Fair Access Rule. *See* Table X.1 in *supra* Section X.B.1.

adversely affect trading costs and execution quality.

A lower volume threshold would include a greater number of small Government Securities ATSs to be subject to the Fair Access Rule compared to the proposal. To avoid being subject to the Fair Access Rule, small Government Securities ATSs that are close to satisfying the volume threshold for certain government securities could limit the trading in those government securities on their ATSs over some period to stay below the volume threshold. The order flow that was being executed on those small Government Securities ATSs might be absorbed and redistributed amongst other Government Securities ATSs. If a Government Securities ATS that is the sole provider of a niche service limits the trading in certain government securities to avoid being subject to the Fair Access Rule, it could require some market participants to seek execution on other trading venues, which could result in higher trading costs. A lower volume threshold for the Fair Access Rule could cause a greater number of small ATSs to exit the market for government securities and repo execution services resulting in a lower number of ATSs and less competition compared to the proposal. If there are fewer options in the selection of trading venues, investors could face higher trading costs or lower execution quality for their orders compared to the proposal.

A higher volume threshold for Regulation SCI would result in a smaller number of Government Securities ATSs that are subject to Regulation SCI than under the proposal.[813] Compared to the proposal, a higher volume threshold for Regulation SCI could exclude Government Securities ATSs that play a significant role (*i.e.,* capture a significant portion of trading volume) in the market for government securities execution services and have the potential to impact investors, the overall market, and the trading of government securities should an SCI event occur. With a higher volume threshold for Regulation SCI, the Commission believes that a smaller number of Government Securities ATSs would incur compliance costs discussed in Section X.C.2.b to comply with Regulation SCI requirements than under the proposal. This could lower barriers to entry in the market for government securities execution services and increase competition compared to the proposal, resulting in lower trading costs or better execution quality for investors.

A lower volume threshold for Regulation SCI likely would promote the establishment of more robust systems, help reduce the duration and severity of any system distributions, and help prevent system issues from occurring on small Government Securities ATSs that met the volume thresholds, which could help prevent interruptions in the price discovery process and liquidity flows and thus may help prevent periods with pricing inefficiencies from occurring compared to the proposal.[814] With a lower volume threshold for Regulation SCI, more Government Securities ATSs would incur compliance costs discussed in Section X.C.2.b to comply with Regulation SCI requirements than under the proposal. A greater number of small Government Securities ATSs could exit the market for government securities and repos and hence decrease competition resulting in higher trading costs or worse execution quality for investors compared to the proposal. A lower volume threshold would cause a greater number of small Government Securities ATSs to be subject to Regulation SCI requirements compared to the proposal. To avoid being subject to Regulation SCI, small Government Securities ATSs that are close to satisfying the volume threshold for certain government securities could limit the trading in those government securities on their ATSs over some period to stay below the volume threshold. The order flow that was being executed on those small Government Securities ATSs might be absorbed and redistributed amongst other Government Securities ATSs. If a Government Securities ATS that is the sole provider of a niche service limits the trading in certain government securities to avoid being subject to Regulation SCI, it could require some market participants to seek execution on other trading venues, which could result in higher trading costs. The Commission believes that compliance costs associated with Regulation SCI could cause a greater number of small ATSs to exit the market for government securities execution services resulting in a lower number of ATSs and less competition compared to the proposal. To the extent that there are fewer options in the selection of trading venues, investors could face higher trading costs and/or lower execution quality for their orders compared to the proposal.

6. Apply Rule 301(b)(6) of Regulation ATS to Government Securities ATSs

Another alternative for the Commission is to apply Rule 301(b)(6)[815] of Regulation ATS to Government Securities ATSs instead of extending Regulation SCI.[816] The Commission believes that the application of the Capacity, Integrity, and Security Rule to certain Government Securities ATSs could help enhance the price discovery process and price efficiency of government securities by reducing disruptions in trading due to failures or capacity issues with respect to automated systems that support order entry, order routing, order execution, transaction reporting, and trade comparison of the ATSs. Under this alternative, Government Securities ATSs would be subject to the Capacity, Integrity, and Security Rule in Rule 301(b)(6). The scope and requirements of the Capacity, Integrity, and Security Rule would be narrower than those of Regulation SCI. For example, Rule 301(b)(6) of Regulation ATS would apply to narrower set of systems, as compared to Regulation SCI. Rule 301(b)(6) of Regulation ATS applies only to systems that support order entry, order routing, order execution, transaction reporting, and trade comparison, which is narrower than the definition of SCI system. Thus, the Commission believes that this alternative would reduce the potential benefits discussed in Sections X.C.1.b and X.C.3.c, as compared to the proposal. Furthermore, the Commission believes that compliance costs associated with the Capacity, Integrity, and Security Rule would be significantly less than those under the proposal because the scope and requirements of the Capacity, Integrity, and Security Rule would be narrower than those of Regulation SCI. For example, the Capacity, Integrity, and Security Rule would not require

[813] If the proposed volume thresholds were 10 percent, the Commission estimates 2 Government Securities ATSs would be subject to Regulation SCI, whereas under the proposed volume threshold of five percent, the Commission estimates 3 Government Securities ATSs would be subject to Regulation SCI. *See* Table X.1 in *supra* Section X.B.1.

[814] If the proposed volume thresholds were three percent, the Commission estimates 4 Government Securities ATSs would be subject to Regulation SCI. If the proposed volume thresholds were two percent, the Commission estimates 5 Government Securities ATSs would be subject to Regulation SCI. *See* Table X.1 in *supra* Section X.B.1.

[815] As also explained above, Rule 301(b)(6) addresses the capacity, integrity, and security requirements of automated systems for ATSs that meet certain volume thresholds. *See supra* note 355.

[816] Applying the dollar volume threshold of 20 percent or more of the average daily volume traded in the United States during at least four of the preceding six calendar months, the Commission estimates one Government Securities ATS would be subject to Rule 301(b)(6) of Regulation ATS. *See supra* note 57.

Government Securities ATSs to maintain a backup facility to comply with the requirements of Regulation SCI related to business continuity and disaster recovery plans. As compared to the proposal, the significantly lower compliance costs of this alternative could result in lower trading costs for market participants to the extent that Government Securities ATSs pass on these compliance costs to their subscribers. Furthermore, the lower compliance costs of this alternative could lower barriers to entry in the market for government securities execution services and increase competition compared to the proposal, resulting in lower trading costs or better execution quality for investors.

As another alternative, the Commission could apply the Capacity, Integrity, and Security Rule in Rule 301(b)(6) to smaller Government Securities ATSs and extend Regulation SCI to larger Government Securities ATSs as proposed. For example, the Commission could require a Government Securities ATS that falls within a volume range for U.S. Treasury Securities of 5 percent and 10 percent to comply with Rule 301(b)(6) of Regulation ATS and a Government Securities ATS that exceeds a 10 percent volume threshold for U.S. Treasury Securities to be subject to Regulation SCI.[817] Under this alternative, the Commission believes that smaller Government Securities ATSs subject to Rule 301(b)(6) would incur additional compliance costs, as compared to the proposal where these smaller Government Securities ATSs would be subject to neither Regulation SCI or Rule 301(b)(6). Smaller Government Securities ATSs subject to Rule 301(b)(6) would incur compliance costs associated with, among other things, upgrading systems to an adequate capacity level, the independent review of their systems on an annual basis, recordkeeping requirements, and notification requirements.[818] The application of Rule 301(b)(6) to smaller Government Securities ATSs could result in higher trading costs (*e.g.,* in the form of higher fees) to the extent that the Government Securities ATSs pass on the additional compliance costs associated with Rule 301(b)(6) to their subscribers. However, the Commission believes that the requirements of Rule 301(b)(6) would not impose significant costs and thus would not result in a significant increase in trading costs for market participants, as compared to the proposal.

7. Require Forms ATS–G, ATS, and ATS–R to be Submitted in the Inline XBRL Format

The proposal would require Form ATS–G to be submitted in a custom XML format. Alternatively, the Commission could require these forms to be submitted in the Inline eXtensible Business Reporting Language (''Inline XBRL'') format, a derivation of XML that is designed for business reporting information and is both machine-readable and human-readable.[819] This alternative could include numerical detail tagging of quantitative disclosures (*e.g.,* platform-wide statistics) and text block tagging for narrative disclosures (*e.g.,* trade reporting arrangements).[820] Compared to the proposal, the Inline XBRL alternative for Forms ATS–G, ATS, and ATS–R would provide more sophisticated validation, presentation, and reference features for filers and data users. However, the Inline XBRL alternative would also impose initial implementation costs (*e.g.,* training staff to prepare filings in Inline XBRL, licensing Inline XBRL filing preparation software) upon filers that do not have prior experience structuring data in the Inline XBRL format. By contrast, because the proposal would allow filers to submit Form ATS–G using a web-fillable Form, filers that lack experience structuring data in XML would not incur implementation costs.

8. Require Forms ATS–G, ATS, and ATS–R To Be Filed on EFFS or on Individual ATS Websites

The proposal would require Forms ATS–G, ATS, and ATS–R to be filed on the EDGAR system. Alternatively, the Commission could require a different filing location for these forms, such as the Commission's Electronic Form Filing System (EFFS) or the individual ATSs' websites. Because SCI entities use EFFS to file Form SCI, any Government Securities ATS that is an SCI entity or affiliate thereof will have experience using EFFS and could benefit from such familiarity in filing Form ATS–G.[821] However, to the extent any such Government Securities ATSs are operated by a broker-dealer that files its annual reports on EDGAR or that operates an NMS Stock ATS and files Form ATS–N on EDGAR, there would be no familiarity benefit under an EFFS alternative relative to the proposed EDGAR requirement.[822] In addition, for Government Securities ATSs that are not SCI entities or affiliates thereof and do not have prior EFFS experience, this alternative would impose the burden of submitting an External Account User Application to request access to EFFS.[823] Unlike EDGAR, EFFS does not support the open-source XML format, instead relying on a proprietary XML implementation (XFDL) that requires a data user to license a commercial proprietary viewer. The EFFS alternative would therefore impose additional costs on data users compared to the proposal.

Similarly, requiring Forms ATS–G, ATS, and ATS–R to be posted on the individual ATSs' websites rather than EDGAR would impose additional direct costs on data users, who would need to navigate to and manually retrieve data from different ATSs' websites to aggregate, compare, and analyze the data. In addition, individual websites would not provide the validation capabilities that an EDGAR requirement would enable, and would thus impose on data users the indirect costs associated with lower reliability of the data. An individual website requirement would provide a small benefit to bank-operated Government Securities ATSs relative to the proposal's EDGAR requirement, as those entities would not be required to incur the 0.15 hour

[817] If the proposed U.S. Treasury Security volume threshold range for Rule 301(b)(6) were set to be greater than 5 percent and less than or equal to 10 percent, the Commission estimates 2 Government Securities ATSs would be subject to Rule 301(b)(6) of Regulation ATS. If the proposed U.S. Treasury Security volume threshold range for Regulation SCI were set to be greater than 10 percent, the Commission estimates 1 Government Securities ATS would be subject to Regulation SCI.

[818] *See* Regulation ATS Adopting Release, *supra* note 35, at 70907 for a discussion of costs associated with the Capacity, Integrity, and Security Rule.

[819] Such a requirement would be implemented by revising Regulation S–T (17 CFR 232) and including an Instruction to Forms ATS–G, ATS, and ATS–R which cites to Regulation S–T. In conjunction with the EDGAR Filer Manual, Regulation S–T governs the electronic submission of documents filed with the Commission. Modifying a structured format requirement for a Commission filing or series of filings can generally be accomplished through changes to Regulation S–T, and would not require dispersed changes to the various rules and forms that would be impacted by the format modification.

[820] *See supra* Sections III.C.25.a and III.C.21.

[821] *See* General Instructions A and E to Form SCI. The Commission believes there is one Government Securities ATS that is operated by a broker-dealer that operates an NMS Stock ATS that is an SCI entity, and would therefore have experience using both EFFS (Form SCI) and EDGAR (Form ATS–N). *See supra* Section X.B.6.

[822] *See* 17 CFR 240.17a–5(d)(6) and the Commission's guidance at *https://www.sec.gov/divisions/marketreg/electronic-filing-broker-dealer-annual-reports-instructions.htm. See also* Instruction A.5 to Form ATS–N.

[823] In 2015, the Commission calculated this burden as 0.15 hours per individual requesting access on the ATS's behalf. *See* NMS Stock ATS Proposing Release, *supra* note 62, at 81106.

burden of submitting a Form ID in order to begin making EDGAR filings.[824]

E. Request for Comments

The Commission is sensitive to the potential economic effects, including costs and benefits, of the proposed amendments to Regulation ATS and Regulation SCI. The Commission has identified certain costs and benefits associated with the proposal and requests comment on all aspects of its preliminary economic analysis, including with respect to the specific questions below. The Commission encourages commenters to identify, discuss, analyze, and supply relevant data, information, or statistics regarding any such costs or benefits.

172. Does the baseline accurately reflect the current state of the market and reporting? Please provide any information necessary to correct the baseline.

173. Is the assessment of the current state of competition in the market for trading government securities reasonable? Why or why not?

174. Can commenters provide any additional information on trading activities of non-FINRA-member ATSs?

175. Is subscribers' confidential trading information at risk because Currently Exempted Government Securities ATSs are not required to comply with Regulation ATS, they are not subject to Rule 201(b)(10) and Rule 303(a)(1)?

176. Have commenters encountered any problems with the current operational reporting requirements or the required method of intake?

177. The provisions of Regulation SCI and Rule 301(b)(6) of Regulation ATS do not apply to the government securities activities of an ATS. Therefore, a Currently Exempted Government Securities ATS would not be subject to the rules and procedures of Regulation SCI, and a Legacy Filer would only be subject to them if its transaction volume in non-government securities exceeded the thresholds. Although most Government Securities ATSs are not subject to these requirements with respect to their government securities activities, a comment letter received in response to the Treasury Request for Information stated that many Government Securities ATSs adopted system testing and control procedures that followed the recommended best practices of the Treasury Market Practices Group. Is voluntary adoption of best practices sufficient to mitigate systemic risks?

178. Do differences in operational transparency around Government Securities ATSs impede market participants' ability to evaluate whether submitting order flow to a particular Government Securities ATS aligns with its business interests and objectives?

179. Are there any costs and benefits of the proposed rules that are not discussed in the economic analysis? If so, please describe the types of costs and benefits and provide a dollar estimate of these costs and benefits.

180. Would removing the exemption for Currently Exempted Government Securities ATS and proposing amendments to Regulation ATS for Government Securities ATSs enhance the Commission's oversight of these ATSs and ability to monitor trading and their role in the government securities and repo market?

181. Would removing the exemption for Currently Exempted Government Securities ATS and proposing amendments to Regulation ATS for Government Securities ATSs enhance investor protection?

182. Would removing the exemption for Currently Exempted Government Securities ATS result in enhancements to operational transparency regarding the manner of operations and the ATS-related activities of Currently Exempted Government Securities ATS by way of public disclosures on Form ATS–G? Would the proposed enhancements improve market participants' ability to evaluate a Government Securities ATS as a destination for its orders?

183. Would requiring Forms ATS–G, ATS, and ATS–R to be filed in a custom XML format yield the benefits described above, such as improving the usability of the disclosures through facilitation of automated analyses? Do commenters believe the custom XML format requirement for these forms would not impose incremental costs on filers, given the availability of a web-fillable form into which filers can input their disclosures? If not, how would the costs be more accurately characterized? How would the costs and benefits of other format requirements, such as an Inline XBRL requirement, compare to those associated with the proposed custom XML format requirement?

184. Would requiring Forms ATS–G, ATS, and ATS–R to be filed on EDGAR yield the benefits described above, such as the availability of the disclosures in a centralized filing location that is publicly accessible (for Form ATS–G) and provides validation capabilities (for all three forms)? Would the EDGAR requirement impose, at most, a minimal cost on filers? How would the costs and benefits of other location requirements, such as EFFS or the individual ATSs' websites, compare to those associated with the proposed EDGAR requirement?

185. Would removing the exemption for Currently Exempted Government Securities ATS and proposing amendment to Regulation ATS for Government Securities ATSs help ensure the fair treatment of potential and current subscribers to a Currently Exempted Government Securities ATS that consist of a large percentage of trading volume in U.S. Treasury Securities and Agency Securities?

186. Could requiring Government Securities ATSs that meet the volume thresholds to establish and objectively apply the fair access standards help prevent certain market participants from being unfairly denied access to an ATS that trades a significant portion of the market for U.S. Treasury Securities and Agency Securities? Are any market participants currently being denied fair access?

187. Would information from Form ATS–R regarding fair access grants, denials, and limitations of access to Government Securities ATSs improve the Commission's ability to oversee those ATSs to evaluate for compliance with the Fair Access Rule?

188. Would the proposed amendments to extend Regulation SCI to include ATSs that trade a significant volume of U.S. Treasury Securities or Agency Securities help reduce market disruptions due to systems issues and help improve system up-time, which would help prevent interruptions in the price discovery process and liquidity flows and thus, may help prevent periods with pricing inefficiencies from occurring?

189. Would the proposed extension of Regulation SCI strengthen the infrastructure and improve the resiliency of the automated systems of Government Securities ATSs that are important to the U.S. securities markets?

190. Would the proposed amendments to Regulation SCI promote the establishment of more robust systems that are less likely to experience a system disruption? If so, do commenters believe that this could lower trading costs and enhance liquidity and price discovery?

191. Would the requirement for a Government Securities ATS that would be an SCI ATS to establish procedures to disseminate information about SCI events to responsible SCI personnel, ATS participants, and the Commission help reduce the duration and severity of any system distributions that do occur?

192. Would the requirement for a Government Securities ATS that meets the definition of SCI ATS to conduct

[824] The Commission believes that one Currently Exempted Government Securities ATS is operated by a bank. *See supra* Section IX.D.2.b.iv.

testing of its business continuity and disaster recovery plans with its designated participants and other industry SCI entities help detect and improve the coordination of responses to system issues that could affect multiple trading venues and participants in the government securities and repo market? What would the cost to designated participants be?

193. Are the Commission's cost estimates, in general, reasonable?

194. What are commenters' views on costs related to a bank-operated Currently Exempted Government Securities ATS complying with the broker-dealer registration requirements under Rule 301(b)(1), as proposed? Is the estimated initial cost of approximately $275,000 to register as a broker-dealer with the commission via Form BD and become a member of FINRA reasonable?

195. Is the estimated ongoing annual cost of approximately $50,000 to maintain the broker-dealer registration with the Commission and FINRA reasonable?

196. What are the costs a bank-operated Currently Exempted Government Securities ATS would incur for effectively completing the application to be a member of FINRA? What other costs related to FINRA examination and surveillance, trade reporting obligations, and investor protection rules may be incurred by a bank-operated Currently Exempted Government Securities ATS? Please provide a description of these costs and cost estimates or a range of potential costs.

197. Would there be a substantial burden imposed on Government Securities ATSs in connection with resubmitting Form ATS–G or a Form ATS–G amendment? Please provide estimates if available.

198. Could the public disclosure of Form ATS–G generate indirect costs for some subscribers to Government Securities ATSs that might currently have more information regarding some ATS features, such as order priority and matching procedures, than other subscribers or market participants?

199. Are the 2018 estimates (the 2018 SCI PRA Extension) of initial paperwork burdens for new SCI entities and ongoing paperwork burdens for all SCI entities under Regulation SCI largely applicable to Government Securities ATSs?

200. Would Government Securities ATSs also incur non-paperwork related direct compliance costs as SCI entities? The Regulation SCI Adopting Release in 2014 estimated that an SCI entity would incur an initial cost of between approximately $320,000 and $2.4 million. Additionally, an SCI entity would incur an ongoing annual cost of between approximately $213,600 and $1.6 million. Are these estimated costs applicable to Government Securities ATSs? How might the actual level of costs Government Securities ATSs would incur differ from the estimates in the Regulation SCI Adopting Release because they differ from existing SCI entities? How might other factors, such as the complexity of SCI entities' systems and the degree to which SCI entities employ third-party systems, affect the estimated costs? Please provide cost estimates or a range for cost estimates, if possible.

201. Could the increase in ATS operational transparency from the proposed amendments to Regulation ATS lower the trading costs and improve the execution quality of market participants, which would enhance the efficiency with which they achieve their trading objectives?

202. Could the increase in ATS operational transparency from the proposed amendments to Regulation ATS increase competition among trading venues in the market for government securities execution services by causing them to decrease their trading fees in order to attract order flow?

203. Could the proposed Regulation ATS and Regulation SCI amendments result in some existing Government Securities ATSs exiting the market for government securities execution services or raise the barriers to entry for new Government Securities ATSs? If so, what would be the effects on competition?

204. To the extent that amendments to Regulation ATS and Regulation SCI reduce the trading costs of U.S. Treasury Securities, would the reductions in trading costs be significant enough to decrease their yields, lowering the risk-free rate? As a result, would this decrease the cost of capital for firms and promote capital formation?

205. Would the alternative to require Currently Exempted Government Securities ATSs to file Form ATS, but not require Form ATS to be publicly disclosed make Government Securities ATSs' operations less transparent for market participants and result in larger the search costs for subscribers?

206. Do commenters agree with the Commission's analysis of the alternative to require proposed Form ATS–G be filed but treat the information as confidential?

207. Do commenters agree with the Commission's analysis of alternative to initiate differing levels of public disclosure expending on Government Securities ATS dollar volume?

208. Do commenters agree with the Commission's analysis of the alternative to extend the proposed transparency requirements of Regulation ATS to all non-ATSs trading venues for government securities?

209. Do commenters agree with the Commission's analysis of the alternative to alter the proposed volume thresholds for the Fair Access Rule and Regulation SCI?

210. Do commenters agree with the Commission's analysis of the alternatives to apply Rule 301(b)(6) of Regulation ATS to Government Securities ATSs?

211. Do commenters agree with the Commission's analysis of the alternative to require Form ATS–G to be filed in a filing location other than EDGAR, such as EFFS or individual ATS websites?

XI. Consideration of Impact on the Economy

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996,[825] the Commission requests comment on the potential effect of the proposed amendments and Form ATS–G on the United States economy on an annual basis. The Commission also requests comment on any potential increases in costs or prices for consumers or individual industries, and any potential effect on competition, investment, or innovation. Commenters are requested to provide empirical data and other factual support for their views to the extent possible.

XII. Regulatory Flexibility Act Certification

Section 3(a) of the Regulatory Flexibility Act of 1980[826] (''RFA'') requires the Commission to undertake an initial regulatory flexibility analysis of the impact of the proposed rule amendments on small entities unless the Commission certifies that the rule, if adopted, would not have a significant economic impact on a substantial number of small entities.[827] For purposes of Commission rulemaking in connection with the RFA,[828] a small

[825] 5 U.S.C. 603.

[826] 5 U.S.C. 603(a).

[827] 5 U.S.C. 605(b).

[828] Although Section 601(b) of the RFA defines the term ''small entity,'' the statute permits agencies to formulate their own definitions. The Commission has adopted definitions for the term ''small entity'' for the purposes of Commission rulemaking in accordance with the RFA. Those definitions, as relevant to this proposed rulemaking, are set forth in Rule 0–10 under the Exchange Act, 17 CFR 240.0–10. *See* Securities Exchange Act Release No. 18451 (January 28, 1982), 47 FR 5215 (February 4, 1982) (File No. AS–305).

entity includes a broker or dealer that: (1) Had total capital (net worth plus subordinated liabilities) of less than $500,000 on the date in the prior fiscal year as of which its audited financial statements were prepared pursuant to Rule 17a–5(d) under the Exchange Act,[829] or, if not required to file such statements, a broker-dealer with total capital (net worth plus subordinated liabilities) of less than $500,000 on the last day of the preceding fiscal year (or in the time that it has been in business, if shorter); and (2) is not affiliated with any person (other than a natural person) that is not a small business or small organization.[830]

All Government Securities ATSs would be required to register as broker-dealers, including those that are currently exempt from such requirement.[831] The Commission examined recent FOCUS data for the 19 broker-dealers that currently operate ATSs that indicated on their Form ATS that they trade government securities and repos and concluded that 2 of the broker-dealer operators of these ATSs had total capital of less than $500,000 on the last day of the preceding fiscal year (or in the time that it has been in business, if shorter).[832] The Commission notes that these broker-dealer operators have never reported any transaction volume in any security, including a government security or repo, to the Commission on Form ATS–R. Given that these ATSs have never reported any transaction volume in government securities to the Commission, the Commission believes that these ATSs would likely not submit a Form ATS–G if the proposed amendments to Regulation ATS are adopted. The Commission has also recently examined recent FOCUS data for the 6 broker-dealers that are Currently Exempted Government Securities ATSs and concluded that none of the broker-dealer operators of ATSs that currently trade government securities had total capital of less than $500,000 on the last day of the preceding fiscal year (or in the time that it has been in business, if shorter). Consequently, the Commission certifies that the proposed amendments to Regulation ATS would not, if adopted, have a significant economic impact on a substantial number of small entities.

The Commission encourages written comments regarding this certification. The Commission solicits comment as to whether the proposed amendments could have impacts on small entities that have not been considered. The Commission requests that commenters describe the nature of any impacts on small entities and provide empirical data to support the extent of such effect. Such comments will be placed in the same public file as comments on the proposed amendments to Regulation ATS. Persons wishing to submit written comments should refer to the instructions for submitting comments in the front of this release.

XIII. Statutory Authority and Text of Proposed Amendments

Pursuant to Exchange Act, 15 U.S.C. 78a *et seq.,* and particularly Sections 3(b), 5, 6, 15, 15C, 17(a), 17(b), 19, 23(a), and 36 thereof (15 U.S.C. 78c(b), 78e, 78f, 78*o,* 78*o*–5, 78q(a), 78q(b), 78s, 78w(a), and 78mm), the Commission proposes amendments to Form ATS–G under the Exchange Act, Regulation ATS under the Exchange Act, and 17 CFR 232, 240, 242 and 249.

List of Subjects in 17 CFR Parts 232, 240, 242, and 249

Administrative practices and procedure, Brokers, Confidential business information, Fraud, Reporting and recordkeeping requirements, Securities.

For the reasons stated in the preamble, title 17, chapter II of the Code of Federal Regulations is proposed as follows:

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

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

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

* * * * *

■ 2. Amend § 232.101 by adding paragraphs (a)(1)(xxii) through (xxiv) to read as follows:

§ 232.101 Mandated electronic submissions and exceptions.

(a) * * *

(1) * * *

(xxii) Form ATS (§ 249.637 of this chapter).

(xxiii) Form ATS–R (§ 249.638 of this chapter).

(xxiv) Form ATS–G (§ 249.642 of this chapter).

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1934

■ 3. The general authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78*o,* 78*o*–4, 78*o*–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78dd, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.;* and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; Pub. L. 111–203, 939A, 124 Stat. 1376 (2010); and Pub. L. 112–106, secs. 503 and 602, 126 Stat. 326 (2012), unless otherwise noted.

* * * * *

■ 4. Amend § 240.3a1–1 by adding paragraphs (b)(3)(viii) and (ix) to read as follows:

§ 240.3a1–1 Exemption from the definition of "Exchange" under Section 3(a)(1) of the Act.

(a) * * *

(b) * * *

(3) * * *

(viii) U.S. Treasury Securities, which shall have the same meaning as in § 242.300(p), and for which transactions are reported to a self-regulatory organization.

(ix) Agency Securities, which shall have the same meaning as in § 242.300(q), and for which transactions are reported to a self-regulatory organization.

PART 242—REGULATIONS M, SHO, ATS, AC, NMS, AND SBSR AND CUSTOMER MARGIN REQUIREMENTS FOR SECURITY FUTURES

■ 5. The authority citation for part 242 continues to read as follows:

Authority: 15 U.S.C. 77g, 77q(a), 77s(a), 78b, 78c, 78g(c)(2), 78i(a), 78j, 78k–1(c), 78*l,* 78m, 78n, 78*o*(b), 78*o*(c), 78*o*(g), 78q(a), 78q(b), 78q(h), 78w(a), 78dd–1, 78mm, 80a–23, 80a–29, and 80a–37.

* * * * *

■ 6. Amend § 242.300 by:

[829] 17 CFR 240.17a–5(d).

[830] *See* 17 CFR 240.0–10(c). *See also* 17 CFR 240.0–10(i) (providing that a broker or dealer is affiliated with another person if: Such broker or dealer controls, is controlled by, or is under common control with such other person; a person shall be deemed to control another person if that person has the right to vote 25 percent or more of the voting securities of such other person or is entitled to receive 25 percent or more of the net profits of such other person or is otherwise able to direct or cause the direction of the management or policies of such other person; or such broker or dealer introduces transactions in securities, other than registered investment company securities or interests or participations in insurance company separate accounts, to such other person, or introduces accounts of customers or other brokers or dealers, other than accounts that hold only registered investment company securities or interests or participations in insurance company separate accounts, to such other person that carries such accounts on a fully disclosed basis).

[831] *See supra* Section II.C. *See also* 17 CFR 242.301(b)(1).

■ a. Adding ''An NMS Stock ATS shall not trade securities other than NMS stocks.'' at the end of paragraph (k); and
■ b. Adding paragraphs (l) through (q) to read as follows:

§ 242.300 Definitions.

* * * * *

(l) *Government Securities ATS* means an alternative trading system, as defined in paragraph (a) of this section, that trades government securities, as defined in section 3(a)(42) of the Act (15 U.S.C. 78c(a)(42)) or repurchase and reverse repurchase agreements on government securities. A Government Securities ATS shall not trade securities other than government securities or repurchase and reverse repurchase agreements on government securities.

(m) *Covered ATS* means an NMS Stock ATS or Government Securities ATS, as applicable.

(n) *Covered Form* means a filing on Form ATS–N or Form ATS–G, as applicable.

(o) *Legacy Government Securities ATS* means a Government Securities ATS operating as of [date 120 calendar days after the date of publication of the final rule in the **Federal Register**].

(p) *U.S. Treasury Security* means a security issued by the U.S. Department of the Treasury.

(q) *Agency Security* means a debt security issued or guaranteed by a U.S. executive agency, as defined in 5 U.S.C. 105, or government-sponsored enterprise, as defined in 2 U.S.C. 622(8).

■ 7. Amend § 242.301 by:
■ a. Removing and reserving paragraphs (a)(4)(ii)(A) through (C);
■ b. In paragraph (b)(1), adding ''or section 15C(a)(1)(A) of the Act (15 U.S.C. 78o–5(a)(1)(A))'' after the phrase ''section 15 of the Act, (15 U.S.C. 78o)'';
■ c. In paragraph (b)(2)(vi), adding the words ''and information filed pursuant to paragraph (b)(9)'' after the words ''pursuant to this paragraph (b)(2)'';
■ d. Revising paragraph (b)(2)(vii);
■ e. Revising paragraph (b)(2)(viii);
■ f. In paragraph (b)(5)(i)(A), adding the word ''share'' after the phrase ''average daily'';
■ g. In paragraph (b)(5)(i)(B), adding the word ''share'' after the phrase ''average daily trading'';
■ h. In paragraphs (b)(5)(i)(C) and (D), adding the word ''dollar'' after the phrase ''average daily'';
■ i. In paragraph (b)(5)(i)(C), adding the phrase ''as provided by the self-regulatory organization to which such transactions are reported'' after the phrase ''in the United States'';
■ j. In paragraph (b)(5)(i)(C), removing the word ''or'' after the phrase ''average daily volume traded in the United States'';
■ k. In paragraph (b)(5)(i)(D), adding the phrase ''as provided by the self-regulatory organization to which such transactions are reported'' after the phrase ''in the United States'';
■ l. In paragraph (b)(5)(i)(D), removing ''.'' after the phrase ''in the United States'' and adding in its place '';'';
■ m. Adding paragraphs (b)(5)(i)(E) and (F);
■ n. In paragraph (b)(5)(ii)(A), adding the word ''reasonable'' before the phrase ''written standards'';
■ o. Removing paragraph (b)(5)(iii);
■ p. In paragraphs (b)(6)(i)(A) and (B), adding the word ''dollar'' after the phrase ''average daily'';
■ q. Removing paragraph (b)(6)(iii);
■ r. In paragraph (b)(9)(i), removing the word ''Separately'' and the phrase ''for transactions in NMS stocks, as defined in paragraph (g) of this section, and transactions in securities other than NMS stocks'', and capitalizing the word ''File''; and
■ s. In paragraph (b)(9)(ii), removing the word ''Separately'' and the phrase ''for transactions in NMS stocks and transactions in securities other than NMS stocks'', and capitalizing the word ''File''.

The additions and revisions read as follows:

§ 242.301 Requirements for alternative trading systems.

* * * * *

(b) * * *

(2) * * *

(vii) An ATS must file a Form ATS or Form ATS–R in accordance with the instructions therein. The reports provided for in paragraphs (b)(2) and (b)(9) of this section shall be filed on Form ATS or Form ATS–R, as applicable, and include all information as prescribed in Form ATS or Form ATS–R, as applicable, and the instructions thereto. Any such document shall be executed at, or prior to, the time Form ATS or Form ATS–R is filed and shall be retained by the ATS in accordance with §§ 242.303 and § 232.302 of this chapter, and the instructions in Form ATS or Form ATS–R, as applicable. Duplicates of the reports provided for in paragraphs (b)(2)(i) through (v) of this section must be filed with surveillance personnel designated as such by any self-regulatory organization that is the designated examining authority for the alternative trading system pursuant to § 240.17d–1 of this chapter simultaneously with filing with the Commission. Duplicates of the reports required by paragraph (b)(9) of this section shall be provided to surveillance personnel of such self-regulatory authority upon request. All reports filed pursuant to this paragraph (b)(2) and paragraph (b)(9) of this section (except for types of securities traded provided on Form ATS and Form ATS–R) will be accorded confidential treatment subject to applicable law.

(viii) A Legacy Government Securities ATS operating pursuant to an initial operation report on Form ATS on file with the Commission as of [date 120 calendar days after the date of publication of the final rule in the **Federal Register**] shall be subject to the requirements of paragraphs (b)(2)(i) through (vii) of this section until that ATS files an initial Form ATS–G with the Commission pursuant to § 242.304(a)(1)(iv)(A). Thereafter, the Legacy Government Securities ATS shall file reports pursuant to § 242.304 and shall not be subject to the requirements of paragraphs (b)(2)(i) through (vii) of this section. A Legacy Government Securities ATS that was formerly not required to comply with Regulation ATS (§ 242.300 through 242.304) pursuant to an exemption prior to [the effective date of the final rule], shall file reports pursuant to § 242.304 and shall not be subject to the requirements of paragraphs (b)(2)(i) through (vii) of this section. As of [date 120 calendar days after the date of publication of the final rule in the **Federal Register**], an entity seeking to operate as a Government Securities ATS shall not be subject to the requirements of paragraphs (b)(2)(i) through (vii) of this section and shall file reports pursuant to § 242.304. An NMS Stock ATS or entity seeking to operate as an NMS Stock ATS shall not be subject to the requirements of paragraphs (b)(2)(i) through (vii) of this section and shall file reports pursuant to § 242.304. An ATS that is not an NMS Stock ATS or Government Securities ATS shall be subject to paragraph (b)(2) of this section. An NMS Stock ATS or a Government Securities ATS that is operated by a broker-dealer that is the registered broker-dealer for more than one ATS must independently comply with Regulation ATS, including the filing requirements of § 242.304 of this chapter.

* * * * *

(5) *Fair access.*

(i) * * *

(E) With respect to U.S. Treasury Securities, 5 percent or more of the average weekly dollar volume traded in the United States as provided by the self-regulatory organization to which such transactions are reported; or

(F) With respect to Agency Securities, 5 percent or more of the average daily

dollar volume traded in the United States as provided by the self-regulatory organization to which such transactions are reported.

* * * * *

■ 8. Amend § 242.304 by:

■ a. Revising the section heading;

■ b. In paragraph (a), removing ''an NMS Stock ATS'' before the phrase ''must comply'' and adding in its place ''a Covered ATS'';

■ c. In the title to paragraph (a)(1), removing ''Form ATS–N'' and adding in its place ''Covered Form'';

■ d. In paragraph (a)(1)(i), adding ''applicable'' after the phrase ''files with the Commission an'' and adding a sentence at the end of the paragraph;

■ e. In paragraph (a)(1)(ii)(A)(1), removing the phrase ''the Form ATS–N is unusually lengthy or raises novel or complex issues that require additional time for review'' and adding in its place ''the Commission determines that a longer period is appropriate'';

■ f. In paragraphs (a)(1)(i) through (iii),

■ 1. Removing each reference to ''NMS Stock ATS'' and adding in its place ''Covered ATS'';

■ 2. Removing each reference to ''an NMS Stock ATS'' and adding in its place ''a Covered ATS''; and

■ 3. Removing each reference to ''Form ATS–N'' and adding in its place ''Covered Form'';

■ g. In the title to paragraph (a)(2), removing ''Form ATS–N'' and adding in its place ''Covered Form'';

■ h. In paragraph (a)(2)(i),

■ 1. Removing ''An NMS Stock ATS'' before the phrase ''shall amend'' and replacing it with ''A Covered ATS''; and

■ 2. Removing ''Form ATS–N'' after the phrase ''shall amend a'' and replacing it with ''Covered Form'';

■ i. In paragraph (a)(2)(i)(A), removing ''NMS Stock ATS'' after the phrase ''change to the operations of the'' and replacing it with ''Covered ATS'';

■ j. In paragraph (a)(2)(i)(A) through (C), removing each reference to ''Form ATS–N'' and adding in its place ''Covered Form'';

■ k. In paragraphs (a)(2)(ii), (a)(3), (a)(4), (b), and (c),

■ 1. Removing each reference to ''NMS Stock ATS'' and adding in its place ''Covered ATS'';

■ 2. Removing each reference to ''an NMS Stock ATS'' and adding in its place ''a Covered ATS''; and

■ 3. Removing each reference to ''Form ATS–N'' and adding in its place ''Covered Form'';

■ l. In paragraph (a)(1)(iv),

■ 1. Removing each reference to ''Form ATS–N'' and adding in its place ''Form ATS–G''; and

■ 2. Removing each reference to ''Legacy NMS Stock ATS'' and adding in its place ''Legacy Government Securities ATS'';

■ m. In paragraph (a)(1)(iv)(A),

■ 1. Adding the phrase ''operating pursuant to an initial operation report on Form ATS on file with the Commission as of [date 120 calendar days after the date of publication of the final rule in the **Federal Register**]'' immediately preceding the phrase, ''shall supersede and replace'';

■ 2. Removing ''January 7, 2019'' and adding in its place ''[date 120 calendar days after the date of publication of the final rule in the **Federal Register**]''; and

■ 3. Removing ''February 8, 2019'' and adding in its place ''[date 150 calendar days after the date of publication of the final rule in the **Federal Register**]'';

■ n. In paragraph (a)(1)(iv)(B)(*1*), removing the phrase ''the initial Form ATS–N is unusually lengthy or raises novel or complex issues that require additional time for review'' and adding in its place ''the Commission determines that a longer period is appropriate'';

■ o. In paragraph (a)(2)(i)(D),

■ 1. Adding ''or Part III, Item 24 on Form ATS–G'' immediately preceding the phrase, ''has become inaccurate or incomplete''; and

■ 2. Removing the phrase ''Order Display and Fair Access Amendment'' and adding in its place ''Contingent Amendment'';

■ p. In paragraph (b)(2)(iii)(B), removing the phrase ''Order Display and Fair Access'' wherever it appears and adding in its place the word ''Contingent''; and

■ q. Revising paragraph (b)(3).

The additions and revisions read as follows:

§ 242.304 Covered ATSs.

(a) * * *

(1) * * *

(i) * * * Notwithstanding the foregoing, a Legacy Government Securities ATS that was formerly not required to comply with Regulation ATS (§ 242.300 through 242.304) pursuant to an exemption prior to [the effective date of the final rule], may continue to operate pursuant to Regulation ATS until its initial Form ATS–G becomes effective.

* * * * *

(b) * * *

(3) Each Covered ATS shall make public via posting on its website:

(i) A direct URL hyperlink to the Commission's website that contains the documents enumerated in paragraph (b)(2) of this section; and

(ii) The most recently disseminated Covered Form (excluding Part IV) within one business day after publication on the Commission's website, except for any amendment that the Commission has declared ineffective or that has been withdrawn. The most recently disseminated Covered Form shall be maintained on the Covered ATS's website until:

(A) The Covered ATS ceases operations; or

(B) The exemption of the Covered ATS is revoked or suspended, in which cases, the Covered ATS shall remove the Covered Form from its website within one business day of such cessation, revocation or suspension, as applicable.

* * * * *

■ 9. Amend § 242.1000 by:

■ a. Adding, in alphabetical order, a definition for ''Agency Securities'';

■ b. At the end of paragraph (1)(ii), under the definition of ''SCI alternative trading system or SCI ATS'', removing the word, ''or'';

■ c. Under the definition of ''SCI alternative trading system or SCI ATS'', redesignating paragraph (3) as paragraph (5);

■ d. Under the definition of ''SCI alternative trading system or SCI ATS'', adding a new paragraph (3) and paragraph (4); and

■ e. In newly redesignated paragraph (5), removing ''paragraphs (1) or (2)'' and adding in its place ''paragraphs (1), (2), (3), or (4)''; and

■ f. Adding, in alphabetical order, a definition for ''U.S. Treasury Securities''.

The additions read as follows:

§ 242.1000 Definitions.

* * * * *

Agency Security has the meaning set forth in § 242.300(q).

* * * * *

SCI alternative trading system or *SCI ATS* * * *

(3) Had with respect to U.S. Treasury Securities, five percent (5%) or more of the average weekly dollar volume traded in the United States as provided by the self-regulatory organization to which such transactions are reported; or

(4) Had with respect to Agency Securities, five percent (5%) or more of the average daily dollar volume traded in the United States as provided by the self-regulatory organization to which such transactions are reported.

* * * * *

U.S. Treasury Security has the meaning set forth in § 242.300(p).

* * * * *

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 10. The general authority citation for part 249 continues to read as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.;* 12 U.S.C. 5461 *et seq.;* 18 U.S.C. 1350; Sec. 953(b), Pub. L. 111–203, 124 Stat. 1904; Sec. 102(a)(3), Pub. L. 112–106, 126 Stat. 309 (2012); Sec. 107, Pub. L. 112–106, 126 Stat. 313 (2012), and Sec. 72001, Pub. L. 114–94, 129 Stat. 1312 (2015), unless otherwise noted.

* * * * *

■ 11. Amend Form ATS (referenced in § 249.637) by:

■ a. In the General Instructions, revising Items A.3 through A.6;

■ b. In the General Instructions, revising the fifth and seventh paragraphs of Item A.7;

■ c. At the top of page 1 of the form, removing ''INITIAL OPERATION REPORT'', ''AMENDMENT TO INITIAL OPERATION REPORT'', ''CESSATION OF OPERATIONS REPORT'' and accompanying check boxes and adding text under a new heading ''Type of Filing (select one)'';

■ d. Revising Item 1;

■ e. Removing the text on page 1 of the form beginning ''EXECUTION'', the signature block below, the instruction that states ''This page must always be completed in full with original, manual signature and notarization. Affix notary stamp or seal where applicable.'' and ''DO NOT WRITE BELOW THIS LINE—FOR OFFICIAL USE ONLY'' and adding in its place text under a new heading ''CONTACT INFORMATION, SIGNATURE BLOCK, AND CONSENT TO SERVICE''; and

■ f. On page 2 of the form, removing the following text:

BILLING CODE 8011–01–P

Alternative trading system name:	CRD Number:
Filing date:	SEC File Number: 8-

The revisions read as follows:

Note: The text of Form ATS does not and this amendment will not appear in the Code of Federal Regulations

FORM ATS

* * * * *

A. **GENERAL INSTRUCTIONS**

* * * * *

3. **CONTACT EMPLOYEE** - The individual listed as the contact employee must be authorized to receive all contact information, communications and mailings and be responsible for disseminating that information within the alternative trading system's organization.

4. **EDGAR FILING** - Any report required to be submitted pursuant to Rule 301 of Regulation ATS shall be prepared, formatted, and submitted in accordance with Regulation S-T and the EDGAR Filer Manual.

5. **EDGAR ACCEPTANCE** - A filing that is defective may be rejected and not be accepted by the EDGAR system. Any filing so rejected shall be deemed not to have been filed. See generally Regulation S-T (17 CFR part 232).

6. **RECORDKEEPING** - A copy of this Form ATS must be retained by the ATS in accordance with the EDGAR Filer Manual and Rule 303 of Regulation ATS and must be made available for inspection upon a regulatory request.

7. **PAPERWORK REDUCTION ACT DISCLOSURE**

- * * *
- * * *
- * * *
- * * *
- It is estimated that an alternative trading system will spend approximately 20.5 hours completing the initial operation report on Form ATS, approximately 4.75 hours preparing each amendment to Form ATS, and approximately 2 hours preparing a cessation of operations report on Form ATS.
- * * *
- All reports provided to the Commission on Form ATS (except for types of securities traded provided on Form ATS and Form ATS-R) will be afforded confidential treatment and will be available only to the examination of Commission staff , state securities authorities, and the self-regulatory organizations. Subject to the provisions of the Freedom of Information Act, 5 U.S.C. 522 ("FOIA") and the Commission's rules thereunder (17 CFR

200.80(b)(4)(iii)), the Commission does not generally publish or make available information contained in any reports, summaries, analyses, letters, or memoranda arising out of, in anticipation of, or in connection with, an examination or inspection of the books and records of any person or any other investigation.

* * * * *

WARNING: Failure to keep this form current and to file accurate supplementary information on a timely basis, or the failure to keep accurate books and records or otherwise to comply with the provisions of law applying to the conduct of alternative trading systems would violate the federal securities laws and may result in disciplinary, administrative or criminal action.

INTENTIONAL MISSTATEMENTS OR OMISSIONS OF FACTS MAY CONSTITUTE CRIMINAL VIOLATIONS

Type of Filing (select one):

☐ Initial operation report Rule 301(b)(2)(i)

☐ Material amendment Rule 301(b)(2)(ii)

☐ Periodic amendment Rule 301(b)(2)(iii)

☐ Correcting amendment Rule 301(b)(2)(iv)

☐ Cessation of operations report Rule 301(b)(2)(v)

- Date the ATS will cease to operate: mm/dd/yyyy

---

1. Provide the following identifying information:

A. Indicate the following:

i. Is the organization, association, Person, group of Persons, or system filing the Form ATS a broker-dealer registered with the Commission?

Yes☐ No☐

ii. Is the registered broker-dealer authorized by a national securities association to operate an ATS?

Yes☐ No☐

B. Full name of registered broker-dealer of the ATS ("Broker-Dealer Operator") as stated on Form BD:_____

C. Full name(s) of the ATS under which business is conducted, if

different:_____

D. Provide the SEC file number and CRD number of the Broker-Dealer Operator:

i. SEC File No.:_____

ii. CRD No.:_____

E. Provide the full name of the national securities association of the Broker-Dealer Operator, the effective date of the Broker-Dealer Operator's membership with the national securities association, and Market Participant Identifier ("MPID") of the ATS:

i. National Securities Association: _____

ii. Effective Date of Membership: _____

iii. MPID of the ATS: _____

F. Provide, if any, the website URL of the ATS:_____

G. Provide the primary, and if any, secondary, physical street address(es) of the ATS matching system: _____

CONTACT INFORMATION, SIGNATURE BLOCK, AND CONSENT TO SERVICE

Provide the following information of the Person at {ATS} prepared to respond to questions for this submission:

First Name: Last Name:

Title:

Email: Telephone:

Primary Street Address of the ATS:

Mailing Address of the ATS (if different):

The {ATS} consents that service of any civil action brought by, or notice of any proceeding before, the SEC or a self-regulatory organization in connection with the alternative trading system's activities may be given by registered or certified mail to the contact employee at the primary street address or mailing address (if different) of the ATS, or via email, at the addresses provided on this Form ATS. The undersigned deposes and says that he/she has executed this form on behalf of, and with the authority of, said alternative trading system. The undersigned and {ATS} represent that the information and statements contained herein, including exhibits,

schedules, or other documents attached hereto, and other information filed herewith, all of which are made a part hereof, are current, true, and complete.

Date {auto fill} {ATS}

By: _____ Title_____

2. If this is an initial operation report, the date the alternative trading system expects to commence operation: _____

■ 12. Amend Form ATS–R (referenced in § 249.634) by:
■ a. In the General Instructions, revising Items A.3 through A.6;
■ b. In the General Instructions, revising the fifth and seventh paragraphs of Item A.7;
■ c. In the Explanation of Terms, adding the definitions of ''Agency Securities'' and ''U.S. Treasury Securities'';
■ d. On page 1 of the form, immediately before Section 1, adding text under a new heading ''Type of Filing'';
■ e. Revising Item 1;
■ f. Removing text on page 1 of the form beginning ''EXECUTION'', the signature block below, the instruction that states ''This page must always be completed in full with original, manual signature and notarization. Affix notary stamp or seal where applicable.'' and ''DO NOT WRITE BELOW THIS LINE – FOR OFFICIAL USE ONLY'' and adding in its place text under a new heading ''CONTACT INFORMATION, SIGNATURE BLOCK, AND CONSENT TO SERVICE'';
■ g. On page 2 and 3 of the form, removing the following text:

DO NOT WRITE BELOW THIS LINE – FOR OFFICIAL USE ONLY

Alternative trading system name:	CRD Number:
Filing date:	SEC File Number: 8-

■ h. Revising Item 4;
■ i. Adding Items 5.C and 5.D;
■ j. Revising Items 6.B through 6.C, and
■ k. Adding Item 8.

The additions and revisions read as follows:

Note: The text of Form ATS–R does not and this amendment will not appear in the Code of Federal Regulations.

FORM ATS-R

* * * * *

A. GENERAL INSTRUCTIONS

* * * * *

3. **CONTACT EMPLOYEE** - The individual listed as the contact employee must be authorized to receive all contact information, communications and mailings and be responsible for disseminating that information within the alternative trading system's organization.

4. **EDGAR FILING** - Any report required to be submitted pursuant to Rule 301 of Regulation ATS shall be prepared, formatted, and submitted in accordance with Regulation S-T and the EDGAR Filer Manual.

5. **EDGAR ACCEPTANCE** - A filing that is defective may be rejected and not be accepted by the EDGAR system. Any filing so rejected shall be deemed not to have been filed. See generally Regulation S-T (17 CFR part 232).

6. **RECORDKEEPING** - A copy of this Form ATS-R must be retained by the ATS in accordance with the EDGAR Filer Manual and Rule 303 of Regulation ATS and must be made available for inspection upon a regulatory request.

7. PAPERWORK REDUCTION ACT DISCLOSURE

- * * *
- * * *
- * * *
- * * *

- It is estimated that an alternative trading system will spend approximately 4.75 hours completing Form ATS-R.

- * * *

- All reports provided to the Commission on Form ATS-R (except for types of securities traded provided on Form ATS and Form ATS-R) will be afforded confidential treatment and will be available only to the examination of Commission staff, state securities authorities and the self-regulatory organizations. Subject to the provisions of the Freedom of Information Act, 5 U.S.C. 522 ("FOIA") and the Commission's rules thereunder (17 CFR 200.80(b)(4)(iii)), the Commission does not generally publish or make available information contained in any reports, summaries, analyses, letters, or memoranda arising out of, in anticipation of, or in connection with an examination or inspection of the books and records of any person or any other investigation.

* * * * *

B. EXPLANATION OF TERMS

AGENCY SECURITIES – Shall mean a debt security issued or guaranteed by a U.S. executive agency, as defined in 5 U.S.C. 105, or government-sponsored enterprise, as defined in 2 U.S.C. 622(8).

* * * * *

U.S. TREASURY SECURITIES – Shall mean a security issued by the U.S. Department of the Treasury.

* * * * *

Alternative Trading System Name:_____

Period covered by this report: _____ to _____

Type of Filing (select one):

☐ Quarterly report Rule 301(b)(9)(i)

☐ Report for an ATS that has ceased to operate Rule 301(b)(9)(ii)

- Date the ATS ceased to operate: mm/dd/yyyy

---

1. Provide the following identifying information:

A. Full name of registered broker-dealer of the ATS ("Broker-Dealer Operator") as stated on Form BD:_____

B. Full name(s) of the ATS under which business is conducted, if different:_____

C. Provide the SEC file number and CRD number of the Broker-Dealer Operator:

i. SEC File No.:_____

ii. CRD No.:_____

D. Provide the full name of the national securities association of the Broker-Dealer Operator, the effective date of the Broker-Dealer Operator's membership with the national securities association, and Market Participant Identifier ("MPID") of the ATS:

i. National Securities Association: _____

ii. Effective Date of Membership: _____

iii. MPID of the ATS: _____

E. Provide, if any, the website URL of the ATS:_____

F. Provide the primary, and if any, secondary, physical street address(es) of the ATS matching system: _____

2. Attach as Exhibit A, a list of all subscribers that were participants of the alternative trading system at any time during the period covered by this report.

3. Attach as Exhibit B, a list of all securities that were traded on the alternative trading system at any time during the period covered by this report.

CONTACT INFORMATION, SIGNATURE BLOCK, AND CONSENT TO SERVICE

Provide the following information of the Person at {ATS} prepared to respond to questions for this submission:

First Name: Last Name:

Title:

Email: Telephone:

Primary Street Address of the ATS:

Mailing Address of the ATS (if different):

The {ATS} consents that service of any civil action brought by, or notice of any proceeding before, the SEC or a self-regulatory organization in connection with the alternative trading system's activities may be given by registered or certified mail to the contact employee at the primary street address or mailing address (if different) of the ATS, or via email, at the addresses provided on this Form ATS-R. The undersigned deposes and says that he/she has executed this form on behalf of, and with the authority of, said alternative trading system. The undersigned and {ATS} represent that the information and statements contained herein, including exhibits, schedules, or other documents attached hereto, and other information filed herewith, all of which are made a part hereof, are current, true, and complete.

Date {auto fill} {ATS}

By: _____ Title_____

4. Provide the total unit and dollar volume of transactions in the following securities. For securities reported in 4J-4O, report total settlement value in U.S. Dollars. Enter "None," "N/A" or "0" where appropriate.

Category of Securities	Total Unit Volume of Transactions	Total Dollar Volume of Transactions
A. Listed Equity Securities		
B. Nasdaq Global Market Securities		
C. Nasdaq Capital Market Securities		
D. Equity securities issued pursuant to Rule 144A of the Securities Act of 1933		
E. Penny Stock, other than any securities included in Items 4A-4D above		
F. Other equity securities not included in Items 4A-4E above		
G. Rights and warrants		
H. Listed options		
I. Unlisted options		

J. Government securities		
i. U.S. Treasury Securities		
ii. Agency Securities		
K. Repurchase agreements and reverse repurchase agreements	N/A	
L. Municipal securities		
M. Corporate debt securities		
N. Mortgage related securities		
O. Debt securities other than any securities included in Items 4J-4N above		

5. * * *

C. List the types of securities subject to repurchase and reverse repurchase agreements reported in Item 4K above: _____

D. List the types of listed options reported in Item 4H above: _____

6. Provide the total unit and dollar volume of transactions for after-hours trading in the following securities. Enter "None," "N/A" or "0" where appropriate.

Category of Securities	Total Unit Volume of Transactions	Total Dollar Volume of Transactions
A. Listed Equity Securities		
B. Nasdaq Global Market Securities		
C. Nasdaq Capital Market Securities		
D. Listed options		

* * * * *

8. Was the ATS subject to the fair access obligations under Rule 301(b)(5) during any portion of the period covered by the report?

Yes No

* * * * *

■ 13. Amend Form ATS–N (referenced in § 149.640) by:

■ a. On page 1 of the form, removing the following:

- Does the NMS Stock ATS currently operate pursuant to a Form ATS?

☐ Yes No

■ b. On page 1 of the form, revising text under ''Type of Filing (select one)'',

■ c. Revising Part I, Item 1;

■ d, Revising Part I, Item 10;

■ e. Revising Part II, Item 4.b;

■ f. Revising Part II, Item 6.a;

■ g. Revising Part III, Item 1;

■ h. Revising Part III, Item 4.a;

■ i. Revising Part III, Item 6.b;

■ j. Revising Part III, Item 7.a;

■ k. Revising Part III, Item 10;

■ l. Revising Part III, Item 13.a;

■ m. Revising Part III, Item 17.a;

■ n. Revising Part III, Item 18;

■ o. Revising Part III, Item 19.a;

■ p. Revising Part IV;

■ q. In FORM ATS–N INSTRUCTIONS, revising Item A.4;

■ r. In FORM ATS–N INSTRUCTIONS, revising Items A.6 through A.7;

■ s. In FORM ATS–N INSTRUCTIONS, revising Item D; and

■ t. In FORM ATS–N INSTRUCTIONS, under Item E, revising the definitions of ''NMS STOCK ATS'' and ''PERSON''.

The revisions read as follows:

Note: The text of Form ATS–N does not and this amendment will not appear in the Code of Federal Regulations.

THE SECURITIES AND EXCHANGE COMMISSION HAS NOT PASSED UPON THE MERITS OR ACCURACY OF THE DISCLOSURES IN THIS FILING.

United States Securities and Exchange Commission

Washington, DC

FORM ATS-N

Intentional Misstatements or Omissions of Facts May Constitute Criminal Violations

See 18 U.S.C.1001 and 15 U.S.C. 78ff(a)

File No:

{NMS Stock ATS} is making this filing pursuant to the Rule 304 under the Securities Exchange Act of 1934

Type of Filing (select one)

☐ Initial Form ATS-N Rule 304(a)(1)(i)
☐ Material Amendment Rule 304(a)(2)(i)(A)
☐ Updating Amendment Rule 304(a)(2)(i)(B)
☐ Correcting Amendment Rule 304(a)(2)(i)(C)
☐ Contingent Amendment Rule 304(a)(2)(i)(D)

* * * * *

Part I: Identifying Information

1. Indicate the following:

a. Is the organization, association, Person, group of Persons, or system filing the Form ATS-N a broker-dealer registered with the Commission?

Yes☐ No☐

b. Is the registered broker-dealer authorized by its national securities association to operate an ATS?

Yes☐ No☐

* * * * *

10. For filings made pursuant to Rule 304(a)(2)(i)(A) through (D) (i.e., Form ATS-N Amendments), attach as Exhibit 3 a document marked to indicate changes to "yes" or "no" answers or additions to or deletions from any Item in Part I, II, and III, as applicable. Do not include in Exhibit 3 Items that are not changing.

Part II: Activities of the Broker-Dealer Operator and its Affiliates

* * * * *

Item 4: Arrangements with Trading Centers

a. * * *

b. Are there any formal or informal arrangements between an Affiliate of the Broker-Dealer Operator and a Trading Center to access the NMS Stock ATS services?

Yes☐ No☐

If yes, identify the Trading Center and ATS services and provide a summary of the terms and conditions of the arrangement.

* * * * *

Item 6: Activities of Service Providers

a. Does any employee of the Broker-Dealer Operator or employee of its Affiliate that services both the operations of the NMS Stock ATS and any other business unit or any Affiliate of the Broker-Dealer Operator ("shared employee") have access to confidential trading information on the NMS Stock ATS?

Yes☐ No☐

If yes, identify the business unit, Affiliate, or both that the shared employee services, and provide a summary of the role and responsibilities of the shared employee at the ATS and the business unit, Affiliate, or both that the shared employee services.

* * * * *

Part III: Manner of Operations

Item 1: Types of ATS Subscribers

Select the type(s) of Subscribers that can use the NMS Stock ATS services:

☐ Investment Companies ☐ Retail Investors ☐ Issuers ☐ Brokers

☐ Asset Managers ☐ Principal Trading Firms ☐ Hedge Funds

☐ Market Makers ☐ Banks ☐ Dealers

☐ Insurance Companies ☐ Pension Funds ☐ Corporations

☐ Other

If other, identify the type(s) of subscriber.

* * * *

Item 4: Hours of Operations

a. Provide the days and hours of operations of the NMS Stock ATS, including the times when orders or trading interest can be entered on the ATS, and any hours of operations outside of its regular trading hours.

* * * *

Item 6: Connectivity and Co-location

a. * * *

b. If yes to Item 6(a), are the terms and conditions required to be identified in Item 6(a) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

* * * *

Item 7: Order Types and Attributes

a. Identify and explain each order type offered by the NMS Stock ATS. In your explanation, include the following:

i. * * *

ii. conditions, including any price conditions (e.g., how price conditions affect the rank and price at which the order type can be executed; conditions on the display or non-display of an order; or conditions on executability and routability);

* * * *

Item 10: Opening and Reopening

a. Explain how the NMS Stock ATS opens or re-opens for trading, including when and how orders and trading interest are priced, prioritized, matched, and executed, and identify any order types allowed prior to the start of its regular trading hours or following a stoppage of trading in a security during its regular trading hours.

b. * * *

c. Explain how unexecuted orders and trading interest are handled at the time the NMS Stock ATS begins regular trading at the start of its regular trading hours or following a stoppage of trading in a security during its regular trading hours.

d. Are the processes or procedures governing unexecuted orders and trading at the time the NMS Stock ATS begins regular trading at the start of its regular trading hours, or following a stoppage of trading in a security during its regular trading hours, the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

e. Are there any differences between pre-opening executions, executions following a stoppage of trading in a security during the NMS Stock ATS's regular trading hours, and/or executions during its regular trading hours?

Yes☐ No☐

If yes, identify and explain the differences.

* * * *

Item 13: Segmentation; Notice

a. Are orders and trading interest in the NMS Stock ATS segmented into categories, classifications, tiers, or levels (e.g., segmented by type of participant, order size, duration, source, or nature of trading activity)?

Yes☐ No☐

If yes, explain the segmentation procedures, including (i) a description of how orders and trading interest are segmented; (ii) identify and describe any categories, classification, tiers, or levels and the types of orders and trading interest that are included in each; (iii) provide a summary of the parameters for each segmented category and length of time each segmented category is in effect; (iv) any procedures for overriding a determination of segmented category; and (v) how segmentation can affect order interaction.

* * * *

Item 17: Closing

a. Are there any differences between how orders and trading interest are treated on the NMS Stock ATS during the close and how orders and trading interest are treated during its regular trading hours?

Yes☐ No☐

If yes, identify and explain the differences as compared to the information provided in the relevant Part III Items of this form.

* * * *

Item 18: Trading Outside of Regular Trading Hours

a. * * *

b. If yes to Item 18(a), are there any differences between trading outside of its regular trading hours and trading during its regular trading hours in the NMS Stock ATS?

Yes☐ No☐

If yes, identify and explain the differences.

c. If yes to Item 18(a), is the treatment of orders and trading interest outside of its regular trading hours the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 19: Fees

a. Identify and describe any fees or charges for use of the NMS Stock ATS services, including the type of fees (e.g., subscription, connectivity, market data), the structure of the fees (e.g., fixed, volume-based, transaction-based), variables that impact the fees (e.g., types of securities traded, block orders, form of connectivity to the ATS), differentiation among types of Subscribers (e.g., broker-dealers, institutional investors, retail) and range of fees (e.g., high and low).

* * * *

Part IV: Contact Information, Signature Block, and Consent to Service

* * * *

The {NMS Stock ATS} consents that service of any civil action brought by, or notice of any proceeding before, the SEC or a self-regulatory organization in connection with the alternative trading system's activities may be given by registered or certified mail to the contact employee at the primary street address or mailing address (if different) of the NMS Stock ATS, or via email, at the addresses provided on this Form ATS-N. The undersigned deposes and says that he/she has executed this form on behalf of, and with the authority of, said alternative trading system. The undersigned and {NMS Stock ATS} represent that the information and statements contained herein, including exhibits, schedules, or other documents attached hereto, and other information filed herewith, all of which are made a part hereof, are current, true, and complete.

* * * *

FORM ATS-N INSTRUCTIONS

A. FILING FORM ATS-N:

* * * *

4. An NMS Stock ATS must respond to each request in detail unless the request indicates that the ATS is required to disclose "summary" information.

5. * * *

6. Initial Form ATS-N: Prior to commencing operations, an NMS Stock ATS shall file an initial Form ATS-N and the initial Form ATS-N must become effective. If an NMS Stock ATS is currently operating pursuant to a Form ATS it must indicate such on the Form ATS-N.

7. Form ATS-N Amendment

a. * * *

b. A Material Amendment, except as provided by Rule 304(a)(2)(i)(D) for a Contingent Amendment, must be filed at least 30 calendar days prior to the date of implementation of a material change to the operations of the NMS Stock ATS or to the activities of the Broker-Dealer Operator or its Affiliates that are subject to disclosure on Form ATS-N.

c. * * *

d. * * *

e. A Contingent Amendment must be filed no later than seven calendar days after information required to be disclosed in Part III, Items 24 and 25 on Form ATS-N has become inaccurate or incomplete.

f. * * *

g. For each Amendment, indicate the Part and Item number of the Form ATS-N that is the subject of the change(s), provide a brief summary of the change(s), and state whether or not the change(s) apply to all Subscribers and the Broker-Dealer Operator.

* * * *

D. PAPERWORK REDUCTION ACT DISCLOSURE

- * * *
- * * *
  - * * *
    - File a Form ATS Amendment: (1) at least 30 calendar days prior to the date of implementation of a material change to the operations of the NMS Stock ATS or to the activities of the Broker-Dealer Operator or its Affiliates that are subject to disclosure on Form ATS-N (Material Amendment); (2) no later than 30 calendar days after the end of each calendar quarter to correct any other information that has become inaccurate or incomplete for any reason and was not previously required to be reported to the Commission as a Form ATS-N amendment pursuant to Rule 304(a)(2)(i)(A), Rule 304(a)(2)(i)(C), or Rule 304(a)(2)(i)(D) (Updating Amendment); (3) promptly, to correct information in any previous disclosure on Form ATS-N, after discovery that any information previously filed on Form ATS-N was materially inaccurate or incomplete when filed (Correcting Amendment); or (4) no later than seven calendar days after information required to be disclosed in Part III, Items 24 and 25 on Form ATS-N has become inaccurate or incomplete (Contingent Amendment). During the Commission review period of an initial Form ATS-N filing, an NMS Stock ATS shall amend a filed Material Amendment pursuant to the requirements for Updating and Correcting Amendments.

* * * *

E. EXPLANATION OF TERMS

* * * *

- **NMS STOCK ATS**: Shall mean an alternative trading system, as defined in Rule 300(a) under the Exchange Act, that trades NMS stocks, as defined in Rule 300(g) under the Exchange Act. An NMS Stock ATS shall not trade securities other than NMS stocks. 17 CFR 242.300(k).

* * * *

• **PERSON**: Shall mean a natural person, company, government, or political subdivision, agency, or instrumentality of a government. 15 U.S.C. 78c(a)(9).

* * * *

■ 14. Add §249.642 to subpart G to read as follows:

Note: The text of Form ATS–G does not and this amendment will not appear in the Code of Federal Regulations.

§ 249.642 Form ATS–G, information required of Government Securities ATSs pursuant to §242.304(a) of this chapter.

This form shall be usd by every Government Securities ATS to file required reports under § 242.304(a) of this chapter.

THE SECURITIES AND EXCHANGE COMMISSION HAS NOT PASSED UPON THE MERITS OR ACCURACY OF THE DISCLOSURES IN THIS FILING.

United States Securities and Exchange Commission

Washington, DC

FORM ATS-G

Intentional Misstatements or Omissions of Facts May Constitute Criminal Violations

See 18 U.S.C.1001 and 15 U.S.C. 78ff(a)

File No:

{Government Securities ATS} is making this filing pursuant to the Rule 304 under the Securities Exchange Act of 1934

- Was the Government Securities ATS operating (either pursuant to a Form ATS or to an exemption) as of [the date 120 calendar days after the date of publication of the final rule in the Federal Register]?

  Yes☐ No☐

Type of Filing (select one)

☐ Initial Form ATS-G Rule 304(a)(1)(i)
☐ Material Amendment Rule 304(a)(2)(i)(A)
☐ Updating Amendment Rule 304(a)(2)(i)(B)
☐ Correcting Amendment Rule 304(a)(2)(i)(C)
☐ Contingent Amendment Rule 304(a)(2)(i)(D)

- Statement about the Form ATS-G Amendment pursuant to Instruction A.7(g) of this form:

- Provide the EDGAR accession number for the Form ATS-G filing to be amended:

☐ Notice of Cessation Rule 304(a)(3)

- Date the Government Securities ATS will cease to operate: mm/dd/yyyy

☐ Withdrawal of Form ATS-G filing

Provide the EDGAR accession number for the Form ATS-G filing to be withdrawn:

Part I: Identifying Information

1. Indicate the following:

a. Is the organization, association, Person, group of Persons, or system filing the Form ATS-G a broker-dealer registered with the Commission?

Yes☐ No☐

b. Is the registered broker-dealer authorized by a national securities association to operate an ATS?

Yes☐ No☐

2. Full name of registered broker-dealer, government securities broker, or government securities dealer of the Government Securities ATS ("Broker-Dealer Operator") as stated on Form BD:

3. Full name(s) of Government Securities ATS under which business is conducted, if different:

4. Provide the SEC file number and CRD number of the Broker-Dealer Operator:

a. SEC File No.:
b. CRD No.:

5. Please indicate the types of government securities that the ATS trades:

☐ U.S. Treasury Securities
☐ Agency Securities
☐ Repurchase or Reverse Repurchase Agreements on Government Securities ("repos")
☐ Other

If other, identify the types of government securities that the ATS trades:

6. Provide the full name of the national securities association of the Broker-Dealer Operator, the effective date of the Broker-Dealer Operator's membership with the national securities association, and Market Participant Identifier ("MPID") of the Government Securities ATS:

a. National Securities Association:
b. Effective Date of Membership:
c. MPID of the Government Securities ATS:

7. Provide, if any, the website URL of the Government Securities ATS:

8. Provide the primary, and if any, secondary, physical street address(es) of the Government Securities ATS matching system:

9. Attach as Exhibit 1, the most recently filed or amended Schedule A of Form BD for the Broker-Dealer Operator disclosing information related to direct owners and executive officers.

   ☐ Select if, in lieu of filing, {Government Securities ATS} certifies that the information requested under this Exhibit is available at the website above and is accurate as of the date of this filing.

10. Attach as Exhibit 2, the most recently filed or amended Schedule B of Form BD for the Broker-Dealer Operator disclosing information related to indirect owners.

    ☐ Select if, in lieu of filing, {Government Securities ATS} certifies that the information requested under this Exhibit is available at the website above and is accurate as of the date of this filing.

11. For filings made pursuant to Rule 304(a)(2)(i)(A) through (D) (i.e., Form ATS-G Amendments), attach as Exhibit 3 a document marked to indicate changes to "yes" or "no" answers or additions to or deletions from any Item in Part I, II, and III, as applicable. Do not include in Exhibit 3 Items that are not changing.

Part II: Activities of the Broker-Dealer Operator and its Affiliates

Item 1: Broker-Dealer Operator Trading Activities on the ATS

a. Are business units of the Broker-Dealer Operator permitted to enter or direct the entry of orders and trading interest (*e.g.,* indications of interest) into the Government Securities ATS?

   Yes☐ No☐

   If yes, name and describe each type of business unit of the Broker-Dealer Operator that enters or directs the entry of orders and trading interest into the ATS (*e.g.*, Government Securities ATS, type of trading desks, market maker, sales or client desk) and, for each business unit, provide the applicable MPID and list the capacity of its orders and trading interest (*e.g.,* principal, agency, riskless principal).

b. If yes to Item 1(a), are the services that the Government Securities ATS offers and provides to the business units required to be identified in Item 1(a) the same for all Subscribers?

   Yes☐ No☐

   If no, explain any differences in response to the applicable Item number in Part III of this form, as required, and list the applicable Item number here. If there are differences that are not applicable to Part III, explain those differences here.

c. Are there any formal or informal arrangements with any of the business units required to be identified in Item 1(a) to provide orders or trading interest to the Government Securities ATS (*e.g.*, undertaking to buy or sell continuously, or to meet specified thresholds of trading or quoting activity)?

Yes☐ No☐

If yes, identify the business unit and respond to the request in Part III, Item 12 of this form.

d. Can orders and trading interest in the Government Securities ATS be sent to a trading venue operated or controlled by the Broker-Dealer Operator?

Yes☐ No☐

If yes, identify the trading venue and when and how orders or trading interest are sent from the Government Securities ATS to the trading venue.

Item 2: Affiliates Trading Activities on the ATS

a. Are Affiliates of the Broker-Dealer Operator permitted to enter or direct the entry of orders and trading interest into the Government Securities ATS?

Yes☐ No☐

If yes, name and describe each type of Affiliate that enters or directs the entry of orders and trading interest into the ATS (*e.g.*, broker-dealer, investment company, hedge fund, market maker, principal trading firm), and, for each Affiliate, provide the applicable MPID and list the capacity of its orders and trading interest (*e.g.,* principal, agency, riskless principal).

b. If yes, to Item 2(a), are the services that the Government Securities ATS offers and provides to the Affiliates required to be identified in Item 2(a) the same for all Subscribers?

Yes☐ No☐

If no, explain any differences in response to the applicable Item number in Part III of this form, as required, and list the applicable Item number here. If there are differences that are not applicable to Part III, explain those differences.

c. Are there any formal or informal arrangements with an Affiliate required to be identified in Item 2(a) to provide orders or trading interest to the Government Securities ATS (*e.g.*, undertaking to buy or sell continuously, or to meet specified thresholds of trading or quoting activity)?

Yes☐ No☐

If yes, identify the Affiliate and respond to the request in Part III, Item 12 of this form.

d. Can orders and trading interest in the Government Securities ATS be sent to a trading venue operated or controlled by an Affiliate of the Broker-Dealer Operator?

Yes☐ No☐

If yes, identify the trading venue and when and how orders and trading interest are sent from the Government Securities ATS to the trading venue.

Item 3: Order Interaction with Broker-Dealer Operator; Affiliates

a. Can any Subscriber opt out from interacting with orders and trading interest of the Broker-Dealer Operator in the Government Securities ATS?

Yes☐ No☐

If yes, explain the opt-out process.

b. Can any Subscriber opt out from interacting with the orders and trading interest of an Affiliate of the Broker-Dealer Operator in the Government Securities ATS?

Yes☐ No☐

If yes, explain the opt-out process.

c. If yes to Item 3(a) or 3(b), are the terms and conditions of the opt-out processes required to be identified in Item 3(a), 3(b), or both, the same for all Subscribers?

Yes☐ No☐

If no, identify and explain any differences.

Item 4: Arrangements with Other Trading Venues

a. Are there any formal or informal arrangements (*e.g.*, mutual, reciprocal, or preferential access arrangements) between the Broker-Dealer Operator and another trading venue (*e.g.*, ATS, OTC market maker, futures or options market) to access the Government Securities ATS services (*e.g.*, arrangements to effect transactions or to submit, disseminate, or display orders and trading interest in the ATS)?

Yes☐ No☐

If yes, identify the trading venue and the ATS services and provide a summary of the terms and conditions of the arrangement.

b. Are there any formal or informal arrangements between an Affiliate of the Broker-Dealer Operator and another trading venue to access the Government Securities ATS services?

Yes☐ No☐

If yes, identify the trading venue and ATS services and provide a summary of the terms and conditions of the arrangement.

Item 5: Other Products and Services

a. Does the Broker-Dealer Operator offer Subscribers any products or services for the purpose of effecting transactions or submitting, disseminating, or displaying orders and trading interest in the Government Securities ATS (*e.g.*, algorithmic trading products that send orders to the ATS, order management or order execution systems, data feeds regarding orders and trading interest in, or executions occurring on, the ATS, order hedging or aggregation functionality)?

Yes☐ No☐

If yes, identify the products or services offered, provide a summary of the terms and conditions for use, and list here the applicable Item number in Part III of this form where the use of the product or service is explained. If there is no applicable Item in Part III, explain the use of the product or service with the ATS here.

b. If yes to Item 5(a), are the terms and conditions of the services or products required to be identified in Item 5(a) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

c. Does any Affiliate of the Broker-Dealer Operator offer Subscribers, the Broker-Dealer Operator, or both, any products or services for the purpose of effecting transactions or submitting, disseminating, or displaying orders or trading interest in the Government Securities ATS?

Yes☐ No☐

If yes, identify the products or services offered, provide a summary of the terms and conditions for use, and list here the applicable Item number in Part III of this form where the use of the product or service is explained. If there is no applicable item in Part III, explain the use of the product or service with the ATS here.

d. If yes to Item 5(c), are the terms and conditions of the services or products required to be identified in Item 5(c) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 6: Activities of Service Providers

a. Does any employee of the Broker-Dealer Operator or employee of its Affiliate that services both the operations of the Government Securities ATS and any other business unit or any Affiliate of the Broker-Dealer Operator ("shared employee") have access to confidential trading information on the Government Securities ATS?

Yes☐ No☐

If yes, identify the business unit, Affiliate, or both that the shared employee services, and provide a summary of the role and responsibilities of the shared employee at the ATS and the business unit, Affiliate, or both that the shared employee services.

b. Does any entity, other than the Broker-Dealer Operator, support the services or functionalities of the Government Securities ATS ("service provider") that are required to be explained in Part III of this form?

Yes☐ No☐

If yes, both identify the service provider and provide a summary of the role and responsibilities of the service provider in response to the applicable Item number in Part III of this form, as required. List the applicable Item number here. If there are services or functionalities that are not applicable to Part III, identify the service provider, the services and functionalities, and also provide a summary of the role and responsibilities of the service provider here.

c. If yes to Item 6(b), does the service provider, or any of its Affiliates, use the Government Securities ATS services?

Yes☐ No☐

If yes, identify the service provider, or the Affiliate as applicable, and the ATS services that the service provider or its Affiliates use.

d. If yes to Item 6(c), are the services that the Government Securities ATS offers and provides to the entity required to be identified in Item 6(c) the same for all Subscribers?

Yes☐ No☐

If no, identify and explain any differences.

Item 7: Protection of Confidential Trading Information

a. Describe the written safeguards and written procedures to protect the confidential trading information of Subscribers to the Government Securities ATS, including:

i. written standards controlling employees of the ATS that trade for employees' accounts; and
ii. written oversight procedures to ensure that the safeguards and procedures described above are implemented and followed.

b. Can a Subscriber consent to the disclosure of its confidential trading information to any Person (not including those employees of the Government Securities ATS who are operating the system or responsible for its compliance with applicable rules)?

Yes☐ No☐

If yes, explain how and under what conditions.

c. If yes to Item 7(b), can a Subscriber withdraw consent to the disclosure of its confidential trading information to any Person (not including those employees of the Government Securities ATS who are operating the system or responsible for its compliance with applicable rules)?

Yes☐ No☐

If yes, explain how and under what conditions.

d. Provide a summary of the roles and responsibilities of any Persons that have access to confidential trading information, the confidential trading information that is accessible by them, and the basis for the access.

Part III: Manner of Operations

Item 1: Types of ATS Subscribers

Select the type(s) of Subscribers that can use the Government Securities ATS services:

☐ Investment Companies ☐ Retail Investors ☐ Brokers

☐ Asset Managers ☐ Principal Trading Firms ☐ Hedge Funds

☐ Market Makers ☐ Banks ☐ Dealers

☐ Insurance Companies ☐ Pension Funds ☐ Corporations

☐ Other

If other, identify the type(s) of subscriber.

Item 2: Eligibility for ATS Services

a. Does the Government Securities ATS require Subscribers to be registered broker-dealers?

Yes☐ No☐

b. Are there any other conditions that the Government Securities ATS requires a Person to satisfy before accessing the ATS services?

Yes☐ No☐

If yes, list and provide a summary of the conditions.

c. If yes to Item 2(b), are the conditions required to be identified in Item 2(b) the same for all Persons?

Yes☐ No☐

If no, identify and describe any differences.

d. Does the Government Securities ATS require Subscribers to enter a written agreement to use the ATS services?

Yes☐ No☐

Item 3: Exclusion from ATS Services

a. Can the Government Securities ATS exclude, in whole or in part, any Subscriber from the ATS services?

Yes☐ No☐

If yes, list and provide a summary of the conditions for excluding, in whole or in part, a Subscriber from the ATS services.

b. If yes to Item 3(a), are the conditions required to be identified in Item 3(a) the same for all Subscribers?

Yes☐ No☐

If no, identify and explain any differences.

Item 4: Hours of Operations

a. Provide the days and hours of operations of the Government Securities ATS, including the times when orders or trading interest can be entered on the ATS, and any hours of operations outside of its regular trading hours.

b. Are the hours of operations the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 5: Means of Entry

a. Does the Government Securities ATS permit orders and trading interest to be entered directly into the ATS (*e.g.*, via Financial Information eXchange ("FIX") protocol, Binary)?

Yes☐ No☐

If yes, explain the protocol that can be used to directly enter orders and trading interest into the ATS.

b. If yes to Item 5(a), are the protocols required to be identified in Item 5(a) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

c. Are there any other means for entering orders and trading interest into the Government Securities ATS (*e.g.*, smart order router, algorithm, order management system, sales desk, or aggregation functionality)?

Yes☐ No☐

If yes, identify and explain the other means for entering orders and trading interest, indicate whether the means are provided through the Broker-Dealer Operator, either by itself or through a third-party contracting with the Broker-Dealer Operator, or through an Affiliate of the Broker-Dealer Operator, and list and provide a summary of the terms and conditions for entering orders or trading interest into the ATS through these means.

d. If yes to Item 5(c), are the terms and conditions required to be identified in Item 5(c) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 6: Connectivity and Co-location

a. Does the Government Securities ATS offer co-location and related services (*e.g.,* cabinets and equipment, cross-connects)?

Yes☐ No☐

If yes, provide a summary of the terms and conditions for co-location and related services, including the speed and connection (*e.g.,* fiber, copper) options offered.

b. If yes to Item 6(a), are the terms and conditions required to be identified in Item 6(a) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

c. Does the Government Securities ATS offer any other means besides co-location and related services required to be explained in this Item 6(a) to increase the speed of communication with the ATS?

Yes☐ No☐

If yes, explain the means to increase the speed of communication with the ATS and provide a summary of the terms and conditions for its use.

d. If yes to Item 6(c), are the terms and conditions required to be identified in Item 6(c) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

e. Does the Government Securities ATS offer any means to reduce the speed of communication with the ATS (*e.g.*, speed bumps)?

Yes☐ No☐

If yes, explain the methods to reduce the speed of communication with the ATS and provide a summary of the terms and conditions for its use.

f. If yes to Item 6(e), are the terms and conditions required to be identified in Item 6(e) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 7: Order Types and Attributes

a. Identify and explain each order type offered by the Government Securities ATS. In your explanation, include the following:

i. priority, including the order type's priority upon order entry and any subsequent change to priority (if applicable); whether and when the order type can receive a new time stamp; the order type's priority vis-à-vis other orders on the book due to changes a reference price; and any instance in which the order type could lose execution priority to a later arriving order at the same price;

ii. conditions, including any price conditions (*e.g.*, how price conditions affect the rank and price at which the order type can be executed; conditions on the display or non-display of an order; or conditions on executability and routability);

iii. order types designed not to remove liquidity (*e.g.*, post-only orders, store orders), including what occurs when such order is marketable against trading interest on the Government Securities ATS when received;

iv. order types that adjust their price as changes to the order book occur (*e.g.,* price sliding orders or pegged orders) or have a discretionary range, including an order's rank and price upon order entry and whether such prices or rank may change based on market conditions when using such order type; when the order type is executable and at what price the execution would occur; whether the price at which the order type can be executed ever changes; and if the order type can operate in different ways, the default operation of the order type;

v. the time-in-force instructions that can be used or not used with each order type;

vi. the circumstances under which order types may be combined with another order type, modified, replaced, canceled, rejected, or removed from the Government Securities ATS; and

vii. the availability of order types across all forms of connectivity to the Government Securities ATS and differences, if any, in the availability of an order type across those forms of connectivity.

b. Are the terms and conditions for each order type and attribute the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 8: Order Sizes

a. Does the Government Securities ATS have any requirements related to the permissible size of trading interest (*e.g.*, minimum or maximum size, odd-lot, mixed-lot, trading increments)?

Yes☐ No☐

If yes, specify any trading interest size requirements and any related handling procedures.

b. If yes to Item 8(a), are the requirements and procedures required to be identified in Item 8(a) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 9: Indications of Interest

a. Does the Government Securities ATS send or receive any messages indicating trading interest (*e.g.*, IOIs)?

Yes☐ No☐

If yes, identify and explain the use of the messages, including information contained in messages (*e.g.*, price or size minimums), how the message is transmitted (*e.g.*, order management system, FIX), when the message is transmitted (*e.g.*, automatically by the ATS, or upon the sender's request), the type of Persons that receive the message (*e.g.*, Subscribers, markets), responses to IOIs (*e.g.*, submission to firm-up), and the conditions under which the message might result in an execution in the ATS (*e.g.*, response time parameters, interaction, and matching).

b. If yes to Item 9(a), are the terms and conditions governing indications of interest the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 10: Opening and Reopening

a. Explain how the Government Securities ATS opens or re-opens for trading, including when and how orders and trading interest are priced, prioritized, matched, and executed, and identify any order types allowed prior to the start of its regular trading hours or following a stoppage of trading in a security during its regular trading hours.

b. Are the processes and procedures governing opening and re-opening the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

c. Explain how unexecuted orders and trading interest are handled at the time the Government Securities ATS begins regular trading at the start of its regular trading hours or following a stoppage of trading in a security during its regular trading hours.

d. Are the processes or procedures governing unexecuted orders and trading at the time the Government Securities ATS begins regular trading at the start of its regular trading hours,

or following a stoppage of trading in a security during its regular trading hours, the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

e. Are there any differences between pre-opening executions, executions following a stoppage of trading in a security during the Government Securities ATS's regular trading hours, and/or executions during its regular trading hours?

Yes☐ No☐

If yes, identify and explain the differences.

Item 11: Trading Services, Facilities and Rules

a. Provide a summary of the structure of the Government Securities ATS marketplace (*e.g.*, crossing system, auction market, limit order matching book, voice) and explain the means and facilities for bringing together the orders of multiple buyers and sellers on the Government Securities ATS.

b. Are the means and facilities required to be identified in Item 11(a) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

c. Explain the established, non-discretionary rules and procedures of the Government Securities ATS, including order interaction rules for the priority, pricing methodologies, allocation, matching, and execution of orders and trading interest, and other procedures governing trading, such as price improvement functionality, price protection mechanisms, short sales, protocols to work-up or negotiate matched orders or trading interest, functionality to adjust or hedge orders, locked-crossed markets, the handling of execution errors, and the time-stamping of orders and executions.

d. Are the established, non-discretionary rules and procedures required to be identified in Item 11(c) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 12: Liquidity Providers

Are there any formal or informal arrangements with any Subscriber or the Broker-Dealer Operator to provide orders or trading interest to the Government Securities ATS (*e.g.*, undertaking to buy or sell continuously, or to meet specified thresholds of trading or quoting activity)?

Yes☐ No☐

If yes, describe the arrangement, including the terms and conditions.

Item 13: Segmentation; Notice

a. Are orders and trading interest in the Government Securities ATS segmented into categories, classifications, tiers, or levels (*e.g.*, segmented by type of participant, order size, duration, source, or nature of trading activity)?

Yes☐ No☐

If yes, explain the segmentation procedures, including (i) a description of how orders and trading interest are segmented; (ii) identify and describe any categories, classification, tiers, or levels and the types of orders and trading interest that are included in each; (iii) provide a summary of the parameters for each segmented category and length of time each segmented category is in effect; (iv) any procedures for overriding a determination of segmented category; and (v) how segmentation can affect order interaction.

b. If yes to Item 13(a), is the segmentation of orders and trading interest the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

c. Does the Government Securities ATS identify orders or trading interest entered by a customer of a broker-dealer on the Government Securities ATS as a customer order?

Yes☐ No☐

d. If yes to Item 13(a), does the Government Securities ATS disclose to any Person the designated segmented category, classification, tier, or level of orders and trading interest?

Yes☐ No☐

If yes, provide a summary of the content of the disclosure, when and how the disclosure is communicated, who receives it, and whether and how such designation can be contested.

e. If yes to Item 13(d), are the disclosures required to be identified in 13(d) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 14: Counter-Party Selection

a. Can orders or trading interest be designated to interact or not interact with certain orders or trading interest in the Government Securities ATS (*e.g.*, designated to execute against a specific Subscriber's orders or trading interest or prevent a Subscriber's order from executing against itself)?

Yes☐ No☐

If yes, explain the counter-party selection procedures, including how counter-parties can be selected, and whether the designations affect the interaction and priority of trading interest in the ATS.

b. If yes to Item 14(a), are the procedures for counter-party selection required to be identified in Item 14(a) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 15: Display

a. Are Subscriber orders and trading interest bound for or resting in the Government Securities ATS displayed or made known to any Person (not including those employees of the Government Securities ATS who are operating the system) (*e.g.*, market data feeds)?

Yes☐ No☐

If yes, explain the display procedures, including how and when Subscriber orders and trading interest are displayed, how long orders and trading interest are displayed, what information about orders and trading interest is displayed, and the functionality of the Broker-Dealer Operator and types of market participants that receive the displayed information.

b. If yes to Item 15(a), are the display procedures required to be identified in Item 15(a) the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 16: Interaction with Related Markets

a. Does the Broker-Dealer Operator or any of its affiliates offer functionality or procedures to facilitate trading on, or source pricing for, the Government Securities ATS using markets for financial instruments related to government securities (e.g., futures, currencies, swap, fixed income markets), including offering order types to facilitate transactions on both markets, or procedures to allow subscribers to perform multi-leg transactions involving the identified market(s)?

Yes☐ No☐

If yes, (i) identify the functionality, procedures, and source of pricing and the related market; (ii) state whether the functionality, procedure, and source of pricing is provided or operated by the broker-dealer operator or an affiliate of the broker-dealer operator and whether the related market is provided or operated by the broker-dealer operator or its affiliate; and (iii) explain the use of the functionality, procedures, and source of pricing with regard to the related market and the Government Securities ATS, including how and when the functionality, procedures, and source of pricing can be used, by whom, and with what markets.

b. Are the functionality, procedures, and source pricing identified in Item 16 the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 17: Closing

a. Are there any differences between how orders and trading interest are treated on the Government Securities ATS during its closing session(s) and how orders and trading interest are treated during its regular trading hours?

Yes☐ No☐

If yes, identify and explain the differences as compared to the information provided in the relevant Part III Items of this form.

b. Is the treatment of orders and trading interest during the closing session(s) of the Government Securities ATS the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 18: Trading Outside of Regular Trading Hours

a. Does the Government Securities ATS conduct trading outside of its regular trading hours?

Yes☐ No☐

b. If yes to Item 18(a), are there any differences between trading outside of its regular trading hours and trading during its regular trading hours in the Government Securities ATS?

Yes☐ No☐

If yes, identify and explain the differences.

c. If yes to Item 18(a), is the treatment of orders and trading interest outside of its regular trading hours the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 19: Fees

a. Identify and describe any fees or charges for use of the Government Securities ATS services, including the type of fees (*e.g.*, subscription, connectivity, market data), the structure of the fees (*e.g.*, fixed, volume-based, transaction-based), variables that impact the fees (*e.g.*, types of securities traded, block orders, form of connectivity to the ATS),

differentiation among types of Subscribers (*e.g.*, broker-dealers, institutional investors, retail) and range of fees (*e.g.*, high and low).

b. Identify and describe any fees or charges for use of the Government Securities ATS services that are bundled with the Subscriber's use of non-ATS services or products offered by the Broker-Dealer Operator or its Affiliates, including a summary of the bundled services and products, the structure of the fee, variables that impact the fee, differentiation among types of Subscribers, and range of fees.

c. Identify and describe any rebate or discount of fees or charges required to be identified in Items 19(a) and 19(b), including the type of rebate or discount, structure of the rebate or discount, variables that impact the rebate or discount, differentiation among types of Subscribers, and range of rebate or discount.

Item 20: Suspension of Trading

a. Explain any procedures for suspending or stopping trading on the Government Securities ATS, including the suspension of trading in a U.S. Treasury Security or an Agency Security.

b. Are the procedures for suspending or stopping trading the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 21: Trade Reporting

a. Explain any procedures and material arrangements for reporting transactions on the Government Securities ATS, including where an ATS reports transactions and under what circumstances.

b. Are the procedures and material arrangements for reporting transactions on the Government Securities ATS the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 22: Clearance and Settlement

a. Describe any procedures and material arrangements undertaken to facilitate the clearance and settlement of transactions on the Government Securities ATS (*e.g.*, whether the ATS becomes a counterparty, whether it submits trades to a registered clearing agency or whether it requires Subscribers to have arrangements with a clearing firm).

b. Are the procedures and material arrangements undertaken to facilitate the clearance and settlement of transactions on the Government Securities ATS the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 23: Market Data

a. Identify the sources of market data in government securities and repos used by the Government Securities ATS (*e.g.*, feeds from trading venues), and how the ATS uses market data from these sources to provide the services that it offers, including how the ATS uses market data to determine the BBO, and display, price, prioritize, execute, and remove orders and trading interest on the ATS.

b. Are the sources of market data in government securities and repos, and how the Government Securities ATS uses market data for the services that it offers, the same for all Subscribers and the Broker-Dealer Operator?

Yes☐ No☐

If no, identify and explain any differences.

Item 24: Fair Access

a. Has the Government Securities ATS executed 5% or more of the average weekly trading volume in a U.S. Treasury Security as reported to and disseminated by a self-regulatory organization during four of the preceding six calendar months?

Yes☐ No☐

b. Has the Government Securities ATS executed 5% or more of average daily trading volume in an Agency Security as reported to and disseminated by a self-regulatory organization during four of the preceding six calendar months?

Yes☐ No☐

c. If yes to Item 24(a) or 24(b), is the Government Securities ATS required to comply with Rule 301(b)(5)(ii) of Regulation ATS?

Yes☐ No

If yes, describe the written standards for granting access to trading on the ATS pursuant to Rule 301(b)(5)(ii)(A) of Regulation ATS.

Item 25: Aggregate Platform Data

Does the Government Securities ATS publish or otherwise provide to one or more Subscribers aggregate platform-wide order flow and execution statistics of the ATS?

Yes☐ No☐

If yes,

i. Attach, as Exhibit 4, the most recent disclosure of aggregate platform-wide order flow and execution statistics of the ATS that the ATS provided to one or more Subscribers as of the end of each calendar quarter.

☐ Select if, in lieu of filing, {Government Securities ATS} certifies that the information requested under Exhibit 4 is available at the website provided in Part I, Item 7 of this form and is accurate as of the date of this filing.

ii. Attach, as Exhibit 5, a list and explanation of the categories or metrics for the aggregate platform-wide order flow and execution statistics provided as Exhibit 4 and explain the criteria or methodology used to calculate aggregate platform-wide order flow and execution statistics.

☐ Select if, in lieu of filing, {Government Securities ATS} certifies that the information requested under Exhibit 5 is available at the website provided in Part I, Item 7 of this form and is accurate as of the date of this filing.

Part IV: Contact Information, Signature Block, and Consent to Service

Provide the following information of the Person at {Government Securities ATS} prepared to respond to questions for this submission:

First Name: Last Name:

Title:

Email: Telephone:

Primary Street Address of the Government Securities ATS:

Mailing Address of the Government Securities ATS (if different):

The {Government Securities ATS} consents that service of any civil action brought by, or notice of any proceeding before, the SEC or a self-regulatory organization in connection with the alternative trading system's activities may be given by registered or certified mail to the contact employee at the primary street address or mailing address (if different) of the Government Securities ATS, or via email, at the addresses provided on this Form ATS-G. The undersigned deposes and says that he/she has executed this form on behalf of, and with the authority of, said alternative trading system. The undersigned and {Government Securities ATS} represent that the information and statements contained herein, including exhibits, schedules, or other documents attached hereto, and other information filed herewith, all of which are made a part hereof, are current, true, and complete.

Date {auto fill} {Government Securities ATS}

By: _____ Title_____

FORM ATS-G INSTRUCTIONS

A. FILING FORM ATS-G:

1. Form ATS-G is a public reporting form that is designed to provide market participants and the Commission with information about the operations of the Government Securities ATS and the ATS-related activities of its Broker-Dealer Operator and its Affiliates. Among other things, a Government Securities ATS must file Form ATS-G to be exempt from the definition of "exchange" pursuant to Exchange Act Rule 3a1-1(a)(2).

2. A separate Form ATS-G is required for each Government Securities ATS operated by the same Broker-Dealer Operator.

3. A Government Securities ATS must provide all the information required by Form ATS-G, including responses to each Item, as applicable, and the Exhibits, and disclose information that is accurate, current, and complete.

4. A Government Securities ATS must respond to each request in detail unless the request indicates that the ATS is required to disclose "summary" information.

5. Any report required to be submitted pursuant to Rule 304 of Regulation ATS shall be prepared, formatted, and submitted in accordance with Regulation S-T and the EDGAR Filer Manual. Filers have the option of submitting the information to EDGAR using the most recent version of the XML schema for Rule 304 as specified by the EDGAR Filer Manual, or submitting the information using the web-fillable form for Rule 304 in EDGAR.

6. Initial Form ATS-G: Prior to commencing operations, a Government Securities ATS shall file an initial Form ATS-G and the initial Form ATS-G must become effective. If a Government Securities ATS is currently operating pursuant to a Form ATS it must indicate such on the Form ATS-G. If the Government Securities ATS is operating pursuant to a previously filed initial operation report on Form ATS as of [the date 120 calendar days after the date of publication of the final rule in the Federal Register], such Government Securities ATS shall file with the Commission a Form ATS-G no earlier than [the date 120 calendar days after the date of publication of the final rule in the Federal Register], and no later than [the date 150 calendar days after the date of publication of the final rule in the Federal Register].

7. Form ATS-G Amendment

   a. A Government Securities ATS shall amend a Form ATS-G in accordance with the conditions of Rule 304.

b. A Material Amendment, except as provided by Rule 304(a)(2)(i)(D) for a Contingent Amendment, must be filed at least 30 calendar days prior to the date of implementation of a material change to the operations of the Government Securities ATS or to the activities of the Broker-Dealer Operator or its Affiliates that are subject to disclosure on Form ATS-G.

c. An Updating Amendment must be filed no later than 30 calendar days after the end of each calendar quarter to correct any other information that has become inaccurate or incomplete for any reason and was not previously required to be reported to the Commission as a Form ATS-G Amendment pursuant to Rule 304(a)(2)(i)(A), Rule 304(a)(2)(i)(C), or Rule 304(a)(2)(i)(D).

d. A Correcting Amendment must be filed promptly to correct information in any previous disclosure on Form ATS-G, after discovery that any information previously filed on Form ATS-G was materially inaccurate or incomplete when filed.

e. A Contingent Amendment must be filed no later than seven calendar days after information required to be disclosed in Part III, Item 24 on Form ATS-G has become inaccurate or incomplete.

f. A Government Securities ATS must select only one "Type of Amendment" for each Form ATS-G Amendment filed with the Commission.

g. For each Amendment, indicate the Part and Item number of the Form ATS-G that is the subject of the change(s), provide a brief summary of the change(s), and state whether or not the change(s) apply to all Subscribers and the Broker-Dealer Operator.

h. For each Amendment, provide the EDGAR accession number for the filing that is being amended.

8. Notice of Cessation: A Government Securities ATS shall notice its cessation of operations on Form ATS-G at least 10 business days prior to the date the Government Securities ATS will cease to operate as a Government Securities ATS.

9. Withdrawal: If a Government Securities ATS determines to withdraw a filing, it must check the "Withdrawal of Form ATS-G filing" check box for the type of filing and provide the EDGAR accession number of the Form ATS-G filing that is being withdrawn. A Government Securities ATS may withdraw an initial Form ATS-G or an Amendment before the end of the applicable Commission review period. A Government Securities ATS may withdraw a notice of cessation of operations at any time before the date that the Government Securities ATS had indicated it intended to cease operating. A Legacy Government Securities ATS may not withdraw its initial Form ATS-G at any time.

10. A filing that is defective may be rejected and not be accepted by the EDGAR system. Any filing so rejected shall be deemed not to have been filed. See generally Regulation S-T (17 CFR part 232).

B. CONTACT INFORMATION

- The individual listed on the Government Securities ATS's response to Part IV of Form ATS-G as the contact representative must be authorized to receive all incoming communications and be responsible for disseminating that information, as necessary, within the Government Securities ATS. The contact information provided in Part IV of Form ATS-G will not be made public.

C. RECORDKEEPING

- A copy of this Form ATS-G must be retained by the Government Securities ATS in accordance with the EDGAR Filer Manual and Rule 303 of Regulation ATS and must be made available for inspection upon a regulatory request.

D. PAPERWORK REDUCTION ACT DISCLOSURE

- Form ATS-G requires a Government Securities ATS to provide the Commission with certain information regarding: (1) the operation of the Government Securities ATS and the ATS-related activities of the Broker-Dealer Operator and its Affiliates; (2) material and other changes to the operations and disclosures of the Government Securities ATS; and (3) notice upon ceasing operation of the Government Securities ATS. Form ATS-G is designed to provide the public with information to, among other things, help them make informed decisions about whether to participate on the Government Securities ATS. In addition, the Form ATS-G is designed to provide the Commission with information to permit it to carry out its market oversight and investor protection functions.

- The information provided on Form ATS-G will help the Commission to determine whether a Government Securities ATS is in compliance with the federal securities laws and the rules or regulations thereunder, including Regulation ATS. A Government Securities ATS must:

  o File an initial Form ATS-G prior to commencing operations.

  o File a Form ATS–G Amendment: (1) at least 30 calendar days prior to the date of implementation of a material change to the operations of the Government Securities ATS or to the activities of the Broker-Dealer Operator or its Affiliates that are subject to disclosure on Form ATS-G (Material Amendment); (2) no later than 30 calendar days after the end of each calendar quarter to correct any other information that has become inaccurate or incomplete for any reason and was not previously required to be reported to the Commission as a Form ATS-G amendment pursuant to Rule 304(a)(2)(i)(A), Rule 304(a)(2)(i)(C), or Rule 304(a)(2)(i)(D) (Updating Amendment); (3) promptly, to correct information in any previous disclosure on Form ATS-G, after discovery that any information previously filed on Form ATS-G was materially inaccurate or incomplete when filed (Correcting Amendment); or (4) no later than seven calendar days after information required to be disclosed in Part III,

Items 24 on Form ATS-G has become inaccurate or incomplete (Contingent Amendment). During the Commission review period of an initial Form ATS-G filing, a Government Securities ATS that is operating as of the date 120 days from publication of the final rule in the Federal Register shall amend its filed Form ATS-G pursuant to these requirements, and a Government Securities ATS that was not operating as of the date 120 days from publication of the final rule in the Federal Register shall amend its filed Form ATS-G pursuant to the requirements for Updating and Correcting Amendments. During the Commission review period of an initial Form ATS-G filing, a Government Securities ATS shall amend a filed Material Amendment pursuant to the requirements for Updating and Correcting Amendments.

o Notice its cessation of operations at least 10 business days before the date the Government Securities ATS ceases to operate as a Government Securities ATS.

- This collection of information will be reviewed by the Office of Management and Budget in accordance with the clearance requirements of 44 U.S.C. 3507. 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. We estimate that a Government Securities ATS will spend approximately 134 hours completing the Form ATS-G, approximately 9.4 hours preparing each amendment to Form ATS-G, and approximately 2 hours preparing a notice of cessation on Form ATS-G. Any member of the public may direct to the Commission any comments concerning the accuracy of this burden estimate and any suggestions for reducing this burden.

E. EXPLANATION OF TERMS

The following terms are defined for purposes of Form ATS-G.

- **AFFILIATE**: Shall mean, with respect to a specified Person, any Person that, directly or indirectly, controls, is under common control with, or is controlled by, the specified Person.

- **AGENCY SECURITY:** Shall mean a debt security issued or guaranteed by a U.S. executive agency, as defined in 5 U.S.C. 105, or government-sponsored enterprise, as defined in 2 U.S.C. 622(8).

- **ALTERNATIVE TRADING SYSTEM**: Shall mean any organization, association, Person, group of Persons, or system: (1) that constitutes, maintains, or provides a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange within the meaning of Rule 3b-16 under the Exchange Act; and (2) that does not (i) set rules governing the conduct of subscribers other than the conduct of such subscribers' trading on such organization, association, Person, group of Persons, or system, or (ii) discipline subscribers other than by exclusion from trading. 17 CFR 242.300(a).

- **BROKER-DEALER OPERATOR**: Shall mean the registered broker-dealer or government securities broker or government securities dealer of the Government Securities ATS pursuant to 17 CFR 242.301(b)(1).

- **CONTROL**: Shall mean the power, directly or indirectly, to direct the management or policies of the broker-dealer of an alternative trading system, whether through ownership of securities, by contract, or otherwise. A Person is presumed to control the broker-dealer of an alternative trading system if that Person: (1) is a director, general partner, or officer exercising executive responsibility (or having similar status or performing similar functions); (2) directly or indirectly has the right to vote 25 percent or more of a class of voting securities or has the power to sell or direct the sale of 25 percent or more of a class of voting securities of the broker-dealer of the alternative trading system; or (3) in the case of a partnership, has contributed, or has the right to receive upon dissolution, 25 percent or more of the capital of the broker-dealer of the alternative trading system. 17 CFR 242.300(f).

- **GOVERNMENT SECURITY**: Shall mean securities defined in section 3(a)(42) of the Exchange Act. 15 U.S.C. 78c(a)(42).

- **GOVERNMENT SECURITIES ATS**: Shall mean an alternative trading system that trades government securities or repurchase and reverse repurchase agreements on government securities. A Government Securities ATS shall not trade securities other than government securities or repurchase and reverse repurchase agreements on government securities.

- **ORDER**: Shall mean any firm indication of a willingness to buy or sell a security as either principal or agent, including any bid or offer quotation, market order, limit order, or other priced order. 17 CFR 242.300(e).

- **PERSON**: Shall mean a natural person, company, government, or political subdivision, agency, or instrumentality of a government. 15 U.S.C. 78c(a)(9).

- **SUBSCRIBER**: Shall mean any Person that has entered into a contractual agreement with an alternative trading system to access an alternative trading system for the purpose of effecting transactions in securities, or for submitting, disseminating or displaying orders on such alternative trading system, including a customer, member, user, or participant in an alternative trading system. A subscriber, however, shall not include a national securities exchange or association. 17 CFR 242.300(b).

- **U.S. TREASURY SECURITY**: Shall mean a security issued by the U.S. Department of the Treasury.

By the Commission.

Dated: September 28, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–21781 Filed 12–22–20; 4:15 pm]

BILLING CODE 8011–01–C

FEDERAL REGISTER

Vol. 85 Thursday,

No. 251 December 31, 2020

Part IV

Environmental Protection Agency

40 CFR Part 50

Review of the Ozone National Ambient Air Quality Standards; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2018–0279; FRL–10019–04–OAR]

RIN 2060–AU40

Review of the Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: Based on the Environmental Protection Agency's (EPA's) review of the air quality criteria and the national ambient air quality standards (NAAQS) for photochemical oxidants including ozone (O_3), the EPA is retaining the current standards, without revision.

DATES: This final action is effective December 31, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0279. Incorporated into this docket is a separate docket established for the Integrated Science Assessment for this review (Docket ID No. EPA–HQ–ORD–2018–0274). All documents in these dockets are listed on the *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. With the exception of such material, publicly available docket materials are available electronically through *https://www.regulations.gov/.* Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

Availability of Information Related to This Action

A number of the documents that are relevant to this action are available through the EPA's website at *https://www.epa.gov/naaqs/ozone-o3-air-quality-standards.* These documents include the Integrated Review Plan for the Ozone National Ambient Air Quality Standards (IRP [U.S. EPA, 2019b]), available at *https://www.epa.gov/naaqs/ozone-o3-standards-planning-documents-current-review,* the Integrated Science Assessment for Ozone and Related Photochemical Oxidants (ISA [U.S. EPA, 2020a]), available at *https://www.epa.gov/naaqs/ozone-o3-standards-integrated-science-assessments-current-review,* the Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (PA [U.S. EPA, 2020b]), available at *https://www.epa.gov/naaqs/ozone-o3-standards-policy-assessments-current-review.* These and other related documents are also available for inspection and copying in the EPA docket identified above.

FOR FURTHER INFORMATION CONTACT: Dr. Deirdre Murphy, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504–06, Research Triangle Park, NC 27711; telephone: (919) 541–0729; fax: (919) 541–0237; email: *murphy.deirdre@epa.gov.*

SUPPLEMENTARY INFORMATION:

Basis for Immediate Effective Date

In accordance with section 307(d)(1)(V), the Administrator has designated this action as being subject to the rulemaking procedures in section 307(d) of the Clean Air Act (CAA). Section 307(d)(1) of the CAA states that: ''The provisions of section 553 through 557 * * * of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies.'' Thus, section 553(d) of the Administrative Procedure Act (APA), which requires publication of a substantive rule to be made ''not less than 30 days before its effective date'' subject to limited exceptions, does not apply to this action. In the alternative, the EPA concludes that it is consistent with APA section 553(d) to make this action effective December 31, 2020.

Section 553(d)(3) of the APA, 5 U.S.C. 553(d)(3), provides that final rules shall not become effective until 30 days after publication in the **Federal Register** ''except . . . as otherwise provided by the agency for good cause found and published with the rule.'' ''In determining whether good cause exists, an agency should 'balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling.'' *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996) (quoting *United States* v. *Gavrilovic,* 551 F.2d 1099, 1105 (8th Cir. 1977)). The purpose of this provision is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Id.; see also Gavrilovic,* 551 F.2d at 1104 (quoting legislative history).

The EPA is determining that in light of the nature of this action, good cause exists to make this final action effective immediately because the Agency seeks to provide regulatory certainty as soon as possible and the Administrator's decision to retain the current NAAQS does not change the status quo or impose new obligations on any person or entity. As a result, there is no need to provide parties additional time to adjust their behavior, and no person will be harmed by making the action immediately effective as opposed to delaying the effective date by 30 days. Accordingly, the EPA is making this action effective immediately upon publication.

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Executive Summary

This document presents the Administrator's decisions in the current review of the primary (health-based) and secondary (welfare-based) O_3 NAAQS, to retain the current standards, without revision. In reaching these decisions, the Administrator has considered the currently available scientific evidence in the ISA, quantitative and policy analyses presented in the PA, advice from the Clean Air Scientific Advisory Committee (CASAC), and public comments on the proposed decision. This document provides background and summarizes the rationale for these decisions.

This review of the O_3 standards, required by the Clean Air Act (CAA) on a periodic basis, was initiated in 2018. In the last review, completed in 2015, the EPA significantly strengthened the primary and secondary O_3 standards by revising the level of both standards from 75 parts per billion (ppb) to 70 ppb and retaining their indicators (O_3), forms (annual fourth-highest daily maximum, averaged across three consecutive years) and averaging times (eight hours) (80 FR 65291, October 26, 2015). In subsequent litigation on the 2015 decisions, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) upheld the 2015 primary standard but remanded the 2015 secondary standard to the EPA for further justification or reconsideration. The court's remand of the secondary standard has been considered in reaching the decision described in this document on this standard, and in associated conclusions and judgments, also described here. Accordingly, this decision incorporates the EPA's response to the judicial remand of the 2015 secondary standard.

In this review as in past reviews of the air quality criteria and NAAQS for O_3 and related photochemical oxidants, the health and welfare effects evidence evaluated in the ISA is focused on O_3. Ozone is the most prevalent photochemical oxidant in the atmosphere and the one for which there is a large body of scientific evidence on health and welfare effects. A component of smog, O_3 in ambient air is a mixture of mostly tropospheric O_3 and some stratospheric O_3. Tropospheric O_3 forms in the atmosphere when emissions of precursor pollutants, such as nitrogen oxides and volatile organic compounds (VOCs), interact with solar radiation. Such emissions result from man-made sources (*e.g.* motor vehicles and power plants) and natural sources (*e.g.* vegetation and wildfires). In addition, O_3 that is created naturally in the stratosphere also mixes with tropospheric O_3 near the tropopause, and, less frequently can mix nearer the earth's surface.

Based on the current health effects evidence and quantitative information, as well as consideration of CASAC advice and public comment, the Administrator concludes that the current primary standard is requisite to protect public health, including the health of at-risk populations, with an adequate margin of safety, and should be retained, without revision. This decision has been informed by key aspects of the health effects evidence newly available in this review, in conjunction with the full body of evidence critically evaluated in the ISA, that continues to support prior conclusions that short-term O_3 exposure causes and long-term O_3 exposure is likely to cause respiratory effects. The strongest evidence continues to come from studies of short- and long-term O_3 exposure and an array of respiratory health effects, including effects related to asthma exacerbation in people with asthma, particularly children with asthma. The clearest evidence comes from controlled human exposure studies, available at the time of the last review, of individuals exposed for 6.6 hours during quasi-continuous exercise, that report an array of respiratory responses including lung function decrements and respiratory symptoms. Epidemiologic studies additionally describe consistent, positive associations between O_3 exposures and hospital admissions and emergency department visits, particularly for asthma exacerbation in children. Populations and lifestages at risk include people with asthma, children, the elderly, and outdoor workers. The quantitative analyses of population exposure and risk, as well as policy considerations in the PA, summarized in this document and described in detail in the PA, also inform the decision on the primary standard. The general approach and methodology used for the exposure-based assessment is similar to that used in the last review, although a number of updates and improvements have been implemented. These include a more recent period (2015–2017) of ambient air monitoring data in which O_3 concentrations in the areas assessed are at or near the current standard, as well as improvements and updates to models, model inputs and underlying databases.

In its advice to the Administrator, the CASAC stated that the newly available health effects evidence does not differ substantially from that available in the last review when the standard was set. Part of CASAC concluded that the primary standard should be retained. Another part of CASAC expressed concern regarding the margin of safety provided by the current standard, pointing to comments from the 2014 CASAC, who while agreeing that the evidence supported a standard level of 70 ppb, additionally provided policy advice expressing support for a lower standard. In summary, the current evidence and quantitative analyses, advice from the CASAC and consideration of public comments have informed the Administrator's judgments in reaching his decision that the current primary standard of 70 ppb O_3, as the annual fourth-highest daily maximum 8-hour concentration averaged across three consecutive years, provides the requisite public health protection, with an adequate margin of safety.

Based on the current welfare effects evidence and quantitative information, as well as consideration of CASAC advice and public comment, the Administrator concludes that the current secondary standard is requisite to protect the public welfare from known or anticipated adverse effects of O_3 and related photochemical oxidants in ambient air, and should be retained, without revision. This decision has been informed by key aspects of the welfare effects evidence newly available in this review, in conjunction with the full body of evidence critically evaluated in the ISA, that supports, sharpens and expands somewhat on the conclusions reached in the last review. The currently available evidence describes an array of O_3 effects on vegetation and related ecosystem effects, as well as the role of O_3 in radiative forcing and subsequent climate-related effects. The ISA includes findings of causal or likely causal

relationships for a number of such effects with O_3 in the ambient air. As in the last review, the strongest evidence, including quantitative characterizations of relationships between O_3 exposure and occurrence and magnitude of effects, is for vegetation effects. The scales of these effects range from the individual plant scale to the ecosystem scale, with potential for impacts on the public welfare.

While the welfare effects of O_3 vary widely with regard to the extent and level of detail of the available information that describes the exposure circumstances that may elicit them, such information is most advanced for plant growth-related effects. For example, the information on exposure metric and relationships for these effects with the cumulative, concentration-weighted exposure index, W126, is long-standing, having been first described in the 1997 review. Utilizing this information in reviewing the public welfare protection provided by the current secondary standard, reduced growth has been considered as proxy or surrogate for a broad array of related vegetation effects. Quantitative analyses of air quality and vegetation exposure, including in terms of the W126 index, as well as policy-relevant considerations discussed in the PA, have also informed the Administrator's decision on the secondary standard. These include analyses of air quality monitoring data in areas meeting the current standard across the U.S., as well as in Class I areas, updated and expanded from analyses conducted in the last review. Lastly, in its advice to the Administrator on the secondary standard, the full CASAC found the current evidence to support the current standard and concurred with the draft PA that it should be retained without revision. In summary, the current evidence and quantitative analyses, advice from the CASAC and consideration of public comments have informed the Administrator's judgments in reaching his decision that the current secondary standard of 70 ppb O_3, as the annual fourth-highest daily maximum 8-hour concentration averaged across three consecutive years, provides the requisite public welfare protection.

I. Background

A. Legislative Requirements

Two sections of the CAA govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those pollutants ''emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare''; ''the presence of which in the ambient air results from numerous or diverse mobile or stationary sources''; and for which he ''plans to issue air quality criteria . . . .'' (42 U.S.C. 7408(a)(1)). Air quality criteria are intended to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air . . . .'' (42 U.S.C. 7408(a)(2)).

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants for which air quality criteria are issued (42 U.S.C. 7409(a)). Section 109(b)(1) defines primary standards as ones ''the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' [1] Under section 109(b)(2), a secondary standard must ''specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' [2]

In setting primary and secondary standards that are ''requisite'' to protect public health and welfare, respectively, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See generally, *Whitman* v. *American Trucking Ass'ns,* 531 U.S. 457, 465–472, 475–76 (2001). Likewise, ''[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.'' See *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1185 (D.C. Cir. 1981); *accord Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 623–24 (D.C. Cir. 2019). At the same time, courts have clarified the EPA may consider ''relative proximity to peak background . . . concentrations'' as a factor in deciding how to revise the NAAQS in the context of considering standard levels within the range of reasonable values supported by the air quality criteria and judgments of the Administrator. See *American Trucking Ass'ns,* v. *EPA,* 283 F.3d 355, 379 (D.C. Cir. 2002), hereafter referred to as ''*ATA III.*''

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries Ass'n* v. *EPA,* 647 F.2d 1130, 1154 (D.C. Cir. 1980); *American Petroleum Institute* v. *Costle,* 665 F.2d at 1186; *Coalition of Battery Recyclers Ass'n* v. *EPA,* 604 F.3d 613, 617–18 (D.C. Cir. 2010); *Mississippi* v. *EPA,* 744 F.3d 1334, 1353 (D.C. Cir. 2013). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels (see *Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1156 n.51, *Mississippi* v. *EPA,* 744 F.3d at 1351), but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s),[3]

[1] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

[2] Under CAA section 302(h) (42 U.S.C. 7602(h)), effects on welfare include, but are not limited to, ''effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

[3] As used here and similarly throughout this document, the term population (or group) refers to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or life stage. As summarized in section II.A.2.c below, the identification of sensitive groups (called at-risk groups or at-risk populations) involves consideration of susceptibility and vulnerability.

and the kind and degree of uncertainties. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1161–62; *Mississippi* v. *EPA,* 744 F.3d at 1353.

Section 109(d)(1) of the Act requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge concerning the effects of the pollutant on public health and welfare. Under the same provision, the EPA is also to periodically review and, if appropriate, revise the NAAQS, based on the revised air quality criteria.[4]

Section 109(d)(2) addresses the appointment and advisory functions of an independent scientific review committee. Section 109(d)(2)(A) requires the Administrator to appoint this committee, which is to be composed of ''seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.'' Section 109(d)(2)(B) provides that the independent scientific review committee ''shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate . . .'' Since the early 1980s, this independent review function has been performed by the CASAC of the EPA's Science Advisory Board. A number of other advisory functions are also identified for the committee by section 109(d)(2)(C), which reads:

> Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

As previously noted, the Supreme Court has held that section 109(b) ''unambiguously bars cost considerations from the NAAQS-setting process,'' in *Whitman* v. *American Trucking Ass'ns,* 531 U.S. 457, 471 (2001). Accordingly, while some of the issues listed in section 109(d)(2)(C) as those on which Congress has directed the CASAC to advise the Administrator, are ones that are relevant to the standard setting process, others are not. Issues that are not relevant to standard setting may be relevant to implementation of the NAAQS once they are established.[5]

B. Related O_3 Control Programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under sections 110 and 171 through 185 of the CAA, and related provisions and regulations, states are to submit, for the EPA's approval, state implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the prevention of significant deterioration of air quality program that covers these pollutants. *See* 42 U.S.C. 7470–7479. In addition, federal programs provide for nationwide reductions in emissions of O_3 precursors and other air pollutants under Title II of the Act, 42 U.S.C. 7521–7574, which involves controls for automobile, truck, bus, motorcycle, nonroad engine and equipment, and aircraft emissions; the new source performance standards under section 111 of the Act, 42 U.S.C. 7411; and the national emissions standards for hazardous air pollutants under section 112 of the Act, 42 U.S.C. 7412.

C. History of the Air Quality Criteria and Standards

Primary and secondary NAAQS were first established for photochemical oxidants in 1971 (36 FR 8186, April 30, 1971) based on the air quality criteria developed in 1970 (U.S. DHEW, 1970; 35 FR 4768, March 19, 1970). The EPA set both primary and secondary standards at 0.08 parts per million (ppm), as a 1-hour average of total photochemical oxidants, not to be exceeded more than one hour per year. Since that time, the EPA has reviewed the air quality criteria and standards a number of times, with the most recent review being completed in 2015.

The EPA initiated the first periodic review of the NAAQS for photochemical oxidants in 1977. Based on the 1978 air quality criteria document (AQCD [U.S. EPA, 1978]), the EPA proposed revisions to the original NAAQS in 1978 (43 FR 26962, June 22, 1978) and adopted revisions in 1979 (44 FR 8202, February 8, 1979). At that time, the EPA changed the indicator from photochemical oxidants to O_3, revised the level of the primary and secondary standards from 0.08 to 0.12 ppm and revised the form of both standards from a deterministic (*i.e.,* not to be exceeded more than one hour per year) to a statistical form. With these changes, attainment of the standards was defined to occur when the average number of days per calendar year (across a 3-year period) with maximum hourly average O_3 concentration greater than 0.12 ppm equaled one or less (44 FR 8202, February 8, 1979; 43 FR 26962, June 22, 1978). Several petitioners challenged the 1979 decision. Among those, one claimed natural O_3 concentrations and other physical phenomena made the standard unattainable in the Houston area.[6] The U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) rejected this argument, holding (as noted in section I.A above) that attainability and technological feasibility are not relevant considerations in the promulgation of the NAAQS (*American Petroleum Institute* v. *Costle,* 665 F.2d at 1185). The court also noted that the EPA need not tailor the NAAQS to fit each region or locale, pointing out that Congress was aware of the difficulty in meeting standards in some locations and had addressed it through various compliance-related provisions in the CAA (*id.* at 1184–86).

The next periodic reviews of the criteria and standards for O_3 and other

[4] This section of the Act requires the Administrator to complete these reviews and make any revisions that may be appropriate ''at five-year intervals.''

[5] Because some of these issues are not relevant to standard setting, some aspects of CASAC advice may not be relevant to EPA's process of setting primary and secondary standards that are requisite to protect public health and welfare. Indeed, were the EPA to consider costs of implementation when reviewing and revising the standards ''it would be grounds for vacating the NAAQS.'' *Whitman* v. *American Trucking Ass'ns,* 531 U.S. 457, 471 n.4 (2001). At the same time, the CAA directs CASAC to provide advice on ''any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance'' of the NAAQS to the Administrator under section 109(d)(2)(C)(iv). In *Whitman,* the Court clarified that most of that advice would be relevant to implementation but not standard setting, as it ''enable[s] the Administrator to assist the States in carrying out their statutory role as primary *implementers* of the NAAQS'' (*id.* at 470 [emphasis in original]). However, the Court also noted that CASAC's ''advice concerning certain aspects of 'adverse public health . . . effects' from various attainment strategies is unquestionably pertinent'' to the NAAQS rulemaking record and relevant to the standard setting process (*id.* at 470 n.2).

[6] The EPA has determined that air quality in the area including Houston has attained the 1979 1-hour standard (85 FR 8411, February 14, 2020).

photochemical oxidants began in 1982 and 1983, respectively (47 FR 11561, March 17, 1982; 48 FR 38009, August 22, 1983). As part of these reviews, the EPA published an AQCD, a Staff Paper, and a supplement to the AQCD (U.S. EPA, 1986; U.S. EPA, 1989; U.S. EPA, 1992). The schedule for completion of this review was governed by court order. In August of 1992, the EPA proposed to retain the existing primary and secondary standards (57 FR 35542, August 10, 1992). In March 1993, the EPA concluded this review by finalizing its proposed decision to retain the standards, without revision (58 FR 13008, March 9, 1993).

In the next review of the air quality criteria and standards for O_3 and other photochemical oxidants, for which the EPA had announced in August 1992 its intention to proceed rapidly, the EPA developed an AQCD and Staff Paper (57 FR 35542, August 10, 1992; U.S. EPA, 1996a; U.S. EPA, 1996b). Based on consideration of these assessments, the EPA proposed revisions to both the primary and secondary standards (61 FR 65716, December 13, 1996). The EPA completed this review in 1997 by revising both standards to 0.08 ppm, as the annual fourth-highest daily maximum 8-hour average concentration, averaged over three years (62 FR 38856, July 18, 1997).

In response to challenges to the EPA's 1997 decision revising the standards, the D.C. Circuit remanded the standards to the EPA, finding that section 109 of the CAA, as interpreted by the EPA, effected an unconstitutional delegation of legislative authority. See *American Trucking Ass'ns* v. *EPA,* 175 F.3d 1027, 1034–1040 (D.C. Cir. 1999). The court also directed that, in responding to the remand, the EPA should consider the potential beneficial health effects of O_3 pollution in shielding the public from the effects of solar ultraviolet (UV) radiation, as well as adverse health effects (*id.* at 1051–53). See *American Trucking Ass'ns* v. *EPA,* 195 F.3d 4, 10 (D.C. Cir. 1999) (granting panel rehearing in part but declining to review the ruling on consideration of the potential beneficial effects of O_3 pollution). After granting petitions for *certiorari,* the U.S. Supreme Court unanimously reversed the judgment of the D.C. Circuit on the constitutional issue, holding that section 109 of the CAA does not unconstitutionally delegate legislative power to the EPA. See *Whitman* v. *American Trucking Ass'ns,* 531 U.S. 457, 472–74 (2001). The Court remanded the case to the D.C. Circuit to consider challenges to the 1997 O_3 NAAQS that had not yet been addressed. On remand, the D.C. Circuit found the 1997 O_3 NAAQS to be ''neither arbitrary nor capricious,'' and so denied the remaining petitions for review. See *ATA III,* 283 F.3d at 379.

Coincident with the continued litigation of the other issues, the EPA responded to the court's 1999 remand to consider the potential beneficial health effects of O_3 pollution in shielding the public from effects of UV radiation (66 FR 57268, Nov. 14, 2001; 68 FR 614, January 6, 2003). In 2001, the EPA proposed to leave the 1997 primary standard unchanged (66 FR 57268, Nov. 14, 2001). After considering public comment on the proposed decision, the EPA published its final response to this remand in 2003, re-affirming the 8-hour primary standard set in 1997 (68 FR 614, January 6, 2003).

The EPA initiated the fourth periodic review of the air quality criteria and standards for O_3 and other photochemical oxidants with a call for information in September 2000 (65 FR 57810, September 26, 2000). In this review, the EPA developed an AQCD, Staff Paper and related technical support documents and proposed revisions to the primary and secondary standards (U.S. EPA, 2006; U.S. EPA, 2007; 72 FR 37818, July 11, 2007). The review was completed in March 2008 with revision of the levels of both the primary and secondary standards from 0.08 ppm to 0.075 ppm, and retention of the other elements of the prior standards (73 FR 16436, March 27, 2008). A number of petitioners filed suit challenging this decision.

In September 2009, the EPA announced its intention to reconsider the 2008 O_3 standards,[7] and initiated a rulemaking to do so. At the EPA's request, the court held the consolidated cases in abeyance pending the EPA's reconsideration of the 2008 decision. In January 2010, the EPA issued a notice of proposed rulemaking to reconsider the 2008 final decision (75 FR 2938, January 19, 2010). Later that year, in view of the need for further consideration and the fact that the Agency's next periodic review of the O_3 NAAQS required under CAA section 109 had already begun (as announced in September 2008),[8] the EPA consolidated the reconsideration with its statutorily required periodic review.[9]

In light of the EPA's decision to consolidate the reconsideration with the review then ongoing, the D.C. Circuit proceeded with the litigation on the 2008 O_3 NAAQS decision. On July 23, 2013, the court upheld the EPA's 2008 primary standard, but remanded the 2008 secondary standard to the EPA. See *Mississippi* v. *EPA,* 744 F.3d 1334 (D.C. Cir. 2013). With respect to the secondary standard, the court held that the EPA's explanation for the setting of the secondary standard identical to the revised 8-hour primary standard was inadequate under the CAA because the EPA had not adequately explained how that standard provided the required public welfare protection.

At the time of the court's decision, the EPA had already completed significant portions of its next statutorily required periodic review of the O_3 NAAQS, which had been formally initiated in 2008, as summarized above. The documents developed for this review included the ISA,[10] Risk and Exposure Assessments (REAs) for health and welfare, and PA (Frey, 2014a, Frey, 2014b, Frey, 2014c, U.S. EPA, 2013, U.S. EPA, 2014a, U.S. EPA, 2014b, U.S. EPA, 2014c).[11] In late 2014, the EPA proposed to revise the 2008 primary and secondary standards (79 FR 75234, December 17, 2014). The EPA's final decision in this review established the now-current standards (80 FR 65292, October 26, 2015; 40 CFR 50.19). In this decision, based on consideration of the health effects evidence on respiratory effects of O_3 in at-risk populations, the EPA revised the primary standard from a level of 0.075 ppm to a level of 0.070 ppm, while retaining all other elements of the standard (80 FR 65292, October 26, 2015). The EPA's decision on the level for the standard was based on the weight of the scientific evidence and quantitative exposure/risk information. The level of the secondary standard was also revised from 0.075 ppm to 0.070 ppm based on the scientific evidence of O_3 effects on welfare, particularly the evidence of O_3 impacts on vegetation, and quantitative analyses available in the review. The other elements of the standard were retained. This decision on the secondary standard also incorporated the EPA's response to the

[7] The press release of this announcement is available at: *https://archive.epa.gov/epapages/newsroom_archive/newsreleases/85f90b7711acb0c88525763300617d0d.html.*

[8] A ''Call for Information'' initiated the review (73 FR 56581, September 29, 2008).

[9] This rulemaking, completed in 2015, concluded the reconsideration process.

[10] The ISA, as the AQCD in prior reviews, serves the purpose of reviewing the air quality criteria.

[11] The PA presents an evaluation, for consideration by the Administrator, of the policy implications of the currently available scientific information, assessed in the ISA; the quantitative air quality, exposure or risk analyses presented in the PA and developed in light of the ISA findings; and related limitations and uncertainties. The role of the PA is to help ''bridge the gap'' between the Agency's scientific assessment and quantitative technical analyses, and the judgments required of the Administrator in his decisions in the NAAQS review.

D.C. Circuit's remand of the 2008 secondary standard in *Mississippi* v. *EPA,* 744 F.3d 1344 (D.C. Cir. 2013).[12]

After publication of the final rule, a number of industry groups, environmental and health organizations, and certain states filed petitions for judicial review in the D.C. Circuit. The industry and state petitioners argued that the revised standards were too stringent, while the environmental and health petitioners argued that the revised standards were not stringent enough to protect public health and welfare as the Act requires. On August 23, 2019, the court issued an opinion that denied all the petitions for review with respect to the 2015 primary standard while also concluding that the EPA had not provided a sufficient rationale for aspects of its decision on the 2015 secondary standard and remanding that standard to the EPA. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597 (D.C. Cir. 2019). The court's decision on the secondary standard focused on challenges to particular aspects of EPA's decision. The court concluded that EPA's identification of particular benchmarks for evaluating the protection the standard provided against welfare effects associated with tree growth loss was reasonable and consistent with CASAC's advice. However, the court held that EPA had not adequately explained its decision to focus on a 3-year average for consideration of the cumulative exposure, in terms of W126, identified as providing requisite public welfare protection, or its decision to not identify a specific level of air quality related to visible foliar injury. The EPA's decision not to use a seasonal W126 index as the form and averaging time of the secondary standard was also challenged, but the court did not reach a decision on that issue, concluding that it lacked a basis to assess the EPA's rationale because the EPA had not yet fully explained its focus on a 3-year average W126 in its consideration of the standard. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 618 (D.C. Cir. 2019). Accordingly, the court remanded the secondary standard to EPA for further justification or reconsideration. The court's remand of the secondary standard has been considered in reaching the decision, and associated conclusions and judgments, described in section III.B.3 below.

In the August 2019 decision, the court additionally addressed arguments regarding considerations of background O_3 concentrations, and socioeconomic and energy impacts. With regard to the former, the court rejected the argument that the EPA was required to take background O_3 concentrations into account when setting the NAAQS, holding that the text of CAA section 109(b) precluded this interpretation because it would mean that if background O_3 levels in any part of the country exceeded the level of O_3 that is requisite to protect public health, the EPA would be obliged to set the standard at the higher nonprotective level (*id.* at 622–23). Thus, the court concluded that the EPA did not act unlawfully or arbitrarily or capriciously in setting the 2015 NAAQS without regard for background O_3 (*id.* at 624). Additionally, the court denied arguments that the EPA was required to consider adverse economic, social, and energy impacts in determining whether a revision of the NAAQS was ''appropriate'' under section 109(d)(1) of the CAA (*id.* at 621–22). The court reasoned that consideration of such impacts was precluded by *Whitman's* holding that the CAA ''unambiguously bars cost considerations from the NAAQS-setting process'' (531 U.S. at 471, summarized in section I.A above). Further, the court explained that section 109(d)(2)(C)'s requirement that CASAC advise the EPA ''of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance'' of revised NAAQS had no bearing on whether costs are to be considered in setting the NAAQS (*Murray Energy Corp.* v. *EPA,* 936 F.3d at 622). Rather, as described in *Whitman* and discussed further in section I.A above, most of that advice would be relevant to implementation but not standard setting (*id.*).

D. Current Review of the Air Quality Criteria and Standards

In May 2018, the Administrator directed his Assistant Administrators to initiate this current review of the O_3 NAAQS (Pruitt, 2018). In conveying this direction, the Administrator further directed the EPA staff to expedite the review, implementing an accelerated schedule aimed at completion of the review within the statutorily required period (Pruitt, 2018). Accordingly, the EPA took immediate steps to proceed with the review. In June 2018, the EPA announced the initiation of the periodic reviews of the air quality criteria for photochemical oxidants and of the O_3 NAAQS and issued a call for information in the **Federal Register** (83 FR 29785, June 26, 2018). Two types of information were called for: Information regarding significant new O_3 research to be considered for the ISA for the review, and policy-relevant issues for consideration in this NAAQS review. Based in part on the information received in response to the call for information, the EPA developed a draft IRP, which was made available for consultation with the CASAC and for public comment (83 FR 55163, November 2, 2018; 83 FR 55528, November 6, 2018). Comments from the CASAC (Cox, 2018) and the public were considered in preparing the final IRP (U.S. EPA, 2019b).

Under the plan outlined in the IRP and consistent with revisions to the process identified by the Administrator in his 2018 memo directing initiation of the review, the current review of the O_3 NAAQS has progressed on an accelerated schedule (Pruitt, 2018). The EPA has incorporated a number of efficiencies in various aspects of the review process, as summarized in the IRP, to support the accelerated schedule (Pruitt, 2018). As one example of such an efficiency, rather than produce separate documents for the PA and associated quantitative analyses, the human exposure and health risk analyses (that inform the decision on the primary standard) and the air quality and exposure analyses (that inform the decision on the secondary standard) are included as appendices in the PA, along with other technical appendices that inform these standards decisions. The draft PA (including these analyses as appendices) was reviewed by the CASAC and made available for public comment while the draft ISA was also being reviewed by the CASAC and was available for public comment (84 FR 50836, September 26, 2019; 84 FR 58711, November 1, 2019).[13] The CASAC was assisted in its review by a pool of consultants with expertise in a number of fields (84 FR 38625, August 7, 2019). The approach employed by the CASAC in utilizing outside technical expertise represents an additional modification of the process from past reviews. Rather than join with some or all of the CASAC members in a CASAC review panel as has been common in other NAAQS reviews in the past, in this O_3 NAAQS review (and also in the recent CASAC review of the PA for the

[12] The 2015 revisions to the NAAQS were accompanied by revisions to the data handling procedures, ambient air monitoring requirements, the air quality index and several provisions related to implementation (80 FR 65292, October 26, 2015).

[13] The draft ISA and draft PA were released for public comment and CASAC review on September 26, 2019 and October 31, 2019, respectively. The charges for the CASAC review summarized the overarching context for the document review (including reference to Pruitt [2018], and the CASAC's functions under section 109(d)(2)(B) and (C) of the Act), as well as specific charge questions for review of each of the documents.

particulate matter NAAQS), the consultants comprised a pool of expertise that CASAC members drew on through the use of specific questions, posed in writing prior to the public meeting, regarding aspects of the documents being reviewed, obtaining subject matter expertise for their review in a focused, efficient and transparent manner.

The CASAC discussed its review of both the draft ISA and the draft PA over three days at a public meeting in December 2019 (84 FR 58713, November 1, 2019).[14] The CASAC discussed its draft letters describing its advice and comments on the documents in a public teleconference in early February 2020 (85 FR 4656; January 27, 2020). The letters to the Administrator conveying the CASAC advice and comments on the draft PA and draft ISA were released later that month (Cox, 2020a; Cox, 2020b).

The letters from the CASAC and public comment on the draft ISA and draft PA informed completion of the final documents and further informed development of the Administrator's proposed and final decisions in this review. Comments from the CASAC on the draft ISA were considered by the EPA and led to a number of revisions in developing the final document. The CASAC review of the draft ISA and the EPA's consideration of CASAC comments are described in Appendix 10, section 10.4.5 of the final ISA. In his reply to the CASAC letter conveying its review, ''Administrator Wheeler noted, 'for those comments and recommendations that are more significant or cross-cutting and which were not fully addressed, the Agency will develop a plan to incorporate these changes into future O_3 ISAs as well as ISAs for other criteria pollutant reviews' '' (ISA, p. 10–28; Wheeler, 2020). The ISA was completed and made available to the public in April 2020 (85 FR 21849, April 20, 2020).[15] Based on the rigorous scientific approach utilized in its development, summarized in Appendix 10 of the final ISA, the EPA considers the final ISA to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [O_3] in the ambient air, in varying quantities'' as required by the CAA (42 U.S.C. 7408(a)(2)).

The CASAC comments additionally provided advice with regard to the primary and secondary standards, as well as a number of comments intended to improve the PA. These comments were considered in completing that document (85 FR 31182, May 22, 2020). The CASAC advice to the Administrator regarding the O_3 standards has also been described and considered in the PA, and in sections II and III below. The CASAC advice on the primary standard is summarized in II.B.2 below and its advice on the secondary standard is summarized in section III.B.1.b.

Materials upon which this proposed decision is based, including the documents described above, are available to the public in the docket for the review.[16] As in prior NAAQS reviews, the EPA is basing its decision in this review on studies and related information included in the air quality criteria, which have undergone CASAC and public review. The studies assessed in the ISA [17] and PA, and the integration of the scientific evidence presented in them, have undergone extensive critical review by the EPA, the CASAC, and the public. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. Decisions on the NAAQS can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by the EPA but also by the statutorily mandated independent scientific advisory committee, as well as the public review that accompanies this process. Some commenters have referred to and discussed individual scientific studies on the health effects of O_3 that were not included in the ISA (' 'new' studies'') and that have not gone through this comprehensive review process. In considering and responding to comments for which such ''new'' studies were cited in support, the EPA has provisionally considered the cited studies in the context of the findings of the ISA. The EPA's provisional consideration of these studies did not and could not provide the kind of in-depth critical review described above, but rather was focused on determining whether they warranted reopening the review of the air quality criteria to enable the EPA, the CASAC and the public to consider them further.

This approach, and the decision to rely on studies and related information included in the air quality criteria, which have undergone CASAC and public review, is consistent with the EPA's practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and the EPA has consistently followed this approach. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. See 71 FR 61144, 61148 (October 17, 2006, final decision on review of NAAQS for particulate matter) for a detailed discussion of this issue and the EPA's past practice.

As discussed in the EPA's 1993 decision not to revise the O_3 NAAQS, ''new'' studies may sometimes be of such significance that it is appropriate to delay a decision in a NAAQS review and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR at 13013–13014, March 9, 1993). In the present case, the EPA's provisional consideration of ''new'' studies concludes that, taken in context, the ''new'' information and findings do not materially change any of the broad scientific conclusions regarding the health and welfare effects of O_3 in

[14] While simultaneous review of first drafts of both documents has not been usual in past reviews, there have been occurrences of the CASAC review of a draft PA (or draft REA when the process involved a policy assessment being included within the REA document) simultaneous with review of a second (or later) draft ISA (*e.g.,* 73 FR 19835, April 11, 2008; 73 FR 34739, June 18, 2008; 77 FR 64335, October 19, 2012; 78 FR 938, January 7, 2013).

[15] The ISA builds on evidence and conclusions from previous assessments, focusing on synthesizing and integrating the newly available evidence (ISA, section IS.1.1). Past assessments are generally cited when providing further, still relevant, details that informed the current assessment but are not repeated in the latest assessment.

[16] The docket for this review, EPA–HQ–OAR–2018–0279, has incorporated the ISA docket (EPA–HQ–ORD–2018–0274) by reference. Both are publicly accessible at *www.regulations.gov.*

[17] In addition to the review's opening ''Call for Information'' (83 FR 29785, June 26, 2018), systematic review methodologies were applied to identify relevant scientific findings that have emerged since the 2013 ISA, which included peer reviewed literature published through July 2011. Search techniques for the current ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2011 (providing some overlap with the cutoff date for the last ISA) and March 30, 2018. Studies published after the literature cutoff date for this ISA were also considered if they were submitted in response to the Call for Information or identified in subsequent phases of ISA development, particularly to the extent that they provide new information that affects key scientific conclusions (ISA, Appendix 10, section 10.2). References that are cited in the ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/index.cfm/project/page/project_id/2737.*

ambient air made in the air quality criteria. For this reason, reopening the air quality criteria review would not be warranted.

Accordingly, the EPA is basing the final decisions in this review on the studies and related information included in the O_3 air quality criteria that have undergone rigorous review by the EPA, the CASAC and the public. The EPA will consider these ''new'' studies for inclusion in the air quality criteria for the next O_3 NAAQS review, which the EPA expects to begin soon after the conclusion of this review and which will provide the opportunity to fully assess these studies through a more rigorous review process involving the EPA, the CASAC, and the public.

E. Air Quality Information

Ground level O_3 concentrations are a mix of mostly tropospheric O_3 and some stratospheric O_3. Tropospheric O_3 is formed due to chemical interactions involving solar radiation and precursor pollutants including VOCs and nitrogen oxides (NO_X). Methane (CH_4) and carbon monoxide (CO) are also important precursors, particularly at the regional to global scale. The precursor emissions leading to tropospheric O_3 formation can result from both man-made sources (*e.g.,* motor vehicles and electric power generation) and natural sources (*e.g.,* vegetation and wildfires). In addition, O_3 that is created naturally in the stratosphere also contributes to O_3 in the troposphere. The stratosphere routinely mixes with the troposphere high above the earth's surface and, less frequently, there are intrusions of stratospheric air that reach deep into the troposphere and even to the surface. Once formed, O_3 near the surface can be transported by winds before eventually being removed from the atmosphere via chemical reactions or deposition to surfaces. In sum, O_3 concentrations are influenced by complex interactions between precursor emissions, meteorological conditions, and topographical characteristics (PA, section 2.1; ISA, Appendix 1).

For compliance and other purposes, state and local environmental agencies operate O_3 monitors across the U.S. and submit the data to the EPA. At present, there are approximately 1,300 monitors across the U.S. reporting hourly O_3 averages during the times of the year when local O_3 pollution can be important (PA, section 2.3.1).[18] Most of this monitoring is focused on urban areas where precursor emissions tend to be largest, as well as locations directly downwind of these areas. There are also over 100 routine monitoring sites in rural areas, including sites in the Clean Air Status and Trends Network (CASTNET) which is specifically focused on characterizing conditions in rural areas. Based on the monitoring data for the three year period from 2016 to 2018, the EPA identified 142 counties, in which together approximately 106 million Americans reside where O_3 design values[19] were above 0.070 ppm, the level of the existing NAAQS (PA, section 2.4.1). Across these areas, the highest design values are typically observed in California, Texas, Denver, around Lake Michigan and along the Northeast Corridor, locations with some of the most densely populated areas in the country (*e.g.,* PA, Figure 2–8).

From a temporal perspective, the highest O_3 concentrations tend to occur during the afternoon and within the warmer months of the year due to higher levels of solar radiation and other conducive meteorological conditions during these times. The exceptions to this general rule include (1) some rural sites where transport of O_3 from upwind urban areas can occasionally result in high nighttime levels of O_3, (2) high-elevation sites which can be episodically influenced by stratospheric intrusions in other months of the year, and (3) mountain basins in the western U.S. where large quantities of O_3 precursors emissions associated with oil and gas development can be trapped in a shallow inversion layer and form O_3 under clear, calm skies with snow cover during the colder months (PA, section 2.1; ISA, Appendix 1).

Monitoring data indicate long-term reductions in peak O_3 concentrations. For example, monitoring sites operating since 1980 indicate a 32% reduction in the national average annual fourth highest daily maximum 8-hour concentration from 1980 to 2018. (PA, Figure 2–10). This has been accompanied by appreciable reductions in peak 1-hour concentrations, as seen by reductions in annual second highest daily maximum 1-hour concentrations (PA, Figure 2–17).

Concentrations of O_3 in ambient air that result from natural and non-U.S. anthropogenic sources are collectively referred to as U.S. background O_3 (USB; PA, section 2.5). As in the last review, we generally characterize O_3 concentrations that would exist in the absence of U.S. anthropogenic emissions (as USB). Findings from air quality modeling analyses performed for this review to investigate patterns of USB in the U.S. are largely consistent with conclusions reached in the last review (PA, section 2.5.4). The current modeling analysis indicates spatial variation in USB O_3 concentrations that is related to geography, topography and proximity to international borders and is also influenced by seasonal variation, with long-range international anthropogenic transport contributions peaking in the spring while U.S. anthropogenic contributions tend to peak in summer. The West is predicted to have higher USB concentrations than the East, with higher contributions from natural and international anthropogenic sources that exert influences in western high-elevation and near-border areas. The modeling predicts that for both the West and the East, days with the highest 8-hour concentrations of O_3 generally occur in summer and are likely to have substantially greater concentrations due to U.S. anthropogenic sources. While the USB contributions to O_3 concentrations on days with the highest 8-hour concentrations are generally predicted to come largely from natural sources, the modeling also indicates that some areas near the Mexico border may receive appreciable contributions from a combination of natural and international anthropogenic sources on these days. In such locations, the modeling suggests the potential for relatively infrequent events with substantial background contributions where daily maximum 8-hour O_3 concentrations approach or exceed the level of the current NAAQS (*i.e.,* 70 ppb). This contrasts with most monitor locations in the U.S. for which international contributions are predicted to be the lowest during the season with the most frequent occurrence of daily maximum 8-hour O_3 concentrations above 70 ppb. This is generally because, except for in near-border areas, larger international contributions are associated with long-distance transport and that is most efficient in the springtime (PA, section 2.5.4).

II. Rationale for Decision on the Primary Standard

This section presents the rationale for the Administrator's decision to retain the current primary O_3 standard. This rationale is based on the scientific information presented in the ISA, on human health effects associated with

[18] O_3 monitoring seasons in each state vary from five months (May to September in Oregon and Washington) to year round (in 11 states), with March to October being most common (27 states).

[19] A design value is a statistic that summarizes the air quality data for a given area in terms of the indicator, averaging time, and form of the standard. Design values can be compared to the level of the standard and are typically used to designate areas as meeting or not meeting the standard and assess progress towards meeting the NAAQS.

photochemical oxidants including O_3 and pertaining to the presence of these pollutants in ambient air. As summarized in section I.D above, the ISA was developed based on a thorough review of the latest scientific information generally published between January 2011 and March 2018, as well as more recent studies identified during peer review, submitted in response to the Call for Information, or public comments on the draft ISA, integrated with the information and conclusions from previous assessments (ISA, section IS.1.2 and Appendix 10, section 10.2). The Administrator's rationale also takes into account: (1) The PA evaluation of the policy-relevant information in the ISA and presentation of quantitative analyses of air quality, human exposure and health risks; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the ISA and PA at public meetings and in the CASAC's letters to the Administrator; and (3) public comments on the proposed decision.

Within this section, introductory and background information is presented in section II.A. Section II.A.1 summarizes the 2015 establishment of the existing standard, as background for this review. Section II.A.2 provides an overview of the currently available health effects evidence, and section II.A.3 provides an overview of the current exposure and risk information, drawing on the quantitative analyses presented in the PA. Section II.B summarizes the basis for the proposed decision (II.B.1), discusses public comments on the proposed decision (II.B.2), and presents the Administrator's considerations, conclusions and decision in this review of the primary standard (II.B.3). The decision on the current primary standard is summarized in section II.C.

A. Introduction

As in prior reviews, the general approach to reviewing the current primary standard is based, most fundamentally, on using the Agency's assessments of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding a primary standard for photochemical oxidants that is requisite to protect the public health with an adequate margin of safety. The EPA's assessments are primarily documented in the ISA and PA, both of which have received CASAC review and public comment (84 FR 50836, September 26, 2019; 84 FR 58711, November 1, 2019; 84 FR 58713, November 1, 2019; 85 FR 21849, April 20, 2020; 85 FR 31182, May 22, 2020). In bridging the gap between the scientific assessments of the ISA and the judgments required of the Administrator in his decisions on the current standard, the PA evaluates policy implications of the assessment of the current evidence in ISA and the quantitative exposure and risk analyses documented extensively in appendices of the PA. In evaluating the public health protection afforded by the current standard, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively.

The final decision on the adequacy of the current primary standard is a public health policy judgment to be made by the Administrator. In reaching conclusions on the standard, the decision draws on the scientific information and analyses about health effects, population exposure and risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Clean Air Act and with how the EPA and the courts have historically interpreted the Act (summarized in section I.A. above). These provisions require the Administrator to establish primary standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups.[20]

1. Background on the Current Standard

As a result of the last O_3 NAAQS review, completed in 2015, the level of the primary standard was revised from 0.075 to 0.070 ppm,[21] in conjunction with retaining the existing indicator, averaging time, and form. This revision, establishing the current standard, was based on the scientific evidence and quantitative exposure and risk analyses available at that time, as well as the Administrator's judgments regarding the available health effects evidence, the appropriate degree of public health protection for the revised standard, and the available exposure and risk information regarding the exposures and risk that may be allowed by such a standard (80 FR 65292, October 26, 2015). In establishing this standard, the Administrator considered the extensive body of evidence spanning several decades documenting the causal relationship between O_3 exposure and a broad range of respiratory effects (80 FR 65292, October 26, 2015; 2013 ISA, p. 1–14),[22] that had been augmented by evidence available since the prior review was completed in 2008. Such effects range from small, reversible changes in pulmonary function and pulmonary inflammation (documented in controlled human exposure studies involving exposures ranging from 1 to 8 hours)[23] to more serious health outcomes such as asthma-related emergency department visits and hospital admissions, which have been associated with ambient air concentrations of O_3 in epidemiologic studies (2013 ISA, section 6.2).[24] The 2015 decision, which provided increased protection for at-risk populations,[25] such as children and

[20] As noted in section I.A above, consideration of such protection is focused on the sensitive group of individuals and not a single person in the sensitive group (see S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 [1970]).

[21] Although ppm are the units in which the level of the standard is defined, the units, ppb, are more commonly used throughout this document for greater consistency with the more recent literature. The level of the current primary standard, 0.070 ppm, is equivalent to 70 ppb.

[22] In addition to concluding there to be a causal relationship between short-term O_3 exposures and respiratory effects, and that the relationship between longer-term exposure and respiratory effects was likely to be causal, the 2013 ISA also concluded there likely to be a causal relationship between short-term exposure and mortality, as well as short-term exposure and cardiovascular effects, including related mortality, and that the evidence was suggestive of causal relationships between long-term exposures and total mortality, cardiovascular effects and reproductive, developmental effects, and between short- and long-term exposure and nervous system effects (2013 ISA, p. 1–14, section 2.5.2).

[23] Study subjects in most of the controlled human exposure studies are generally healthy adults.

[24] The evidence base also includes experimental animal studies that provide insight into potential modes of action, contributing to the coherence and robust nature of the evidence.

[25] As used here and similarly throughout the document, the term population refers to persons having a quality or characteristic in common, such as, and including, a specific pre-existing illness or a specific age or lifestage. A lifestage refers to a distinguishable time frame in an individual's life characterized by unique and relatively stable behavioral and/or physiological characteristics that are associated with development and growth. Identifying at-risk populations includes consideration of intrinsic (*e.g.,* genetic or developmental aspects) or acquired (*e.g.,* disease or smoking status) factors that increase the risk of health effects occurring with exposure to a

people with asthma, against an array of adverse health effects, drew upon the available scientific evidence assessed in the 2013 ISA, the exposure and risk information presented and assessed in the 2014 health REA (HREA), the consideration of that evidence and information in the 2014 PA, the advice and recommendations of the CASAC, and public comments on the proposed decision (79 FR 75234, December 17, 2014).

Across the different study types, the controlled human exposure studies, which were recognized to provide the most certain evidence indicating the occurrence of health effects in humans following specific O_3 exposures, additionally document the roles of ventilation rate [26] and exposure duration, in addition to exposure concentration, in eliciting responses to O_3 exposure (80 FR 65343, October 26, 2015; 2014 PA, section 3.4).[27] These aspects of the evidence were represented in exposure-based analyses developed to inform the NAAQS decision with estimates of exposure and risk associated with air quality conditions just meeting the then-existing standard, and also for air quality conditions just meeting potential alternative standards (U.S. EPA, 2014a, hereafter 2014 HREA). The exposure-based analyses given greatest weight in the Administrator's consideration of the HREA estimates involved comparison of estimates for study area populations of children of exposure at elevated exertion to exposure benchmark concentrations (exposures of concern). The benchmark concentrations (60, 70 and 80 ppb) were identified from controlled human exposure studies (conducted with generally healthy adults).

In weighing the health effects evidence and making judgments regarding the public health significance of the quantitative estimates of exposures and risks allowed by the then-existing standard and potential alternative standards considered, as well as judgments regarding margin of safety, the Administrator's 2015 decision considered the currently available information and commonly accepted guidelines or criteria within the public health community, including statements of the American Thoracic Society (ATS), an organization of respiratory disease specialists, advice from the CASAC, and public comments. In so doing, she recognized that the determination of what constitutes an adequate margin of safety is expressly left to the judgment of the EPA Administrator. See *Lead Industries Ass'n* v. *EPA,* 647 F.2d 1130, 1161–62 (D.C. Cir 1980); *Mississippi* v. *EPA,* 744 F.3d 1334, 1353 (D.C. Cir. 2013). In NAAQS reviews generally, evaluations of how particular primary standards address the requirement to provide an adequate margin of safety include consideration of such factors as the nature and severity of the health effects, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties present. Consistent with past practice and long-standing judicial precedent, the Administrator took the need for an adequate margin of safety into account as an integral part of her decision-making.

In the decisions regarding adequacy of protection provided by the then-existing primary standard and on alternatives for a new revised standard, primary consideration was given to the evidence of respiratory effects from controlled human exposure studies, including those newly available in the review, and for which the exposure concentrations were at the lower end of those studied (80 FR 65342–47 and 65362–66, October 26, 2015). This emphasis was consistent with comments on the strength of this evidence from the CASAC at that time (Frey, 2014b, p. 5). In placing weight on these studies, the Administrator at that time took note of the variety of respiratory effects reported from the studies of healthy adults engaged in quasi-continuous exercise within a 6.6-hour exposure to O_3 concentrations of 60 ppb and higher.[28] The lowest exposure concentration in such studies for which a combination of statistically significant reduction in lung function and increase in respiratory symptoms was somewhat above 70 ppb,[29] while reduced lung function and increased pulmonary inflammation were reported following such exposures to O_3 concentrations as low as 60 ppb. In considering these findings, the Administrator noted that the combination of O_3-induced lung function decrements and respiratory symptoms met ATS criteria for an adverse response,[30] and noted CASAC comments, which included a caution regarding the potential for effects in some groups of people, such as people with asthma, at exposure concentrations below those affecting healthy subjects (Frey, 2014b, pp. 5–6; 80 FR 65343, October 26, 2015). With regard to the epidemiologic evidence, the Administrator noted the ISA finding that the pattern of effects observed across the range of exposures assessed in the controlled human exposure studies, increasing in severity at higher exposures, is coherent with (*i.e.,* reasonably related to) the health outcomes reported to be associated with ambient air concentrations in epidemiologic studies. Additionally, while recognizing that most O_3 epidemiologic studies reported health outcome associations with O_3 concentrations in ambient air that violated the then-existing standard, the Administrator took note of a study that reported associations between short-term O_3 concentrations and asthma emergency department visits in children and adults in a U.S. location that would have met the then-existing standard over the entire 5-year study period (80 FR 65344, October 26, 2015; Mar and Koenig, 2009).[31] Taken together, the Administrator concluded that the scientific evidence from controlled human exposure and epidemiologic studies called into question the adequacy of the public health protection provided by the 75 ppb standard that had been set in 2008.

In considering the exposure and risk information, the Administrator's 2015 decision gave particular attention to the exposure-based comparison-to-benchmarks analysis, focusing on the estimates of exposures of concern for

substance (such as O_3) as well as extrinsic, nonbiological factors, such as those related to socioeconomic status, reduced access to health care, or exposure.

[26] Ventilation rate ($\dot{V}_E$) is a specific technical term referring to breathing rate in terms of volume of air taken into the body per unit of time. A person engaged in different activities will exert themselves at different levels and experience different ventilation rates.

[27] For example, the exposure concentrations eliciting a given level of response in subjects at rest are higher than those eliciting such response in subjects exposed while at elevated ventilation, such as while exercising (2013 ISA, section 6.2.1.1).

[28] The studies given primary focus were those in which O_3 exposures occurred over the course of 6.6 hours during which the subjects engaged in six 50-minute exercise periods separated by 10-minute rest periods, with a 35-minute lunch period occurring after the third hour (*e.g.,* Folinsbee et al., 1988 and Schelegle et al., 2009). Responses after O_3 exposure were compared to those after filtered air exposure.

[29] For the 70 ppb target exposure, Schelegle et al. (2009) reported, based on O_3 measurements during the six 50-minute exercise periods, that the mean O_3 concentration during the exercise portion of the study protocol was 72 ppb. Based on the six exercise period measurements, the time weighted average concentration across the full 6.6-hour exposure was 73 ppb (Schelegle et al., 2009).

[30] The most recent statement from the ATS available at the time of the 2015 decision stated that ''[i]n drawing the distinction between adverse and nonadverse reversible effects, this committee recommended that reversible loss of lung function in combination with the presence of symptoms should be considered as adverse'' (ATS, 2000).

[31] The design values in this location during the study period were at or somewhat below 75 ppb (Wells, 2012).

children [32] in 15 urban study areas for air quality conditions just meeting the then-current standard. Consistent with the finding that larger percentages of children than adults were estimated to experience exposures at or above benchmarks, the Administrator focused on the results for all children and for children with asthma, noting that the results for these two groups, in terms of percent of the population group, are virtually indistinguishable (2014 HREA, sections 5.3.2, 5.4.1.5 and section 5F–1). The Administrator placed the greatest weight on estimates of two or more days with occurrences of exposures at or above the benchmarks, in light of her increased concern about the potential for adverse responses with repeated occurrences of such exposures, noting that the types of effects shown to occur following exposures to O_3 concentrations from 60 ppb to 80 ppb, such as inflammation, if occurring repeatedly as a result of repeated exposure, could potentially result in more severe effects (80 FR 65343, 65345, October 26, 2015; 2013 ISA, section 6.2.3).[33] The Administrator also considered estimates for single exposures at or above the higher benchmarks of 70 and 80 ppb (80 FR 65345, October 26, 2015). With regard to the 60 ppb benchmark, while the Administrator recognized the effects reported from controlled human exposure studies of 60 ppb to be less severe than those for higher O_3 concentrations, she also recognized there were limitations and uncertainties in the evidence base with regard to unstudied population groups. As a result, she judged it appropriate for the standard, in providing an adequate margin of safety, to provide some control of exposures at or above the 60 ppb benchmark (80 FR 65345–65346, October 26, 2015).

In considering public health implications of the exposure and risk information, the Administrator concluded that the exposures and risks projected to remain upon meeting the then-current (75 ppb) standard were reasonably judged important from a public health perspective. This conclusion was particularly based on her judgment that it is appropriate to set a standard that would be expected to eliminate, or almost eliminate, the occurrence of exposures, while at moderate exertion, at or above 70 and 80 ppb (80 FR 65346, October 26, 2015). In addition, given that in the air quality scenario for the existing standard, the average percent of children estimated to experience two or more days with exposures at or above the 60 ppb benchmark approached 10% in some urban study areas (on average across the analysis years), the Administrator concluded that the existing standard did not incorporate an adequate margin of safety against the potentially adverse effects that could occur following repeated exposures at or above 60 ppb (80 FR 65345–46, October 26, 2015). Thus, the exposure and risk estimates [34] were judged to support a conclusion that the existing standard was not sufficiently protective and did not incorporate an adequate margin of safety. In consideration of all of the above, as well as the CASAC advice, which included the unanimous recommendation ''that the Administrator revise the current primary ozone standard to protect public health'' (Frey, 2014b, p. 5),[35] the Administrator concluded that the then-current primary O_3 standard (with its level of 75 ppb) was not requisite to protect public health with an adequate margin of safety, and should be revised to provide increased public health protection (80 FR 65346, October 26, 2015).

With regard to the most appropriate indicator for the revised standard, key considerations included the finding that O_3 is the only photochemical oxidant (other than nitrogen dioxide) that is routinely monitored and for which a comprehensive database exists, and the consideration that, since the precursor emissions that lead to the formation of O_3 also generally lead to the formation of other photochemical oxidants, measures leading to reductions in population exposures to O_3 can generally be expected to lead to reductions in other photochemical oxidants (2013 ISA, section 3.6; 80 FR 65347, October 26, 2015). The CASAC also indicated O_3 to be the appropriate indicator ''based on its causal or likely causal associations with multiple adverse health outcomes and its representation of a class of pollutants known as photochemical oxidants'' (Frey, 2014b, p. ii). Based on all of these considerations and public comments, the Administrator retained O_3 as the indicator for the primary standard (80 FR 65347, October 26, 2015).

With regard to averaging time, eight hours was the duration established in 1997 with the replacement of the then-existing 1-hour standard (62 FR 38856, July 18, 1997). The decision at that time was based on evidence from numerous controlled human exposure studies reporting adverse respiratory effects resulting from 6- to 8-hour exposures, as well as quantitative analyses indicating the control provided by an 8-hour averaging time of both 8-hour and 1-hour peak exposures and associated health risk (62 FR 38861, July 18, 1997; U.S. EPA, 1996b). The 1997 decision was also consistent with CASAC advice at that time (62 FR 38861, July 18, 1997; 61 FR 65727, December 13, 1996). For similar reasons, the 8-hour averaging time was retained in the subsequent 2008 review (73 FR 16436, March 27, 2008). In 2015, the decision, based on then-available health effects information, was to again retain the 8-hour averaging time, as appropriate for addressing health effects associated with short-term exposures to ambient air O_3, and based on the conclusion that it could effectively limit health effects attributable to both short- and long-term O_3 exposures (80 FR 65348, 65350, October 26, 2015).

With regard to the form for the standard, the existing *n*th-high metric form had been established in the 1997 review, when the form was revised from an expected exceedance form. At that time, it was recognized that a concentration-based form, by giving proportionally more weight to years when 8-hour O_3 concentrations are well above the level of the standard than years when concentrations are just above the level, better reflects the continuum of health effects associated with increasing O_3 concentrations than does an expected exceedance form (80 FR 65350–65352, October 26, 2015).[36] The subsequent 2008 review also

[32] Consideration focused on estimates for children, reflecting the finding that the estimates for percent of children experiencing an exposure at or above the benchmarks were higher than percent of adults due to the greater time children spend outdoors engaged in activities at elevated exertion (2014 HREA, section 5.3.2).

[33] In addition to recognizing the potential for continued inflammation to evolve into other outcomes, the 2013 ISA also recognized that inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely (2013 ISA, p. 6–76; 80 FR 65331, October 26, 2015).

[34] Although the Administrator recognized increased uncertainty in and placed less weight on the other types of HREA risk estimates, she found they supported her conclusion of public health importance on a broad national scale (80 FR 65347).

[35] The Administrator also noted that the CASAC for the prior review (2008) likewise recommended the standard level be revised below 75 ppb based on the evidence and information in the record for the 2008 decision (Samet, 2011; Frey and Samet, 2012).

[36] With regard to a specific concentration-based form, the fourth-highest daily maximum was selected in 1997, recognizing that a less restrictive form (*e.g.,* fifth highest) would allow a larger percentage of sites to experience O_3 peaks above the level of the standard, and would allow more days on which the level of the standard may be exceeded when the site attains the standard (62 FR 38868–38873, July 18, 1997), and there was no basis identified for selection of a more restrictive form (62 FR 38856, July 18, 1997).

considered the potential value of a percentile-based form, but the EPA concluded that, because of the differing lengths of the monitoring season for O_3 across the U.S., such a form would not be effective in ensuring the same degree of public health protection across the country (73 FR 16474–75, March 27, 2008). Additionally, the EPA recognized the importance of a form that provides stability to ongoing control programs and insulation from the impacts of extreme meteorological events that are conducive to O_3 occurrence (73 FR 16474–16475, March 27, 2008). In the 2015 decision, based on all of these considerations, and including advice from the CASAC, which stated that this form ''provides health protection while allowing for atypical meteorological conditions that can lead to abnormally high ambient ozone concentrations which, in turn, provides programmatic stability'' (Frey, 2014b, p. 6), the existing form (the annual fourth-highest daily maximum 8-hour O_3 average concentration, averaged over three consecutive years) was retained (80 FR 65352, October 26, 2015).

As for the decision on adequacy of protection provided by the combination of all elements of the existing standard, the 2015 decision to set the level of the revised standard at 70 ppb placed the greatest weight on the results of controlled human exposure studies and on quantitative analyses based on information from these studies, particularly analyses of O_3 exposures of concern, consistent with CASAC advice and interpretation of the scientific evidence (80 FR 65362, October 26, 2015; Frey, 2014b).[37] This weighting reflected the recognition that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following specific O_3 exposures, and, in particular, that the effects reported in the controlled human exposure studies are due solely to O_3 exposures, and are not complicated by the presence of co-occurring pollutants or pollutant mixtures (as is the case in epidemiologic studies) (80 FR 65362–65363, October 26, 2015). With regard to this evidence, the Administrator at that time recognized that: (1) The largest respiratory effects, and the broadest range of effects, have been studied and reported following exposures to 80 ppb O_3 or higher (*i.e.,* decreased lung function, increased airway inflammation, increased respiratory symptoms, airway hyperresponsiveness, and decreased lung host defense); (2) exposures to O_3 concentrations somewhat above 70 ppb have been shown to both decrease lung function and to result in respiratory symptoms; and (3) exposures to O_3 concentrations as low as 60 ppb have been shown to decrease lung function and to increase airway inflammation (80 FR 65363, October 26, 2015). The Administrator also noted that 70 ppb was well below the O_3 exposure concentration documented to result in the widest range of respiratory effects (*i.e.,* 80 ppb), and below the lowest O_3 exposure concentration shown in 6.6 hour exposures with quasi-continuous exercise to result in the combination of lung function decrements and respiratory symptoms (80 FR 65363, October 26, 2015).

In considering the degree of protection to be provided by a revised standard, and the extent to which that standard would be expected to limit population exposures to the broad range of O_3 exposures shown to result in health effects, the Administrator focused particularly on the HREA estimates of two or more exposures of concern. Placing the most emphasis on a standard that limits repeated occurrences of exposures at or above the 70 and 80 ppb benchmarks, while at elevated ventilation, the Administrator noted that a revised standard with a level of 70 ppb was estimated to eliminate the occurrence of two or more days with exposures at or above 80 ppb and to virtually eliminate the occurrence of two or more days with exposures at or above 70 ppb for all children and children with asthma, even in the worst-case year and location evaluated (80 FR 65363–65364, October 26, 2015).[38] The Administrator's consideration of exposure estimates at or above the 60 ppb benchmark (focused most particularly on multiple occurrences), an exposure to which the Administrator was less confident would result in adverse effects,[39] as discussed above, was primarily in the context of considering the extent to which the health protection provided by a revised standard included a margin of safety against the occurrence of adverse O_3-induced effects (80 FR 65364, October 26, 2015). In this context, the Administrator noted that a revised standard with a level of 70 ppb was estimated to protect the vast majority of children in urban study areas (*i.e.,* about 96% to more than 99% of children in individual areas) from experiencing two or more days with exposures at or above 60 ppb (while at moderate or greater exertion). This represented a more than 60% reduction in repeated exposures over the estimates for the then-existing standard, with its level of 75 ppb.

Given the considerable protection provided against repeated exposures of concern for all three benchmarks, including the 60 ppb benchmark, the Administrator judged that a standard with a level of 70 ppb would incorporate a margin of safety against the adverse O_3-induced effects shown to occur in the controlled human exposure studies following exposures (while at moderate or greater exertion) to a concentration somewhat higher than 70 ppb (80 FR 65364, October 26, 2015).[40] The Administrator also judged the HREA estimates of one or more exposures (while at moderate or greater exertion) at or above 60 ppb to also provide support for her somewhat broader conclusion that ''a standard with a level of 70 ppb would incorporate an adequate margin of safety against the occurrence of O_3 exposures that can result in effects that are adverse to public health'' (80 FR 65364, October 26, 2015).[41] Although she placed less

[37] The Administrator viewed the results of other quantitative analyses in this review—the lung function risk assessment, analyses of O_3 air quality in locations of epidemiologic studies, and epidemiologic-study-based quantitative health risk assessment—as being of less utility for selecting a particular standard level among a range of options (80 FR 65362, October 26, 2015).

[38] Under conditions just meeting an alternative standard with a level of 70 ppb across the 15 urban study areas, the estimate for two or more days with exposures at or above 70 ppb was 0.4% of children, in the worst year and worst area (80 FR 65313, Table 1, October 26, 2015).

[39] The Administrator was ''notably less confident in the adversity to public health of the respiratory effects that have been observed following exposures to O_3 concentrations as low as 60 ppb,'' based on her consideration of the ATS statement on judging adversity from transient lung function decrements alone, the uncertainty in the potential for such decrements to increase the risk of other, more serious respiratory effects in a population (per ATS recommendations on population-level risk), and the less clear CASAC advice regarding potential adversity of effects at 60 ppb compared to higher concentrations studied (80 FR 65363, October 26, 2015).

[40] In so judging, she noted that the CASAC had recognized the choice of a standard level within the range it recommended based on the scientific evidence (which was inclusive of 70 ppb) to be a policy judgment (80 FR 65355, October 26, 2015; Frey, 2014b).

[41] While the Administrator was less concerned about single exposures, especially for the 60 ppb benchmark, she judged the HREA one-or-more estimates informative to margin of safety considerations. In this regard, she noted that ''a standard with a level of 70 ppb is estimated to (1) virtually eliminate all occurrences of exposures of concern at or above 80 ppb; (2) protect the vast majority of children in urban study areas from experiencing any exposures of concern at or above 70 ppb (*i.e.,* ≥ about 99%, based on mean estimates; Table 1); and (3) to achieve substantial reductions, compared to the [then-]current standard, in the occurrence of one or more exposures of concern at or above 60 ppb (*i.e.,* about a 50% reduction; Table 1)'' (80 FR 65364, October 26, 2015).

weight on the other HREA risk estimates and epidemiologic evidence for considering the standard level, in light of associated uncertainties, the Administrator judged that a standard with a level of 70 ppb would be expected to result in important reductions in the population-level risk of endpoints on which these types of information are focused and provide associated additional public health protection, beyond that provided by the then-existing standard (80 FR 65364, October 26, 2015). In summary, based on the evidence, exposure and risk information, advice from the CASAC, and public comments, the 2015 decision was to revise the primary standard to be 70 ppb, in terms of the 3-year average of annual fourth-highest daily maximum 8-hour average O_3 concentrations, to provide the requisite protection of public health, including the health of at-risk populations, with an adequate margin of safety (80 FR 65365, October 26, 2015).

2. Overview of Health Effects Information

The information summarized in this section is an overview of the scientific assessment of the health effects evidence available in this review; the assessment is documented in the ISA and its policy implications are further discussed in the PA. In this review, as in past reviews, the health effects evidence evaluated in the ISA for O_3 and related photochemical oxidants is focused on O_3 (ISA, section IS.1.1). Ozone is concluded to be the most prevalent photochemical oxidant present in the atmosphere and the one for which there is a very large, well-established evidence base of its health and welfare effects (ISA, section IS.1.1). Thus, the current health effects evidence and the Agency's review of the evidence, including the evidence newly available in this review,[42] continues to focus on O_3. The subsections below briefly summarize the following aspects of the evidence: The nature of O_3-related health effects, the potential public health implications and populations at risk, and exposure concentrations associated with health effects.

a. Nature of Effects

The evidence base available in the current review includes decades of extensive evidence that clearly describes the role of O_3 in eliciting an array of respiratory effects and recent evidence indicates the potential for relationships between O_3 exposure and metabolic effects. As was established in prior reviews, the effects for which the evidence is strongest are transient decrements in pulmonary function and respiratory symptoms, such as coughing and pain on deep inspiration, as a result of short-term exposures particularly when breathing at elevated rates (ISA, section IS.4.3.1; 2013 ISA, p. 2–26). These effects are demonstrated in the large, long-standing evidence base of controlled human exposure studies[43] (1978 AQCD, 1986 AQCD, 1996 AQCD, 2006 AQCD, 2013 ISA, ISA). The epidemiologic evidence base documents consistent, positive associations of O_3 concentrations in ambient air with lung function effects in panel studies (2013 ISA, section 6.2.1.2; ISA, Appendix 3, section 3.1.4.1.3), and with more severe health outcomes, including asthma-related emergency department visits and hospital admissions (2013 ISA, section 6.2.7; ISA, Appendix 3, sections 3.1.5.1 and 3.1.5.2). Extensive experimental animal evidence informs a detailed understanding of mechanisms underlying the short-term respiratory effects, and studies in animal models describe effects of longer-term O_3 exposure on the developing lung (ISA, Appendix 3, sections 3.1.11 and 3.2.6).

The full body of evidence continues to support the conclusions of a causal relationship of respiratory effects with short-term O_3 exposures and of a relationship of respiratory effects with longer-term exposures that is likely to be causal (ISA, sections IS.4.3.1 and IS.4.3.2). Further, the ISA determines that the relationship between short-term O_3 exposure and metabolic effects[44] is likely to be causal, based primarily on newly available experimental animal evidence (ISA, section IS.4.3.3). The newly available evidence, particularly from controlled human exposure studies of cardiovascular endpoints, has altered conclusions from the last review with regard to relationships between short-term O_3 exposures and cardiovascular effects and mortality, such that the evidence no longer supports conclusions that the relationships are likely to be causal.[45]

With regard to respiratory effects from short-term O_3 exposure, the strongest evidence comes from controlled human exposure studies, also available in the last review, demonstrating O_3-related respiratory effects in generally healthy adults (ISA, section IS.1.3.1).[46] As in the last review, the key evidence comes from the body of controlled human exposure studies that document respiratory effects in people exposed for short periods (6.6 to 8 hours) during quasi-continuous exercise.[47] The potential for O_3 exposure to elicit health outcomes more serious than those assessed in the controlled human exposure studies continues to be indicated by the epidemiologic evidence of associations of O_3 concentrations in ambient air with increased incidence of hospital admissions and emergency department visits for an array of health outcomes, including asthma exacerbation, chronic obstructive pulmonary disease (COPD) exacerbation, respiratory infection, and combinations of respiratory diseases (ISA, Appendix 3, sections 3.1.5 and 3.1.6). The strongest such evidence is for asthma-related outcomes and specifically asthma-related outcomes for children, indicating an increased risk for people with asthma and particularly children with asthma (ISA, Appendix 3, section 3.1.5.7).

Respiratory responses observed in human subjects exposed to O_3 for periods of 8 hours or less, while intermittently or quasi-continuously exercising, include lung function decrements (*e.g.,* based on forced expiratory volume in one second [FEV_1] measurements),[48] respiratory symptoms,

[42] More than 1600 studies are newly available and considered in the ISA, including more than 1000 health studies (ISA, Appendix 10, Figure 10–2).

[43] The vast majority of the controlled human exposure studies (and all of the studies conducted at the lowest exposures) involved young healthy adults (typically 18–35 years old) as study subjects (2013 ISA, section 6.2.1.1). There are also some controlled human exposure studies of one to eight hours duration in older adults and adults with asthma, and there are still fewer controlled human exposure studies in healthy children (*i.e.,* individuals aged younger than 18 years) or children with asthma (See, for example, PA, Appendix 3A, Table 3A–3).

[44] The term metabolic effects is used in the ISA to refer metabolic syndrome (a collection of risk factors including alterations in glucose and insulin homeostasis, high blood pressure, adiposity, elevated triglycerides and low high density lipoprotein cholesterol), diabetes, metabolic disease mortality, and indicators of metabolic syndrome that include peripheral inflammation, liver function, neuroendocrine signaling, and serum lipids (ISA, section IS.4.3.3).

[45] The currently available evidence for cardiovascular, reproductive and nervous system effects, as well as mortality, is ''suggestive of, but not sufficient to infer'' a causal relationship with short- or long-term O_3 exposures (ISA, Table IS–1). The evidence is inadequate to infer the presence or absence of a causal relationship between long-term O_3 exposure and cancer (ISA, section IS.4.3.6.6).

[46] The phrases ''healthy adults'' or ''healthy subjects'' are used to distinguish from subjects with asthma or other respiratory diseases because the ''the study design generally precludes inclusion of subjects with serious health conditions,'' such as individuals with severe respiratory diseases (2013 ISA, p. lx).

[47] A quasi-continuous exercise protocol is common to these controlled exposure studies where study subjects complete six 50-minute periods of exercise, each followed by 10-minute periods of rest (*e.g.,* ISA, Appendix 3, section 3.1.4.1.1, and p. 3–11; 2013 ISA, section 6.2.1.1).

[48] In summarizing FEV_1 responses from controlled human exposure studies as

increased airway responsiveness, mild bronchoconstriction (measured as an increase in specific airway resistance [sRaw]), and pulmonary inflammation, with associated injury and oxidative stress (ISA, Appendix 3, section 3.1.4; 2013 ISA, sections 6.2.1 through 6.2.4). The available mechanistic evidence, discussed in greater detail in the ISA, describes pathways involving the respiratory and nervous systems by which O_3 results in pain-related respiratory symptoms and reflex inhibition of maximal inspiration (inhaling a full, deep breath), commonly quantified by decreases in forced vital capacity (FVC) and total lung capacity. This reflex inhibition of inspiration combined with mild bronchoconstriction contributes to the observed decrease in FEV_1, the most common metric used to assess O_3-related lung function effects. The evidence also indicates that the additionally observed inflammatory response is correlated with mild airway obstruction, generally measured as an increase in sRaw (ISA, Appendix 3, section 3.1.3). As described below, the prevalence and severity of respiratory effects in controlled human exposure studies, including symptoms (*e.g.,* pain on deep inspiration, shortness of breath, and cough), increases with increasing O_3 concentration, exposure duration, and ventilation rate of exposed subjects (ISA, Appendix 3, sections 3.1.4.1 and 3.1.4.2).

Within the evidence base from controlled human exposure studies, the majority of studies involve healthy adult subjects (generally 18 to 35 years), although there are studies involving subjects with asthma, and a limited number of studies, generally of durations shorter than four hours, involving adolescents and adults older than 50 years. A summary of salient observations of O_3 effects on lung function, based on the controlled human exposure study evidence reviewed in the 1996 and 2006 AQCDs, and recognized in the 2013 ISA, continues to pertain to this evidence base as it exists today: ''(1) young healthy adults exposed to ≥80 ppb ozone develop significant reversible, transient decrements in pulmonary function and symptoms of breathing discomfort if minute ventilation (Ve) or duration of exposure is increased sufficiently; (2) relative to young adults, children experience similar spirometric responses [*i.e.,* as measured by FEV_1 and/or FVC] but lower incidence of symptoms from O_3 exposure; (3) relative to young adults, ozone-induced spirometric responses are decreased in older individuals; (4) there is a large degree of inter-subject variability in physiologic and symptomatic responses to O_3, but responses tend to be reproducible within a given individual over a period of several months; and (5) subjects exposed repeatedly to O_3 for several days experience an attenuation of spirometric and symptomatic responses on successive exposures, which is lost after about a week without exposure'' (ISA, Appendix 3, section 3.1.4.1.1, p. 3–11).[49] Repeated daily exposure studies at higher concentrations, such as 300 ppb, have found FEV_1 responses to be enhanced on the second day of exposure. This enhanced response is absent, however, with repeated exposure at lower concentrations, perhaps as a result of a more complete recovery or less damage to pulmonary tissues (2013 ISA, section pp. 6–13 to 6–14; Folinsbee et al., 1994).

With regard to airway inflammation and the potential for repeated occurrences to contribute to further effects, O_3-induced respiratory tract inflammation ''can have several potential outcomes: (1) Inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely; (2) continued acute inflammation can evolve into a chronic inflammatory state; (3) continued inflammation can alter the structure and function of other pulmonary tissue, leading to diseases such as fibrosis; (4) inflammation can alter the body's host defense response to inhaled microorganisms, particularly in potentially at-risk populations such as the very young and old; and (5) inflammation can alter the lung's response to other agents such as allergens or toxins'' (2013 ISA, p. 6–76; ISA Appendix 3, section 3.1.5.6). With regard to O_3-induced increases in airway responsiveness, the controlled human exposure study evidence for healthy adults generally indicates resolution within 18 to 24 hours after exposure, with slightly longer persistence in some individuals (ISA, Appendix 3, section 3.1.4.3.1; 2013 ISA, p. 6–74; Folinsbee and Hazucha, 2000).

The array of O_3-associated respiratory effects, including reduced lung function, respiratory symptoms, increased airway responsiveness, and inflammation are of increased significance to people with asthma given aspects of the disease that contribute to a baseline status that includes chronic airway inflammation and greater airway responsiveness than people without asthma (ISA, section 3.1.5). For example, O_3 exposure of a magnitude that increases airway responsiveness may put such people at potential increased risk for prolonged bronchoconstriction in response to asthma triggers (ISA, Appendix 3, p. 3–7, 3–28; 2013 ISA, section 6.2.9; 2006 AQCD, section 8.4.2). The increased significance of effects in people with asthma and risk of increased exposure for children (from greater frequency of outdoor exercise)[50] is illustrated by the epidemiologic findings of positive associations between O_3 exposure and asthma-related emergency department visits and hospital admissions for children with asthma. Thus, the evidence indicates O_3 exposure to increase the risk of asthma exacerbation, and associated outcomes, in children with asthma.

With regard to an increased susceptibility to infectious diseases, the experimental animal evidence continues to indicate, as described in the 2013 ISA and past AQCDs, the potential role for O_3 exposures through effects on defense mechanisms of the respiratory tract (ISA, section 3.1.7.3; 2013 ISA, section 6.2.5). The evidence base regarding respiratory infections and associated effects has been augmented in this review by a number of epidemiologic studies reporting positive associations between short-term O_3 concentrations and emergency department visits for a variety of respiratory infection endpoints (ISA, Appendix 3, section 3.1.7).

Although the long-term exposure conditions that may contribute to further respiratory effects are less well understood, experimental studies, including with nonhuman infant primates, have provided evidence relating O_3 exposure to asthma-like effects, and epidemiologic cohort studies have reported associations of O_3 concentrations in ambient air with asthma development in children (ISA, IS.4.3.2 and Appendix 3, sections 3.2.4.1.3 and 3.2.6). The biological plausibility of such a role for O_3 has been indicated by animal toxicological

''decrements'', an O_3-induced change in FEV_1 is typically the difference between the change observed with O_3 exposure ([post-exposure FEV_1 minus pre-exposure FEV_1] divided by pre-exposure FEV_1) and what is generally an improvement observed with filtered air (FA) exposure ([post-exposure FEV_1 minus pre-exposure FEV_1] divided by pre-exposure FEV_1).

[49] A spirometric response refers to a change in the amount of air breathed out of the body (forced expiratory volumes) and the associated time to do so (*e.g.,* FEV_1).

[50] Children are the age group most likely to be outdoors at activity levels corresponding to those that have been associated with respiratory effects in the human exposure studies (PA, Appendix 3D, section 3D.2.5.3), as recognized in section II.A.2.b below.

evidence on biological mechanisms (ISA, Appendix 3, sections 3.2.3 and 3.2.4.1.2).

Overall, the respiratory effects evidence newly available in this review is consistent with the evidence base in the last review, supporting a generally similar understanding of the respiratory effects of O_3 (ISA, Appendix 3, section 3.1.4). A few recent studies provide insights in previously unexamined areas, both with regard to human study groups and animal models for different effects, while other studies confirm and provide depth to prior findings with updated protocols and techniques (ISA, Appendix 3, sections 3.1.11 and 3.2.6). Newly available epidemiologic studies of hospital admissions and emergency department visits for a variety of respiratory outcomes supplement the previously available evidence with additional findings of consistent associations with O_3 concentrations across a number of study locations (ISA, Appendix 3, sections 3.1.4.1.3, 3.1.5, 3.1.6.1.1, 3.1.7.1 and 3.1.8). These studies include a number that report positive associations for asthma-related outcomes, as well as a few for COPD-related outcomes. Together these epidemiologic studies continue to indicate the potential for O_3 exposures to contribute to such serious health outcomes, particularly for people with asthma.

As was the case for the evidence available in the last review, the currently available evidence for health effects other than those of O_3 exposures on the respiratory system is more uncertain than that for respiratory effects.[51] Further, the evidence now available has contributed to changes in conclusions for some of these effects. For example, the current evidence for cardiovascular effects and mortality, expanded from that in the last review, is no longer considered sufficient to conclude that the relationships of short-term exposure with these effects are likely to be causal (ISA, sections IS.4.3.4 and IS.4.3.5). These changes stem from newly available evidence in combination with the uncertainties recognized for the evidence available in the last review.[52] Although there exists largely consistent evidence for a limited number of O_3-induced cardiovascular endpoints in animal toxicological studies and cardiovascular mortality in epidemiologic studies, there is a general lack of coherence between these results and findings in controlled human exposure and epidemiologic studies of cardiovascular health outcomes (ISA, section IS.1.3.1, Appendix 6, section 6.1.8). The relationships are now characterized as suggestive of, but not sufficient to infer, a causal relationship (ISA, Appendix 4, section 4.1.17; Appendix 6, section 6.1.8).

With regard to metabolic effects of short-term O_3 exposures, the evidence comes primarily from experimental animal study findings, with a limited number of epidemiologic studies (ISA, section IS.4.3.3 and Appendix 5, section 5.1.8 and Table 5–3). The exposure conditions from the animal studies generally involve much higher O_3 concentrations (*e.g.,* 4-hour concentrations of 400 to 800 ppb [ISA, Appendix 5, Tables 5–8 and 5–10]) than those commonly occurring in areas of the U.S. where the current standard is met, and the concentration in the available controlled human exposure study is similarly high, at 300 ppb (ISA, sections 5.1.3, 5.1.5 and 5.1.8, Table 5–3). The evidence for metabolic effects and long-term exposures is concluded to be suggestive of, but not sufficient to infer, a causal relationship (ISA, section IS.4.3.6.2).

b. Public Health Implications and At-Risk Populations

The public health implications of the evidence regarding O_3-related health effects, as for other effects, are dependent on the type and severity of the effects, as well as the size of the population affected. Judgments or interpretative statements developed by public health experts, particularly experts in respiratory health, also inform consideration of public health implications.

With regard to O_3 in ambient air, the potential public health impacts relate most importantly to respiratory effects. Controlled human exposure studies have documented reduced lung function, respiratory symptoms, increased airway responsiveness, and inflammation, among other effects, in healthy adults exposed while at elevated ventilation, such as while exercising. Ozone effects in individuals with compromised respiratory function, such as individuals with asthma, are plausibly related to emergency department visits and hospital admissions for asthma which have been associated with ambient air concentrations of O_3 in epidemiologic studies (as summarized in section II.A.2.a above; 2013 ISA, section 6.2.7; ISA, Appendix 3, sections 3.1.5.1 and 3.1.5.2).

The clinical significance of individual responses to O_3 exposure depends on the health status of the individual, the magnitude of the responses, the severity of respiratory symptoms, and the duration of the response. While a particular reduction in FEV_1 or increase in inflammation or airway responsiveness may not be of concern for a healthy group, it may increase the risk of a more severe effect in a group with asthma. As a more specific example, the same increase in inflammation or airway responsiveness in individuals with asthma could predispose them to an asthma exacerbation event triggered by an allergen to which they may be sensitized (*e.g.,* ISA, Appendix 3, section 3.1.5.6.1; 2013 ISA, sections 6.2.3 and 6.2.6). Duration and frequency of documented effects is also reasonably expected to influence potential adversity and interference with normal activity.[53] In summary, consideration of differences in magnitude or severity, and also the relative transience or persistence of the responses (*e.g.,* FEV_1 changes) and respiratory symptoms, as well as pre-existing sensitivity to effects on the respiratory system, and other factors, are important to characterizing implications for public health effects of an air pollutant such as O_3 (ATS, 2000; Thurston et al., 2017).

Decisions made in past reviews of the O_3 primary standard and associated judgments regarding adversity or health significance of measurable physiological responses to air pollutants have been informed by guidance, criteria or interpretative statements developed within the public health community, including the ATS, an organization of respiratory disease specialists, as well as

[51] For example, the available evidence for reproductive and developmental effects, as well as for effects on the nervous system, is suggestive of, but not sufficient to infer, a causal relationship (ISA, section IS.4.3.6.5 and Table IS–1).

[52] These aspects of the current evidence base include: (1) A now-larger body of controlled human exposure studies providing evidence that is not consistent with a cardiovascular effect in response to short-term O_3 exposure; (2) a paucity of epidemiologic evidence indicating more severe cardiovascular morbidity endpoints (*e.g.,* emergency department visits and hospital visits for cardiovascular endpoints including myocardial infarctions, heart failure or stroke) that could connect the evidence for impaired vascular and cardiac function from animal toxicological studies with the evidence from epidemiologic studies of cardiovascular mortality; and (3) the remaining uncertainties and limitations recognized in the 2013 ISA (*e.g.,* lack of control for potential confounding by copollutants in epidemiologic studies) still remain.

[53] For example, for most healthy individuals moderate effects on pulmonary function, such as transient FEV_1 decrements smaller than 20% or transient respiratory symptoms, such as cough or discomfort on exercise or deep breath, would not be expected to interfere with normal activity, while larger effects on pulmonary function (*e.g.,* FEV_1 decrements of 20% or larger lasting longer than 24 hours) and/or more severe respiratory symptoms are more likely to interfere with normal activity (*e.g.,* PA, p. 3–30; 2006 AQCD, Table 8–2).

the advice from the CASAC. The ATS released its initial statement (titled *Guidelines as to What Constitutes an Adverse Respiratory Health Effect, with Special Reference to Epidemiologic Studies of Air Pollution*) in 1985 and updated it in 2000 (ATS, 1985; ATS, 2000). The ATS described its 2000 statement, considered in the last review of the O_3 standard, as being intended to ''provide guidance to policy makers and others who interpret the scientific evidence on the health effects of air pollution for the purposes of risk management'' (ATS, 2000). The recent statement further notes that it does not offer ''strict rules or numerical criteria, but rather proposes considerations to be weighed in setting boundaries between adverse and nonadverse health effects,'' providing a general framework for interpreting evidence that proposes a ''set of considerations that can be applied in forming judgments'' for this context (Thurston et al., 2017). Similarly, in the 2000 statement, the ATS describes it as proposing ''principles to be used in weighing the evidence and setting boundaries'' and states that ''the placement of dividing lines should be a societal judgment'' (ATS, 2000). The ATS explicitly states that it does ''not attempt to provide an exact definition or fixed list of health impacts that are, or are not, adverse,'' providing instead ''a number of generalizable 'considerations'" (ATS, 2000). The ATS state there ''cannot be precise numerical criteria, as broad clinical knowledge and scientific judgments, which can change over time, must be factors in determining adversity'' (ATS, 2000).

With regard to pulmonary function decrements, the earlier ATS statement concluded that ''small transient changes in forced expiratory volume in 1 s[econd] (FEV_1) alone were not necessarily adverse in healthy individuals but should be considered adverse when accompanied by symptoms'' (ATS, 2000). The more recent ATS statement continues to support this conclusion and also gives weight to findings of small lung function changes in the absence of respiratory symptoms in individuals with pre-existing compromised function, such as that resulting from asthma (Thurston et al., 2017). In keeping with the intent of these statements to avoid specific criteria, neither statement provides more specific descriptions of such responses, such as with regard to magnitude, duration or frequency, for consideration of such conclusions. The earlier ATS statement, in addition to emphasizing clinically relevant effects, also emphasized both the need to consider changes in ''the risk profile of the exposed population,'' and effects on the portion of the population that may have a diminished reserve that puts its members at potentially increased risk if affected by another agent (ATS, 2000). These concepts, including the consideration of the magnitude of effects occurring in just a subset of study subjects, continue to be recognized as important in the more recent ATS statement (Thurston et al., 2017) and continue to be relevant to the evidence base for O_3.

The information newly available in this review regarding O_3 exposure and health effects among sensitive populations, thoroughly evaluated in the ISA, has not altered our understanding of human populations at particular risk of health effects from O_3 exposures (ISA, section IS.4.4). The respiratory effects evidence, extending decades into the past and augmented by new studies in this review, supports the conclusion that ''individuals with pre-existing asthma are at greater risk of ozone-related health effects based on the substantial and consistent evidence within epidemiologic studies and the coherence with toxicological studies'' (ISA, p. IS–57). Numerous epidemiologic studies document associations of O_3 with asthma exacerbation. Such studies indicate the associations to be strongest for populations of children which is consistent with their generally greater time outdoors while at elevated exertion. Together, these considerations indicate people with asthma, including particularly children with asthma, to be at relatively greater risk of O_3-related effects than other members of the general population (ISA, section IS.4.4.2 and Appendix 3).[54]

With respect to people with asthma, the limited evidence from controlled human exposure studies (which are primarily in adult subjects) indicates similar magnitude of FEV_1 decrements as in people without asthma (ISA, Appendix 3, section 3.1.5.4.1). Across studies of other respiratory effects of O_3 (*e.g.,* increased respiratory symptoms, increased airway responsiveness and increased lung inflammation), the responses observed in study subjects generally do not differ due to the presence of asthma, although the evidence base is more limited with regard to study subjects with asthma (ISA, Appendix 3, section 3.1.5.7). However, the features of asthma (*e.g.,* increased airway responsiveness) contribute to a risk of asthma-related responses, such as asthma exacerbation in response to asthma triggers, which may increase the risk of more severe health outcomes (ISA, section 3.1.5). For example, a particularly strong and consistent component of the epidemiologic evidence is the appreciable number of epidemiologic studies that demonstrate associations between ambient O_3 concentrations and hospital admissions and emergency department visits for asthma (ISA, section IS.4.4.3.1). The strongest associations (*e.g.,* highest effect estimates) or associations more likely to be statistically significant are those for childhood age groups, which are age groups most likely to spend time outdoors during afternoon periods (when O_3 may be highest) and at activity levels corresponding to those that have been associated with respiratory effects in the human exposure studies (ISA, Appendix 3, sections 3.1.4.1 and 3.1.4.2).[55] The epidemiologic studies of hospital admissions and emergency department visits are augmented by a large body of individual-level epidemiologic panel studies that demonstrated associations of short-term ozone concentrations with respiratory symptoms in children with asthma. Additional support comes from epidemiologic studies that observed O_3-associated increases in indicators of airway inflammation and oxidative stress in children with asthma (ISA, section IS.4.3.1). Together, this evidence continues to indicate the increased risk of population groups with asthma,

[54] Populations or lifestages can be at increased risk of an air pollutant-related health effect due to one or more of a number of factors. These factors can be intrinsic, such as physiological factors that may influence the internal dose or toxicity of a pollutant, or extrinsic, such as sociodemographic, or behavioral factors.

[55] Evaluations of activity pattern data in current and last review indicate children to more frequently spend time outdoors during afternoon and early evening hours, while at moderate or greater exertion level, than other age groups (PA, Appendix 3D, section 3D.2.5.3, including Figure 3D–9; 2014 HREA, section 5.4.1.5 and Appendix 5G, section 5G–1.4). For example, for days with some time spent outdoors, children spend, on average, approximately 2¼ hours of afternoon time outdoors, 80% of which is at a moderate or greater exertion level, regardless of their asthma status (PA, Appendix 3D, section 3D.2.5.3). Adults, for days having some time spent outdoors, also spend approximately 2¼ hours of afternoon time outdoors regardless of their asthma status but the percent of afternoon time at moderate or greater exertion levels for adults (about 55%) is lower than that observed for children. Such analyses also note greater participation in outdoor events during the afternoon, compared to other times of day, for children ages 6 through 19 years old during the warm season months (ISA, Appendix 2, section 2.4.1, Table 2–1). Analyses of the limited activity pattern data by health status do not indicate asthma status to have appreciable impact (PA, Appendix 3D, section 3D.2.5.3; 2014 HREA, section 5.4.1.5).

including particularly, children (ISA, Appendix 3, section 3.1.5.7).

Children, and also outdoor adult workers, are at increased risk largely due to their generally greater time spent outdoors while at elevated exertion rates (including in summer afternoons and early evenings when O_3 levels may be higher). This behavior makes them more likely to be exposed to O_3 in ambient air, under conditions contributing to increased dose, *e.g.,* elevated ventilation taking greater air volumes into the lungs [56] (2013 ISA, section 5.2.2.7). In light of the evidence summarized in the prior paragraph, children and outdoor workers with asthma may be at increased risk of more severe outcomes, such as asthma exacerbation. Further, there is experimental evidence from early life exposures of nonhuman primates that indicates potential for effects in childhood when human respiratory systems are under development [57] (ISA, section IS.4.4.4.1). Overall, the evidence available in the current review, while not increasing our knowledge about susceptibility or at-risk status of these population groups, is consistent with that in the last review (ISA, section IS.4.4).[58]

The ISA also expressly considered the evidence regarding O_3 exposure and health effects among populations with several other potential risk factors. As in the last review, the evidence for low income and minority populations, remains ''suggestive'' of increased risk, and includes several inconsistencies (ISA, Tables IS–9 and IS–10).[59] The ISA in the last review additionally identified a role for dietary anti-oxidants such as vitamins C and E in influencing risk of O_3-related effects, such as inflammation, as well as a role for genetic factors to also confer either an increased or decreased risk (2013 ISA, sections 8.1 and 8.4.1). No newly available evidence has been evaluated that would inform or change these prior conclusions (ISA, section IS.4.4 and Table IS–10).

The magnitude and characterization of a public health impact is dependent upon the size and characteristics of the populations affected, as well as the type or severity of the effects. As summarized above, a population most at risk of health effects associated with O_3 in ambient air is people with asthma. The National Center for Health Statistics data for 2017 indicate that approximately 7.9% of the U.S. populations has asthma (CDC, 2019; PA, Table 3–1) and this is one of the principal populations that the primary O_3 NAAQS is designed to protect (80 FR 65294, October 26, 2015). Children under the age of 18 account for 16.7% of the total U.S. population, with 6.2% of the total population being children under 5 years of age (U.S. Census Bureau, 2019). Another at-risk population group, also due to time and activity outdoors, is outdoor workers.[60] Population groups with relatively greater asthma prevalence, such as populations in poverty and children [61] (CDC, 2019, Tables 3–1 and 4–1; PA, Table 3–1), might be expected to have a relatively greater potential for O_3-related health impacts.[62]

c. Exposure Concentrations Associated With Effects

The extensive evidence base for O_3 health effects, compiled over several decades, continues to indicate respiratory responses to short-term exposures as the most sensitive effects. As at the time of the last review, our conclusions regarding O_3 exposure concentrations associated with respiratory effects reflect the extensive longstanding evidence base of controlled human exposure studies of short-term exposures of people with and without asthma (ISA, Appendix 3). As summarized in section II.A.2.a above, these studies have documented an array of respiratory effects, including reduced lung function, respiratory symptoms, increased airway responsiveness, and inflammation, in study subjects following 1- to 8-hour exposures, primarily while exercising.[63]

The current evidence, including that newly available in this review, does not alter the scientific conclusions reached in the last review on exposure duration and concentrations associated with O_3-related health effects. These conclusions were largely based on the body of evidence from the controlled human exposure studies. A limited number of controlled human exposure studies are newly available in the current review, with none involving lower exposure concentrations than those previously studied or finding effects not previously reported (ISA, Appendix 3, section 3.1.4).[64]

The severity of observed responses, the percentage of individuals responding, and strength of statistical significance at the study group level have been found to increase with increasing exposure (ISA; 2013 ISA; 2006 AQCD). For example, the magnitude of respiratory response (*e.g.,* size of lung function reductions and magnitude of symptom scores) documented in the controlled human exposure studies is influenced by ventilation rate, exposure duration, and exposure concentration. When performing physical activities requiring elevated exertion, ventilation rate is increased, leading to greater potential for health effects due to an increased internal dose (2013 ISA, section 6.2.1.1, pp. 6–5 to 6–11). Accordingly, the exposure concentrations eliciting a given level of response after a given exposure duration is lower for subjects exposed while at elevated ventilation, such as while exercising (2013 ISA, pp.

[56] Additionally, compared to adults, children have higher ventilation rates relative to their lung volume which tends to increase the dose normalized to lung surface area. (ISA, p. IS–60).

[57] Human lung development begins during the fetal period and continues into early adulthood. This continued development comprises an extended window of potential vulnerability to O_3 (ISA, p. 3–99).

[58] Evidence available in the current review for older adults, a population identified as at risk in the last review, adds little to the evidence previously available (ISA, sections IS.4.4.2 and IS.4.4.4.2). The ISA notes, however, that ''[t]he majority of evidence for older adults being at increased risk of health effects related to ozone exposure comes from studies of short-term ozone exposure and mortality evaluated in the 2013 Ozone ISA'' (ISA, p. IS–52). Such studies are part of the larger evidence base that is now concluded to be suggestive, but not sufficient to infer a causal relationship of O_3 with mortality (ISA, sections IS.4.3.5 and IS.4.4.4.2, Appendix 4, section 4.1.16.1 and 4.1.17).

[59] The 2013 ISA concluded that the overall evidence is suggestive of socioeconomic economic status (SES) as a factor affecting risk of O_3-related health outcomes ''based on collective evidence from epidemiologic studies of respiratory hospital admissions but inconsistency among epidemiologic studies of mortality and reproductive outcomes,'' additionally stating that ''[f]urther studies are needed to confirm this relationship, especially in populations within the U.S.'' (2013 ISA, p. 8–28). The evidence available in the current review adds little to the evidence available at the time of the last review in this area (ISA, section IS.4.4.2 and Table IS–10). Other factors for which the evidence remains suggestive of an influence on risk status are being male or being female and pre-existing obesity (ISA, Table IS–10).

[60] For example, jobs in construction and extraction occupations and protective service occupations, as well as installation, maintenance and repair occupations and building and grounds cleaning and maintenance operations, had high percentages of employees who spent part of their workday outdoors (Bureau of Labor Statistics, 2017). Such jobs often include physically demanding tasks and involve increased ventilation rates, increasing the potential for exposure to O_3.

[61] In 2017 and 2018, the prevalence of asthma in children 0 to 17 years old was 8.4% and 7.5% respectively (CDC, 2019).

[62] As the current standard was set to protect at-risk populations, such as people with asthma, populations with asthma living in areas not meeting the standard would be expected to be at greater risk of effects than others in those areas.

[63] The risk of more severe health outcomes associated with such effects is increased in people with asthma as illustrated by the epidemiologic findings of positive associations between O_3 exposure and asthma-related ED visits and hospital admissions.

[64] The newly available 3-hour controlled human exposure studies (involving intermittent exercise) reported statistically significant respiratory response at 120 ppb in adults 55 to 70 years old (ISA, Appendix 3, section 3.1.4; PA, Appendix 3A, Table 3A–3).

6–5 to 6–6; ISA Appendix 3, section 3.1.4.2). For example, in studies of healthy young adults exposed while at rest for 2 hours, 500 ppb is the lowest concentration eliciting a statistically significant O_3-induced group mean lung function decrement, while a 1- to 2-hour exposure to 120 ppb produces a statistically significant response in lung function when the ventilation rate of the group of study subjects is sufficiently increased with exercise (2013 ISA, pp. 6–5 to 6–6).[65]

The exposure conditions (*e.g.,* duration and exercise) given primary focus in the past several O_3 NAAQS reviews are those of the 6.6-hour study design, which involves six 50-minute exercise periods during which subjects maintain a moderate level of exertion to achieve a ventilation rate of approximately 20 L/min per m^2 body surface area while exercising.[66] The 6.6 hours of exposure in these quasi-continuous exercise studies has generally occurred in an enclosed chamber and the study design includes three hours in each of which is a 50-minute exercise period and a 10-minute rest period, followed by a 35-minute lunch (rest) period, which is followed by three more hours of exercise and rest, as before lunch.[67] Most of these studies performed to date involve exposure maintained at a constant (unchanging) concentration for the full duration, although a subset of studies have concentrations that vary (generally in a stepwise manner) across the exposure period and are selected so as to achieve a specific target concentration as the exposure average.[68]

Evidence from studies with similar duration and quasi-continuous exercise aspects (6.6-hour duration with six 50-minute exercise periods) demonstrates an exposure-response (E–R) relationship for O_3-induced reduction in lung function (Table 1; ISA, Appendix 3, Figure 3–3 PA, Figure 3–2).[69] No studies of the 6.6-hour design are newly available in this review. The previously available studies of this design document statistically significant O_3-induced reduction in lung function (FEV_1) and increased pulmonary inflammation in young healthy adults exposed to O_3 concentrations as low as 60 ppb. Statistically significant group mean changes in FEV_1, also often accompanied by statistically significant increases in respiratory symptoms, become more consistent across such studies of exposures to higher O_3 concentrations, such as somewhat above 70 ppb (73 ppb),[70] and 80 ppb (Table 1 and Appendix 3A, Table 3A–1). The lowest exposures concentration for which these studies document a statistically significant increase in respiratory symptoms is somewhat above 70 ppb, at 73 ppb (Schelegle et al., 2009). In the 6.6-hour studies, the group means of O_3-induced[71] FEV_1 reductions for target exposure concentrations at or below 70 ppb are approximately 6% or lower (Table 1). For example, the group means of O_3-induced FEV_1 decrements reported in these studies that are statistically significantly different from the responses in filtered air are 6.1% for 70 ppb and 1.7% to 3.5% for 60 ppb (Table 1).

The group mean O_3-induced FEV_1 decrements generally increase with increasing O_3 exposures, reflecting increases in both the number of the individuals experiencing FEV_1 reductions and the magnitude of the FEV_1 reduction (Table 1; ISA, Appendix 3, Figure 3–3; PA, Figure 3–2). For example, following 6.6-hour exposures to a lower concentration (40 ppb), for which decrements were not statistically significant at the group mean level, none of 60 subjects across two separate studies experienced an O_3-induced FEV_1 reduction as large as 15% or more (Table 1; PA, Appendix 3D, Table 3D–19). The group mean O_3-induced FEV_1 decrements generally increase with increasing O_3 exposures, reflecting increases in both the number of the individuals experiencing FEV_1 reductions and the magnitude of the FEV_1 reduction (Table 1; ISA, Appendix 3, Figure 3–3; PA, Figure 3–2). For example, following 6.6-hour exposures to a lower concentration (40 ppb), for which decrements were not statistically significant at the group mean level, none of 60 subjects across two separate studies experienced an O_3-induced FEV_1 reduction as large as 15% or more (Table 1; PA, Appendix 3D, Table 3D–19). Across the four experiments (with number of subjects ranging from 30 to 59) that have reported results for a 60 ppb target exposure,[72] the number of subjects experiencing this magnitude of FEV_1 reduction (at or above 15%) varied (zero of 30, one of 59, two of 31 and two of 30 exposed subjects), while, together, they represent 3% of all 150 subjects. This percentage of subjects (with reductions of 15% or more) increased to 10% (three of 31 subjects) for the study at 73 ppb (70 ppb target) (PA, Appendix 3D, Table 3D–19; Schelegle et al., 2009), and is higher still (16%) in a variable exposure study at 80 ppb (PA, Appendix 3D, Table 3D–20; Schelegle et al., 2009). In addition to illustrating the E–R relationship, these findings also illustrate the considerable variability in magnitude of responses observed among study subjects (ISA, Appendix 3, section 3.1.4.1.1; 2013 ISA, p. 6–13).[73]

[65] The lowest exposure concentration that has elicited a statistically significant O_3-induced reduction in group mean lung function in an exposure of 2 hours or less is 120 ppb, occurring in trained cyclists after a 1-hour exposure during continuous, very heavy exercise (2013 ISA, section 6.2.1.1; Gong et al., 1986) and in young healthy adults after a 2-hour exposure during intermittent heavy exercise (2013 ISA, section 6.2.1.1; McDonnell et al., 1983).

[66] Ventilation rate ($\dot{V}_E$) is a specific technical term referring to breathing rate in terms of volume of air taken into the body per unit of time. The units for $\dot{V}_E$ are usually liters (L) per minute (min). Another related term is equivalent ventilation rate (EVR), which refers to $\dot{V}_E$ normalized by a person's body surface area in square meters (m^2). Accordingly, the units for EVR are generally L/min per m^2.

[67] A few studies have involved exposures by facemask rather than freely breathing in a chamber. To date, there is little research differentiating between exposures conducted with a facemask and in a chamber since the pulmonary responses of interest do not seem to be influenced by the exposure mechanism. However, similar responses have been seen in studies using both exposure methods at higher O_3 concentrations (Adams, 2002; Adams, 2003). In the facemask designs, there is a short period of zero O_3 exposure, such that the total period of exposure is closer to 6 hours than 6.6 (Adams, 2000; Adams, 2002; Adams, 2003).

[68] In these studies, the exposure concentration changes for each of the six hours in which there is exercise and the concentration during the 35-minute lunch is the same as in the prior (third) hour with exercise. For example, in the study by Adams (2006), the protocol for the 6.6-hour period is as follows: 60 minutes at 40 ppb, 60 minutes at 70 ppb, 95 minutes at 90 ppb, 60 minutes at 70 ppb, 60 minutes at 50 ppb and 60 minutes at 40 ppb.

[69] The relationship also exists for size of FEV_1 decrement with alternative exposure or dose metrics, including total inhaled O_3 and intake volume averaged concentration (ISA, Appendix 3).

[70] The design for the study on which the 70 ppb benchmark concentration is based, Schelegle et al. (2009), involved varying concentrations across the full exposure period, with a 35-minute lunch period following the third exposure hour during which the exposure concentration remains the same as in the third hour. The study reported the average O_3 concentration measured during each of the six exercise periods. The mean concentration across these six values is 72 ppb. The time weighted average for the full 6.6-hour exposure period, based on the six reported measurements and the study design, is 73 ppb (Schelegle et al., 2009). Other 6.6-hour studies have not reported measured concentrations for each exposure, but have generally reported an exposure concentration precision at or tighter than 3 ppb (*e.g.,* Adams 2006).

[71] Consistent with the ISA and 2013 ISA, the phrase "O_3-induced" decrement or reduction in lung function or FEV_1 refers to the percent change from pre-exposure measurement of the O_3 exposure minus the percent change from pre-exposure measurement of the filtered air exposure (2013 ISA, p. 6–4).

[72] For these four experiments, the average concentration across the 6.6 hour period ranged from 60 to 63 ppb (PA, Appendix 3A, Table 3A–2).

[73] With regard to decrements at or above 10%, the percentages of study subjects with such a response

Continued

TABLE 1—SUMMARY OF 6.6-HOUR CONTROLLED HUMAN EXPOSURE STUDY-FINDINGS, HEALTHY ADULTS

Endpoint	O_3 target exposure concentration [A]	Statistically significant effect [B]	O_3-induced group mean response [B]	Study
FEV_1 Reduction	120 ppb	Yes	−10.3% to −15.9% [C]	Horstman et al. 1990; Adams 2002; Folinsbee et al. (1988); Folinsbee et al. (1994); Adams, 2002; Adams 2000; Adams and Ollison 1997.[D]
	100 ppb	Yes	−8.5% to −13.9% [C]	Horstman et al., 1990; McDonnell et al., 1991.[D]
	87 ppb	Yes	−12.2%	Schelegle et al., 2009.
	80 ppb	Yes	−7.5%	Horstman et al., 1990.
			−7.7%	McDonnell et al., 1991.
			−6.5%	Adams, 2002.
			−6.2% to −5.5% [C]	Adams, 2003.
			−7.0% to −6.1% [C]	Adams, 2006.
			−7.8%	Schelegle et al., 2009.
		ND [E]	−3.5%	Kim et al., 2011.[F]
	70 ppb	Yes	−6.1%	Schelegle et al., 2009.
	60 ppb	Yes [G]	−2.9%	Adams, 2006; Brown et al., 2008.
			−2.8%	
		Yes	−1.7%	Kim et al., 2011.
		No	−3.5%	Schelegle et al., 2009.
	40 ppb	No	−1.2%	Adams, 2002.
		No	−0.2%	Adams, 2006.
Increased Respiratory Symptoms	120 ppb	Yes	Increased symptom scores.	Horstman et al. 1990; Adams 2002; Folinsbee et al. 1988; Folinsbee et al. 1994; Adams, 2002; Adams 2000; Adams and Ollison 1997; Horstman et al., 1990; McDonnell et al., 1991; Schelegle et al., 2009; Adams, 2003; Adams, 2006.[H]
	100 ppb	Yes		
	87 ppb	Yes		
	80 ppb	Yes		
	70 ppb	Yes		
	60 ppb	No		Adams, 2006; Kim et al., 2011; Schelegle et al., 2009; Adams, 2002.[H]
	40 ppb	No		
Airway Inflammation	80 ppb	Yes	Multiple indicators [I]	Devlin et al., 1991; Alexis et al., 2010.
	60 ppb	Yes	Increased neutrophils	Kim et al., 2011.
Increased Airway Resistance and Responsiveness.	120 ppb	Yes	Increased	Horstman et al., 1990; Folinsbee et al., 1994 (O_3 induced sRaw not reported).
	100 ppb	Yes		Horstman et al., 1990.
	80 ppb	Yes		Horstman et al., 1990.

[A] This refers to the average concentration across the six exercise periods as targeted by authors. This differs from the time-weighted average concentration for the full exposure periods (targeted or actual). For example, as shown in Appendix 3A, Table 3A–2, in chamber studies implementing a varying concentration protocol with targets of 0.03, 0.07, 0.10, 0.15, 0.08 and 0.05 ppm, the exercise period average concentration is 0.08 ppm while the time weighted average for the full exposure period (based on targets) is 0.082 ppm due to the 0.6 hour lunchtime exposure between periods 3 and 4. In some cases this also differs from the exposure period average based on study measurements. For example, based on measurements reported in Schelegle et al., (2009), the full exposure period average concentration for the 70 ppb target exposure is 73 ppb, and the average concentration during exercise is 72 ppb.

[B] Statistical significance based on the O_3 compared to filtered air response at the study group mean (rounded here to decimal).

[C] Ranges reflect the minimum to maximum FEV_1 decrements across multiple exposure designs and studies. Study-specific values and exposure details provided in the PA, Appendix 3A, Tables 3A–1 and 3A–2, respectively.

[D] Citations for specific FEV_1 findings for exposures above 70 ppb are provided in PA, Appendix 3A, Table 3A–1.

[E] ND (not determined) indicates these data have not been subjected to statistical testing.

[F] The data for 30 subjects exposed to 80 ppb by Kim et al. (2011) are presented in Figure 5 of McDonnell et al. (2012).

[G] Adams (2006) reported FEV_1 data for 60 ppb exposure by both constant and varying concentration designs. Subsequent analysis of the FEV_1 data from the former found the group mean O_3 response to be statistically significant ($p < 0.002$) (Brown et al., 2008; 2013 ISA, section 6.2.1.1). The varying-concentration design data were not analyzed by Brown et al., 2008.

[H] Citations for study-specific respiratory symptoms findings are provided in the PA, Appendix 3A, Table 3A–1.

[I] Increased numbers of bronchoalveolar neutrophils, permeability of respiratory tract epithelial lining, cell damage, production of proinflammatory cytokines and prostaglandins (ISA, Appendix 3, section 3.1.4.4.1; 2013 ISA, section 6.2.3.1).

For shorter exposure periods (*e.g.,* one to two hours), with heavy intermittent or very heavy continuous exercise, higher exposure concentrations, ranging up from 80 ppb up to 400 ppb, have been studied (ISA, section 3.1; 2013 ISA, section 6.2.1.1; 2006 AQCD, chapter 6; PA, Appendix 3A, Table 3A–3). Across these shorter-duration studies (which involved ventilation rates 2–3 times greater than in the prolonged [6.6- or 8-hour] exposure studies) the lowest exposure concentration for which statistically significant respiratory effects were reported is 120 ppb, for a 1-hour exposure combined with continuous very heavy exercise and a 2-hour exposure with intermittent heavy exercise. As recognized above, the increased ventilation rate associated with increased exertion increases the

increased from 7% of the 150 subjects of the four studies with target exposures of 60 ppb (average exposure ranged from 60 to 63) to 19% for the study at 73 ppb to more than 32% in one variable exposure study of 80 ppb (PA, Appendix 3D, Table 3D–20).

amount of O_3 entering the lung, where depending on dose and the individual's susceptibility, it may cause respiratory effects (2013 ISA, section 6.2.1.1). Thus, for exposures involving a lower exertion level, a comparable response would not be expected to occur without a longer exposure duration (ISA, Appendix 3, Figure 3–3; PA, Appendix 3A, Table 3A–1).

With regard to the epidemiologic studies reporting associations between O_3 and respiratory health outcomes such as asthma-related emergency department visits and hospitalizations, these studies are generally focused on investigating the existence of a relationship between O_3 occurring in ambient air and specific health outcomes. Accordingly, while as a whole, this evidence base of epidemiologic studies provides strong support for the conclusions of causality,[74] these studies provide less information on details of the specific O_3 exposure circumstances that may be eliciting health effects associated with such outcomes, and whether these occur under air quality conditions that meet the current standard.[75] Further, the vast majority of these studies were conducted in locations and during time periods that would not have met the current standard.[76] The extent to which reported associations with health outcomes in the resident populations in these studies are influenced by the periods of higher concentrations during times that did not meet the current standard is unknown. While this does not lessen their importance in the evidence base documenting the causal relationship between O_3 and respiratory effects, it means they are less informative in considering O_3 exposure concentrations occurring under air quality conditions allowed by the current standard.

With regard to the experimental animal evidence (largely in rodents) and exposure conditions associated with respiratory effects, the exposure concentrations are generally much greater than those examined in the controlled human exposure studies (summarized above), and higher than concentrations commonly occurring in ambient air in areas of the U.S. where the current standard is met. This is also true for the small number of early life studies in nonhuman primates that reported O_3 to contribute to asthma-like effects in infant primates.[77] The exposures eliciting the effects in these studies included multiple 5-day periods with O_3 concentrations of 500 ppb over 8-hours per day (ISA, Appendix 3, section 3.2.4.1.2).

Thus, as in the last review the exposures given greatest attention in this review, particularly with regard to considering O_3 exposures expected under air quality conditions that meet the current standard, are those informed by the controlled human exposure studies. The full body of evidence continues to indicate respiratory effects as the effects associated with lowest exposures, with conditions of exposure (duration, ventilation rate, as well as concentration) influencing dose and associated response. Evidence for other categories of effects does not indicate effects at comparably low exposures.[78]

3. Overview of Exposure and Risk Information

Consideration of the scientific evidence available in the current review, as at the time of the last review, is informed by results from quantitative analyses of estimated population exposure and consequent risk of respiratory effects. These analyses in this review have focused on exposure-based risk analyses, producing two types of risk metrics. The first metric estimates population occurrences of daily maximum 7-hour average exposure concentrations (during periods of elevated breathing rates) at or above concentrations of potential concern (benchmark concentrations). The second metric (lung function risk) uses E–R information for O_3 exposures and FEV_1 decrements to estimate the portion of the simulated at-risk population expected to experience one or more days with an O_3-related FEV_1 decrement of at least 10%, 15% or 20%. Both of these metrics were used to characterize health risk associated with O_3 exposures among the simulated population during periods of elevated breathing rates. Similar risk metrics were also derived in the 2014 HREA for the last review and the associated estimates informed the Administrator's 2015 decision on the current standard (80 FR 65292, October 26, 2015).

The currently available evidence in this review continues to demonstrate a causal relationship between short-term O_3 exposures and respiratory effects, with the current evidence base for respiratory effects largely consistent with that for the last review, as summarized in section II.A.2 above. Accordingly, the exposure-based analyses performed in this review, summarized below, are conceptually similar to those in the last review while also incorporating a number of updates that contribute to reduced uncertainty. Drawing on the summary in section II.C of the proposal, while giving relatively greater focus on the comparison-to-benchmarks analysis, the short sections below provide an overview of key aspects of the assessment design (II.A.3.a), key limitations and uncertainties (II.A.3.b), and exposure/risk estimates (II.A.3.c).

a. Key Design Aspects

Exposure and risk estimates were derived for air quality conditions just meeting the current primary O_3 standard, and for two additional scenarios reflecting conditions just meeting design values just lower and just higher than the level of the current

[74] Combined with the coherent evidence from experimental studies, the epidemiologic studies ''can support and strengthen determinations of the causal nature of the relationship between health effects and exposure to ozone at relevant ambient air concentrations'' (ISA, p. ES–17).

[75] For example, these studies generally do not measure personal exposures of the study population or track individuals in the population with a defined exposure to O_3 alone.

[76] Consistent with the evaluation of the epidemiologic evidence of associations between O_3 exposure and respiratory health effects in the ISA, this focuses on those studies conducted in the U.S. and Canada as including populations and air quality characteristics that may be most relevant to circumstances in the U.S. (ISA, Appendix 3, section 3.1.2). Among the epidemiologic studies finding a statistically significant positive relationship of short- or long-term O_3 concentrations with respiratory effects, there are no single-city studies conducted in the U.S. in locations with ambient air O_3 concentrations that would have met the current standard for the entire duration of the study (ISA, Appendix 3, Tables 3–13, 3–14, 3–39, 3–41, 3–42 and Appendix 6, Tables 6–5 and 6–8; PA, Appendix 3B, Table 3B–1). There are two single city studies conducted in Canada that include locations for which the highest-monitor design values calculated in the PA fell below 70 ppb, at 65 and 69 ppb (PA, Appendix 3B, Table 3B–1; Kousha and Rowe, 2014; Villeneuve et al., 2007). These studies did not include analysis of correlations with other co-occurring pollutants or of the strength of the associations when accounting for effects of copollutants in copollutant models (ISA, Appendix 3, Tables 3–14 and 3–39).

[77] These studies indicate that sufficient early-life O_3 exposure can cause structural and functional changes that could potentially contribute to airway obstruction and increased airway responsiveness (ISA, Table IS–10, p. 3–92 and p.3–113).

[78] For example, the evidence base for metabolic effects is comprised primarily of experimental animal studies, and generally involve much higher O_3 concentrations (400–800 ppb, [ISA, Appendix 5, Table 5–87]) than those examined in the controlled human exposure studies of respiratory effects (and much higher than concentrations commonly occurring in ambient air in areas of the U.S. where the current standard is met). There are only two epidemiologic studies reporting statistically significant positive associations of O_3 with metabolic effects (*e.g.*, changes in glucose, insulin, metabolic clearance), both based in Asian countries, in which there is a potential for appreciable differences from the U.S. in air quality patterns, limiting their usefulness for informing our understanding of exposure concentrations and conditions eliciting such effects in the U.S. (ISA, Appendix 5, section 5.1).

standard (65 and 75 ppb).[79] The analyses estimated population exposure and risk for simulated populations in eight urban study areas which represent a variety of circumstances with regard to population exposure to short-term concentrations of O_3 in ambient air. The areas (Atlanta, Boston, Dallas, Detroit, Philadelphia, Phoenix, Sacramento and St. Louis) range in total population size from approximately two to eight million and are distributed across seven regions of the U.S.: Northeast, Southeast, Central, East North Central, South, Southwest and West (PA, Appendix 3D, Table 3D–1). Study-area-specific characteristics contribute to variation in the estimated magnitude of exposure and associated risk across the urban study areas that reflect an array of air quality, meteorological, and population exposure conditions. The current set of study areas, streamlined compared to the 15-area set in the last review, was chosen to ensure it reflects the full range of air quality and exposure variation expected in major urban areas in the U.S. with air quality that just meets the current standard. Seven of the eight study areas were also included in the 2014 HREA; the eighth study area (Phoenix) is newly added in the current assessment to insure representation of a large city in the southwest. Additionally, the O_3 concentrations simulated in these areas are somewhat nearer the current standard than was the case for the 2014 HREA (PA, Appendix 3C, Table 3C and 2014 HREA, Table 4–1). This contributes to a reduction in the uncertainty associated with development of the air quality scenarios of interest, particularly the one reflecting air quality conditions that just meet the current standard.

With regard to the objectives for the analysis approach, the analyses and the use of a case study approach are intended to provide assessments of air quality scenarios, including particularly one just meeting the current standard, for a diverse set of areas and associated exposed populations. These analyses are not intended to provide a comprehensive national assessment (PA, section 3.4.1). Nor is the objective to present an exhaustive analysis of exposure and risk in the areas that currently just meet the current standard and/or of exposure and risk associated with air quality adjusted to just meet the current standard in areas that currently do not meet the standard. Rather, the purpose is to assess, based on current tools and information, the potential for exposures and risks beyond those indicated by the information available at the time the standard was established. Accordingly, use of this approach recognizes that capturing an appropriate diversity in study areas and air quality conditions[80] is an important aspect of the role of the exposure and risk analyses in informing the Administrator's conclusions on the public health protection afforded by the current standard.

Consistent with the health effects evidence in this review (summarized in section II.A.2 above), the focus of the quantitative assessment is on short-term exposures of individuals in the population during times when they are breathing at an elevated rate. Exposure and risk are characterized for four population groups. Two are populations of school-aged children, aged 5 to 18 years: All children and children with asthma; two are populations of adults: All adults and adults with asthma. Estimates for adults, in terms of percentages, are generally lower due to the lesser amount and frequency of time spent outdoors at elevated exertion (PA, Appendix 3D, section 3D.3.2). The exception is outdoor workers who, due to the requirements of their job, spend more time outdoors at elevated exertion. For a number of reasons, including the appreciable data limitations (*e.g.,* related to specific durations of time spent outdoors and activity data), and associated uncertainties summarized in Table 3D–64 of Appendix 3D of the PA, the group was not simulated in these analyses, a decision also made for past exposure assessments.[81] Asthma prevalence estimates for the full populations in the eight study areas range from 7.7 to 11.2%; the rates for children in these areas range from 9.2 to 12.3% (PA, Appendix 3D, section 3D.3.1).

The approach for this analysis incorporates an array of models and data (PA, section 3.4.1). Ambient air O_3 concentrations were estimated in each study area for the air quality conditions of interest by adjusting hourly ambient air concentrations, from monitoring data for the years 2015–2017, using a photochemical model-based approach and then applying a spatial interpolation technique to produce air quality surfaces with high spatial and temporal resolution (PA, Appendix 3C). The final products were datasets of ambient air O_3 concentration estimates with high temporal and spatial resolution (hourly concentrations in 500 to 1,700 census tracts) for each of the eight study areas (PA, section 3.4.1 and Appendix 3C, section 3C.7) representing the three air quality scenarios assessed.

Population exposures were estimated using the EPA's Air Pollutant Exposure model (APEX) version 5, which probabilistically generates a large sample of hypothetical individuals from population demographic and activity pattern databases and simulates each individual's movements through time and space to estimate their time series of O_3 exposures occurring within indoor, outdoor, and in-vehicle microenvironments (PA, Appendix 3D, section 3D.2).[82] The APEX model accounts for the most important factors that contribute to human exposure to O_3 from ambient air, including the temporal and spatial distributions of people and ambient air O_3 concentrations throughout a study area, the variation of ambient air-related O_3 concentrations within various microenvironments in which people conduct their daily activities, and the effects of activities involving different levels of exertion on breathing rate (or ventilation rate) for the exposed individuals of different sex, age, and body mass in the study area (PA, Appendix 3D, section 3D.2).[83] By incorporating individual activity

[79] All analyses are summarized more fully in the PA section 3.4 and Appendices 3C and 3D.

[80] A broad variety of spatial and temporal patterns of O_3 concentrations can exist when ambient air concentrations just meet the current standard. These patterns will vary due to many factors including the types, magnitude, and timing of emissions in a study area, as well as local factors, such as meteorology and topography. We focused our current assessment on specific study areas having ambient air concentrations close to conditions that reflect air quality that just meets the current standard. Accordingly, assessment of these study areas is more informative to evaluating the health protection provided by the current standard than would be an assessment that included areas with much higher and much lower concentrations.

[81] Limited exploratory analyses of a hypothetical outdoor worker population in the 2014 HREA (single study area, single year) for the 75 ppb air quality scenario estimated an appreciably greater portion of this population to experience exposures at or above benchmark concentrations than the full adult or child populations simulated, although there are a number of uncertainties associated with the estimates due to appreciable limitations in the data underlying the analyses (2014 HREA, section 5.4.3.2). It is expected that if an approach similar to that used in the 2014 HREA had been used for this assessment a generally similar pattern might be observed, although with somewhat lower overall percentages based on the comparison of current estimates with estimates from the 2014 HREA (PA, Appendix 3D, section 3D.3.2.4).

[82] The APEX model has a history of application, evaluation, and progressive model development in estimating human exposure, dose, and risk for reviews of NAAQS for gaseous pollutants, including the last review of the O_3 NAAQS (U.S. EPA, 2008; U.S. EPA, 2009; U.S. EPA, 2010; U.S. EPA, 2014a; U.S. EPA, 2018).

[83] The APEX model generates each simulated person or profile by probabilistically selecting values for a set of profile variables, including demographic variables, health status and physical attributes (*e.g.,* residence with air conditioning, height, weight, body surface area), and activity-specific ventilation rate (PA, Appendix 3D, section 3D.2).

patterns, and estimating physical exertion for each exposure event, the model addresses an important determinant of their exposure (2013 ISA, section 4.4.1).[84] For each exposure event, the APEX model tracks activity performed, ventilation rate, exposure concentration, and duration for all simulated individuals throughout the assessment period, and then utilizes the time-series of exposure events in derivation of the exposure and risk estimates.

The general approach and methodology for the exposure-based assessment used in this review is similar to that used in the last review, although a number of updates and improvements, related to the air quality, exposure, and risk aspects of the assessment, have been implemented (Appendices 3C and 3D). These include (1) a more recent period (2015–2017) of ambient air monitoring data in which O_3 concentrations in the eight study areas are at or near the current standard; (2) the most recent version of the photochemical air quality model, CAMx (comprehensive air quality model with extensions), with updates to the treatment of atmospheric chemistry and physics within the model; (3) a significantly expanded CHAD, that now has nearly 180,000 diaries, with over 25,000 school aged children; (4) updated National Health and Nutrition Examination Survey data (2009–2014), which are the basis for the age- and sex-specific body weight distributions used to specify the individuals in the modeled populations; (5) updated algorithms used to estimate age- and sex-specific resting metabolic rate, a key input to estimating a simulated individual's activity-specific ventilation (or breathing) rate; (6) updates to the ventilation rate algorithm itself; and (7) an approach that better matches the simulated exposure estimates with the 6.6-hour duration of the controlled human exposure studies and with the study subject ventilation rates. Further, the current APEX model uses the most recent U.S. Census demographic and commuting data (2010), NOAA Integrated Surface Hourly meteorological data to reflect the assessment years studied (2015–2017), and updated estimates of asthma prevalence for all census tracts in all study areas based on 2013–2017 National Health Interview Survey and Behavioral Risk Factor Surveillance System data. Additional details are described in the PA (*e.g.,* PA, section 3.4.1, Appendices 3C and 3D).

The comparison-to-benchmarks analysis characterizes the extent to which individuals in at-risk populations could experience O_3 exposures, while engaging in their daily activities, with the potential to elicit the effects reported in controlled human exposure studies for concentrations at or above specific benchmark concentrations. Results are characterized through comparison of exposure concentrations to three benchmark concentrations of O_3: 60, 70, and 80 ppb. These are based on the three lowest concentrations targeted in studies of 6- to 6.6-hour exposures, with quasi-continuous exercise, and that yielded different occurrences, of statistical significance, and severity of respiratory effects, as summarized in section II.A.2.c above and section II.C.1 of the proposal (PA, section 3.3.3; PA, Appendix 3A, section 3A.1; PA, Appendix 3D, section 3D.2.8.1). The lowest benchmark, 60 ppb, represents the lowest exposure concentration for which controlled human exposure studies have reported statistically significant respiratory effects, as summarized in section II.A.2.c above. Exposure to approximately 70 ppb averaged over 6.6 hours resulted in a larger group mean lung function decrement, as well as a statistically significant increase in prevalence of respiratory symptoms (Table 1; ISA, Appendix 3, Figure 3–3 and section 3.1.4.1.1; Schelegle et al., 2009). Studies of exposures to approximately 80 ppb have reported larger lung function decrements at the study group mean than following exposures to 60 or 70 ppb, in addition to an increase in airway inflammation, increased respiratory symptoms, increased airway responsiveness, and decreased resistance to other respiratory effects (ISA, Appendix 3, sections 3.1.4.1—3.1.4.4; PA, Figure 3–2 and section 3.3.3).

The APEX-generated exposure concentrations for comparison to these benchmark concentrations is the average of concentrations encountered by an individual while at an activity level that elicits the specified elevated ventilation rate. The incidence of such exposures above the benchmark concentrations are summarized for each simulated population, study area, and air quality scenario in Appendix 3D of the PA.

The lung function risk analysis estimates the extent to which individuals in exposed populations could experience O_3-induced lung function decrements of different sizes in two different ways. The population-based E–R function approach uses quantitative descriptions of the E–R relationships for study group incidence of different magnitudes of lung function decrements based on individual study subject observations (PA, Appendix 3D, section 3D.2.8.2.1). The individual-based McDonnell-Smith-Stewart (MSS) model uses quantitative estimates of biological processes identified as important in eliciting the different sizes of decrements at the individual level, with a factor that also provides a representation of intra- and inter-individual response variability (PA, Appendix 3D, section 3D.2.8.2.2; McDonnell et al., 2013). The two approaches, summarized in sections II.C and II.D.1 of the proposal and described in detail in Appendix 3D of the PA, utilize evidence from the 6.6-hour controlled human exposure studies in different ways, and accordingly, differ in strengths, limitations and uncertainties.

While the lung function risk analysis focuses only on the specific O_3 effect of FEV_1 reduction, the comparison-to-benchmark analysis, with its use of multiple benchmark concentrations, provides for risk characterization of the array of respiratory effects elicited by O_3 exposure, the type and severity of which increase with increased exposure concentration. In this way, the comparison-to-benchmark analysis (involving comparison of daily maximum 7-hour average exposure concentrations that coincide with 7-hour average elevated ventilation rates at or above the target rate to benchmark concentrations) provides perspective on the extent to which the air quality being assessed could be associated with discrete exposures to O_3 concentrations reported to result in an array of respiratory effects. For example, estimates of such exposures can indicate the potential for O_3-related effects in the exposed population, including effects for which we do not have E–R functions that could be used in quantitative risk analyses. Thus, the comparison-to-benchmark analysis provides for a broader risk characterization with consideration of the array of O_3-related respiratory effects.

b. Key Limitations and Uncertainties

Uncertainty in the exposure and risk analyses was characterized using a

[84] To represent personal time-location-activity patterns of simulated individuals, the APEX model draws from the consolidated human activity database (CHAD) developed and maintained by the EPA (McCurdy, 2000; U.S. EPA, 2019a). The CHAD provides data on human activities through a database system of human diaries or daily time series or daily time location activity logs collected in surveys at city, state, and national levels. Included are personal attributes of survey participants (*e.g.,* age, sex), along with the locations they visited, activities performed throughout a day, time-of-day the activities occurred and activity duration (PA, Appendix 3D, section 3D.2.5.1).

largely qualitative approach adapted from the World Health Organization approach for characterizing uncertainty in exposure assessment (WHO, 2008) augmented by several quantitative sensitivity analyses for key aspects of the assessment approach (PA, section 3.4.4 and Appendix 3D, section 3D.3.4). This characterization and associated analyses build on information generated from a previously conducted quantitative uncertainty analysis of population-based O_3 exposure modeling (Langstaff, 2007), considering the various types of data, algorithms, and models that together yield exposure and risk estimates for the eight study areas. In this way, we considered the limitations and uncertainties underlying these data, algorithms, and models and the extent of their influence on the resultant exposure/risk estimates using the general approach applied in past risk and exposure assessments for O_3, nitrogen dioxide, carbon monoxide, and sulfur dioxide (U.S. EPA, 2008; U.S. EPA, 2010; U.S. EPA, 2014a; U.S. EPA, 2018).

Key uncertainties and limitations in data and tools that affect the quantitative estimates of exposure and risk and their interpretation in the context of considering the current standard are summarized here. These include uncertainty related to estimation of the concentrations in ambient air for the current standard and the additional air quality scenarios; lung function risk approaches that rely, to varying extents, on extrapolating from controlled human exposure study conditions to lower exposure concentrations, lower ventilation rates, and shorter durations; and characterization of risk for particular population groups that may be at greatest risk, particularly for people with asthma, and particularly children with asthma. Areas in which uncertainty has been reduced by new or updated information or methods include the use of updated air quality modeling, with a more recent model version and model inputs, applied to study areas with design values near the current standard, as well as updates to several inputs to the exposure model, including changes to the exposure duration to better match those in the controlled human exposure studies and an alternate approach to characterizing periods of activity while at moderate or greater exertion for simulated individuals.

With regard to the analysis approach overall, two updates since the 2014 HREA reduce uncertainty in the results. The first relates to identifying when simulated individuals may be at moderate or greater exertion, with the new approach reducing the potential for overestimation of the number of people achieving the associated ventilation rate, which was an important uncertainty in the 2014 HREA. Additionally, the current analysis focus on exposures of 7 hours duration better represents the 6.6-hour exposures from the controlled human exposure studies (than the 8-hour exposure durations used for the 2014 HREA and prior assessments).

Additional aspects of the analytical design pertaining to both exposure-based risk metrics include the estimation of ambient air O_3 concentrations for the air quality scenarios, and main components of the exposure modeling. Uncertainties include the modeling approach used to adjust ambient air concentrations to meet the air quality scenarios of interest and the method used to interpolate monitor concentrations to census tracts. While the adjustment to conditions near, just above, or just below the current standard is an important area of uncertainty, the size of the adjustment needed to meet a given air quality scenario is minimized with the selection of study areas for which recent O_3 design values were near the level of the current standard. Also, more recent data are used as inputs for the air quality modeling, such as more recent O_3 concentration data (2015–2017), meteorological data (2016) and emissions data (2016), as well as a recently updated air quality photochemical model which includes state-of-the-science atmospheric chemistry and physics (PA, Appendix 3C). Further, the number of ambient monitors sited in each of the eight study areas provides a reasonable representation of spatial and temporal variability for the air quality conditions simulated in those areas. Among other key aspects, there is uncertainty associated with the simulation of study area populations (and at-risk populations), including those with particular physical and personal attributes. As also recognized in the 2014 HREA, exposures could be underestimated for some population groups that are frequently and routinely outdoors during the summer (*e.g.,* outdoor workers, children). In addition, longitudinal activity patterns do not exist for these and other potentially important population groups (*e.g.,* those having respiratory conditions other than asthma), limiting the extent to which the exposure model outputs reflect information that may be particular to these groups. Important uncertainties in the approach used to estimate energy expenditure (*i.e.,* metabolic equivalents of work or METs used to estimate ventilation rates), include the use of longer-term average MET distributions to derive short-term estimates, along with extrapolating adult observations to children. Both of these approaches are reasonable based on the availability of relevant data and appropriate evaluations conducted to date, and uncertainties associated with these steps are somewhat reduced in the current analyses (compared to the 2014 HREA) because of the added specificity, and use of redeveloped METs distributions (based on newly available information), which is expected to more realistically estimate activity-specific energy expenditure.

There are some uncertainties that apply to the estimation of lung function risk and not to the comparison-to-benchmarks analysis. For example, both lung function risk approaches utilized in the risk analyses incorporate some degree of extrapolation beyond the exposure circumstances evaluated in the controlled human exposure studies. Accordingly, the uncertainty in the lung function risk estimates increases with decreasing exposure concentration and is particularly increased for concentrations below those evaluated in controlled human exposure studies (85 FR 49857–49859, PA, section 3.4.4 and Appendix 3D, section 3D.3.4). The two lung function risk approaches differ in how they extrapolate beyond the controlled human exposure study conditions and in the impact on the estimates. The E–R function approach generates nonzero predictions from the full range of nonzero concentrations for 7-hour average durations in which the average exertion levels meets or exceeds the target. The MSS model, which draws on evidence-based concepts of how human physiological processes respond to O_3, extrapolates beyond the controlled experimental conditions with regard to exposure concentration, duration and ventilation rate (both magnitude and duration). Differences in percent of the risk estimates for days for which the highest 7-hour average concentration is below the lowest 6.6-hour exposure concentration tested, as presented in the PA, Tables 3–6 and 3–7, illustrate the impact.

An overarching area of uncertainty, remaining from the last review and important to consideration of the exposure and risk analysis results, relates to the underlying health effects evidence base. Although the quantitative analysis focuses on the evidence providing the ''strongest evidence'' of O_3 respiratory effects (ISA,

p. IS–1), the controlled human exposure studies, and on the array of respiratory responses documented in those studies, evidence is lacking from controlled human exposure studies at the lower concentrations (*e.g.,* 60, 70 and 80 ppb) for children and for people of any age with asthma. While the limited evidence informing our understanding of potential risk to people with asthma is uncertain, it indicates the potential for this group, given their disease status, to be at great risk, as summarized in section II.A.2 above. Such a conclusion is consistent with the epidemiologic study findings of positive associations of O_3 concentrations with asthma-related ED visits and hospital admissions (and the higher effect estimates from these studies).

c. Summary of Exposure and Risk Estimates

The benchmark-based risk metric results are summarized in terms of the percent of the simulated populations of all children and children with asthma estimated to experience at least one day per year [85] with a 7-hour average exposure concentration at or above the different benchmark concentrations while breathing at elevated rates under air quality conditions just meeting the current standard (Table 2). Given the recognition of people with asthma as an at-risk population and the relatively greater amount and frequency of time spent outdoors at elevated exertion of children, this summary focuses on the estimates from the comparison-to-benchmarks analysis for children, including children with asthma, which were the focus of the Administrator's proposed decision. Under air quality conditions just meeting the current standard, less than 0.1% of any study area's children with asthma, on average, were estimated to experience any days per year with a 7-hour average exposure at or above 80 ppb, while breathing at elevated rates (Table 3; PA, section 3.4 and Appendix 3D). With regard to the 70 ppb benchmark, the study areas' estimates for children with asthma range up to 0.7 percent (0.6% for all children), on average across the 3-year period, and range up to 1.0% in a single year. Approximately 3% to nearly 9% of each study area's simulated children with asthma, on average across the 3-year period, are estimated to experience one or more days per year with a 7-hour average exposure at or above 60 ppb. This range is very similar for the populations of all children.

Regarding multiday occurrences, the analyses indicate that no children would be expected to experience more than a single day with a 7-hour average exposure at or above 80 ppb in any year simulated in any location (Table 2). For the 70 ppb benchmark, the estimate is less than 0.1% of any area's children (on average across 3-year period), both those with asthma and all children. The estimates for the 60 ppb benchmark are slightly higher, with up to 3% of children estimated to experience more than a single day with a 7-hour average exposure at or above 60 ppb, on average (and more than 4% in the highest year across all eight study area locations).

Framed from the perspective of estimated protection provided by the current standard, these results indicate that, in the single year with the highest concentrations across the 3-year period, 99% of the population of children with asthma would not be expected to experience such a day with an exposure at or above the 70 ppb benchmark; 99.9% would not be expected to experience such a day with exposure at or above the 80 ppb benchmark. The estimates, on average across the 3-year period, indicate that over 99.9%, 99.3% and 91.2% of the population of children with asthma would not be expected to experience a day with a 7-hour average exposure while at elevated ventilation that is at or above 80 ppb, 70 ppb and 60 ppb, respectively (Table 1). Further, more than approximately 97% of all children or children with asthma are estimated to be protected against multiple days of exposures at or above 60 ppb.

TABLE 2—PERCENT AND NUMBER OF SIMULATED CHILDREN AND CHILDREN WITH ASTHMA ESTIMATED TO EXPERIENCE AT LEAST ONE OR MORE DAYS PER YEAR WITH A 7-HOUR AVERAGE EXPOSURE AT OR ABOVE INDICATED CONCENTRATION WHILE BREATHING AT AN ELEVATED RATE IN AREAS JUST MEETING THE CURRENT STANDARD

Exposure concentration (ppb)	One or more days		Two or more days		Four or more days	
	Average per year	Highest in a single year	Average per year	Highest in a single year	Average per year	Highest in a single year
Children with asthma—percent of simulated population [A]						
≥80	0 [B]–<0.1 [C]	0.1	0	0	0	0
≥70	0.2–0.7	1.0	<0.1	0.1	0	0
≥60	3.3–8.8	11.2	0.6–3.2	4.9	<0.1–0.8	1.3
—number of individuals [A]						
≥80	0–67	202	0	0	0	0
≥70	93–1145	1616	3–39	118	0	0
≥60	1517–8544	11776	282–2609	3977	23–637	1033
All children—percent of simulated population [A]						
≥80	0 [B]–<0.1	0.1	0	0	0	0
≥70	0.2–0.6	0.9	<0.1	0.1	0–<0.1	<0.1
≥60	3.2–8.2	10.6	0.6–2.9	4.3	<0.1–0.7	1.1
—number of individuals [A]						
≥80	0–464	1211	0	0	0	0
≥70	727–8305	11923	16–341	660	0–5	14

[85] While the duration of an O_3 season for each year may vary across the study areas, for the purposes of the exposure and risk analyses, the O_3 season in each study area is considered synonymous with a year. These seasons capture the times during the year when concentrations are elevated (80 FR 65419–65420, October 26, 2015).

TABLE 2—PERCENT AND NUMBER OF SIMULATED CHILDREN AND CHILDREN WITH ASTHMA ESTIMATED TO EXPERIENCE AT LEAST ONE OR MORE DAYS PER YEAR WITH A 7-HOUR AVERAGE EXPOSURE AT OR ABOVE INDICATED CONCENTRATION WHILE BREATHING AT AN ELEVATED RATE IN AREAS JUST MEETING THE CURRENT STANDARD—Continued

Exposure concentration (ppb)	One or more days		Two or more days		Four or more days	
	Average per year	Highest in a single year	Average per year	Highest in a single year	Average per year	Highest in a single year
≥60	14928–69794	96261	2601–24952	36643	158–5997	9554

[A] Estimates for each study area were averaged across the 3-year assessment period. Ranges reflect the ranges of averages.
[B] A value of zero (0) means that there were no individuals estimated to have the selected exposure in any year.
[C] An entry of <0.1 is used to represent small, non-zero values that do not round upwards to 0.1 (*i.e.,* <0.05).

These estimates are of generally similar magnitude to those which were the focus in the 2015 decision establishing the current standard (Table 3; PA, sections 3.1 and 3.4, Appendix 3D, section 3D.3.2.4, Table 3D–38).[86] The differences observed are generally slight, likely reflecting influences of a number of the differences in the quantitative modeling and analyses performed in the current assessment from those for the 2014 HREA, summarized in section II.A.3.a above (*e.g.,* 2015–2017 vs. 2006–2010 distribution of ambient air O_3 concentrations, better matching of simulated exposure estimates with the 6.6-hour duration of the controlled human exposure studies and with the study subject ventilation rates). Much larger differences are seen between different air quality scenario results for the same benchmark. For example, for the 70 ppb benchmark, the differences between the 75 ppb and current standard scenario (or between the 65 ppb and current standard scenarios) in either assessment are appreciably larger than the slight differences between the two assessments for any one air quality scenario.

TABLE 3—COMPARISON OF CURRENT ASSESSMENT AND 2014 HREA (ALL STUDY AREAS) FOR PERCENT OF CHILDREN ESTIMATED TO EXPERIENCE AT LEAST ONE, OR TWO, DAYS WITH AN EXPOSURE AT OR ABOVE BENCHMARKS WHILE AT MODERATE OR GREATER EXERTION

Air Quality Scenario (DV,[C] ppb)	Estimated average % of simulated children with at least one day per year at or above benchmark (highest in single season)		Estimated average % of simulated children with at least two days per year at or above benchmark (highest in single season)	
	Current PA [A]	2014 HREA [B]	Current PA [A]	2014 HREA [B]
Benchmark Exposure Concentration of 80 ppb				
75	<0.1 [A]–0.3 (0.6)	0–0.3 (1.1)	0–<0.1 (<0.1)	0 (0.1)
70	0–<0.1 (0.1)	0–0.1 (0.2)	0 (0)	0 (0)
65	0–<0.1 (<0.1)	0 (0)	0 (0)	0 (0)
Benchmark Exposure Concentration of 70 ppb				
75	1.1–2.0 (3.4)	0.6–3.3 (8.1)	0.1–0.3 (0.7)	0.1–0.6 (2.2)
70	0.2–0.6 (0.9)	0.1–1.2 (3.2)	<0.1 (0.1)	0–0.1 (0.4)
65	0–0.2 (0.2)	0–0.2 (0.5)	0–<0.1 (<0.1)	0 (0)
Benchmark Exposure Concentration of 60 ppb				
75	6.6–15.7 (17.9)	9.5–17.0 (25.8)	1.7–8.0 (9.9)	3.1–7.6 (14.4)
70	3.2–8.2 (10.6)	3.3–10.2 (18.9)	0.6–2.9 (4.3)	0.5–3.5 (9.2)
65	0.4–2.3 (3.7)	0–4.2 (9.5)	<0.1–0.3 (0.5)	0–0.8 (2.8)

[A] For the current analysis, calculated percent is rounded to the nearest tenth decimal using conventional rounding. Values equal to zero are designated by "0" (there are no individuals exposed at that level). Small, non-zero values that do not round upwards to 0.1 (i.e., <0.05) are given a value of "<0.1".
[B] For the 2014 HREA. calculated percent was rounded to the nearest tenth decimal using conventional rounding. Values that did not round upwards to 0.1 (i.e., <0.05) were given a value of "0".
[C] The monitor location with the highest concentrations in each area had a design value just equal to the indicated value.

[86] For example, the 2015 decision to set the standard level at 70 ppb noted that "a revised standard with a level of 70 ppb is estimated to eliminate the occurrence of two or more exposures of concern to O_3 concentrations at or above 80 ppb and to virtually eliminate the occurrence of two or more exposures of concern to O_3 concentrations at or above 70 ppb for all children and children with asthma, even in the worst-case year and location evaluated" (80 FR 65363, October 26, 2015). This statement remains true for the current assessment (Table 3). For the 60 ppb benchmark, on which the 2015 decision placed relatively greater weight for multiple (versus single) occurrences of exposures at or above it, the Administrator at that time noted the 2014 HREA estimates for the 70 ppb air quality scenario that estimated 0.5 to 3.5% of children to experience multiple such occurrences on average across the study areas, stating that the now-current standard "is estimated to protect the vast majority of children in urban study areas . . . from experiencing two or more exposures of concern at or above 60 ppb" (80 FR 65364, October 26, 2015). The corresponding estimates, on average across the 3-year period in the current assessments, are remarkably similar at 0.6 to 2.9% (Table 3).

B. Conclusions on the Primary Standard

In drawing conclusions on the adequacy of the current primary standard, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the currently available health effects evidence and exposure/risk information. He additionally has considered the evidence base, information, and policy judgments that were the foundation of the last review, to the extent they remain relevant in light of the currently available information. The Administrator has taken into account both evidence-based and exposure- and risk-based considerations discussed in the PA, as well as advice from the CASAC and public comments. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence, particularly that from controlled human exposure studies and epidemiologic studies evaluating health effects related to O_3 exposures as presented in the ISA, with a focus on policy-relevant considerations as discussed in the PA (summarized in sections II.B and II.D.1 of the proposal and section II.A.2 above). The exposure- and risk-based considerations draw from the results of the quantitative analyses presented and considered in the PA (as summarized in section II.C of the proposal and section II.A.3 above).

The consideration of the evidence and exposure/risk information in the PA informed the Administrator's proposed conclusions and judgments in this review, and his associated proposed decision. Section II.B.1 below briefly summarizes the basis for the Administrator's proposed decision, drawing from section II.D of the proposal. Section II.B.1.a provides a brief overview of key aspects of the policy evaluations presented in the PA, and the advice and recommendations of the CASAC are summarized in section II.B.1.b. An overview of the Administrator's proposed conclusions is presented in section II.B.1.c. Public comments on the proposed decision are addressed in section II.B.2, and the Administrator's conclusions and decision in this review regarding the adequacy of the current primary standard and whether any revisions are appropriate are described in section II.B.3.

1. Basis for Proposed Decision

a. Policy-Relevant Evaluations in the PA

The main focus of the policy-relevant considerations in the PA is consideration of the question: Does the currently available scientific evidence- and exposure/risk-based information support or call into question the adequacy of the protection afforded by the current primary O_3 standard? The PA response to this overarching question takes into account discussions that address the specific policy-relevant questions for this review, focusing first on consideration of the evidence, as evaluated in the ISA, including that newly available in this review, and the extent to which it alters key conclusions supporting the current standard. The PA also considers the quantitative exposure and risk estimates drawn from the exposure/risk analyses (presented in detail in Appendices 3C and 3D of the PA), including associated limitations and uncertainties, and the extent to which they may indicate different conclusions from those in the last review regarding the magnitude of risk, as well as level of protection from adverse effects, associated with the current standard. The PA additionally considers the key aspects of the evidence and exposure/risk estimates that were emphasized in establishing the current standard, as well as the associated public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to the Administrator's consideration of whether the currently available information supports or calls into question the adequacy of the current primary O_3 standard (PA, section 3.5).

As summarized in section II.D.1 of the proposal, based on the evidence in the ISA, the PA concludes that the respiratory effects evidence newly available in this review is consistent with the evidence base in the last review, supporting a generally similar understanding of the respiratory effects of O_3 (PA, section 3.5.4; ISA, Appendix 3). As was the case for the evidence available in the last review, the currently available evidence for health effects other than those of O_3 exposures on the respiratory system is more uncertain than that for respiratory effects. Such effects include metabolic effects, for which the evidence available in this review is sufficient to conclude there to likely be a causal relationship with short-term O_3 exposures and suggestive of, but not sufficient to infer, such a relationship between long-term O_3 exposure (ISA, section IS.1.3.1). These new determinations are based on evidence largely from experimental animal studies, that is newly available in this review (ISA, Appendix 5). Additionally, newly available evidence regarding cardiovascular effects and mortality, in combination with uncertainties in the previously available evidence that had been identified in the last review, contributes to conclusions that the evidence is suggestive of, but not sufficient to infer, causal relationships with O_3 exposures (ISA, Appendix 4, section 4.1.17 and Appendix 6, section 6.1.8). As in the last review, the evidence is also suggestive of such relationships for reproductive and developmental effects, and nervous system effects (ISA, section IS.1.3.1).

In evaluating the policy implications of the current evidence, the PA observes that within the respiratory effects evidence base, the most certain evidence comes from controlled human exposure studies, the majority of which involve healthy adult subjects (generally 18 to 35 years), although there are studies (generally not at the lowest studied exposures) involving subjects with asthma, and a limited number of studies, generally of durations shorter than four hours, involving adolescents and adults older than 50 years. Respiratory responses observed in human subjects exposed to O_3 for periods of 8 hours or less, while intermittently or quasi-continuously exercising, include lung function decrements (*e.g.,* based on FEV_1 measurements), respiratory symptoms, increased airway responsiveness, mild bronchoconstriction (measured as an increase in sRaw), and pulmonary inflammation, with associated injury and oxidative stress (ISA, Appendix 3, section 3.1.4; 2013 ISA, sections 6.2.1 through 6.2.4). Newly available epidemiologic studies of hospital admissions and emergency department visits for a variety of respiratory outcomes supplement the previously available evidence with additional findings of consistent associations with O_3 concentrations across a number of study locations (ISA, Appendix 3, sections 3.1.4.1.3, 3.1.5, 3.1.6.1.1, 3.1.7.1 and 3.1.8). Together, the clinical and epidemiological bodies of evidence, in combination with the insights gained from the experimental animal evidence, continue to indicate the potential for O_3 exposures to contribute to serious health outcomes and to indicate the increased risk of population groups with asthma, including particularly, children (ISA, Appendix 3, section 3.1.5.7).

The PA concludes that the newly available evidence in this review does not alter conclusions from the last review on exposure duration and concentrations associated with O_3-related effects, observing that the 6.6-hour controlled human exposure studies

of respiratory effects remain the focus for our consideration of exposure circumstances associated with O_3 health effects. The PA additionally recognizes that while the evidence clearly demonstrates that short-term O_3 exposures cause respiratory effects, as was the case in the last review, uncertainties remain in several aspects of our understanding of these effects. These include uncertainties related to exposures likely to elicit effects (and the associated severity and extent) in population groups not studied, or less well studied (including individuals with asthma and children) and also the severity and prevalence of responses to short (*e.g.,* 6.6- to 8-hour) O_3 exposures, at and below 60 ppb, while at increased exertion levels.

The PA additionally includes exposure/risk analyses of air quality scenarios in eight study areas, with a focus on the scenario for air quality that just meets the current standard, as described in section II.C of the proposal and summarized in section II.A.3 above. In considering the results of these analyses, the PA gives particular emphasis to the comparison-to-benchmarks analysis, which provides a characterization of the extent to which population exposures to O_3 concentrations, similar to those evaluated in controlled human exposure studies, have the potential to occur in areas of the U.S. when air quality just meets the current standard (PA, section 3.4). The policy evaluations of the exposure/risk analyses focus on children and children with asthma as key at-risk populations, and consideration of the potential for one versus multiple exposures to occur. The PA recognizes that consideration of differences in magnitude or severity of responses (*e.g.,* FEV_1 changes) including the relative transience or persistence of the responses and respiratory symptoms, as well as pre-existing sensitivity to effects on the respiratory system, and other factors, are important to characterizing implications for public health effects of an air pollutant such as O_3 (PA, sections 3.3.2, 3.4.5 and 3.5).

In summary, the PA concludes that the newly available health effects evidence, critically assessed in the ISA as part of the full body of evidence, reaffirms conclusions on the respiratory effects recognized for O_3 in the last review on which the current standard is based. The PA additionally draws on the quantitative exposure and risk estimates for conditions just meeting the current standard (PA, sections 3.4 and 3.5.2). Limitations and uncertainties associated with the available information remain (PA, sections 3.5.1 and 3.5.2). The PA recognizes that the newly available quantitative exposure/risk estimates for conditions just meeting the current standard indicate a generally similar level of protection for at-risk populations from respiratory effects, as that described in the last review for the now-current standard (section II.A.3, Table 3, above; PA, sections 3.1 and 3.4, Appendix 3D, section 3D.3.2.4, Table 3D–38). Collectively, in consideration of the evidence and quantitative exposure/risk information available in the current review, as well as advice from the CASAC, the PA concludes that it is appropriate to consider retaining the current primary standard of 0.070 ppm O_3, as the fourth-highest daily maximum 8-hour concentration averaged across three years, without revision.

b. CASAC Advice in This Review

In comments on the draft PA, the CASAC agreed with the draft PA findings that the health effects evidence newly available in this review does not substantially differ from that available in the 2015 review, stating that, ''[t]he CASAC agrees that the evidence newly available in this review that is relevant to setting the ozone standard does not substantially differ from that of the 2015 Ozone NAAQS review'' (Cox, 2020a, Consensus Responses to Charge Questions p. 12). With regard to the adequacy of the current standard, views of individual CASAC members differed. Part of the CASAC ''agree with the EPA that the available evidence does not call into question the adequacy of protection provided by the current standard, and thus support retaining the current primary standard'' (Cox, 2020a, p. 1). Another part of the CASAC indicated its agreement with the previous CASAC's advice, based on review of the 2014 draft PA, that a primary standard with a level of 70 ppb may not be protective of public health with an adequate margin of safety, including for children with asthma (Cox, 2020a, p. 1 and Consensus Responses to Charge Questions p. 12).[87] Additional comments from the CASAC in the ''Consensus Responses to Charge Questions'' on the draft PA attached to the CASAC letter provide recommendations on improving the presentation of the information on health effects and exposure and risk estimates in completing the final PA. The EPA considered these comments, making a number of revisions to address them in completing the PA. The comments from the CASAC also took note of uncertainties that remain in this review of the primary standard and identified a number of additional areas for future research and data gathering that would inform the next review of the primary O_3 NAAQS (Cox, 2020a, Consensus Responses to Charge Questions p. 14). The recommendations from the CASAC were considered in the proposed decision and have been considered by the Administrator in his decision in this review, summarized in section II.B.3 below.

c. Administrator's Proposed Conclusions

In reaching conclusions on the adequacy and appropriateness of protection provided by the current primary standard and his proposed decision to retain the standard, the Administrator carefully considered: (1) The assessment of the current evidence and conclusions reached in the ISA; (2) the currently available exposure and risk information, including associated limitations and uncertainties, described in detail in the PA; (3) the considerations and staff conclusions and associated rationales presented in the PA, including consideration of commonly accepted guidelines or criteria within the public health community, including the ATS, an organization of respiratory disease specialists; (4) the advice and recommendations from the CASAC; and (5) public comments that had been offered up to that point (85 FR 49830, August 14, 2020). In so doing, he considered the evidence base on health effects associated with exposure to photochemical oxidants, including O_3, in ambient air, noting the health effects evidence newly available in this review, and the extent to which it alters key scientific conclusions in the last review. He additionally considered the quantitative exposure and risk estimates

[87] In the last review, the advice from the prior CASAC included a range of recommended levels for the standard, with the CASAC concluding that ''there is adequate scientific evidence to recommend a range of levels for a revised primary ozone standard from 70 ppb to 60 ppb'' (Frey, 2014b, p. ii). In so doing, the prior CASAC noted that ''[i]n reaching its scientific judgment regarding a recommended range of levels for a revised ozone primary standard, the CASAC focused on the scientific evidence that identifies the type and extent of adverse effects on public health'' and further acknowledged ''that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act'' (Frey, 2014b, p. ii). The prior CASAC then described that its ''*policy advice* [emphasis added] is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account [the Administrator's] judgment regarding the desired margin of safety to protect public health, and taking into account that lower levels will provide incrementally greater margins of safety'' (Frey, 2014b, p. ii).

developed in this review, including associated limitations and uncertainties, and what they indicate regarding the magnitude of risk, as well as level of protection from adverse effects, associated with the current standard. The Administrator also considered the key aspects of the evidence and exposure/risk estimates from the 2015 review that were emphasized in establishing the standard at that time. Further, he considered uncertainties in the current evidence and the exposure/risk information, as a part of public health judgments that are essential and integral to his decision on the adequacy of protection provided by the standard, similar to the judgments made in establishing the current standard. Such judgments include public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses. The Administrator drew on the considerations and conclusions in the current PA, taking note of key aspects of the associated rationale, and he considered the advice and conclusions of the CASAC, including particularly its overall agreement that the currently available evidence does not substantially differ from that which was available in the 2015 review when the current standard was established.

As an initial matter, the Administrator recognized the continued support in the current evidence for O_3 as the indicator for photochemical oxidants, taking note that no newly available evidence has been identified in this review regarding the importance of photochemical oxidants other than O_3 with regard to abundance in ambient air, and potential for health effects. For such reasons, described with more specificity in the ISA and PA and summarized in the proposal, he proposed to conclude it is appropriate for O_3 to continue to be the indicator for the primary standard for photochemical oxidants and focused on the current information for O_3 (85 FR 49830, August 14, 2020).

With regard to O_3 health effects, the Administrator recognized the long-standing evidence that has established there to be a causal relationship between respiratory effects and short-term O_3 exposures. He recognized that the strongest and most certain evidence for this conclusion, as in the last review, is that from controlled human exposure studies that report an array of respiratory effects in study subjects (which are largely generally healthy adults) engaged in quasi-continuous or intermittent exercise. He also recognized the supporting experimental animal and epidemiologic evidence, including the epidemiologic studies reporting positive associations for asthma-related hospital admissions and emergency department visits, which are strongest for children, with short-term O_3 exposures (85 FR 49830, August 14, 2020).

Regarding the current evidence and EPA conclusions for populations at increased risk of O_3-related health effects (ISA, section 4.4), the Administrator took particular note of the robust evidence that continues to identify people with asthma as being at increased risk of O_3 related respiratory effects, including specifically asthma exacerbation and associated health outcomes, and also children, particularly due to their generally greater time outdoors while at elevated exertion (PA, section 3.3.2; ISA, sections IS.4.3.1, IS.4.4.3.1, and IS.4.4.4.1, Appendix 3, section 3.1.11). Based on this evidence and related factors, the Administrator proposed to conclude it appropriate to give particular focus to people with asthma and children (population groups for which the evidence of increased risk is strongest) in evaluating whether the current standard provides requisite protection based on the judgment that such a focus will also provide protection of other population groups, identified in the ISA, for which the current evidence is less robust and clear as to the extent and type of any increased risk, and the exposure circumstances that may contribute to it.

The Administrator additionally recognized newly available evidence and conclusions regarding O_3 exposures and metabolic effects. In so doing, he also noted that the basis for the conclusions is largely experimental animal studies in which the exposure concentrations were well above those in the controlled human exposure studies for respiratory effects, and also above those likely to occur in areas of the U.S. that meet the current standard. In light of these considerations, he further proposed to judge the current standard to be protective of such circumstances, leading him to continue to focus on respiratory effects in evaluating whether the current standard provides requisite protection (85 FR 49830, August 14, 2020).

With regard to exposure circumstances of interest for respiratory effects, the Administrator focused particularly on the 6.6-hour controlled human exposure studies involving exposure, with quasi-continuous exercise, that examine exposures from 60 to 80 ppb. In so doing, he recognized that this information on exposure concentrations that have been found to elicit effects in exercising study subjects is unchanged from what was available in the last review. He additionally recognized that while, as a whole, the epidemiologic studies of associations between O_3 and respiratory effects and health outcomes (*e.g.,* asthma-related hospital admission and emergency department visits) provide strong support for the conclusions of causality, they are less useful for his consideration of the potential for O_3 exposures associated with air quality conditions allowed by the current standard to contribute to such health outcomes, taking note of the scarcity of U.S. studies conducted in locations in which and during time periods when the current standard would have been met (85 FR 49830, August 14, 2020).

In reaching his proposed decision to retain the 2015 standard, the Administrator took note of several aspects of the rationale by which it was established, giving weight to the considerations summarized here. The 2015 decision considered the breadth of the O_3 respiratory effects evidence, recognizing the relatively greater significance of effects reported for exposures while at elevated exertion to average O_3 concentrations at and above 80 ppb, as well as to the greater array of effects elicited. The decision also recognized the significance of effects observed at the next lower studied exposures (slightly above 70 ppb) that included both lung function decrements and respiratory symptoms. The standard level was set to provide a high level of protection from such exposures. The decision additionally emphasized consideration of lower exposures down to 60 ppb, particularly with regard to consideration of a margin of safety in setting the standard. In this context, the 2015 decision identified the appropriateness of a standard that provided a degree of control of multiple or repeated occurrences of exposures, while at elevated exertion, at or above 60 ppb (80 FR 65365, October 26, 2015).[88] The controlled human exposure study evidence as a whole provided context for consideration of the 2014 HREA estimates for the

[88] With the 2015 decision, the prior Administrator judged there to be uncertainty in the adversity of the effects shown to occur following exposures to 60 ppb O_3, including the inflammation reported by the single study at the level, and accordingly placed greater weight on estimates of multiple, *versus* single, exposures for the 60 ppb benchmark, particularly when considering the extent to which the current and revised standards incorporate a margin of safety (80 FR 65344–45, October 26, 2015). She based this, at least in part, on consideration of effects at this exposure level, the evidence for which remains the same in the current review, and she considered this information in judgments regarding the 2014 HREA estimates for the 60 ppb benchmark.

comparison-to-benchmarks analysis (80 FR 65363, October 26, 2015). The current Administrator proposed to similarly consider the currently available exposure and risk analyses in this review (85 FR 49830, August 14, 2020).

The Administrator also recognized some uncertainty, reflecting limitations in the evidence base, with regard to the exposure levels eliciting effects (as well as the severity of the effects) in some population groups not well represented in the available controlled human exposure studies, such as children and individuals with asthma. In so doing, the Administrator recognizes that the controlled human exposure studies, primarily conducted in healthy adults, on which the depth of our understanding of O_3-related health effects is based, provide limited, but nonetheless important information with regard to responses in people with asthma or in children. Additionally, some aspects of our understanding continue to be limited, as in the 2015 review; among these aspects are the risk posed to these less studied population groups by 7-hour exposures with exercise to concentrations as low as 60 ppb that are estimated in the exposure analyses. Collectively, these aspects of the evidence and associated uncertainties contribute to a recognition that for O_3, as for other pollutants, the available evidence base in a NAAQS review generally reflects a continuum, consisting of ambient levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain.

As in the 2015 decision, the Administrator's proposed decision in this review recognized that the exposure and risk estimates developed from modeling exposures to O_3 in ambient air are critically important to consideration of the potential for exposures and risks of concern under air quality conditions of interest, and consequently are critically important to judgments on the adequacy of public health protection provided by the current standard. Thus taking into consideration related information, limitations and uncertainties recognized in the proposal, the Administrator considered the exposure and risk estimates across the eight study areas (with their array of exposure conditions) for air quality conditions just meeting the current standard. In light of factors recognized above and summarized in section II.D.4 of the proposal, the Administrator, in his consideration of the exposure and risk analyses, focused in the proposal on the results for children and children with asthma. In considering the public health implications of estimated occurrences of exposures, while at increased exertion, at or above the three benchmark concentrations (60, 70, and 80 ppb), the Administrator considered the effects reported in controlled human exposure studies of this range of concentrations during 6.6 hours of quasi-continuous exercise. While the Administrator noted reduced uncertainty in several aspects of the exposure and risk approaches as compared to the analyses in the last review, he recognized the relatively greater uncertainty associated with the lung function risk estimates compared to the results of the comparison-to-benchmarks analysis. In light of these uncertainties, as well as the recognition that the comparison-to-benchmarks analysis provides for characterization of risk for the broad array of respiratory effects compared to a narrower focus limited to lung function decrements, the Administrator focused in the proposal primarily on the estimates of exposures at or above different benchmark concentrations that represent different levels of significance of O_3-related effects, both with regard to the array of effects and severity of individual effects (85 FR 49830, August 14, 2020).

In his consideration of the exposure analysis estimates for exposures at or above the different benchmark concentrations (with reduced associated uncertainty compared to the analysis available in 2015) and based on the greater severity of responses reported in controlled human exposures, with quasi-continuous exercise, at and above 73 ppb, the Administrator focused in the proposal first on the higher two benchmark concentrations (which at 70 and 80 ppb are, respectively, slightly below and above this level) and the estimates for one-or-more-day occurrences. In this context, he proposed to judge it desirable that the standard provide a high level of protection against one or more occurrences of days with exposures, while breathing at an elevated rate, to concentrations at or above 70 ppb. With regard to the 60 ppb benchmark, the Administrator gave greater weight to estimates of occurrences of two or more (rather than one or more) days with an exposure at or above that benchmark, taking note of the lesser severity of responses observed in studies of the lowest benchmark concentration of 60 ppb and other considerations summarized in the proposal, including potential risks for at-risk populations. Based on this weighting of the exposure analysis results for the eight urban study areas, the Administrator noted what was indicated by the exposure estimates for air quality conditions just meeting the current standard with regard to protection for the simulated at-risk populations. Some 97% to more than 99% of all children (including those with asthma), on average, and more than 95% in the single highest year, are estimated to be protected from experiencing two or more days with exposures at or above 60 ppb while at elevated exertion. More than 99% of children with asthma (and of all children), on average per year, are estimated to be protected from a day or more with an exposure at or above 70 ppb. Lastly, the percentage (for both population groups) for at least one day with such an exposure at or above 80 ppb is 99.9% or more in each of the three years simulated, with no simulated children estimated to experience more than a single such day. The Administrator proposed to judge that protection from this set of exposures provides a strong degree of protection to at-risk populations, such as children with asthma. In so doing, he found that the updated exposure and risk analyses continue to support a conclusion of a high level of protection, including for at-risk populations, from O_3-related effects of exposures that might be expected with air quality conditions that just meet the current standard (85 FR 49830, August 14, 2020).

In reaching his proposed conclusion, the Administrator additionally took note of the comments and advice from the CASAC, including the CASAC conclusion that the newly available evidence does not substantially differ from that available in the last review, and the conclusion expressed by part of the CASAC, that the currently available evidence supports retaining the current standard (85 FR 49873, August 14, 2020). He also noted that another part of the CASAC indicated its agreement with the prior CASAC comments on the 2014 draft PA, in which the prior CASAC opined that a standard set at 70 ppb may not provide an adequate margin of safety (Cox, 2020a, p. 1). With regard to the latter view (that referenced 2014 comments from the prior CASAC), the Administrator additionally noted that the 2014 advice from the prior CASAC also concluded that the scientific evidence supported a range of standard levels that included 70 ppb and recognized the choice of a level within its recommended range to be ''a policy judgment under the statutory mandate

of the Clean Air Act'' (Frey, 2014b, p. ii).[89]

In reflecting on all of the information currently available, the Administrator also considered the extent to which the currently available information might indicate support for a less stringent standard, noting that the CASAC advice did not convey support for such a standard. He additionally considered the current exposure and risk estimates for the air quality scenario for a design value just above the level of the current standard (at 75 ppb), in comparison to the scenario for the current standard, with its level of 70 ppb. In so doing, he found the markedly increased estimates of exposures to the higher benchmarks under air quality for a higher standard level to be of concern and indicative of less than the requisite protection. Thus, in light of considerations raised in the proposal, including the need for an adequate margin of safety, the Administrator proposed to judge that a less stringent standard would not be appropriate to consider (85 FR 49830, August 14, 2020).

Similarly, the Administrator also considered whether it would be appropriate to consider a more stringent standard that might be expected to result in reduced O_3 exposures. As an initial matter in this regard, he considered the advice from the CASAC (summarized in section II.B.1.b above). With regard to the CASAC advice, he noted that while part of the Committee concluded that the evidence supported retaining the current standard without revision, another part of the Committee reiterated advice from the prior CASAC, which while including the current standard level among the range of recommended standard levels, also provided policy advice to set the standard at a lower level (85 FR 49873, August 14, 2020). In considering the reference to the 2014 CASAC advice, the Administrator noted the slight differences of the current exposure and risk estimates from the 2014 HREA estimates considered by the prior CASAC. The Administrator additionally recognized the PA finding that the factors contributing to these differences, which include the use of air quality data reflecting concentrations much closer to the now-current standard than was the case in the 2015 review, also contribute to a reduced uncertainty in the estimates. Thus, he noted that the current exposure analysis estimates indicate the current standard to provide appreciable protection against multiple days with a maximum exposure at or above 60 ppb. He considered this in the context of the adequacy of protection provided by the standard and of the CAA requirement that the standard protect public health, including the health of at-risk populations, with an adequate margin of safety, and proposed to conclude that the current standard provides an adequate margin of safety, and that a more stringent standard is not needed (85 FR 49873, August 14, 2020).

In light of all of the above, including advice from the CASAC, the Administrator proposed to judge the current exposure and risk analysis results to describe appropriately strong protection of at-risk populations from O_3-related health effects. Thus, based on his consideration of the evidence and exposure/risk information, including that related to the lowest exposures studied and the associated uncertainties, the Administrator proposed to judge that the current standard provides the requisite protection, including an adequate margin of safety, and thus should be retained, without revision (85 FR 49874, August 14, 2020). In so doing, he recognized that the protection afforded by the current standard can only be assessed by considering its elements collectively, including the standard level of 70 ppb, the averaging time of eight hours and the form of the annual fourth-highest daily maximum concentration averaged across three years. The Administrator proposed to judge that the current evidence presented in the ISA and considered in the PA, as well as the current air quality, exposure and risk information presented and considered in the PA, provide continued support to these elements, as well as to the current indicator.

In summary, in the proposal the Administrator recognized that the ISA found the newly available health effects evidence, critically assessed in the ISA as part of the full body of evidence, consistent with the conclusions on the respiratory effects recognized for O_3 in the last review. He additionally noted that the evidence newly available in this review, such as that related to metabolic effects, does not include information indicating a basis for concern for exposure conditions associated with air quality conditions meeting the current standard. Further, the Administrator noted the quantitative exposure and risk estimates for conditions just meeting the current standard that indicate a high level of protection for at-risk populations from respiratory effects. Collectively, these considerations (including those discussed more completely in the proposal) provided the basis for the Administrator's proposed judgments regarding the public health protection provided by the current primary standard of 0.070 ppm O_3, as the fourth-highest daily maximum 8-hour concentration averaged across three years. On this basis, the Administrator proposed to conclude that the current standard is requisite to protect the public health with an adequate margin of safety, and that it is appropriate to retain the standard without revision (85 FR 49874, August 14, 2020).

2. Comments on the Proposed Decision

Over 50,000 individuals and organizations indicated their views in public comments on the proposed decision. Most of these are associated with mass mail campaigns or petitions. Approximately 40 separate submissions were also received from individuals, and 75 from organizations and groups of organizations; forty elected officials also submitted comments. Among the organizations commenting were state and local agencies and organizations of state agencies, organizations of health professionals and scientists, environmental and health protection advocacy organizations, industry organizations and regulatory policy-focused organizations. The comments on the proposed decision to retain the current primary standard are addressed here. Those in support of the proposed decision are addressed in section II.B.2.a and those in disagreement are addressed in section II.B.2.b. Comments related to aspects of the process followed in this review of the O_3 NAAQS (described in section I.D above), as well as comments related to other legal, procedural or administrative issues, and those related to issues not germane to this review are addressed in the separate Response to Comments document.

a. Comments in Support of Proposed Decision

Of the commenters supporting the Administrator's proposed decision to retain the current primary standard, without revision, all generally note their agreement with the rationale provided in the proposal, with the CASAC conclusion that the current evidence is generally consistent with that available in the last review, and with the CASAC members that conclude the evidence does not call into question the adequacy of the current standard. Some commenters further remarked that the primary standard was upheld in the litigation following its 2015

[89] This 2014 advice was considered in the last review's decision to establish the current standard with a level of 70 ppb (80 FR 65362, October 26, 2015).

establishment (*Murray Energy Corp.* v. *EPA,* 936 F.3d 597 [D.C. Cir. 2019]) and that this review is based largely on the same body of respiratory effects evidence. These commenters all find the process for the review to conform to Clean Air Act requirements and the proposed decision to retain the current standard to be well supported, noting that the there are no new controlled human exposure studies (of the type given primary focus in the establishment of the current standard) and concurring with the proposed judgment that at-risk populations are protected with an adequate margin of safety. Some commenters also variously cited EPA statements that the recent metabolic studies, as well as the epidemiologic and toxicological studies newly available in this review for other health endpoints, do not demonstrate effects of O_3 when the current standard is met and thus do not call into question the protection provided by the standard. The EPA agrees with these commenters' conclusion on the current standard.

Further, these comments concur with the EPA's consideration of epidemiologic and toxicological studies of respiratory effects, and with the weight the proposed decision placed on the evidence for other effects, including metabolic and cardiovascular effects, and total mortality. Some of these comments also express the view that health benefits of a more restrictive O_3 standard are highly uncertain, while such a standard would likely cause an increase in nonattainment areas and socioeconomic impacts that the EPA should consider and find to outweigh the uncertain benefits. While, as discussed in section II.B.3 below, the Administrator does not find a more stringent standard necessary to provide requisite public health protection, he does not consider the number of nonattainment areas or economic impacts of alternate standards in reaching this judgment.[90] As summarized in section I.A. above, in setting primary and secondary standards that are ''requisite'' to protect public health and welfare, respectively, as provided in section 109(b), the EPA may not consider the costs of implementing the standards. See generally, *Whitman* v. *American Trucking Ass'ns,* 531 U.S. 457, 465–472, 475–76 (2001). Likewise, ''[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards'' (*American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1185 [D.C. Cir. 1981]; *accord Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 623–24 [D.C. Cir. 2019]). Arguments such as the views on socioeconomic impacts expressed by these commenters have been rejected by the courts, as summarized in section I.A above, including in *Murray Energy,* with the reasoning that consideration of such impacts was precluded by *Whitman's* holding that the ''plain text of the Act 'unambiguously bars cost considerations from the NAAQS-setting process' '' (*Murray Energy Corp.* v. *EPA,* 936 F.3d at 621, quoting *Whitman,* 531 U.S. at 471).

We also note that some commenters that stated their support for retaining the current standard without revision additionally claimed that, based on the results of the exposure and risk analyses in this review, the current standard provides somewhat more public health protection than the EPA recognized in the 2015 decision establishing it. As support for this view, these commenters cite conclusions (including those in the PA) that the exposure and risk estimates are equivalent or slightly lower than those from the 2014 HREA. In generally agreeing with the commenters' observation with regard to the differences in exposure/risk estimates from analyses in this review compared to those from 2014, we note that the current exposure/risk estimates, while based on conceptually similar approaches to those used in the 2014 HREA, reflect a number of improvements to input data and modeling approaches, summarized in section II.A.3 above, which have reduced uncertainties. These updated analyses inform the Administrator's judgments in this review.

b. Comments in Disagreement With Proposed Decision

Of the commenters that disagreed with the proposal to retain the current standard, some recommend tightening the standard, while one submission recommends a less stringent standard. The commenters supporting a less stringent standard generally assert that the current standard is overprotective, stating that information they provide supports returning to the pre-2015 standard of 75 ppb and/or revising the form from the 4th highest daily maximum to the seventh highest daily maximum. The commenters that recommended a more stringent standard describe a need for revision to provide greater public health protection, generally claiming that the current standard is inadequate and does not provide an adequate margin of safety for potentially vulnerable groups. We address these sets of comments in turn below.

(i) Comments in Disagreement With Proposed Decisions—Calling for Less Stringent Standard

The commenters recommending revision to a less stringent standard generally expressed the view that the current standard is more stringent than necessary to protect public health. In support of this view the commenters argue (1) that in this review the EPA ''discredited'' a cardiovascular mortality study on which commenters assert the 2015 decision had placed especially heavy weight; (2) that in light of limitations they assert for the exposure and risk estimate analyses conducted in this review, a 75 ppb standard would meet 2015 objectives; and, (3) that additional factors they identify indicate that the current standard of 70 ppb is too close to background levels while a standard of 75 ppb or one with a form that uses the seventh (*versus* fourth) highest daily maximum 8-hour O_3 concentration would not be.

With regard to the first argument, the EPA knows of no cardiovascular mortality study, much less any health study, that was relied on in the 2015 review that has been discredited, and the commenters provide no citation for such a study. To the extent that the commenter may be intending to refer to the difference of the current review from the 2015 review with regard to the Agency's causality determinations for cardiovascular effects and all-cause mortality, we note that these changes did not involve ''discrediting'' of any studies in the 2013 ISA. Rather, as summarized in section II.A.2.a above, since the time of the last review the controlled human exposure study evidence base has been appreciably expanded from one study to several, none of which report O_3-induced cardiovascular endpoints. This update to the evidence base for cardiovascular effects, which also includes epidemiologic studies, has contributed to a change in the weight of evidence that supports the Agency's causality determinations for both cardiovascular effects and mortality. To the extent that the commenters intend to suggest that these changes in causality determinations indicate that the current standard is more stringent than necessary to protect public health, the Agency disagrees. The Administrator's reasons for concluding that the current standard provides the requisite public

[90] Comments related to implementation programs are not addressed here because, as described in section I.A above, this action is being taken pursuant to CAA section 109(d)(1) and relevant case law. Accordingly, concerns related to implementation of the existing or an alternate standard are outside the scope of this action.

health protection are explained in section II.B.3 below.

With regard to the risk and exposure analyses, the comment argues that 2019 O_3 ambient air monitoring data for locations meeting a design value of 75 ppb indicate that a 75 ppb standard could achieve comparable exposure estimates to those derived for air quality just meeting the current standard by the EPA's exposure/risk analyses. The comment also asserts that uncertainty in the controlled human exposure evidence base with regard to children with asthma suggests ''some latitude'' is needed in the risk calculations. The analysis provided in the comment appears to focus on counties in designated nonattainment areas with 2019 design values ranging from 71 to 75. For these counties, the commenters' analysis appears to sum the population of the subset of these counties with at least one daily maximum 8-hour average concentration in 2019 falling in the range from 73 to 79 ppb (and, separately, the population of counties with at least one such value above 80 ppb). From these population counts, the analysis derives estimates of the subpopulations of children with asthma spending afternoons outdoors (using national estimates for representation of children in the total population, of children with asthma in the total child population, and of children in asthma spending afternoons outdoors using analysis of CHAD diaries for children). The analysis divides the two values by the commenters' estimate of children with asthma in the U.S. (304 million [total population of the U.S.] × 10.5% [percentage representing children] × 9.7% [percentage representing children with asthma]).

There are many aspects of the analysis submitted with the comment that are not focused on the objective of estimating exposures of concern that might be expected to be experienced by at-risk populations in U.S. areas that just meet a standard with an alternative level of 75 ppb. As just one example of these aspects, the denominator in the final step of the commenters' calculation is inflated by population counts for areas of the U.S. excluded from the commenters' analysis (with this larger population multiplied by a national estimates of percent that are children, 10.5%, and a national estimate of percent of children that have asthma, 9.7%), yielding a percentage of unclear relevance to consideration of exposures occurring in areas just meeting an alternative standards of 75 ppb. If the population of the nonattainment areas on which the commenters' focus is substituted in the calculation for the total population of the U.S. as the denominator (29.5 million × 10.5% × 9.7% = 146,664), with the commenters' estimates of children in those areas that may experience an exposure at or above 80 ppb (4,788) or below 80 ppb and at or above 73 ppb (12,641), the percentages are 3.3% and 8.6%, respectively (and the percentage for at or above 73 ppb would be 5.8%).[91] Thus, contrary to the commenters' assertion, their analytical approach, with use of a denominator that reflects the commenters' focus areas, results in higher estimates of the percentage of at-risk children that may experience particular exposures of concern in areas meeting a 75 ppb standard than does the EPA's analysis, which takes into account a number of factors in much greater detail (*e.g.,* through the use of exposure modeling and human activity data to estimate time series contributing to 7-hour exposure periods with average O_3 concentrations at or above benchmarks), and focuses on temporal and spatial patterns of air quality in areas just meeting a standard of 75 ppb. The commenters analysis is not focused on the factors that are key determinants of population exposures of concern, leading to results that are inconsistent with and less informative than the findings of EPA's more detailed, extensive and technically sound exposure and risk analyses (summarized in section II.A.3 above and Appendices 3C and 3D of the PA). Based on consideration of these analyses, among other factors, as described in section II.B.3 below, the EPA disagrees that the available evidence and quantitative analyses supports the conclusion that the current standard is overprotective and that a standard of 75 ppb would protect public health with an adequate margin of safety.

In support of the commenters' additional argument that the current standard is too close to background and that a 75 ppb standard (or a standard using the seventh highest form) would not be, the commenters (1) state that just because a D.C. Circuit decision has stated that EPA is not required to take U.S. background O_3 (USB) into consideration in NAAQS decisions does not mean that such considerations are precluded; (2) cite the lower number of counties (and associated population) that would be in nonattainment for a 75 ppb standard as compared to the current standard (while also suggesting that revision of the form to a seventh highest would appropriately allow for additional high O_3 days due to wildfires); and (3) suggest that the EPA is underestimating USB by a factor of three.

With regard to the legal point, the EPA agrees that while it is not required to take USB into account in NAAQS decisions, it may do so when such consideration is consistent with the Clean Air Act and prior court decisions. The EPA is not relying on consideration of background O_3 levels to support its decision in this review. Moreover, given the differences in public health protection, as noted in the Administrator's proposed conclusions and described in his conclusions in section II.B.3 below, we do not believe that we could use proximity to background concentrations as a basis for revising the current 70 ppb standard to a potential 75 ppb standard.[92] On the commenters' second point, the EPA notes that the number of counties that would or would not be in nonattainment, the size of population living in them, and the increasing number of days for high O_3 due to wildfires are not relevant factors in judging whether a particular standard is requisite under the Clean Air Act. Regardless of such implications of a decision to retain or revise a NAAQS, the key consideration for the review of a primary standard is whether the standard is judged to provide the requisite protection of public health with an adequate margin of safety.[93] The commenters have provided no evidence suggesting that the current standard provides more than the requisite public health protection under the CAA or indicating that an alternate standard

[91] The EPA's exposure and risk analyses estimate <.1 to 0.3% of children with asthma might be expected to experience at least one exposure, while at increased exertion, at or above 80 ppb, on average across a 3-year period in areas just meeting a potential alternative standard of 75 ppb (85 FR 49865,Table 4, August 14, 2020). For the 70 ppb benchmark, these percentages are 1.1 to 2.0%.

[92] Taken together, the EPA generally understands prior court decisions addressing consideration of background O_3 in NAAQS reviews to hold that while the Agency may not establish a NAAQS that is outside the range of reasonable values supported by the air quality criteria and the judgments of the Administrator because of proximity to background concentrations, it is not precluded from considering relative proximity to background O_3 as one factor in selecting among standards that are within that range (*American Trucking Ass'ns* v. *EPA,* 283 F.3d 355, 379 [D.C. Cir. 2002]; *Murray Energy* v. *EPA,* 936 F.3d at 622–624; *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1185 [D.C. Cir. 1982]).

[93] Comments related to implementation programs are not addressed here because, as described in section I.A above, this action is being taken pursuant to CAA section 109(d)(1) and relevant case law. Furthermore, leaving the NAAQS unaltered will not require the EPA to make new air quality designations, nor require States or authorized tribes to undertake new planning or control efforts. Accordingly, concerns related to implementation of the existing or an alternate standard are outside the scope of this action.

with a level of 75 ppb or with a seventh highest form would provide requisite protection. For these reasons, we do not find these comments persuasive in supporting consideration of revising the current standard to an alternate standard with a level of 75 ppb or with a seventh highest form.

With regard to USB, the commenters present an argument focused on an urban/''rural'' comparison and one focused on a 1-month analysis of O_3 concentrations in response to population mobility changes attributed to restrictions placed to manage infections of Corona virus 19 disease (COVID–19). We find there to be limitations in both arguments that undercut the conclusions reached by the commenter. As a result, we disagree that the observations made by the commenters support their statements regarding USB and with the implication that they contradict the EPA's findings from the detailed and extensive analyses presented in the PA (PA, section 2.5 and Appendix 2B).

With regard to the urban/''rural'' comparison, the commenters' first cite EPA's analysis in the PA which indicated, based on daily maximum 8-hour (MDA8) concentrations for the nation as a whole, that from one quarter (10 out of 42 ppb) to one third (14 out of 45 ppb) of average MDA8 concentrations in spring and summer, respectively, are derived from anthropogenic sources. They then state that differences in monthly mean MDA8 concentration between two sets of monitoring sites in the Philadelphia metropolitan area that they identify as the three highest and the three most rural was 3.3 ppb in April 2020. The commenters suggest that this amount is much smaller than the 10 to 14 ppb that EPA estimated to be from anthropogenic sources. Based on these two statements, they contend that USB is being underestimated by a factor of three.

We find the commenters' analysis to have several flaws that undercut their conclusion. First, the difference between the two sets of sites, all of which fall in the Philadelphia metropolitan area, are not indicative of either USA (*i.e.,* U.S. anthropogenic) or USB contributions. There is no evidence that this difference is indicative of either USB or USA, and it is especially anomalous given that the commenters' analysis is based on 2020 data (affected by reduced emissions during the reduced travel during the initial months of the COVID–19 epidemic in the U.S.) while EPA's is based on 2016 data. Second, the authors cite a country-wide seasonal average despite the fact that the U.S. anthropogenic contributions are clearly higher in the nonattainment area (than a U.S. average) being referenced. Further, the conclusions about USB underestimation appear quantitatively incorrect and to perhaps confuse USA and USB in the calculations. Even if all USA anthropogenic contributions cited (10 USA and 30 USB of total 40 ppb) in spring of 2016 were actually USB, the underestimation of USB would be 25% at most (0 USA and 40 USB of total 40 ppb; $(40-30)/40 = 25\%$), thus it is unclear how the commenter concluded a factor of three (300%) under-estimation of USB. In addition, the commenter's dataset is for the Philadelphia-Wilmington-Atlantic City CSA, where O_3 more frequently exceeds the level of the standard in May through September (*e.g.,* PA, Appendix 3C, Figure 3C–79), months that have lower USB and higher US anthropogenic than month of April, which the commenters analyzed. Finally, the commenter has focused on low concentration days (averaging ~40–45ppb) that the PA shows tend to be different than high days (PA, section 2.5 and Appendix 2B).

The second argument is based on data on Apple Mobility data [94] and O_3 and NO_2 concentrations for the period from 3/22/2020 to 4/20/2020 (when transportation activity was affected by the behavioral changes in response to COVID–19) and differences from the same period in prior years. Based on the differences, the commenters conclude that O_3 concentrations were less responsive to the 40 to 60% reduction in mobility than were NO_2 concentrations (7% vs 22% difference), indicating to the commenters that society is reaching a period of diminishing returns of actions to control O_3 concentrations. We note, however, that the period of the commenters' analysis is April, while the majority of days with MDA8 greater than 70 ppb in the Philadelphia nonattainment area occur in May to September. In the mid to late summer period, local production of O_3 is increased (see PA section 2.5.3.2) and MDA8 concentrations in the Philadelphia nonattainment area more frequently are above the level of the standard. Thus, the analysis does not support the commenters' argument for a less stringent standard.[95]

(ii) Comments in Disagreement With Proposed Decision and Calling for More Stringent Standard

Among the commenters that disagree with the proposed decision and call for a more stringent standard, most express concerns regarding the process for reviewing the criteria and standards in this review and assert that the proposal must be withdrawn, and a new review conducted. The commenters expressing the view that a more stringent standard is needed variously cite a number of concerns. Some state that EPA cannot, as some commenters imply it does, simply base its decision on a judgment that the available evidence is similar to that when the standard was established in a prior review, and some argue that the available health effects evidence indicates that adverse health effects occur from exposures allowed by the current standard. Further some commenters express their views that the combined consideration of the complete evidence base indicates that sensitive or vulnerable populations are not protected by the current standard; and/or that the standard does not provide an adequate margin of safety. Additionally, in support of their view that the standard should be made more stringent, some commenters disagree with the conclusions of the exposure and risk analyses, characterizing the analyses as deficient, and contending that other quantitative analyses they cite indicate health impacts that would be avoided by a lower standard level. Most of the commenters advocating a more stringent standard recommend revision of the level to a value at or below 60 ppb and others support a level at or below 65 ppb. Some of these commenters additionally note they had raised similar concerns during the 2015 review.[96] Some commenters also express the view that the EPA should establish a separate long-term standard.

With regard to the process by which this review has been conducted, we disagree with the commenters that it is arbitrary and capricious or that it does not comport with legislative requirements. The review process, summarized in section I.D, implemented a number of features, some of which have been employed in past reviews and others which have not,

[94] *https://covid19.apple.com/mobility.*

[95] We also note, contrary to the commenters' premise, NO_2 and/or NO_X are not conserved over a day. Rather, the overall lifetime of NO_X is on the order of six hours. Further, while the commenter describes the ''local'' nature of O_3, it is well established that O_3 has a large transport component. The diurnal pattern of O_3 concentrations highlighted on this point is likely illustrating O_3 concentrations subject to local NO_X-titration rather than purely local formation as suggested by the commenters.

[96] We note that comments raised in the prior review were fully considered in reaching the decision in that review. Such comments are addressed in the decision and associated Response to Comments (80 FR 65292, October 26, 2020; U.S. EPA, 2015). To the extent that commenters are raising similar issues in support of their comments on the proposed decision in this review, we have addressed them in the current decision, based on the information now available.

and several which represent efficiencies in consideration of the statutorily required time frame for completion of the review. The comments that raise concerns regarding specific aspects of the process are addressed in the separate Response to Comments document. As indicated there, the EPA disagrees with these comments. The EPA finds the review to have been lawfully conducted, the process reasonably explained, and thus finds no reason to withdraw the proposal.

We disagree with some commenters' contention that the EPA based its proposed decision simply on the similarity of the health effects evidence to that available in the last review. While the health effects information is generally similar to that available in the last review, particularly with regard to respiratory effects (the effects causally related to O_3 exposure), the current health effects evidence base includes hundreds of new health studies. Based on consideration of the full evidence base, including that the newly available in the current review, the EPA has reached different conclusions regarding some categories of effects (as summarized in II.A.2.a above). The EPA's observation that the nature of the evidence has not substantially changed with regard to effects causally related to O_3 exposure, was not, as implied by the comment, the primary consideration in the Administrator's proposed decision. The Administrator considered a number of factors in reaching his proposed decision, including the full extent of the currently available health effects evidence, and the details in which it is, and is not, similar to the last review, which has led to conclusions similar to prior conclusions for some categories of O_3 effects and resulted in changes to others (85 FR 49868–49874, August 14, 2020).[97] Further, in reaching his final decision in this review, as described in section II.B.3 below, he has again considered the currently available information, now in light of the public comments received on the proposal, among other factors.[98] In sum, while we have noted the similarities in the health effects information between this review and the last review (particularly for respiratory effects), we have engaged in independent analysis and assessment of the health effects information in this review, and the Administrator has exercised his independent judgment based on the current health effects assessment, in combination with current exposure/risk information, advice from the CASAC and public comment. Thus, contrary to the suggestion by these commenters, the decision on the primary standard has been made in consideration of the current health effects evidence, current analyses of air quality, exposure and risk, advice from the CASAC, and public comments, consistent with requirements under the CAA.

In support of their position that the available health effects evidence indicates that O_3 exposures occurring in areas that meet the current standard are causing adverse effects, some commenters cite studies that investigate associations of O_3 concentrations and effects, such as respiratory effects, mortality, and preterm birth.[99] These studies include some already evaluated in the air quality criteria,[100] [101] some published subsequent to the literature cutoff date for the ISA, and some which some commenters claim the EPA arbitrarily dismissed or inconsistently weighed in reaching the proposed decision.[102] As discussed in I.D above, we have provisionally considered these ''new'' studies that have not already been evaluated in the air quality criteria and that were cited by commenters in support of their comments on the proposed decision (Luben et al., 2020). Based on this consideration, we conclude that these studies do not materially change the broad conclusions of the ISA with regard to these health effects, including the conclusions that there is a causal relationship of short-term respiratory effects with O_3 exposures; a relationship of long-term respiratory effects with O_3 exposure that is likely to be causal; evidence that is suggestive of, but not sufficient to infer, causal relationships of cardiovascular effects and total mortality with short- or long-term O_3 exposure; evidence that is suggestive of, but not sufficient to infer, causal relationships of central nervous system effects with short- or long-term O_3 exposure; and, evidence that is suggestive of, but not sufficient to infer, causal relationships of reproductive and developmental effects with long-term O_3 exposure (ISA, section IS.1.3.1). Nor do we find that these studies warrant reopening the air quality criteria for further review (Luben et al., 2020). Thus, we do not find these publications to be contrary to the discussions and associated conclusions in the PA and proposal or to indicate the current standard to be inadequate. We disagree that studies cited by commenters show these categories of effects to be caused by O_3 exposures associated with O_3 air quality that meets the current standard. We continue to focus on the studies of respiratory effects as most important to the Administrator's judgments concerning the public health protection provided by the current standard.

The epidemiologic studies of respiratory effects identified by the commenters include some investigating associations of O_3 exposure with hospital admissions or emergency department visits for respiratory outcomes, or with various respiratory effects for selected population groups. Studies of O_3 and respiratory effects cited by these commenters in support of their comment include studies that have already been evaluated in the air quality criteria (Goodman et al., 2017; O'Lenick et al., 2017; Jerrett et al., 2009; Lin et al., 2008; Islam et al., 2009; Galizia et al., 1999; Peters et al., 1999; Wendt et al., 2014), and also several ''new'' studies, including four that investigate a relationship between O_3 and COVID–19 (Ware et al., 2016; Strosnider et al., 2019; Wang et al., 2019a; Adhikari and Yin, 2020; Zhu et al., 2020; Zoran et al., 2020; Petroni et al., 2020).[103] We do not

[97] As just one example, the causal determinations for cardiovascular effects and total mortality in this review differ from those made in the last review, as described in section II.A.2.a.

[98] In so doing, to the extent the current evidence before the Administrator continues to support or reinforce conclusions reached in prior reviews, he may reasonably reach those same conclusions.

[99] With regard to effects other than respiratory effects, studies cited by these commenters include studies of cardiovascular effects (Day et al., 2017; Shin et al., 2019; Wang et al., 2019b), all-cause mortality (Bell et al., 2014; Cohen et al., 2017; Di et al., 2017a, b), neurological effects (Cleary et al., 2018), and reproductive and developmental effects (Wallace et al., 2016; Lavigne et al., 2016; Salam et al., 2005; Steib et al, 2019; Morello-Frosch et al., 2010).

[100] In updating the air quality criteria in the current review, the current ISA evaluates relevant scientific literature published since the 2013 ISA, integrating with key information and judgments contained in the 2013 Ozone ISA and previous assessments (ISA, p. lxix; 2013 ISA; U.S. EPA, 2006; U.S. EPA, 1996a; U.S. EPA, 1982; U.S. EPA, 1986; U.S. EPA 1978; NAPCA, 1969).

[101] This commenter cited a epidemiologic study (Day et al., 2017) that had been among studies of short term O_3 and cardiovascular effects excluded from the draft ISA due to location, however this study was considered by the EPA in response to advice from the CASAC on the draft ISA (Luben, 2020). This consideration of these studies did not change EPA's analysis of the weight of evidence from that described in the draft ISA, thus supporting the causality determination for cardiovascular effects described in the final ISA (ISA, section IS.4.3).

[102] We note that one study identified by a commenter to support their view that O_3 concentrations allowed by the current standard is causing health effects does not include O_3 among the pollutants it examines (Gan et al., 2014). Accordingly, we do not find the study to provide support to the commenter's point.

[103] As discussed in section I.D above, the ''new'' studies identified by commenters have not been through the comprehensive CASAC and public review process that the air quality criteria went through. To address these comments, we have provisionally considered these studies, as discussed in I.D above, and found they do not materially

Continued

find these studies to contradict any of the scientific conclusions on respiratory effects described in the ISA.

With regard to the four studies on COVID–19, we disagree with the commenters that they provide evidence that O_3 exposure contributes to COVID–19 incidence, much less that they indicate that O_3 concentrations occurring when the current standard is met would do so. These studies investigate an association between O_3 and COVID–19 cases or deaths. We note, however, that the time-series study design used in three of these studies (Zhu et al., 2020 [incorrectly cited by some commenters as Yongiian et al, 2020]; Adhikari and Yin, 2020; Zoran et al., 2020) is not appropriate for infectious disease cases, which do not follow a Poisson distribution, as they increase exponentially with community spread. The fourth study, an ecological study (Petroni et al. 2020), is also limited by its study design, which is susceptible to confounding or other biases related to ecologic fallacy,[104] as well as its manner of assigning exposure to the population.[105] Further, the time periods in none of the four studies is long enough to rule out a coincidental increase in the community spread of COVID–19 with the increased O_3 concentrations expected with the beginning of O_3 season in these areas (*e.g.,* March–April). Lastly, the biological basis by which a gaseous pollutant such as O_3 would be expected to contribute to incidence of this disease is unclear.[106] Thus, we do not find these studies to support a conclusion that O_3 exposure causes COVID–19 morbidity or mortality.[107]

With regard to the commenters' claims that effects other than respiratory effects (see above) are occurring as a result of O_3 concentrations allowed by the current standard, we note that the standard is exceeded in nearly all of the locations and time periods analyzed in these studies.[108] Although some studies analyzed multiple cities or locations in which the current standard was met during some time periods, air quality during other time periods or locations in the dataset does not meet the current standard. As noted in past reviews, compared to single-city studies, there is additional uncertainty in interpreting relationships between O_3 air quality in individual study cities and reported O_3 multicity effect estimates. Specifically, as recognized in section II.A.2.c above, the available multicity effect estimates in studies of short-term O_3 do not provide a basis for considering the extent to which O_3 health effect associations are influenced by individual locations with ambient O_3 concentrations low enough to meet the current O_3 standards versus locations with O_3 concentrations that violate this standard (85 FR 49853, August 14, 2020; 80 FR 65344, October 26, 2015).[109] Thus, based on this information and the full health effects evidence base for O_3, we disagree with commenters about the implications of the cited epidemiologic studies regarding health risks of O_3 exposures resulting from the O_3 concentrations in ambient air allowed by the current standard.

Protection of Sensitive Groups: Commenters expressing the view that the current standard does not protect sensitive or at-risk populations, variously state that the EPA does not consider risks to a number of population groups the commenters identify as at higher risk for O_3-related health effects, and that retaining the current standard ''creates additional and unacceptable risks'' for Black and low-income communities. Further, some commenters express the views that together the evidence from controlled human exposure studies and from epidemiologic studies indicates adverse effects associated with exposures allowed by the current standard; and that the EPA has not appropriately considered a number of aspects of the evidence related to risks to people with asthma.

Some commenters, in addition to contending that the current standard will not protect populations for which the EPA has concluded there is adequate evidence for identification of increased risk (*e.g.,* people with asthma, children, and outdoor workers), additionally assert that the current standard will not protect populations of color, American Indian/American Native groups, low SES communities, people of any age with respiratory issues other than asthma, diabetes or atrial fibrillation and pregnant women. As described in section I.A. above, primary NAAQS are intended to protect the public health, including at-risk populations, with an adequate margin of safety. Accordingly, in reviewing the air quality criteria, the EPA evaluates the evidence with regard to factors that place some populations at increased risk of harm from the subject pollutant. In this review, the populations for which the evidence indicates increased risk include people with asthma, children and outdoor workers, among other groups, as summarized in section II.A.2.b above (ISA, section IS.4.4).

In support of their argument that individuals with atrial fibrillation are at increased risk of O_3-related health effects, the commenter cited a study of O_3 exposure and total mortality that has been evaluated in the ISA (Medina-Ramon and Schwartz, 2008). It was initially evaluated in the last review and explicitly discussed again as part of the evidence base available in the current review (ISA, section 6.1.5.2 and Table IS–10; 2013 ISA, sections 6.6.2.2 and 8.2.4). Based on consideration of that study and others investigating a potential for increased risk among populations with cardiovascular disease

change the broad scientific conclusions of the ISA with regard to respiratory effects, or warrant re-opening the air quality criteria for further review (Luben et al., 2020).

[104] Ecologic fallacy is a specific type of bias that results when group- or population-level data are used to estimate individual-level risks in an epidemiologic study

[105] This study uses 2016 summertime average O_3 as a surrogate for O_3 from 3/1/2020 to 7/11/2020 (Petroni et al., 2020). Yet COVID–19 cases did not surge in many parts of the U.S. until late summer or fall 2020. To the extent these areas (*e.g.,* rural upper midwest) have lower O_3 concentrations than areas of the country where COVID–19 cases surged earlier (*e.g.,* New York City), a correlation between O_3 concentrations and COVID–19 deaths would be overestimated.

[106] While there may be correlations between O_3 concentrations and COVID–19 cases and deaths, they could be explained by coincidental timing of the COVID–19 community transmission period in New York City and Milan with the early part of the O_3 seasons in those areas, and neither the investigators or commenters provide evidence supporting an alternative plausible basis (Adhikari and Yin, 2020; Zoran et al., 2020).

[107] While the full evidence base indicates the potential for O3 to increase susceptibility to some respiratory infections, the studies cited by commenters do not provide evidence that short-term or long-term O_3 exposure increases susceptibility to COVID–19.

[108] Locations and time periods analyzed in these studies include three large metropolitan areas in Texas before 2012 (Goodman et al., 2017); Atlanta, Dallas and St. Louis from 2002 to 2008 (O'Lenick et al., 2017); large cities across the U.S. from late 1970s through 2000 (Jerrett et al., 2009); New York State, primarily during the 1990s (Lin et al., 2008); U.S. location chosen for O3 concentrations not meeting the standard (Galizia and Kinney, 1999); a set of southern California communities during period (1990s) recognized to be exceeding the NAAQS (Peters et al., 1999; Islam et al., 2009); Houston metropolitan area during 2005 to 2007 (Wendt et al., 2014); multiple locations including St. Louis, Memphis and Atlanta 2003 through 2012 (Ware et al., 2016); six U.S. metropolitan areas, including Los Angeles, Baltimore and New York City, from 1999 thru 2018 (Wang et al., 2019a); and 894 U.S. counties, including those for New York City and Los Angeles, 2001 to 2014 (Strosnider et al., 2019). Air quality data and design values derived by the U.S. indicate that the current 70 ppb standard was not met throughout the study period, or, for multicity studies for which single-city analyses not performed, was not met in all cities throughout the study (PA, Appendix 3B and Excell files available at: *https://www.epa.gov/air-trends/air-quality-design-values*).

[109] This uncertainty applies specifically to interpreting air quality analyses within the context of multicity effect estimates for short-term O_3 concentrations, where effect estimates for individual study cities are not presented, as is the case for some of the multicity studies identified by commenters (85 FR 49870, August 14, 2020).

(CVD), the 2013 ISA concluded that the evidence was ''inadequate to classify pre-existing CVD as a potential at-risk factor for O_3-related health effects'' (2013 ISA, sections 8.2.4). In the current review, while a limited number of recent studies add to the evidence available in the 2013 ISA,[110] collectively the evidence remains inadequate to conclude whether individuals with pre-existing CVD are at greater risk of O_3-related health effects (ISA, Table IS–10, section IS.4.4.3.5). Thus, the evidence does not support the commenters assertion that populations with atrial fibrillation are at increased risk of O_3-related effects and that the current standard does not protect these groups.

The commenters who contend pregnant women are at increased risk do not provide supporting evidence, and the ISA does not reach such a conclusion based on the currently available evidence. Further, the ISA determined the evidence to be suggestive of, but not sufficient to infer, a causal relationship between O_3 exposure and reproductive effects (ISA, section IS.4.3.6.3). Thus, we disagree with the commenters that pregnant women may be at increased risk of O_3-related effects and disagree that the current standard does not protect these groups.

With regard to a potential for increased risk of O_3-related health effects based upon race or ethnicity, including American Indians or Native Americans), the available evidence is inadequate to make such a determination (ISA, section IS.4.4, Tables IS–9 and IS–10).[111] Additionally, the evidence of increased O_3 risk based on SES has been evaluated in the ISA and concluded to be ''suggestive,'' but the evidence is limited by inconsistencies (ISA, section IS.4.4). Thus, contrary to the view expressed by some commenters, the EPA has considered this factor in this review and the evidence was not adequate to identify SES as a risk factor for O_3 related health effects. As noted by the commenters, the evidence for low SES populations is ''suggestive'' of increased risk (ISA, section IS.4.4), in part because it includes several inconsistencies (as summarized in section II.A.2.b above), including studies that did not find O_3-related risk to be higher in lower SES communities.[112] While we agree with the commenters that populations of some particular races or ethnic backgrounds or with low SES have higher rates of some health conditions, including asthma,[113] the available evidence is not adequate to conclude an increased risk status based solely on racial, ethnic or income variables alone (ISA, section IS.4.4). Thus, we disagree with commenters that EPA has arbitrarily not considered such factors in reaching the decision on the primary standard.

Some commenters further claim that tribal populations and communities of color are at increased risk of O_3-related health effects due to increased impacts of COVID–19. We disagree with commenters that the studies they cite provide support for the role of O_3 exposure in the observed increase in prevalence. The studies cited simply describe greater prevalence of COVID–19 among such communities and do not investigate and therefore do not provide evidence for a role for O_3 exposure.[114] An additional study cited by one commenter in support of their statement that people with COVID–19 are more susceptible to effects of O_3, does not include any analyses with O_3 among its analyses (Wu et al, 2020). With regard to diabetes, we note that the evidence related to a potential for this to affect risk of O_3-related effects has been explicitly evaluated and found to be inadequate, thus indicating a lack of basis in the evidence for the statement by some commenters that diabetes prevalence in a community increases the risk of O_3-related effects (ISA, Table IS–10).

Additionally, commenters that contend that retaining the current standard ''creates additional and unacceptable risks'' for minority and low-income populations variously cite higher rates of asthma and other preexisting conditions in these populations and higher levels of pollution.[115] In making this claim, these commenters state that non-Hispanic Blacks have been found to be more likely to live in counties with higher O_3 pollution. To the extent that such patterns in the distribution of certain population groups and O_3 concentrations result in these populations residing in areas that do not currently meet the current standard, we note that they are at greater risk than populations residing in areas that meet the current standard, and implementing the standard will reduce their risks. But we disagree with the commenters' conclusion that retaining the current standard, without any change, creates additional risks for these populations.

Thus, contrary to statements by some commenters, the EPA's proposed decision to retain the current standard did consider evidence regarding risk to and thus protection of specific populations, such as those of particular races or ethnicities or low-income populations. The proposed decision, and the Administrator's decision described in section II.B.3 below, are based on consideration of the currently available evidence, particularly that with regard to populations that may be at greater risk of O_3-related health effects than the general population. As described in section II.B.3 below, the Administrator judges that by basing his decision on consideration of these populations, including adults and children with asthma, the at-risk population groups for which the

[110] Further, we note that a more recent study than that cited by the commenters investigated the potential for an association of O_3-related mortality risk with individuals with atrial fibrillation and observed no evidence of an association (ISA, Appendix 6, p. 6–11).

[111] In support of their view that O_3-related risk is increased in Black populations, some commenters cite a study published after the ISA (Gharibi et al., 2019). We have provisionally considered this study, as described in section I.D. above, and found that it does not materially affect the broad conclusions in the ISA, including those regarding the adequacy of evidence for finding an influence on O_3-related risk of different categories of population status, or warrant reopening the air quality criteria for further review (Luben et al., 2020).

[112] We note that two studies described by one commenter as indicating that those with low SES or who live in low SES communities face higher risk of hospital admissions and emergency department visits related to O_3 pollution have been evaluated by the EPA and found not to report such findings (2013 ISA, section 8.3.3; ISA, Table IS–10). In the first, a study of O_3 exposure and respiratory hospital admissions in 10 Canadian cities (Cakmak et al., 2006) ''no consistent trend in the effect was seen across quartiles of income,'' and the second, a study of O_3 exposure and asthma hospital admissions and emergency visits (Burra et al., 2009), ''reported inverse effects for all levels of SES'' (2013 ISA, p. 8–27; ISA, Table IS–10).

[113] This is noted in the PA and proposal with regard to Black non-Hispanic and several Hispanic population groups (PA, Table 3–1). As some commenters note, this is also the case for American Indian and Native American population groups. Based on the recently available, 2016–2018 National Health Interview Survey, while just under 8% of the U.S. population is estimated to have asthma, the estimate is more than 10% for American Indian or Native American populations in the U.S. (*https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm;* document identifier EPA–HQ–OAR–2018–0279–0086).

[114] The commenter cites Price-Haywood et al. (2020), Stokes et al. (2020), Millett et al. (2020), Killerby et al. (2020), and Gold et al. (2020). These studies present information regarding COVID–19 cases, hospitalizations and/or deaths among various population groups, but they do not investigate association of those occurrences with O_3.

[115] In making their argument, these commenters do not provide any explanation for why retaining the existing standard (*i.e.,* making no regulatory change) would create additional risk for these populations. Rather, these commenters seem to be describing differences in predicted risk or mortality of air quality associated with a lower standard level and that of the current standard. In that way, they are claiming that retaining the current standard ''creates'' additional risk. We address comments advocating a lower standard based on commenter-cited risk estimates (*e.g.,* mortality) further below.

evidence is strongest and most extensive, will also provide protection for other at-risk populations for which the evidence is less certain and less complete.

The commenters who express the view that the current standard does not provide sufficient protection of people with asthma raise concerns with the EPA's consideration of this group and O_3-related effects. Further, some commenters state that the EPA has not adequately explained how its approach for decision-making in this review protects at-risk populations, such as people with asthma. Such commenters state that the EPA does not explain how the proposed decision accounts for the greater vulnerability of people with asthma, given the attention to evidence from controlled human exposure studies of largely healthy subjects. Some commenters contend that the EPA arbitrarily focuses on lung function decrements and respiratory symptoms ahead of lung inflammation, and/or that the EPA has not rationally considered the most recent ATS statement with regard to consideration of effects in people with respiratory disease, such as asthma (which the commenters describe as a difference from past reviews).

We disagree with these commenters. In this review, as in past reviews, the EPA has fully considered the health effects evidence in this review, including for sensitive populations, such as people with asthma, and explained its conclusions regarding the adequacy of public health protection offered by the current standard, including for such populations. Thus, the decision in this review, as described in section II.B.3 below, is based on the current scientific information. Further, our approach in this review does not differ appreciably from our approach in the last review. This approach is consistent with the applicable legal requirements for this review, including with provisions of the CAA related to the review of the NAAQS, and with how the EPA and the courts have historically interpreted the CAA. The approach is based fundamentally on the current health effects evidence in the ISA and quantitative analyses of exposure and risk in the PA. The policy implications of this information, along with guidance, criteria or interpretive statements developed within the public health community, including, also, statements from the ATS, in addition to advice from the CASAC are evaluated in the PA for consideration by the Administrator. The PA evaluations inform the Administrator's public health policy judgments and conclusions. Thus, as in past reviews, the Administrator's decision on the adequacy of the current primary standard draws upon the scientific evidence for health effects, quantitative analyses of population exposures and health risks, CASAC advice, and judgments about how to consider the uncertainties and limitations that are inherent in the scientific evidence and quantitative analyses, as well as public comments on the proposed decision.

As described in section II.B.3 below, key aspects of the evidence informing the Administrator's decision-making in this review include: (1) The causal relationship of O_3 with respiratory effects, based on the full health effects evidence base, including both the controlled human exposure studies conducted primarily in largely healthy adult subjects, and the epidemiologic studies of health outcomes for people with asthma, and particularly children with asthma; (2) the increased risk to children and people with asthma, among other groups (3) the respiratory effects reported at the lowest exposures in the controlled human exposure studies; and (4) features of asthma that contribute to the susceptibility of people with asthma to O_3-related effects. As a whole, the evidence base in this NAAQS review generally reflects a continuum, consisting of exposure levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. As summarized in section I.A above, the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels (see *Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1156 n.51, *Mississippi* v. *EPA,* 744 F.3d at 1351), but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. The Administrator's consideration of the scientific evidence is informed by the quantitative estimates of exposure and risk for air quality allowed by the current standard, and associated judgments on the adequacy of public health protection provided by the current standard are informed by advice from the CASAC and statements from ATS on adversity.

With regard to the most recent ATS statement, the commenters' claim that the EPA does not adequately consider the implications of the sentence that ''small lung function changes should be considered adverse in individuals with extant compromised function, such as that resulting from asthma, even without accompanying respiratory symptoms'' and to consider the importance of examining effects in susceptible subsets of broader populations (Thurston et al., 2017). We disagree. The ATS statements (from the initial statement in 1985 to the recent 2017 statement) and their role in primary O_3 standard reviews, summarized in section II.A.2.b above, occupy a prominent role in consideration of public health implications in the PA and the proposal (PA, section 3.3.2; 85 FR 49848, 49866, 49871, August 14, 2020), and the Administrator considers them in his decision, as described in section II.B.3 below. The PA presentation includes summaries of the purpose and intentions articulated by the ATS, and of the evolution and areas of consistency across the statements. The PA gave particular attention to the ATS emphasis on consideration of the significance or adversity of effects, particularly for more susceptible individuals. It recognized both the 2000 ATS statement concluding that ''small transient changes in forced expiratory volume in 1 s[econd] (FEV_1) alone were not necessarily adverse in healthy individuals, but should be considered adverse when accompanied by symptoms'' (ATS, 2000), and also the more recent statement that also gives weight to findings of such lung function changes in the absence of respiratory symptoms in individuals with pre-existing compromised function, such as that resulting from asthma (Thurston et al., 2017). With regard to population risk (another aspect of the ATS statement cited by commenters), the PA and proposal summarized the 2000 and 2017 ATS statements, recognizing that the 2017 statement references and further describes concepts described in the 2000 statement, such as its discussion of considering effects on the portion of the population that may have a diminished reserve that puts its members at potentially increased risk if affected by another agent (ATS, 2000).[116] As described in section II.B.3 below, the Administrator considers the ATS statements in reaching his conclusions in this review.

In support of their claim that the EPA has not appropriately considered the ATS statements, some commenters

[116] The sentence in the 2017 statement of which one commenter quoted only a part, ''As discussed in the previous ATS statement, a small but statistically significant mean reduction in FEV_1 in a population means that some people had larger reductions, with the likelihood that reductions in a subset of susceptible subjects can have passed a threshold for clinical importance'' This paragraph goes on to note that a study in which the mean decrement is about 3%, included two subjects with decrements greater than 10% (Thurston et al., 2017).

additionally take issue with the EPA's use of the number of subjects experiencing at least a 15% FEV_1 decrement in its description in the proposal of the increased response evident by comparing from the lowest exposure levels studied (40 ppb) up to 70 ppb (85 FR 49851, August 14, 2020). These comments also state that EPA did not discuss the clinical significance of FEV_1 decrements of 10% or higher for people with existing lung disease, while stating that the ATS statement mentions this magnitude of decrement. The ATS statement references decrements at or above 10% in illustrating a point about variation of subject responses beyond a group mean, noting that while the mean of an exposed group of study subjects may be small, some group members have larger reductions and can have passed a threshold for clinical importance. It does not provide a discussion of thresholds of clinical importance.[117] In claiming that EPA's discussion on this represents a difference from the last review, the commenters cite the 2014 HREA and state that we have not considered FEV_1 decrements at or above 10% in the current review, however this is not the case.[118] Furthermore, the PA states that the mid- to upper-end of the range of moderate levels of functional responses and higher (*i.e.,* FEV_1 decrements ≥15% and ≥20%) are included to generally represent potentially adverse lung function decrements in active healthy adults, while for people with asthma or lung disease, a focus on moderate functional responses (FEV_1 decrements down to 10%) may be appropriate (PA, Appendix 3D, p. 3D–76).

In objecting to the EPA's approach to considering the ATS statement, these commenters cite a reference to the ATS statement in CASAC's advice as additional evidence that the EPA approach to considering the ATS statement is arbitrary.[119] This comment was made within the context of the CASAC comments on the draft PA that emphasized the need to improve discussion of the susceptibility of people with asthma, including giving attention to the occurrence of lung function decrements in susceptible groups, specifically children with asthma. This section of the CASAC letter also cautions against too great a focus on lung function decrements and emphasizes the need for fuller consideration of respiratory effects that are likely to be important in people with asthma due to features of that disease. In consideration of these comments, the final PA includes an improved discussion on the unique vulnerability of people with asthma (PA, sections 3.3.1.1, 3.3.2, 3.3.4, and 3.5.1) that contributes to due consideration of this population group in decision-making on the primary O_3 standard. Further, in considering the exposure and risk analysis results, we recognize the comparison-to-benchmarks analysis as providing a more robust consideration of risk to sensitive groups as it provides the ability to consider O_3 effects more broadly, with each benchmark representing the array of effects, at different severities, associated with that exposure level. This is one of the reasons (consistent with the CASAC advice) that this analysis (rather than the lung function risk analysis) receives greater emphasis in the PA, consistent with the CASAC advice in this area.

In light of the above discussion, we note that the PA, the proposal, and the decision described in section II.B.3 below, focus specifically on consideration of people with asthma, and particularly children with asthma. While the evidence regarding the susceptibility of people with asthma to the effects of O_3 is robust, our understanding of the exposures at which various effects (of varying severity) would be elicited is less defined. For example, the inherent characteristics of asthma contribute to a risk of asthma-related responses, such as asthma exacerbation in response to asthma triggers, which may increase the risk of more severe health outcomes (ISA, section 3.1.5). This is supported by the strong and consistent epidemiologic evidence that demonstrates associations between ambient O_3 concentrations and hospital admissions and emergency department visits for asthma (ISA, section IS.4.4.3.1). In moving to consideration of the potential specific exposure scenarios (*e.g.,* multiple-hour exposures to 60 to 80 ppb O_3 during quasi-continuous exercise), we note that the evidence is for largely healthy adult subjects. With regard to lung function decrements, the limited evidence from controlled human exposure studies (primarily at higher exposures and in adult subjects) indicates similar magnitude of O_3-related FEV_1 decrements for people with as for people without asthma (ISA, Appendix 3, section 3.1.5.4.1). Further, across other respiratory effects of O_3 (*e.g.,* increased respiratory symptoms, increased airway responsiveness and increased lung inflammation), the evidence has also found the observed responses to generally not differ due to the presence of asthma, although the evidence base is more limited with regard to study subjects with asthma (ISA, Appendix 3, section 3.1.5.7). Thus, in light of the uncertainties in the evidence base with respect to people with asthma and exposures eliciting effects and the severity of those effects, other aspects of the evidence are informative to the necessary judgments. Accordingly, the advice from the CASAC and the statements from the ATS are important to the judgments made by the Administrator in basing his decision on the current evidence and ensuring a primary standard that protects at-risk populations, such as people with asthma.

Contrary to the claim from some commenters, our consideration of effects in people with asthma did not focus solely on lung function responses. As noted above, we recognize that the inherent characteristics of asthma as a disease provide the potential for O_3 exposures to trigger asthmatic responses, such as through causing an increase in airway responsiveness. Based on the available evidence, we consider the potential for such a response to be greater, in general, at relatively higher, versus lower, exposure concentrations, noting 80 ppb to be the lowest exposure concentration at which increased airway responsiveness has been reported in generally healthy adults. We recognize that this evidence and the evidence represented by the three benchmark concentrations used in the exposure/risk analyses (60, 70 and 80 ppb) is for largely healthy adults and does not include data for people with

[117] With regard to 10% as a magnitude decrement, the prior ATS statement noted that the EPA had graded this ''mild'' in a prior review, while noting that such a grading has not been evaluated against other measures (ATS, 2000). In this review, as in past reviews, the EPA has summarized study results with regard to multiple magnitudes of lung function decrement, including 10%, recognizing that 10% has been used in clinical settings to detect a FEV_1 change likely indicative of a response rather than intrasubject variability, *e.g.,* for purposes of identifying subjects with responses to increased ventilation (Dryden, 2010). For example, the PA in the current review provides such a summary (PA, Appendix 3D, p. 3D–77).

[118] Contrary to this claim, the lung function risk analysis in the current review (which is an update of the very same analysis in the 2014 HREA to which the commenters cite) presents the results for exactly the same categories of lung function decrement (at/above 10%, at/above 15% and at/above 20%) as in the 2014 HREA (*e.g.,* PA, Table 3–4).

[119] The citation provided by the commenters is the CASAC letter on the draft PA; in this letter the CASAC cites the ATS statement in making a comment on the draft PA indicating that the concept that lung function decrements in the absence of symptoms do not represent an adverse health effect should not apply to the susceptible group of children with asthma (Cox, 2020a, Consensus Responses to Charge Questions, pp. 8–9).

asthma. In reaching his decision in this review, the Administrator gives additional consideration to the effects of particular concern for people with asthma, such as asthma exacerbation, in light of the limitations of the evidence represented by the benchmarks in this regard, as discussed in section II.B.3 below.

In support of their view that the EPA gives too little weight to effects reported in studies of 60 ppb, some commenters assert that the EPA arbitrarily focused on the evidence for lung function decrements and respiratory symptoms, and does not explain how the proposed decision protects against the harm posed by inflammatory responses to O_3. In making this statement they cite the study by Kim et al. (2011) and discussions in the ISA regarding studies documenting the role of O_3 in eliciting inflammatory responses and regarding possible conceptual mechanisms by which inflammatory responses can contribute to other effects (including cardiovascular effects). In so doing, they contend that exposures lower than those for which the current standard is intended can cause inflammation resulting in permanent lung damage and the development of severe lung disease. They additionally state that airway inflammation of O_3 is of particular concern for people with asthma as airway inflammation is a feature in the definition of asthma.

Contrary to the view of some commenters, the Administrator has given significant consideration (in the proposal and in section II.B.3 below) to the exposure estimates for the 60 ppb benchmark. In considering the O_3 inflammatory response, we note that inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely (2013 ISA, p. 6–76). Thus, the inflammatory response observed following the single exposure to 60 ppb in the study by Kim et al. (2011) of largely healthy subjects is not necessarily an adverse response.[120] We further consider the comments from the CASAC regarding airway inflammation as an important aspect of asthma, including the CASAC's description of increased airway inflammation in people with asthma as having the potential to increase the risk of an asthma exacerbation. As described in section II.B.3 below, the Administrator also considers this, while noting also the lack of evidence from studies of people with asthma at 60 ppb. In so doing, he recognizes that, due to interindividual variability in responsiveness, both in regard to O_3 and in regard to asthma exacerbation triggering events, not every occurrence of an exposure considered to have the potential to increase airway inflammation will result in such an adverse effect. We find it important to note, however, that continued acute inflammation can contribute to a chronic inflammatory state, with the potential to affect the structure and function of the lung (2013 ISA, p. 6–76; ISA, sections 3.1.4.4.2 and 3.1.5.6.2).[121] In light of this evidence, the Administrator, in his consideration of the exposure/risk estimates of exposures at or above the 60 ppb benchmark (described in section II.B.3 below), is less concerned about such estimates representing a single occurrence, and gives weight to estimates of multiple occurrences and their associated greater risk. Thus, rather than a sole focus on a single exposure level or type of effect (such as lung function decrements), the Administrator considers the quantitative estimates for all three benchmarks (with regard to single and multiple occurrences), recognizing that they represent differing levels of significance and severity of O_3-related effects, both with regard to the array of effects and severity of each type of effects, as well as the implications for the at-risk populations, including people with asthma. The comparison-to-benchmarks analysis provides for this full characterization of risk for the broad array of respiratory effects, including inflammation and airway responsiveness, thus avoiding an inadequate and narrower focus, *e.g.,* limited to lung function decrements (85 FR 49872, August 14, 2020).

Contrary to the commenters' claims, the Administrator, in reaching his proposed decision, and in his final decision, as described in section II.B.3 below, placed primary focus on what the evidence indicates with regard to health effects in the at-risk population of people with asthma, particularly children with asthma, and on results of the exposure and risk analysis for this population. In so doing, he recognizes key aspects of the evidence, as summarized in section II.A.2.a above, that indicate the array of O_3-associated respiratory effects to be of increased significance to people with asthma given aspects of the disease that may put such peoples at increased risk for prolonged bronchoconstriction in response to asthma triggers. The increased significance of effects in people with asthma and risk of increased exposure for children (from greater frequency of outdoor exercise) is illustrated by the epidemiologic findings of positive associations between O_3 exposure and asthma-related emergency department visits and hospital admissions for children with asthma. In this context, the Administrator focuses on the breadth of O_3 respiratory effects evidence at the lowest exposures tested in the controlled human exposure studies which provide the most certain evidence, considering this in light of the fuller evidence base which provides a foundation for necessary judgments in light of uncertainties.

Thus, we disagree with commenters that we have not considered the full body of evidence and quantitative information available in this review with regard to exposures that might be expected to elicit effects in at-risk populations. In so doing, as summarized in section II.A.2.a above, section II.B.1.a of the proposal, and the PA, we recognize that the currently available evidence supports the conclusion of a causal relationship between short-term O_3 exposure and respiratory effects, with the strongest evidence coming from controlled human exposure studies that document subtle reversible effects in 6.6-hour exposures of largely healthy adult subjects, engaged in quasi-continuous exercise, to average concentrations as low as 60 ppb. The epidemiologic evidence of associations of O_3 concentrations in ambient air with

[120] One commenter contends that inflammation is apparent from short-term O_3 exposures ranging from 12 to 35 ppb, based on air quality metrics reported in some epidemiologic studies, such as mean 24-hour averages or monthly averages of 8-hour concentrations (ISA, Table 4–28). The commenter implies that such values for these metrics are lower than the level of the standard (70 ppb) means that exposures allowed by the standard are causing outcomes analyzed in the study. However, none of the metrics for which values are cited by the commenter are in terms of design values for the current standard, such that a direct comparison of the values is not meaningful.

[121] The currently available evidence does not support the implication of the commenters that the inflammatory response reported in some individuals after a 6.6-hour exposure to 60 ppb, during quasi-continuous exercise (as in Kim et al., 2011), causes permanent lung damage or development of severe lung disease. While the experimental animal evidence indicates the potential for repeated exposures to elevated concentrations (*e.g.,* at or above 500 ppb over multiple days) can contribute to other effects in animal models or to other asthmatic responses in animal models of asthma, the full evidence base for single exposures to lower concentrations does not provide such a finding (ISA, sections 3.1.4.4, 3.1.4.4.2 and 3.1.5.6.2; 2013 ISA, section 6.2.3). Thus, the potential for effects reported from 6.6-hour exposures to 60 ppb O_3, during quasi-continuous exercise, including the inflammation reported by Kim et al. (2011) to contribute to adverse health effects is uncertain. Newly available evidence in this review does not reduce this uncertainty or provide a contradiction to conclusion regarding the implications of inflammation induced by single or isolated exposures (ISA, Appendix 3).

increased incidence of hospital admissions and emergency department visits for an array of respiratory health outcomes further indicates the potential for O_3 exposures to elicit health outcomes more serious than those assessed in the experimental studies, particularly for children with asthma, and the evidence base of such epidemiologic studies as a whole provides strong support for the conclusion of causality for respiratory effects.[122] Further as described in the PA and the proposal and summarized in section II.A.2.a above, very few of these studies were conducted in locations during periods when the current standard was met. While some commenters cite the low values of some of the air quality metrics analyzed in such studies, those metrics are not in the form of the design value for the current standard and so, contrary to commenters' assertion, cannot show that serious health effects are occurring under air quality conditions allowed by the current 70 ppb standard.

Protection With an Adequate Margin of Safety: Some commenters expressed the view that the current standard does not provide an adequate margin of safety variously argue that the EPA is ignoring precedent and CAA requirements for considering scientific uncertainty in its judgments regarding an adequate margin of safety, and that statements from the prior CASAC and new evidence suggests that the current 70 ppb standard provides little margin of safety for protection of sensitive subpopulations from harm. These commenters generally advocate revision to a 60 ppb standard to address this concern. In support of their views, some state that the EPA is ignoring findings of a statistically significant lung function response to 6.6-hour exposure to 60 ppb during quasi-continuous exercise while others cite the EPA consideration of epidemiologic evidence, claiming that the EPA is inappropriately using identified uncertainties as a basis for not revising the standard. We disagree with these characterizations.

As an initial matter, we note that, contrary to the statements made by these commenters, the Administrator, in reaching his proposed decision, as in reaching his final decision, has considered legal precedent and CAA requirements for a primary standard that protects public health, including the health of sensitive groups, with an adequate margin of safety. With regard to scientific uncertainty, as summarized in section I.A above, the CAA requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries Ass'n* v. *EPA,* 647 F.2d 1130, 1154 (D.C. Cir. 1980); *American Petroleum Institute* v. *Costle,* 665 F.2d at 1186; *Coalition of Battery Recyclers Ass'n* v. *EPA,* 604 F.3d 613, 617–18 (D.C. Cir. 2010); *Mississippi* v. *EPA,* 744 F.3d 1334, 1353 (D.C. Cir. 2013). Thus, in considering whether the primary standard includes an adequate margin of safety, the Administrator is seeking to ensure that the standard not only prevents pollution levels that have been demonstrated to be harmful but also prevents lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. In so doing, however, the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels (see *Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1156 n.51, *Mississippi* v. *EPA,* 744 F.3d at 1351), but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In the proposed decision, as in the decision described in section II.B.3 below, the Administrator's consideration of the kind and degree of uncertainties associated with the current information (as some of the factors the EPA considers in addressing the requirement for an adequate margin of safety) involved a number of judgments. With regard to his consideration of the epidemiologic evidence, for example, the Administrator recognizes that, as a whole, investigations of associations between O_3 and respiratory effects and health outcomes (*e.g.,* asthma-related hospital admission and emergency department visits) provide strong support for the overarching conclusion of that O_3 causes respiratory effects, and its risks to people with asthma. In his consideration of O_3 exposures of concern, the Administrator, agrees with staff evaluations in the PA, that such studies available in this review are less informative to his judgments related to air quality conditions allowed by the current standard (85 FR 49870, August 14, 2020). For example, as summarized in section II.A.2.c above, none of the U.S. studies that show associations between O_3 and the clearly adverse health outcomes of hospital admissions or emergency department visits for respiratory causes were based in locations during time periods when the current standard was always met (PA, section 3.3.3). While there were two such studies based in single cities in Canada, as discussed above, the interpretation of individual single-city results is complicated by the presence of co-occurring pollutants or pollutant mixtures (PA, section 3.3.3).[123] Thus, as in reaching his decision in this review, the Administrator has fully considered conclusions reached in the ISA regarding the epidemiologic evidence and the policy evaluations in the PA, and does not find the currently available epidemiologic studies to provide insights regarding exposure concentrations associated with health outcomes that might be expected under air quality conditions that meet the current standard (85 FR 49870, August 14, 2020). Thus, the EPA's decision on the standard in this review fully and appropriately considers the full evidence base, including the epidemiologic evidence, and associated uncertainties and limitations.

With regard to the controlled human exposure studies, and the nature and degree of effects that might be expected at exposures lower than those studied or in unstudied population groups, the Administrator has considered first what the evidence base indicates with regard to the lowest exposures as well as differences and similarities between the studied populations and the less well studied population groups recognized to be at increased risk. In so doing, he considers the findings of statistically significant respiratory responses in the studies of 60 ppb exposures in largely healthy subjects, particularly in his consideration of the exposure and risk estimates. For example, in reaching his decision in section II.B.3 below, as for his proposed decision, he finds it appropriate to consider the level of protection provided by the current standard from single exposures, but to give greater weight to multiple exposures, in judging adequacy of the margin of safety provided by the current standard.[124] Such considerations

[122] As described in section II.A.2.c above and in the PA, these studies generally do not detail the specific exposure circumstances eliciting such effects.

[123] Accordingly, uncertainties remain with regard to the independent role of O_3 exposures in eliciting the reported health outcomes analyzed, and in the absence of analyses that might reduce such uncertainties (*e.g.,* analyses of the presence and effects of co-occurring pollutants).

[124] Contrary to implications of some commenters, this judgment by the current Administrator is

Continued

contributed to the Administrator's proposed judgments with regard to the requisite level of protection needed to protect at-risk populations with an adequate margin of safety, as required by the Act and consistent with the factors recognized in the relevant case law. Thus, consistent with the CAA requirements and prior judicial decisions, the Administrator based his proposed decision, and bases his final decision (as summarized in II.B.4 below) on the scientific evidence, our current understanding of it, and his judgments concerning associated uncertainties, both those associated with inconclusive scientific and technical information, and those associated with hazards that research has not yet identified. These judgments, along with the factors recognized above that the EPA generally considers in each NAAQS review, contribute to his reasoned decision making in this review, as described in section II.B.3 below.

With regard to advice provide by CASAC in the last review as a general matter, we disagree with the commenters' presumption that it is necessary for EPA to address in this review each statement a prior CASAC made in a prior review. The Clean Air Act does not impose such a requirement. We further note that a prior CASAC's advice would be based on review of the prior air quality criteria, exposure/risk analyses and standard, as well as considerations pertinent in the prior review (which may, depending on the issue, differ from the pertinent evidence, information and considerations before a current CASAC). We note, however, that this specific advice from the prior CASAC on the adequacy of the margin of safety was cited by part of the CASAC in the current review. As summarized in the proposal and in section II.B.1.b above, while the prior CASAC advised that the size of the margin of safety provided varied across different standard levels within the range from 70 to 60 ppb that the prior CASAC recommended, it found a level of 70 ppb could be supported by the scientific evidence. Further, the prior CASAC recognized, as summarized in section II.B.1.b above, that with regard to the ''size'' of the margin of safety, the selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment (*Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1161–62; *Mississippi* v. *EPA,* 744 F.3d at 1353; section I.A above). Thus, in reaching his proposed decision, the Administrator explicitly considered the advice provided by the prior CASAC to the extent it was represented in advice from the current CASAC as emphasized by part of the current CASAC (85 FR 49873, August 14, 2020), and he has similarly again considered it reaching his final decision, as described in section II.B.3 below, in light of public comments raising it.

Some commenters also express the view that EPA is using limited data in sensitive population groups as an excuse for not establishing a level at which there is ''an absence of adverse effect'' in sensitive groups. In support of their view, some commenters claim that the EPA has not addressed a statement of the prior CASAC regarding the potential for lung function decrements and respiratory symptoms to occur in people with asthma with exposure to 70 ppb (while at elevated exertion). Contrary to this claim,[125] the EPA considered in the last review the point made by the prior CASAC in the statement highlighted by the commenters. The statement from the prior CASAC that the commenters reference was provided in the CASAC review of a draft PA in the last review, fully considered in completing the final 2014 PA, and, along with the totality of the prior CASAC advice, taken into account in establishing the current primary standard (80 FR 65292, October 26, 2020). It is not necessary for the EPA to address in this review each statement a prior CASAC made in a prior review.

We agree with commenters who express the view that to protect sensitive populations from effects reported in some largely healthy subjects from the 6.6 hour exposure to 73 ppb (with quasi-continuous exercise), the standard should provide protection against somewhat lower exposures. As summarized in section II.B.3 below, this is an objective the Administrator identifies for the standard and, based on the exposure/risk estimates, he finds the standard to provide strong protection from such exposures (and associated risk of such effects). In addition, in highlighting this isolated statement from the last review, the commenters fail to distinguish CASAC advice on the primary standard from consideration of the exposure benchmark for comparison to a multi-hour exposure while engaged in quasi-continuous exercise.

With regard to the prior CASAC's scientific and policy advice on the primary standard,[126] the prior CASAC concluded that the scientific evidence supported a range of standard levels that included 70 ppb, and also recognized the choice of a level within that range to be ''a policy judgment under the statutory mandate of the Clean Air Act'' (85 FR 49873).[127] We further note that the current CASAC concludes in this review that newly available evidence relevant to standard setting does not substantially differ from that available in the last review (Cox, 2020a, Consensus Responses to Charge Questions p. 12; 85 FR 49873, August 14, 2020). As discussed further below, we note that the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels (see *Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1156 n.51, *Mississippi* v. *EPA,* 744 F.3d at 1351), but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

Some commenters also state that the primary NAAQS must be set at a level at which there is an absence of adverse effects in sensitive populations. While the EPA agrees that the NAAQS must be set to protect sensitive populations with an adequate margin of safety, it is well established that the NAAQS are not

consistent with that made by the prior Administrator in establishing the current standard, as seen from the summary of the prior Administrator's judgment in that regard that was summarized in the proposal and that these commenters cite:

Further, while the Administrator recognized the effects documented in the controlled human exposure studies for exposures to 60 ppb to be less severe than those associated with exposures to higher O_3 concentrations, she also recognized there to be limitations and uncertainties in the evidence base with regard to unstudied population groups. As a result, she judged it appropriate for the standard, in providing an adequate margin of safety, to provide some control of exposures at or above the 60 ppb benchmark (80 FR 65345–65346, October 26, 2015). [85 FR 49841, August 14, 2020]

[125] The context for this statement is in considering the benchmark concentrations utilized in the exposure-to-benchmarks analysis of the 2014 HREA and reflecting on responses reported in controlled human exposure studies of healthy subjects exposed for 6.6 hours with quasi-continuous exercise. With regard to the responses reported from exposure to 72 ppb, on average across the exercise periods, the prior CASAC stated its view ''that these effects almost certainly occur in some people, including asthmatics and others with low lung function . . . at levels of 70 ppb and below'' (Frey, 2014b, p. 6).

[126] In their 2014 advice, the prior CASAC concluded by explicitly stating ''our policy advice is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account your judgment regarding the desired margin of safety to protect public health.''

[127] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.''

meant to be zero risk standards. See *Lead Industries* v. *EPA,* 647 F.2d at 1156 n.51; *ATA III,* 283 F. 3d at 360 (''[t]he lack of a threshold concentration below which these pollutants are known to be harmless makes the task of setting primary NAAQS difficult, as EPA must select standard levels that reduce risks sufficiently to protect public health even while recognizing that a zero-risk standard is not possible''); *Mississippi,* 744 F. 3d at 1351 (same); see also id. at 1343 (''[d]etermining what is 'requisite' to protect the 'public health' with an 'adequate' margin of safety may indeed require a contextual assessment of acceptable risk. See *Whitman,* 531 U.S. at 494–95 (Breyer J. concurring)''). As the Court of Appeals for the D.C. Circuit said in reviewing the 2015 O_3 NAAQS, ''the primary standard for a non-threshold pollutant like ozone is not required to produce zero risk, and '[t]he task of determining what standard is 'requisite' to protect the qualitative value of public health or what margin of safety is 'adequate' to protect sensitive subpopulations necessarily requires the exercise of policy judgment.' '' *Murray Energy,* 936 F.3d at 610 (quoting *Mississippi* v. *EPA*).[128] The Administrator's judgments in this review are rooted in his evaluation of the evidence, which reflects the scientific uncertainty as to the O_3 concentrations at which sensitive subpopulations would experience adverse health effects, and his judgments weigh both the risks and the uncertainties. This is a legitimate, and well recognized, exercise of ''reasoned decision-making.'' *ATA III.* 283 F. 3d at 370; see also id. at 370 (''EPA's inability to guarantee the accuracy or increase the precision of the . . . NAAQS in no way undermines the standards' validity. Rather, these limitations indicate only that significant scientific uncertainty remains about the health effects of fine particulate matter at low atmospheric concentration. . . .''); *Mississippi,* 744 F. 3d at 1352–53 (appropriate for EPA to balance scientific uncertainties in determining level of revised O_3 NAAQS).

Exposure/risk Analyses: In expressing the view that the standard should be made more stringent, some commenters disagree with EPA conclusions based on the exposure/risk analyses, and point to other analyses that they state show that a lower standard level (*e.g.* 65 ppb or lower) would avoid important health effects. These commenters' claims of deficiencies with the exposure/risk analyses include claims that the study area selection is not explained, that population size of the study areas analyzed is too small to support conclusions and does not include particular areas; that the analysis does not include adults, and other groups of interest, and that selection of study areas with air quality close to the current standard contributed to underestimates of population exposures. We disagree with these commenters' claims.

With regard to study area selection and population size for the analysis, we note that an exposure and risk analysis based on eight study areas, all of which are major metropolitan areas provides a robust foundation for population exposure estimates. The eight study areas included reflect the full range of air quality and exposure variation expected across major urban areas in the U.S and seven different NOAA climate regions (PA, section 3.4.1).[129] This number of areas (8) and combined population size (more than 45 million in the combined metropolitan areas [PA, Appendix 3D, Table 3D–1]) are much larger than similar analyses in recent NAAQS reviews for other pollutants (*e.g.,* sulfur dioxide [U.S. 2018]), and not that dissimilar to similar analyses in past O_3 NAAQS reviews.[130] Some commenters claim that the exclusion of specific urban areas in which O_3 concentrations are much higher than those analyzed resulted in underestimates of exposure. We disagree with this claim as the air quality analyzed across all study areas was adjusted to just meet the current standard (or alternative scenarios). Thus, an urban area that currently has O_3 concentrations well in exceedance of the current standard would not necessarily have been found to have higher exposure estimates if it were simulated to have air quality just meeting the current standard. Such estimates would, however, have greater uncertainty, which is the reason such study areas as those identified by commenters (*e.g.,* Los Angeles) were excluded. Areas included were those for which only small adjustments were required for the air quality to just meet the current standard (and alternative scenarios), yielding reduced uncertainty (*e.g.,* given the need for larger air quality adjustments to achieve conditions that just meet the current standard) in these estimates compared to those from the 2014 HREA (PA, sections 3.4.1 and 3.4.4, and Appendix 3D). In selecting such areas, however, we considered a number of other characteristics in order to achieve a varied set of study areas, including with regard to air quality patterns.[131] This variation contributed to variation in exposure estimates, even for the same air quality scenario (PA, Appendix 3D, Tables 3D–26, 3D–28 and 3D–30). Thus, in addition to focusing on study areas with ambient air concentrations close to conditions that reflect air quality that just meets the current standard that would be more informative to evaluating the health protection provided by the current standard than areas with much higher (or much lower) concentrations, the approach employed recognizes that capturing an appropriate diversity in study areas and air quality conditions (that reflect the current standard scenario) is an important aspect of the role of the exposure and risk analyses in informing the Administrator's conclusions on the public health protection afforded by the current standard.

Contrary to one commenter's assertion that adults were not included in the exposure assessment, the populations assessed included two adult populations groups: All adults and

[128] The legislative history of the Clean Air Act provides further support for these holdings, as do the statutory deadlines for attainment. See H. Rep. 95–294, 95th Cong. 1st sess. 127, 123 Cong. Rec. S9423 (daily ed. June 10, 1977) (statement of Senator Muskie during the floor debates on the 1977 Amendments that ''there is no such thing as a threshold for health effects. Even at the national primary standard level, which is the health standard, there are health effects that are not protected against.''

[129] Contrary to the commenters' assertion of a lack of explanation for the study areas included in the analyses, the PA describes the study area selection criteria and process, including steps taken to include adequate representation of diverse conditions. As observed in the PA, seven of the eight study areas were also included in the 2014 HREA, and the eighth study area (Sacramento) was newly added in the current review to insure representation of a large city in the southwest (PA, section 3.4.1 and Appendix 3D, section 3D.2.1). Clarification on this point in the final PA was responsive to the only CASAC comment on completeness of the description of study area selection (Cox, 2020a). We disagree with the implication by some commenters that each review's analyses must focus on the same areas. There is no such requirement under the Act, and such a view ignores the need to consider the current information in each review in planning appropriate analyses.

[130] For example, the exposure assessment for the 1997 O_3 NAAQS review included nine urban study areas, for which the combined population simulated was 41.7 million. The exposure assessment for the current review included eight urban study areas with a combined simulated population size of approximately 39 million (PA, p. 3D–96; U.S. EPA, 1996b, p. 76). We additionally note the focus on analysis results in terms of population percentages rather than population counts.

[131] A broad variety of spatial and temporal patterns of O3 concentrations can exist when ambient air concentrations just meet the current standard. These patterns will vary due to many factors including the types, magnitude, and timing of emissions in a study area, as well as local factors, such as meteorology and topography.

adults with asthma.[132] The results for these groups and all of the populations assessed are presented in detail in the PA (PA, Appendix 3D). As described in the PA and proposal, the estimates for adults as a percentage of the study populations were generally lower than those for children. Thus, we focused discussion on the estimates for children, including particularly children with asthma. As recognized by the Administrator in section II.B.3 below, his judgments on the adequacy of protection provided by the current standard takes into account protection provided to the U.S. population, including those population groups at increased risk, which includes children and people of all ages with asthma, among other groups.

Some commenters claimed that the EPA should have separately assessed exposure for certain additional population subgroups, such as children at summer camps, adults with lung impairments other than asthma or outdoor workers. As an initial matter, we recognize appreciably increased uncertainty regarding key aspects of the information necessary for such simulations for all of these groups. Of the three groups, only outdoor workers are identified as an at-risk population in this review (ISA, Table IS–10), and accordingly this group was explicitly considered in designing the exposure analyses.[133] The information available, however, was considered to be too uncertain to produce estimates for this population, as a separate group, with confidence. As described in the PA, important uncertainties exist in generating the simulated activity patterns for this group, including the limited number of CHAD diary days available for outdoor workers, assignment of diaries to proper occupation categories, and in approximating number of days/week and hours/day outdoors, among other pertinent aspects (PA, Appendix 3D, Table 3D–64). We note that these appreciable data limitations and associated uncertainties were also recognized in the 2014 HREA in which a limited sensitivity analyses was conducted for this subgroup. Those limited analyses, conducted for a single area with air quality just meeting the prior 75 ppb standard, indicated that when diaries were selected to mimic exposures that could be experienced by outdoor workers, the percentages of modeled individuals estimated to experience exposures of concern were generally similar to the percentages estimated for children (*i.e.,* using the full database of diary profiles) in the urban study areas and years with the largest exposure estimates (2014 HREA, section 5.4.3.2, Figure 5–14).[134] Accordingly, in this review, in recognition of the data limitations that remain in the current review,[135] outdoor workers were not assessed as a separate population group, and in light of our consideration of conclusions from the sensitivity analyses in the last review, we have generally given primary focus to the estimates for the populations of children.

In summary, we disagree with comments stating that the exposure/risk analyses were deficient and do not provide support for their conclusions. As summarized above, in planning and conducting the exposure/risk analyses, we have appropriately considered issues raised by the commenters, such that the analyses reasonably reflect current understanding, information, tools and methodologies. Further, in presenting the analyses in the PA, we have recognized any associated limitations and uncertainties in an uncertainty characterization that utilized a largely qualitative approach adapted from the World Health Organization approach (and commonly utilized in NAAQS exposure/risk assessments, as discussed in the PA and proposal [85 FR 49857, August 14, 2020]), accompanied by a number of quantitative sensitivity analyses. This characterization and accompanying analyses build on previously conducted work in the 2014 HREA and provide a transparent and explicit recognition of strengths, limitations and uncertainties of the current exposure/risk analysis that were described the PA, considered in the proposal and also in the Administrator's decision described in section II.B.3 below. Thus, the exposure/risk analyses conducted for this review appropriately and soundly reflect current information and methodologies; and we have interpreted their results appropriately in light of any associated limitations and uncertainties.

With regard to other quantitative analyses identified by some commenters and described as showing health impacts that would be avoided by a more stringent standard (*e.g.* with a level of 65 ppb or lower), we note that these analyses utilize epidemiologic study effect estimates as concentration-response functions to generate predictions of the occurrence of health outcomes, primarily mortality, under different air quality conditions (characterized by the metric used in the epidemiologic study).[136] As an initial matter, we note that our understanding of the relationship between O_3 exposures and total mortality is different in this review than it was in the last review, based on the more extensive evidence base now available. As summarized in section II.A.2.a above, and noted earlier in this section, while our conclusion in the last review was that the relationship of O_3 exposure with mortality was likely to be causal, the current evidence base does not support that conclusion because of limited evidence for cardiovascular mortality, which is by far the largest contributor to total mortality. Rather, the EPA has concluded the evidence in

[132] Further, contrary to the implication of one comment, the exposure/risk analyses did not exclude athletes, hikers and others who exercise outdoors, using their full lung capacity, a group the commenter characterizes as at increased risk. In fact, it is just such individuals who are most likely, depending on their locations, to experience exposures of concern due to their high exertion levels. As described in the PA, the comparison to benchmarks analysis identifies the portion of the exposed population whose 7-hour average concentration, while at moderate or greater exertion, is at or above the benchmarks (PA, section 3.4 and Appendix 3D).

[133] With regard to the other two groups, we note the ISA explicitly evaluated evidence for people with the lung disease, COPD, and concluded the evidence was inadequate to determine whether this lung impairment confers increased risk of O_3 related effects (ISA, Table IS–10). With regard to children at summer camp, we note that to the extent that the behaviors of such children (*e.g.,* exercising outdoors) are represented in the CHAD, they are represented among the at-risk populations of children and children with asthma that were simulated in the exposure/risk analyses.

[134] Similarly, the EPA also did not conduct an exposure analysis for outdoor workers in the 2008 review and instead focused on children since it was judged that school aged children presented the greatest likelihood of being outdoors and exposed under moderate exertion averaged over the critical time period based on prior analysis findings. Thus, while as recognized in multiple reviews, outdoor workers are also at risk, the EPA has focused, in past reviews as in the current one, on children, the population group for which the analysis estimates in terms of percentage of population are greatest (PA, section 3.4.2). Accordingly, providing protection for this population group will provide protection for other at-risk populations as well.

[135] In support of their view that estimates should have been derived for outdoor workers, one group of commenters cites a study on research priorities for assessing climate change impacts on outdoor workers (Moda et al., 2019). We note, that other than being focused on outdoor workers and recognizing there to be significant research needed for impacts assessment, this paper has little relevance in this review. The paper is focused on climate change impacts in tropical developing countries with a focus on sub-Saharan Africa and does not discuss exposure modeling of outdoor workers or O_3.

[136] The analyses cited by these commenters include Cromar et al (2019) and OTC (2020). To address these comments, we have provisionally considered the documents, as discussed in I.D above, and found they do not materially change the broad scientific conclusions of the ISA with regard to respiratory effects, or warrant re-opening the air quality criteria for further review (Luben et al., 2020). Further, some of these commenters reference epidemiologic study based risk, analyses in the 2014 HREA.

this review to be suggestive of, but not sufficient to infer, causal relationships of total mortality with short- or long-term O_3 exposure, as summarized in section II.A.2.a above (ISA, Appendix 6). Thus, we do not find the weight the commenter is suggesting we place on predictions of total mortality from the epidemiologic study based risk analyses cited by commenters to appropriately reflect the current evidence base for O_3 and mortality, or the evidence base for O_3 and cardiovascular effects (the primary contributor to mortality in the U.S.).

With regard to estimates of avoided respiratory mortality from the analyses cited by these commenters, we note that, while the epidemiologic studies that are inputs to the quantitative analyses cited by the commenters are part of the evidence base that supports our conclusion of a causal relationship between short-term O_3 exposure and respiratory effects, there are uncertainties inherent in the derivation of estimates of mortality ascribed to O_3 exposures using effect estimates from these studies. For example, in planning for analyses in this review, the IRP recognized several important uncertainties associated with aspects of the O_3 epidemiologic study-based approach used in the 2014 HREA (one of the analyses cited by commenters), and similar to the approach used in other analyses cited by commenters, that the EPA concluded to have a moderate or greater impact on risk estimates (IRP, Appendix 5A). Such uncertainties include complications posed by the presence of co-occurring pollutants or pollutant mixtures, as well as those involving the correlation of population O_3 exposures and ambient air monitor concentrations (including the use of area wide average O_3 concentrations) and uncertainties in the derived concentration-response functions (IRP, Appendix 5A; PA, Appendix 34D, section 3D.1.4). Specifically with regard to the 2014 HREA estimates of respiratory mortality, the EPA has recognized uncertainty about the extent to which mortality estimates based on the long-term metric in Jerrett et al. (2009) (*i.e.,* seasonal average of 1-hour daily maximum concentrations) reflect associations with long-term average O_3 versus repeated occurrences of elevated short-term concentrations; and given potential nonlinearity of the C–R function to reflect a threshold of the mortality response, these estimates should be viewed with caution (IRP, Appendix 5A). Accordingly, the 2014 HREA concluded that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3, primarily because that analysis relies on just one study (Jerrett et al., 2009), and because of the uncertainty in that study about the existence and identification of a potential threshold in the concentration-response function (2014 HREA, section 9.6; 80 FR 65316, October 26, 2015). The other analysis cited by the commenters for predictions of respiratory mortality is also based its estimates on Jerrett et al. (2009). Thus, we find the conclusions regarding uncertainty and low confidence recognized for the 2014 HREA estimates to also apply to the other analysis by commenters and disagree with the conclusions reached by these commenters on this analysis. Further, we do not find that the 2014 HREA or other analyses cited by the commenters, in combination with the full body of evidence currently available, support a conclusion of significant health outcomes for O_3 air quality that meets the current standard.

Long-term Standard Consideration: In support of their view that EPA should establish an additional primary standard that targets long-term exposure, some commenters stated that recent epidemiologic studies indicate causal linkages between long-term exposures and adverse health outcomes, while also suggesting there was support for such a standard in a statement made by the CASAC in reviewing the draft PA. With regard to the epidemiologic studies, these commenters cite several studies published after the literature cut-off date for the ISA [137] that they describe as showing linkages of long-term O_3 exposure to a number of outcomes, including mortality, smokers progression to COPD, hospital admissions for acute respiratory disease syndrome and emergency department visits (Dominici et al., 2019; Seltzer et al., 2020; Limaye and Knowlton, 2020; Dedoussi et al., 2020; Lim et al., 2019; Paulin et al,. 2020; [138] Rhee et al., 2019; Strosnider et al., 2019).[139] We have provisionally considered these ''new'' studies in addressing these comments consistent with section I.D above (Luben et al., 2020). Of the studies focused on mortality that these commenters cite as providing new information in support of a long-term standard, just three represent new evidence related to investigation of associations of long-term O_3 exposure with mortality (Lim et al., 2019) or respiratory morbidity (Paulin et al., 2020 and Rhee et al., 2019).[140] The study by Lim et al. (2019) analyzes associations between long-term O_3 exposure and respiratory mortality in a U.S. population of older adults in the U.S., reporting a positive association with an effect estimate lower than a previously published study included in the ISA. These results contribute to the evidence base for respiratory effects, *e.g.,* with an additional high-quality study of a previously studied population group (Lim et al., 2019) or with studies investigating additional populations and respiratory outcomes (Paulin et al., 2020; Rhee et al., 2019), albeit with limitations,[141] without reducing uncertainties in the evidence base as a whole. These studies are

[137] These commenters also assert that some other studies published after the ISA cut-off date were arbitrarily included in the ISA, citing just a single study (Garcia et al., 2019). Contrary to implication by the commenters, such an occurrence is clearly described in the ISA, which states ''[s]tudies published after the literature cutoff date for this review were also considered if they were submitted in response to the Call for Information or identified in subsequent phases of ISA development . . ., particularly to the extent that they provide new information that affects key scientific conclusions'' (ISA, Appendix 10, p. 10–1).

[138] Although the commenters submitted a document that appears to be an unpublished draft of an earlier manuscript of this paper, to which they assigned a 2019 publication date and a very slightly different title (rather than the published paper, it is the published study, Paulin et al., (2020) that we have provisionally considered (Luben et al., 2020).

[139] Some commenters imply that projections of increasing O_3 concentrations in response to climate change in the future will ''heighten'' long-term O_3 concentrations and chronic exposures and indicate a need for a long-term standard. In making this claim, they cite an analysis of air quality projected in 2045 through 2055 (Nassikas et al., 2020) and an evaluation of the effects of climate change on air quality including O_3 concentrations. (Archer et al., 2019). The former ''new'' study has been provisionally considered and found not to materially affect the broad scientific conclusions regarding the air quality criteria documented in the ISA or to warrant reopening the air quality criteria (Luben et al., 2020) As neither is evaluating health effects associated with air quality under the current standard, we do not find these studies informative to consideration of a need for a long-term standard to protect public health.

[140] Two others (Dedoussi et al 2020; Seltzer et al, 2020) are quantitative assessments that estimate O_3 impacts based on use of effect estimates from previously published studies that are included in the ISA, another (Dominici et al., 2019) is the full technical report from the Health Effects Institute, the main results of which were previously published in studies that are included in the ISA, and a fourth (Limaye and Knowlton., 2020) is commentary on a previously published study that is included in the ISA. One other study cited by the commenters is focused on short-term O_3 exposures, not long-term O_3 exposure as indicated by the commenters (Strosnider et al., 2019)

[141] While studies by Paulin et al. (2020) and Rhee et al. (2019) provide evidence for a novel population sub-group (smokers) or endpoint (*e.g.,* acute respiratory distress syndrome, ARDS), each study has limitations. For example, the cross-sectional design of Paulin et al. (2020) is a major limitation, while limitations associated with Rhee et al. (2019) relate to linking long-term exposure with hospital admissions for ARDS based on exposure timing and the mechanism for acute vs. chronic development of disease, and to power in the study (*e.g.,* very low hospital admission counts per year per ZIP code [Rhee et al., 2019, Table 2]).

generally consistent with the evidence assessed in the ISA, and they do not materially change the broad conclusions in the ISA regarding the scientific evidence.

We additionally note that the O_3 concentrations did not meet the current standard in all locations and time periods analyzed in these three multicity studies. Although two of these studies include some locations across the U.S. in which the current standard was likely met during some portions of the study period, air quality during other time periods of locations in the dataset did not meet the current standard.[142] Further, the multicity effect estimates in these studies do not provide a basis for considering the extent to which O_3 health effect associations are influenced by individual locations with ambient O_3 concentrations low enough to meet the current O_3 standards versus locations with O_3 concentrations that violate this standard. Thus, while these more recent studies may be consistent with the existing evidence base evaluated in the ISA, they do not provide a basis for conclusions regarding whether the O_3 exposures occurring under air quality conditions allowed by the current standard may be eliciting the effects analyzed.

We additionally note that while epidemiologic studies evaluate the relationship between health effects and specific O_3 concentrations during a defined study period and the generally consistent and coherent associations observed in these epidemiologic studies contribute to the causality determinations and conclusions regarding the causal nature of the effect of O_3 exposure on health effects, ''they do not provide information about which averaging times or exposure metrics may be eliciting the health effects under study'' (ISA, section IS.6.1). As noted in the ISA, ''disentangling the effects of short-term ozone exposure from those of long-term ozone exposure (and vice-versa) is an inherent uncertainty in the evidence base,'' as ''the populations included in epidemiologic studies have long-term, variable, and uncharacterized exposures to ozone and other ambient pollutants'' (ISA, section IS.6.1). As summarized in the proposal, however, we have also considered the toxicological studies of effects associated with long-term exposures and note that they involve much higher exposures than those occurring at the current standard (85 FR, 49853, August 14, 2020).

Lastly, we disagree with the commenters' implication that the EPA has not addressed a CASAC recommendation. The commenters appear to be asserting that the CASAC recommended that EPA consider a long-term standard. However, the CASAC did not make such a recommendation (Cox, 2020a). In making this assertion, the commenter cites a comment the CASAC makes with regard to a sentence in the draft PA that is drawn from the Administrator's conclusions section of the 2015 decision. Rather than ignoring this CASAC comment, as asserted by the commenters, we made a revision to that section of the PA (moving the statement from the draft PA to a footnote in the final PA with the objective of retaining an accurate description of a consideration related to that 2015 decision, while lessening the potential for confusion of a 2015 consideration with considerations in the current review).[143] Notwithstanding sentences pertaining to the last review, we note the PA evaluates the information in the current review with regard to the protection offered by the current standard (and that the Administrator considered the PA evaluation, as well as the CASAC advice in his proposed decision [summarized in section II.B.1.c above] as in his final decision below). We further note that the description of the Administrator's conclusion in the last review, which is also summarized in the proposal (and in section II.A.1 above), does not describe health effects associated with long-term average concentrations likely under the current standard.

Further, in considering an implication of the commenters' claim that a ''long-term standard'' is needed in order to provide protection from health effects that may be elicited by long-term exposures to O_3, we note that the impact of standards with short averaging times, such as eight hours, is not limited to reducing short-term exposures. This is because a reduction in magnitude of short-term exposure concentrations (*e.g.,* daily maximum 8-hour concentrations) is also a reduction in exposure to such concentrations over the longer term. For example, a standard, such as the current one, that limits daily maximum 8-hour concentrations to not exceed 70 ppb as a 3-year average of the annual fourth highest value, in addition to limiting the magnitude of concentrations to which a population is exposed in eight hour periods, also limits the frequency to which the population is exposed to such concentrations over the long term. That is, the reduction in frequency of the higher concentrations reduces exposures to such concentrations over the short and long term. Thus, given that, as indicated by the current and established evidence, the O_3 concentrations most likely to contribute to health effects are the higher concentrations, the current standard provides control of exposures to such concentrations over both the short and long term. In light of all of the considerations raised here, we disagree with the commenters assertion of the need for a long-term O_3 standard.

4. Administrator's Conclusions

Having carefully considered the public comments, as discussed above, the Administrator believes that the fundamental scientific conclusions on effects of photochemical oxidants, including O_3, in ambient air that were reached in the ISA and summarized in the PA, and estimates of potential O_3 exposures and risks described in the PA, and summarized above and in sections II.B and II.C of the proposal, remain valid. Additionally, the Administrator believes the judgments he proposed to reach in the proposal (section II.D.3) with regard to the evidence and the quantitative exposure/risk information remain appropriate. Thus, as described below, the Administrator concludes that the current primary O_3 standard provides the requisite protection of the public health with an adequate margin of safety, including for at-risk populations, and should be retained. In considering the adequacy of the current primary O_3 standard, the Administrator has carefully considered the assessment of the available health effects evidence and conclusions contained in the ISA; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA (summarized in sections II.A.2 and II.A.3 above); the advice and recommendations from the CASAC (summarized in section II.B.1.b above); and public comments (discussed in section II.B.2 above and in the separate RTC document).

[142] The studies by Lim et al (2019) and Rhee et al (2019) include zip codes across the entire U.S., while Paulin et al (2020) includes the cities of Baltimore, Maryland, New York City, New York, Los Angeles and San Francisco, California, Ann Arbor, Michigan, Salt Lake City, Utah and Winston-Salem, North Carolina. The study time periods include ten or more years extending from the early 2000s to the late 2010s; a period within which the design values for most of those identified cities and many other U.S. metropolitan areas exceeded the level of the current standard (as seen by the design values presented for those areas during those time periods at *https://www.epa.gov/air-trends/air-quality-design-values*).

[143] In its comments regarding the 2015 statement, the CASAC and its consultants stated that controls that reduce peak O_3 concentrations will not consistently reduce mean O_3 concentrations. We don't disagree with this statement, and we note that we did not make a statement to the contrary in either the proposal or this final decision document.

In the discussion below, the Administrator considers the key aspects of the evidence and exposure/risk estimates important to his judgment regarding the adequacy of protection provided by the current standard. First, the Administrator considers the evidence base on health effects associated with exposure to photochemical oxidants, including O_3, in ambient air. He additionally considers the quantitative exposure and risk estimates developed in this review, including associated limitations and uncertainties, and what they indicate regarding the magnitude of risk, as well as degree of protection from adverse health effects, associated with the current standard. He additionally considers uncertainties in the evidence and the exposure/risk information, as a part of public health judgments that are essential and integral to his decision on the adequacy of protection provided by the standard. Such judgments include public health policy judgments and judgments about the implications of the uncertainties inherent in the scientific evidence and quantitative analyses. The Administrator draws on the PA considerations, and PA conclusions in the current review, taking note of key aspects of the rationale presented for those conclusions. Further, the Administrator considers the advice and conclusions of the CASAC, including particularly its overall agreement that the currently available evidence does not substantially differ from that which was available in the 2015 review when the current standard was established.

As an initial matter, the Administrator recognizes the continued support in the current evidence for O_3 as the indicator for photochemical oxidants (as recognized in section II.D.1 of the proposal). As recognized in the proposal, no newly available evidence has been identified in this review regarding the importance of photochemical oxidants other than O_3 with regard to abundance in ambient air, and potential for health effects, and the ''the primary literature evaluating the health and ecological effects of photochemical oxidants includes ozone almost exclusively as an indicator of photochemical oxidants'' (ISA, p. IS–3). Accordingly, the information relating health effects to photochemical oxidants in ambient air is also focused on O_3. Thus, the Administrator concludes it is appropriate for O_3 to continue to be the indicator for the primary standard for photochemical oxidants.

With regard to the extensive evidence base for health effects of O_3, the Administrator gives particular attention to the longstanding evidence of respiratory effects causally related to short-term O_3 exposures (summarized in section II.A.2.a above). He recognizes that the strongest and most certain evidence for this conclusion, as in the last review, is that from controlled human exposure studies that report an array of respiratory effects in study subjects (largely generally healthy adults) engaged in quasi-continuous or intermittent exercise. He additionally recognizes the supporting experimental animal and epidemiologic evidence. In so doing, he takes note of the epidemiologic evidence of positive associations for increased incidence of hospital admissions and emergency department visits for an array of respiratory outcomes, with the strongest such evidence being for asthma-related outcomes and specifically asthma-related outcomes for children, with short-term O_3 exposures. As a whole, this strong evidence base continues to demonstrate a causal relationship between short-term O_3 exposures and respiratory effects, including in people with asthma. The Administrator also notes the ISA conclusion that the relationship between long-term exposures and respiratory effects is likely to be causal. These conclusions are also consistent with the conclusions in the last review and reflect a general similarity in the underlying evidence base for such effects.

With regard to conclusions regarding the health effects evidence that differ from those in the last review, the Administrator recognizes the new conclusions regarding metabolic effects, cardiovascular effects and mortality (as summarized in section II.A.2.a above; ISA, Table ES–1). As an initial matter, he takes note of the fact that while the 2013 ISA considered the evidence available in the last review sufficient to conclude that the relationships for short-term O_3 exposure with cardiovascular health effects and mortality were likely to be causal, that conclusion is no longer supported by the now more expansive evidence base which the current ISA determines to be suggestive of, but not sufficient to infer, a causal relationship for these health effect categories (ISA, Appendix 4, section 4.1.17; Appendix 6, section 6.1.8). Further, the Administrator recognizes the new ISA determination that the relationship between short-term O_3 exposure and metabolic effects is likely to be causal (ISA, section IS.4.3.3). In so doing, he takes note that the basis for this conclusion is largely experimental animal studies in which the exposure concentrations were well above those in the controlled human exposure studies for respiratory effects as well as above those likely to occur in areas of the U.S. that meet the current standard (as summarized in section II.A.2.c above). Thus, while recognizing the ISA's conclusion regarding this potential hazard of O_3, he also recognizes that the evidence base is largely focused on circumstances of elevated concentrations above those occurring in areas that meet the current standard. In light of these considerations, he judges the current standard to be protective of such circumstances leading him to continue to focus on respiratory effects in his evaluation of whether the current standard provides requisite protection.

With regard to populations at increased risk of O_3-related health effects, the Administrator notes the populations and lifestages identified in the ISA and summarized in section II.A.2.b above. In so doing, he takes note of the longstanding and robust evidence that supports identification of people with asthma as being at increased risk of O_3-related respiratory effects, including specifically asthma exacerbation and associated health outcomes, and also children, particularly due to their generally greater time outdoors while at elevated exertion (PA, section 3.3.2; ISA, sections IS.4.3.1, IS.4.4.3.1, and IS.4.4.4.1, Appendix 3, section 3.1.11). This tendency of children to spend more time outdoors while at elevated exertion than other age groups, including in the summer when O_3 levels may be higher, makes them more likely to be exposed to O_3 in ambient air under conditions contributing to increased dose due to greater air volumes taken into the lungs. Based on these considerations, the Administrator concludes it is appropriate to give particular focus to people with asthma and children, population groups for which the evidence of increased risk is strongest, in evaluating whether the current standard provides requisite protection. He judges that such a focus will also provide protection of other potentially at-risk population groups, identified in the ISA, for which the current evidence is less robust and clear as to the extent and type of any increased risk, and the exposure circumstances that may contribute to it.

With regard to exposures of interest for respiratory effects, the Administrator refers to the controlled human exposure studies of 6.6-hour exposures, with

quasi-continuous exercise,[144] to concentrations ranging from as low as approximately 40 ppb to 120 ppb (as considered in the PA, and summarized in sections II.A.2.c above). He also notes that, as in the last review, these studies, and particularly those that examine exposures from 60 to 80 ppb, are the primary focus of the PA consideration of exposure circumstances associated with O_3 health effects important to the Administrator's judgments regarding the adequacy of the current standard. The Administrator further recognizes that this information on exposure concentrations that have been found to elicit effects in exercising study subjects is unchanged from what was available in the last review.

With regard to the epidemiologic studies of respiratory effects, the Administrator recognizes that, as a whole, these investigations of associations between O_3 and respiratory effects and health outcomes (*e.g.,* asthma-related hospital admission and emergency department visits) provide strong support for the conclusions of causality (as summarized in section II.A.2.a above). He additionally takes note of the PA observation that these studies are generally focused on investigating the existence of relationships between O_3 in ambient air and specific health outcomes and not on detailing the specific exposure circumstances eliciting such effects (PA, section 3.3.3). In so doing, he takes note of the PA conclusions in this regard, including the scarcity of U.S. studies [145] conducted in locations in which and during time periods when the current standard would have been met (as summarized in sections II.A.2.c above).[146] He also recognizes the additional considerations raised in the PA and summarized in section II.A.2.c above regarding information on exposure concentrations in these studies during times and locations that would not have met the current standard, including considerations such as complications in disentangling specific O_3 exposures that may be eliciting effects (PA, section 3.3.3; ISA, p. IS–86 to IS–88). He takes note that such considerations do not lessen the importance of these studies in the evidence base documenting the causal relationship between O_3 and respiratory effects. With regard to his consideration of exposure concentrations associated with O_3 air quality conditions that meet the current standard, based on information cited here and discussed in the PA and section II.B.2.b(ii) above, he judges these studies that are available in the current review to be less informative. Thus, the Administrator agrees with the PA conclusions in consideration of this evidence from controlled human exposure and epidemiologic studies (as assessed in the ISA and summarized in the PA), and in consideration of public comments in section II.B.2.b(ii) above, that the evidence base in this review does not include new evidence of respiratory effects associated with appreciably different exposure circumstances than the evidence available in the last review, including particularly any circumstances that would also be expected to be associated with air quality conditions likely to occur under the current standard. In light of these considerations, he finds it appropriate to focus on the studies of 6.6-hour exposures with quasi-continuous exercise, and particularly on study results for concentrations ranging from 60 to 80 ppb.

In considering the significance of responses documented in these studies and the full evidence base for his purposes in judging implications of the current information on public health protection provided by the current standard, notes that the responses reported from exposures ranging from 60 to 80 ppb are transient and reversible in the study subjects. In so doing, he also notes that these studies are in largely healthy adult subjects, that such data are lacking at these exposure levels for children and people with asthma, and that the evidence indicates that such responses, if repeated or sustained, particularly in people with asthma, pose risks of effects of greater concern, including asthma exacerbation, as cautioned by the CASAC.[147] The Administrator also takes note of statements from the ATS (summarized in section II.A.2.b above), as well as judgments made by the EPA in considering similar effects (and ATS statements) in previous NAAQS reviews (80 FR 65343, October 26, 2015). With regard to the ATS statements, including the one newly available in this review (Thurston et al., 2017), the Administrator recognizes the role of such statements, as described by the ATS, as proposing principles or considerations for weighing the evidence rather than offering ''strict rules or numerical criteria'' (ATS, 2000, Thurston et al., 2017).

The more recent ATS statement is generally consistent with the prior statement (that was considered in the last O_3 NAAQS review) and the attention that statement gives to at-risk or vulnerable population groups, while also broadening the discussion of effects, responses and biomarkers to reflect the expansion of scientific research in these areas. In this way, the most recent statement updates the prior statement, while retaining previously identified considerations, including, for example, its emphasis on consideration of vulnerable populations, thus expanding upon (*e.g.,* with some increased specificity), while retaining core consistency with, the earlier ATS statement (Thurston et al., 2017; ATS, 2000). One example of this increased specificity that was raised in public comments and discussed in section II.B.2 above, is in the discussion of small changes in lung function (in terms of FEV_1) in people with compromised function, such as people with asthma (Thurston et al., 2017). In considering these statements, the Administrator notes that, in keeping with the intent of these statements to avoid specific criteria, the statements, in discussing what constitutes an adverse health effect, do not comprehensively describe all the biological responses raised, *e.g.,* with regard to magnitude, duration or frequency of small pollutant-related changes in lung function. In so doing, he also recognizes the limitations in the current evidence base with regard to our

[144] These studies employ a 6.6-hour protocol that includes six 50-minute periods of exercise at moderate or greater exertion.

[145] Consistent with the evaluation of the epidemiologic evidence of associations between short-term O_3 exposure and respiratory health effects in the ISA, we focus on those studies conducted in the U.S. and Canada, and most particularly in the U.S., to provide a focus on study populations and air quality characteristics that are most relevant to circumstances in the U.S. (PA, p. 3–45).

[146] Among the epidemiologic studies finding a statistically significant positive relationship of short- or long-term O_3 concentrations with respiratory effects, there are no single-city studies conducted in the U.S. in locations with ambient air O_3 concentrations that would have met the current standard for the entire duration of the study. Nor is there a U.S. multicity study for which all cities met the standard for the entire study period. The extent to which reported associations with health outcomes in the resident populations in these studies are influenced by the periods of higher concentrations during times that did not meet the current standard is unknown. These and additional considerations are summarized in section II.A.2.c above and in the PA.

[147] The CASAC noted that ''[a]rguably the most important potential adverse effect of acute ozone exposure in a child with asthma is not whether it causes a transient decrement in lung function, but whether it causes an asthma exacerbation'' and that increases in airway inflammation also have the potential to increase the risk for an asthma exacerbation. The CASAC further cautioned with regard to repeated episodes of such responses, *e.g.,* airway inflammation, indicating that they have the potential to contribute to irreversible reductions in lung function (Cox, 2020a, Consensus Responses to Charge Questions pp. 7–8).

understanding of these aspects of such changes that may be associated with exposure concentrations of interest. Notwithstanding these limitations and associated uncertainties, he takes note of the emphasis of the ATS statement on consideration of individuals with pre-existing compromised function, such as that resulting from asthma (an emphasis which is reiterated and strengthened in the current statement), and agrees that these are important considerations in his judgment on the adequacy of protection provided by the current standard for at-risk populations, as recognized below.

The Administrator recognizes some uncertainty, reflecting limitations in the evidence base, with regard to the exposure levels eliciting effects (as well as the severity of the effects) in some population groups not included in the available controlled human exposure studies, such as children and individuals with asthma. In so doing, the Administrator recognizes that the controlled human exposure studies, primarily conducted in healthy adults, on which the depth of our understanding of O_3-related health effects is based, in combination with the larger evidence base, informs our conceptual understanding of O_3 responses in people with asthma and in children. Aspects of our understanding continue to be limited, however, including with regard to the risk of particular effects and associated severity for these less studied population groups that may be posed by 7-hour exposures with exercise to concentrations as low as 60 ppb that are estimated in the exposure analyses. Collectively, these aspects of the evidence and associated uncertainties contribute to the Administrator's recognition that for O_3, as for other pollutants, the available evidence base in a NAAQS review generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain.

In light of these uncertainties in the evidence, as well as those associated with the exposure and risk analyses, the Administrator notes that, as is the case in NAAQS reviews in general, his decision regarding the primary O_3 standard in this review depends on a variety of factors, including his science policy judgments and public health policy judgments. These factors include judgments regarding aspects of the evidence and exposure/risk estimates, such as judgments concerning his interpretation of the different benchmark concentrations, in light of the available evidence and of associated uncertainties, as well as judgments on the public health significance of the effects that have been observed at the exposures evaluated in the health effects evidence. These judgments are rooted in his interpretation of the evidence, which reflects a continuum of health-relevant exposures, with less confidence and greater uncertainty in the existence of adverse health effects as one considers lower O_3 exposures. The factors relevant to judging the adequacy of the standards also include the interpretation of, and decisions as to the relative weight to place on, different aspects of the results of the exposure and risk assessment for the eight areas studied and the associated uncertainties. Together, factors described here inform the Administrator's judgment about the degree of protection that is requisite to protect public health with an adequate margin of safety, including the health of sensitive groups, and, accordingly, his conclusion that the current standard is requisite to protect public health with an adequate margin of safety.

As in prior O_3 NAAQS reviews, the Administrator considers the exposure estimates developed from modeling exposures to O_3 in ambient air in this review to be critically important to consideration of the potential for exposures and risks of concern under air quality conditions of interest, and consequently important to his judgments on the adequacy of public health protection provided by the current standard. The exposure/risk analysis provides a framework within which to consider implications of the health effects evidence with regard to protection afforded by the current standard. In his consideration of the exposure/risk estimates, the Administrator places greater weight and gives primary attention to the comparison-to-benchmarks analysis. This focus reflects his recognition of multiple factors, including the relatively greater uncertainty associated with the lung function risk estimates compared to the results of the comparison-to-benchmarks analysis. Additionally, he recognizes that, as noted in the PA, the comparison-to-benchmarks analysis provides for characterization of risk for the broad array of respiratory effects documented in the controlled human exposure studies. Accordingly, this analysis facilitates consideration of an array of respiratory effects, including but not limited to lung function decrements. Accordingly, the Administrator focuses primarily on the estimates of exposures at or above different benchmark concentrations that represent different levels of significance of O_3-related effects, both with regard to the array of effects and severity of individual effects. In so doing, he notes that this assures his consideration of the protection provided by the standard from the array of respiratory effects documented in the currently available evidence base.

In considering the public health implications of estimated occurrences of exposures (while at increased exertion) to the three benchmark concentrations (60, 70 and 80 ppb), the Administrator considers the respiratory effects reported in controlled human exposure studies of this range of concentrations (during quasi-continuous exercise). Accordingly, the controlled human exposure study evidence base, as a whole, provides context for consideration of the exposure/risk estimates. The Administrator recognizes the three benchmarks to represent exposure conditions associated with different levels of respiratory response in the subjects studied and to inform his judgments on different levels of risk that might be posed to unstudied members of at-risk populations. The highest benchmark concentration (80 ppb) represents an exposure where multiple controlled human exposure studies involving 6.6-hour exposures during quasi-continuous exercise demonstrate a range of O_3-related respiratory effects including inflammation and airway responsiveness, as well as respiratory symptoms and lung function decrements in healthy adult subjects. Findings for this O_3 exposure include: A statistically significant increase in multiple types of respiratory inflammation indicators in multiple studies; statistically significantly increased airway resistance and responsiveness; statistically significant FEV_1 decrements; and statistically significant increases in respiratory symptoms (Table 1). In one variable exposure study for which this (80 ppb) was the exposure period average concentration, the study subject mean FEV_1 decrement was nearly 8%, with individual decrements of 15% or greater (moderate or greater) in 16% of subjects and decrements of 10% or greater in 32% of subjects (Schelegle et al 2009); the percentages of individual subjects with decrements great than 10 or 15% were lower in other studies for this exposure. The second benchmark (70 ppb) represents an exposure level below the lowest exposures that have reported both statistically significant FEV_1

decrements[148] and increased respiratory symptoms (reported at 73 ppb, Schelegle et al 2009) or statistically significant increases in airway resistance and responsiveness (reported at 80 ppb, Horstman et al., 1990). The lowest benchmark (60 ppb) represents still lower exposure, and a level for which findings from controlled human exposure studies of largely healthy subjects have included: Statistically significant decrements in lung function (with mean decrements ranging from 1.7% to 3.5% across the four studies with average exposures of 60 to 63 ppb[149]), but not respiratory symptoms; and, a statistically significant increase in a biomarker of airway inflammatory response relative to filtered air exposures in one study (Kim et al, 2011).

In turning to the exposure/risk analysis results, the Administrator considers the evidence represented by these benchmarks noting that due to differences among individuals in responsiveness, not all people experiencing such exposures experience a response, such as a lung function decrement, as illustrated by the percentages cited above. Further, among those that experience a response, not all will experience an adverse effect. Accordingly, the Administrator notes that not all people estimated to experience an exposure of 7-hour duration while at elevated exertion above even the highest benchmark would be expected to experience an adverse effect, even members of at-risk populations. With these considerations in mind, he notes that while single occurrences could be adverse for some people, particularly for the higher benchmark concentration where the evidence base is stronger, the potential for adverse response increases with repeated occurrences (as cautioned by the CASAC).[150] In so doing, he also notes that while the exposure/risk analyses provide estimates of exposures of the at-risk population to concentrations of potential concern, they do not provide information on how many of such populations will have an adverse health outcome. Accordingly, in considering the exposure/risk analysis results, while giving due consideration to occurrences of one or more days with an exposure at or above a benchmark, particularly the higher benchmarks, he judges multiple occurrences to be of greater concern than single occurrences.

In this context, the Administrator considers the exposure risk estimates, focusing first on the results for the highest benchmark concentration (80 ppb), which represents an exposure well established to elicit an array of responses in sensitive individuals among study groups of largely healthy adult subjects, exposed while at elevated exertion. Similar to judgments of past Administrators, the current Administrator judges these effects in combination and severity to represent adverse effects for individuals in the population group studied, and to pose risk of adverse effects for individuals in at-risk populations, most particularly people with asthma, as noted above. Accordingly, he judges that the primary standard should provide protection from such exposures. In considering the exposure/risk estimates, he focuses on the results for children, and children with asthma, given the higher frequency of exposures of potential concern for children compared to adults, in terms of percent of the population groups.[151] The exposure/risk estimates indicate more than 99.9% to 100% of children and children with asthma, on average across the three years, to be protected from one or more occasions of exposure at or above this level; the estimate is 99.9% of children with asthma and of all children for the highest year and study area (Table 2). Further, no children in the simulated populations (zero percent) are estimated to be exposed more than once (two or more occasions) in the 3-year simulation to 7-hr concentrations, while at elevated exertion, at or above 80 ppb (Table 2). These estimates indicate strong protection against exposures of at-risk populations that have been demonstrated to elicit a wide array of respiratory responses in multiple studies.

The Administrator next considers the results for the second benchmark concentration (70 ppb), which is just below the lowest exposure concentration (73 ppb) for which a study has reported a combination of a statistically significant increase in respiratory symptoms and statistically significant lung function decrements in sensitive individuals in a study group of largely healthy adult subjects, exposed while at elevated exertion (Schelegle et al., 2009). Recognizing the lack of evidence for people with asthma from studies at 80 ppb and 73 ppb, as well as the emphasis in the ATS statement on the vulnerability of people with compromised respiratory function, such as people with asthma, the Administrator judges it appropriate that the standard protect against exposure, particularly multiple occurrences of exposure, to somewhat lower levels. In so doing, he notes that the exposure/risk estimates indicate more than 99% of children with asthma, and of all children, to be protected from one or more occasions in a year, on average, of 7-hour exposures to concentrations at or above 70 ppb, while at elevated exertion (Table 2). The estimate is 99% of children with asthma for the highest year and study area (Table 2). Further, he notes that 99.9% of these groups are estimated to be protected from two or more such occasions, and 100% from still more occasions. These estimates also indicate strong protection of at-risk populations against exposures similar to those demonstrated to elicit lung function decrements and increased respiratory symptoms in healthy subjects, a response described as adverse by the ATS.

In consideration of the exposure/risk results for the lowest benchmark (60 ppb), the Administrator notes that the lung function decrements in controlled human exposure studies of largely healthy adult subjects exposed while at elevated exertion to concentrations of 60 ppb, although statistically significant, are much reduced from that observed in the next higher studied concentration (73 ppb), both at the mean and individual level, and are not reported to be associated with increased respiratory symptoms in healthy subjects.[152] In light of these results and the transient nature of the responses, the Administrator does not judge these responses to represent adverse effects for generally healthy individuals. However, he further considers these findings specifically with regard to protection of at-risk populations, such as people with asthma. In so doing, he notes that such data are lacking for at-risk groups, such as people with asthma, and considers the evidence and

[148] The study group mean lung function decrement for the 73 ppb exposure was 6%, with individual decrements of 15% or greater (moderate or greater) in about 10% of subjects and decrements of 10% or greater in 19% of subjects. Decrements of 20% or greater were reported in 6.5% of subjects (Schelegle et al., 2009; PA, Table 3–2 and Appendix 3D, Table 3D–20). In studies of 80 ppb exposure, the percent of study subjects with individual FEV_1 decrements of this size ranged up to nearly double this (PA, Appendix 3D, Table 3D–20).

[149] Among subjects in all four of these studies, individual FEV_1 decrements of at least 15% were reported in 3% of subjects, with 7% of subjects reported to have decrements at or above a lower value of 10% (PA, Appendix 3D, Table 3D–20).

[150] For example, for people with asthma, the risk of an asthma exacerbation event may be expected to increase with repeated occurrences of lung function decrements of 10% or 15% as compared to a single occurrence.

[151] This finding relates to children's greater frequency and duration of outdoor activity, as well as their greater activity level while outdoors (PA, section 3.4.3).

[152] The response for the 60 ppb studies is also somewhat lower than that for the 63 ppb study (Table 1; PA, Appendix 3D, Table 3D–20).

comments from the CASAC regarding the need to consider endpoints of particular importance for this population group, such as risk of asthma exacerbation and prolonged inflammation. He takes note of comments from the CASAC (and also noted in the ATS statement) that small lung function decrements in this at-risk group may contribute to a risk of asthma exacerbation, an outcome described by the CASAC as ''arguably the most important potential adverse effect'' of O_3 exposure for a child with asthma. Thus, he judges it important for the standard to provide protection that reduces such risks. However, he recognizes gaps in our ability to predict risk of such events at the low concentrations such as those represented by the lowest benchmark in the exposure/risk analysis. With regard to the inflammatory response he notes the evidence, discussed in section II.B.2 above, indicating the role of repeated occurrences of inflammation in contributing to severity of response. Thus, he finds repeated occurrences of exposure events of potential concern to pose greater risk than single events, leading him to place greater weight to exposure/risk estimates for multiple occurrences.

In light of the uncertainties associated with the lack of controlled human exposure data for people with asthma, particularly with regard to the extent to which the lower exposure concentrations studied in generally healthy adults might be expected to elicit asthmatic responses in this at-risk population, the Administrator notes that the CASAC also recognized this, describing the gap in clinical studies to be a ''key knowledge gap'' important to considerations of margin of safety for the standard. The Administrator further notes that the CAA requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. This approach is consistent with the requirements of the NAAQS provisions of the CAA and with how the EPA and the courts have historically interpreted the Act (summarized in section I.A. above). These provisions require the Administrator to establish primary standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups.[153]

Thus, in this context, and given that the 70 ppb benchmark represents an exposure level somewhat below the lowest exposure concentration for which both statistically significant lung function decrements and increased respiratory symptoms have been reported in largely healthy adult subjects, the Administrator considers the exposure/risk estimates for the third benchmark of 60 ppb to be informative most particularly to his judgments on an adequate margin of safety. In that context, the Administrator turns to the third benchmark concentration (60 ppb). In so doing, he takes note that these estimates indicate more than 96% to more than 99% of children with asthma to be protected from more than one occasion in a year (two or more), on average, of 7-hour exposures to concentrations at or above this level, while at elevated exertion (Table 2). Additionally, the analysis estimates more than 90% of all children, on average across the three years, to be protected from one or more occasions of exposure at or above this level. The Administrator finds this to indicate an appropriate degree of protection from such exposures.

The Administrator additionally takes note of the new finding in this review of evidence of a likely to be causal relationship between O_3 and metabolic effects. In so doing, he notes the lack of evidence that would suggest such effects to be associated with exposures likely to occur with air quality conditions meeting the current standard, as discussed in section II.A.2.c above. Thus, he judges the current standard to provide protection from effects other than respiratory effects, for which the evidence is less certain. Accordingly, the Administrator concludes that the standard does not need to be revised to provide additional protection from such effects.

In reflecting on all of the information currently available, the Administrator considers the extent to which the currently available information might indicate support for a less stringent standard. He recognizes the advice from the CASAC, which generally indicates support for retaining the current standard without revision or for revision to a more stringent level based on additional consideration of the margin of safety for at-risk populations. He notes that the CASAC advice did not convey support for a less stringent standard. He additionally considers the current exposure and risk estimates for the air quality scenario for a design value just above the level of the current standard (at 75 ppb), in comparison to the scenario for the current standard, as summarized in section II.A.3 above. In so doing, he finds the markedly increased estimates of exposures to the higher benchmarks under air quality for a higher standard level to be of concern and indicative of less than the requisite protection (Table 2). Thus, in light of the considerations raised here, including the need for an adequate margin of safety, the Administrator judges that a less stringent standard would not be appropriate.

The Administrator additionally considers whether it would be appropriate to consider a more stringent standard that might be expected to result in reduced O_3 exposures. As an initial matter, he considers the advice from the CASAC. With regard to the CASAC advice, while part of the Committee concluded the evidence supported retaining the current standard without revision, another part of the Committee reiterated advice from the prior CASAC, which while including the current standard level among the range of recommended standard levels, also provided policy advice to set the standard at a lower level. In considering this advice now in this review, as it was raised by part of the current CASAC, the Administrator notes the slight differences of the current exposure and risk estimates from the 2014 HREA estimates for the lowest benchmark, which were those considered by the prior CASAC (Table 4). For example, while the 2014 HREA estimated 3.3 to 10.2% of children, on average, to experience one or more days with an exposures at or above 60 ppb (and as many as 18.9% in a single year), the comparable estimates for the current analyses are lower, particularly at the upper end (3.2 to 8.2% and 10.6%). While the estimates for two or more days with occurrences at or above 60 ppb, on average across the assessment period, are more similar between the two assessments, the current estimate for the single highest year is much lower (9.2 versus 4.3%). The Administrator additionally recognizes the PA finding that the factors contributing to these differences, which includes the use of air quality data reflecting concentrations much closer to the now-current standard than was the case in the 2015 review, also contribute to a reduced

[153] As noted in section I.A above, consideration of such protection is focused on the sensitive group of individuals and not a single person in the sensitive group (see S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 [1970]).

uncertainty in the current estimates, as summarized in section II.A.3 above (PA, sections 3.4 and 3.5). Thus, he notes that the current exposure analysis estimates indicate the current standard to provide appreciable protection against multiple days with a maximum exposure at or above 60 ppb. In the context of his consideration of the adequacy of protection provided by the standard and of the CAA requirement that the standard protect public health, including the health of at-risk populations, with an adequate margin of safety, the Administrator concludes, in light of all of the considerations raised here, that the current standard provides appropriate protection, and that a more stringent standard would be more than requisite to protect public health.

In light of all of the above, including advice from the CASAC, the Administrator finds the current exposure and risk analysis results to describe appropriately strong protection of at-risk populations from exposures associated with O_3-related health effects. Therefore, based on his consideration of the evidence and exposure/risk information, including that related to the lowest exposures studied in controlled human exposure studies, and the associated uncertainties, the Administrator judges that the current standard provides the requisite protection of public health, including an adequate margin of safety, and thus should be retained, without revision. Accordingly, he concludes that a more stringent standard is not needed to provide requisite protection and that the current standard provides the requisite protection of public health under the Act. With regard to key aspects of the specific elements of the standard, the Administrator recognizes the support in the current evidence base for O_3 as the indicator for photochemical oxidants. In so doing, he notes the ISA conclusion that O_3 is the most abundant of the photochemical oxidants in the atmosphere and the one most clearly linked to human health effects. He additionally recognizes the control exerted by the 8-hour averaging time on associated exposures of importance for O_3-related health effects. Lastly, with regard to form and level of the standard, the Administrator takes note of the exposure and risk results as discussed above and the level of protection that they indicate the elements of the current standard to provide. Beyond his recognition of this support in the available information for the elements of the current standard, the Administrator has considered the elements collectively in evaluating the health protection afforded by the current standard. For all of the reasons discussed above, the Administrator concludes that the current primary O_3 standard (in all of its elements) is requisite to protect public health with an adequate margin of safety, including the health of at-risk populations, and thus should be retained, without revision.

C. Decision on the Primary Standard

For the reasons discussed above and taking into account information and assessments presented in the ISA and PA, the advice from the CASAC, and consideration of public comments, the Administrator concludes that the current primary O_3 standard is requisite to protect public health with an adequate margin of safety, including the health of at-risk populations, and is retaining the current standard without revision.

III. Rationale for Decision on the Secondary Standard

This section presents the rationale for the Administrator's decision to retain the current secondary O_3 standard. This rationale is based on the scientific information presented in the ISA, on welfare effects associated with photochemical oxidants including O_3 and pertaining to the presence of these pollutants in ambient air. As summarized in section I.D above, the ISA was developed based on a thorough review of the latest scientific information generally published between January 2011 and March 2018, as well as more recent studies identified during peer review or by public comments on the draft ISA integrated with the information and conclusions from previous assessments (ISA, section IS.1.2 and Appendix 10, section 10.2). The Administrator's rationale also takes into account: (1) The PA evaluation of the policy-relevant information in the ISA and presentation of quantitative analyses of air quality, exposure, and risk; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the ISA and PA at public meetings, and in the CASAC's letters to the Administrator; (3) public comments on the proposed decision; and also (4) the August 2019 decision of the D.C. Circuit remanding the secondary standard established in the last review to the EPA for further justification or reconsideration. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597 (D.C. Cir. 2019).

Within this section, introductory and background information is presented in section III.A. Section III.A.1 summarizes the 2015 establishment of the existing standard, as background for this review. Sections III.A.2 and III.A.3 provide overviews of the currently available welfare effects evidence and current air quality and environmental exposure information, respectively. Section III.B summarizes the basis for the proposed decision (III.B.1), including CASAC advice, discusses public comments on the proposed decision (III.B.2), and presents the Administrator's considerations, conclusions and decision in this review of the secondary standard (III.B.3). The decision is summarized in section III.C.

A. Introduction

As in prior reviews, the general approach to reviewing the current secondary standard is based, most fundamentally, on using the Agency's assessments of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding a secondary standard for photochemical oxidants that is requisite to protect the public welfare from known or anticipated adverse effects associated with the pollutant's presence in the ambient air. The EPA's assessments are primarily documented in the ISA and PA, both of which have received CASAC review and public comment (84 FR 50836, September 26, 2019; 84 FR 58711, November 1, 2019; 84 FR 58713, November 1, 2019; 85 FR 21849, April 20, 2020; 85 FR 31182, May 22, 2020). In bridging the gap between the scientific assessments of the ISA and the judgments required of the Administrator in his decisions on the current standard, the PA evaluates policy implications of the assessment of the current evidence in the ISA and the quantitative air quality, exposure and risk analyses and information documented in the PA. In evaluating the public welfare protection afforded by the current standard, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively.

The final decision on the adequacy of the current secondary standard is a public welfare policy judgment to be made by the Administrator. In reaching conclusions on the standard, the decision draws on the scientific information and analyses about welfare effects, environmental exposure and risks, and associated public welfare significance, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available evidence generally reflects a continuum that includes ambient air exposures at which

scientists generally agree that effects are likely to occur through lower levels at which the likelihood and magnitude of responses become increasingly uncertain. This approach is consistent with the requirements of the provisions of the Clean Air Act related to the review of NAAQS and with how the EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect the public welfare from known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects.

This decision on the secondary O_3 standard also considers the August 2019 decision by the D.C. Circuit and issues raised by the court in its remand of the 2015 standard to the EPA such that the decision in this review incorporates the EPA's response to the court's remand. The opinion issued by the court concluded, in relevant part, that EPA had not provided a sufficient rationale for aspects of its 2015 decision on the secondary standard. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597 (D.C. Cir. 2019). Accordingly, the court remanded that standard to EPA for further justification or reconsideration, particularly in relation to its decision to focus on a 3-year average for consideration of the cumulative exposure for vegetation, in terms of W126, identified as providing requisite public welfare protection, and its decision to not identify a specific level of air quality related to visible foliar injury.[154] Thus, in addition to considering the currently available welfare effects evidence and quantitative air quality, exposure and risk information, the decision described here, and the associated conclusions and judgments, also consider the court's remand. In consideration of the court remand, for example, certain analyses in this review are expanded compared with those conducted in the last review, issues raised in the remand have been discussed, and additional explanation of rationales for conclusions on these points is provided in this review.

1. Background on the Current Standard

As a result of the last O_3 review, completed in 2015, the level of the secondary standard was revised to 0.070 ppm, in conjunction with retaining the indicator, averaging time and form. This revision, establishing the current standard, was based on the scientific evidence and technical analyses available at that time, as well as the Administrator's judgments regarding the available welfare effects evidence, the appropriate degree of public welfare protection for the revised standard, and available air quality information on seasonal cumulative exposures that may be allowed by such a standard (80 FR 65292, October 26, 2015). In establishing this standard, the Administrator considered the extensive welfare effects evidence base compiled from more than fifty years of extensive research on the phytotoxic effects of O_3, conducted both in and outside of the U.S., that documents the impacts of O_3 on plants and their associated ecosystems (U.S. EPA, 1978, 1986, 1996, 2006, 2013). As was established in prior reviews, O_3 can interfere with carbon gain (photosynthesis) and allocation of carbon within the plant, making fewer carbohydrates available for plant growth, reproduction, and/or yield (U.S. EPA, 1996b, pp. 5–28 and 5–29).[155] The 2015 decision drew upon: (1) The available scientific evidence assessed in the 2013 ISA; (2) assessments in the 2014 PA of the most policy-relevant information in the 2013 ISA regarding evidence of adverse effects of O_3 to vegetation and ecosystems, information on biologically-relevant exposure metrics, 2014 welfare REA (WREA) analyses of air quality, exposure, and ecological risks and associated ecosystem services, and staff analyses of relationships between levels of a W126-based exposure index[156] and potential alternative standard levels in combination with the form and averaging time of the existing standard; (3) additional air quality analyses of the W126 index and design values based on the form and averaging time of the existing standard; (4) CASAC advice and recommendations; and (5) public comments received during the development of these documents and on the 2014 proposal (80 FR 65292, October 26, 2015). In addition to reviewing the most recent scientific information as required by the CAA, the 2015 rulemaking also incorporated the EPA's response to the judicial remand of the 2008 secondary O_3 standard in *Mississippi* v. *EPA,* 744 F.3d 1334 (D.C. Cir. 2013) and, in light of the court's decision in that case, explained the Administrator's conclusions as to the level of air quality judged to provide the requisite protection of public welfare from known or anticipated adverse effects.

Across the different types of studies, the strongest evidence for effects from O_3 exposure on vegetation was from controlled exposure studies of many species of vegetation (2013 ISA, p. 1–15). Primary consideration in the decision was given to the studies of O_3 exposures that reduced growth in tree seedlings from which E–R functions of seasonal relative biomass loss (RBL) have been established (80 FR 65385–86, 65389–90, October 26, 2015). The Administrator considered the effects of O_3 on tree seedling growth, as suggested by the CASAC, as a surrogate or proxy for the broader array of vegetation-related effects of O_3, ranging from effects on sensitive species to broader ecosystem-level effects (80 FR 65369, 65406, October 26, 2015). The metric used for quantifying effects on tree seedling growth in the review was RBL, with the evidence base providing robust and established E–R functions for seedlings of 11 tree species (80 FR 65391–92, October 26, 2015; 2014 PA, Appendix 5C).[157] The Administrator used this metric in her judgments on O_3 effects on the public welfare. In this context, exposure was evaluated in terms of the W126 cumulative seasonal

[154] The EPA's decision not to use a seasonal W126 index as the form and averaging time of the secondary standard was also challenged in this case, but the court did not reach a decision on that issue, concluding that it lacked a basis to assess the EPA's rationale on this point because the EPA had not yet fully explained its focus on a 3-year average W126 in its consideration of the standard. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 618 (D.C. Cir. 2019).

[155] In addition to concluding there to be causal relationships between O_3 and visible foliar injury, reduced vegetation growth, reduced productivity, reduced growth and yield of agricultural crops, and alteration of below-ground biogeochemical cycles, the 2013 ISA also concluded there likely to be a causal relationships between O_3 and reduced carbon sequestration in terrestrial ecosystems, alteration of terrestrial ecosystem water cycling and alteration of terrestrial community composition (2013 ISA, p. lxviii and Table 9–19). The 2013 ISA also found there to be a causal relationship between changes in tropospheric O_3 concentrations and radiative forcing, and likely to be a causal relationship between tropospheric O_3 concentrations and effects on climate as quantified through surface temperature response (2013 ISA, section 10.5).

[156] The W126 index is a cumulative seasonal metric described as the sigmoidally weighted sum of all hourly O_3 concentrations during a specified daily and seasonal time window, with each hourly O_3 concentration given a weight that increases from zero to one with increasing concentration (80 FR 65373–74, October 26, 2015). The units for W126 index values are ppm-hours (ppm-hrs).

[157] These functions for RBL estimate the reduction in a year's growth as a percentage of that expected in the absence of O_3 (2013 ISA, section 9.6.2; 2014 WREA, section 6.2).

exposure index, an index supported by the evidence in the 2013 ISA for this purpose and that was consistent with advice from the CASAC (2013 ISA, section 9.5.3, p. 9–99; 80 FR 65375, October 26, 2015).

The 2015 decision was a public welfare policy judgment made by the Administrator, that drew upon the available scientific evidence for O_3-attributable welfare effects and on quantitative analyses of exposures and public welfare risks, as well as judgments about the appropriate weight to place on the range of uncertainties inherent in the evidence and analyses. Included in this decision were judgments on the weight to place on the evidence of specific vegetation-related effects estimated to result across a range of cumulative seasonal concentration-weighted O_3 exposures; on the weight to give associated uncertainties, including uncertainties of predicted environmental responses (based on experimental study data); variability in occurrence of the specific effects in areas of the U.S., especially in areas of particular public welfare significance; and on the extent to which such effects in such areas may be considered adverse to public welfare. For example, in considering the public welfare protection provided by the then-existing standard, the Administrator gave primary consideration to an analysis of cumulative seasonal exposures in or near Class I areas,[158] which are lands that Congress set aside for specific uses intended to provide benefits to the public welfare, including lands that are to be protected so as to conserve the scenic value and the natural vegetation and wildlife within such areas, and to leave them unimpaired for the enjoyment of future generations.[159] The decision additionally recognized that states, tribes and public interest groups also set aside areas that are intended to provide similar benefits to the public welfare for residents on those lands, as well as for visitors to those areas (80 FR 65390, October 26, 2015). In recognizing that her judgments regarding effects that are adverse to the public welfare consider the intended use of the natural resources and ecosystems affected, the Administrator utilized the RBL as a quantitative tool within a larger framework of considerations pertaining to the public welfare significance of O_3 effects (80 FR 65389, October 26, 2015; 73 FR 16496, March 27, 2008).

In the Administrator's consideration of the adequacy of public welfare protection afforded by the existing standard, she gave particular attention to the air quality analysis for Class I areas that estimated cumulative exposures, in terms of 3-year average W126 index values, at and above 19 ppm-hrs, to have occurred under the standard in nearly a dozen areas distributed across two NOAA climatic regions of the U.S (80 FR 65385–86, October 26, 2015). The Administrator took note of these occurrences of exposures in Class I areas during periods when the existing standard was met, for which the associated estimates of growth effects across the species with E–R functions extend above a magnitude considered to be ''unacceptably high'' by the CASAC (80 FR 65385–65386, 65389–65390, October 26, 2015).[160] Based on this analysis and the considerations summarized above, including consideration of CASAC advice and public comment, the Administrator concluded that the protection afforded by the then-existing standard was not sufficient and that the standard needed to be revised to provide additional protection from known and anticipated adverse effects to public welfare, related to effects on sensitive vegetation and ecosystems, most particularly those occurring in Class I areas, and also in other areas set aside by states, tribes and public interest groups to provide similar benefits to the public welfare. In so doing, she further noted that a revised standard would provide increased protection for other growth-related effects, including relative yield loss (RYL) of crops, reduced carbon storage, and types of effects for which it is more difficult to determine public welfare significance, as well as other welfare effects of O_3, such as visible foliar injury [161] (80 FR 65390, October 26, 2015).

In light of the judicial remand of the 2008 secondary O_3 standard referenced above, the 2015 decision on selection of a revised secondary standard first considered the available evidence and quantitative analyses in the context of an approach for considering and identifying public welfare objectives for the revised standard (80 FR 65403–65408, October 26, 2015). In light of the extensive evidence base of O_3 effects on vegetation and associated terrestrial ecosystems, the Administrator focused on protection against adverse public welfare effects of O_3-related effects on vegetation, giving particular attention to such effects in natural ecosystems, such as those in areas with protection designated by Congress, and areas similarly set aside by states, tribes and public interest groups, with the intention of providing benefits to the public welfare for current and future generations.[162]

In reaching a conclusion on the amount of public welfare protection from the presence of O_3 in ambient air that is appropriate to be afforded by a revised secondary standard, the Administrator gave particular consideration to the following: (1) The nature and degree of effects of O_3 on vegetation, including her judgments as to what constitutes an adverse effect to the public welfare; (2) the strengths and limitations of the available and relevant information; (3) comments from the public on the Administrator's proposed decision, including comments related to identification of a target level of protection; and (4) the CASAC's views regarding the strength of the evidence and its adequacy to inform judgments on public welfare protection. The Administrator recognized that such judgments should neither overstate nor understate the strengths and limitations of the evidence and information nor the appropriate inferences to be drawn as to risks to public welfare, and that the choice of the appropriate level of protection is a public welfare policy judgment entrusted to the Administrator under the CAA taking into account both the available evidence and the uncertainties (80 FR 65404–05, October 26, 2015).[163]

[158] Areas designated as Class I include all international parks, national wilderness areas which exceed 5,000 acres in size, national memorial parks which exceed 5,000 acres in size, and national parks which exceed 6,000 acres in size, provided the park or wilderness area was in existence on August 7, 1977. Other areas may also be Class I if designated as Class I consistent with the CAA.

[159] This emphasis on such lands was consistent with a similar emphasis in the 2008 review of the standard (73 FR 16485, March 27, 2008).

[160] The Administrator focused on the median RBL estimate across the eleven tree species for which robust established E–R functions were available and took note of the CASAC's consideration of RBL estimates presented in the 2014 draft PA, in which it characterized an estimate of 6% RBL in the median studied species as being ''unacceptably high,'' (Frey, 2014b).

[161] As described in the ISA, ''[t]ypical types of visible injury to broadleaf plants include stippling, flecking, surface bleaching, bifacial necrosis, pigmentation (*e.g.,* bronzing), and chlorosis or premature senescence'' and ''[t]ypical visible injury symptoms for conifers include chlorotic banding, tip burn, flecking, chlorotic mottling, and premature senescence of needles'' (ISA, Appendix 8, p. 8–13).

[162] The Administrator additionally recognized that providing protection for this purpose will also provide a level of protection for other vegetation that is used by the public and potentially affected by O_3 including timber, produce grown for consumption, and horticultural plants used for landscaping (80 FR 65403, October 26, 2015).

[163] The CAA does not require that a secondary standard be protective of all effects associated with a pollutant in the ambient air but rather those known or anticipated effects judged adverse to the public welfare (CAA section 109).

With regard to the extensive evidence of welfare effects of O_3, including visible foliar injury and crop RYL, the RBL information available for seedlings of a set of 11 tree species was judged to be more useful (particularly in a role as surrogate for the broader array of vegetation-related effects) in informing judgments regarding the nature and severity of effects associated with different air quality conditions and associated public welfare significance (80 FR 65405–06, October 26, 2015). With regard to visible foliar injury, while the Administrator recognized the potential for this effect to affect the public welfare in the context of affecting value ascribed to natural forests, particularly those afforded special government protection, she also recognized limitations in the available information that might inform consideration of potential public welfare impacts related to this vegetation effect noting the significant challenges in judging the specific extent and severity at which such effects should be considered adverse to public welfare (80 FR 65407, October 26, 2015).[164] Similarly, while O_3-related growth effects on agricultural and commodity crops had been extensively studied and robust E–R functions developed for a number of species, the Administrator found this information less useful in informing her judgments regarding an appropriate level of public welfare protection (80 FR 65405, October 26, 2015).[165] Thus, and in light of the extensive evidence base in this regard, the Administrator focused on the information related to trees and growth impacts in identifying the public welfare objectives for the revised secondary standard.

Accordingly, consideration of the appropriate public welfare protection objective for a revised standard focused on the estimates of tree seedling growth impacts (in terms of RBL) for a range of W126 index values, developed from the E–R functions for 11 tree species (80 FR 65391–92, Table 4, October 26, 2015). The Administrator also incorporated into her considerations the broader evidence base associated with forest tree seedling biomass loss, including other less quantifiable effects of potentially greater public welfare significance. That is, in drawing on these RBL estimates, the Administrator was not simply making judgments about a specific magnitude of growth effect in seedlings that would be acceptable or unacceptable in the natural environment. Rather, though mindful of associated uncertainties, the Administrator used the RBL estimates as a surrogate or proxy for consideration of the broader array of related vegetation-related effects of potential public welfare significance, which included effects on individual species and extending to ecosystem-level effects (80 FR 65406, October 26, 2015). This broader array of vegetation-related effects included those for which public welfare implications are more significant but for which the tools for quantitative estimates were more uncertain.

In using the RBL estimates as a proxy, the Administrator focused her attention on a revised standard that would generally limit cumulative exposures to those for which the median RBL estimate for seedlings of the 11 species with robust and established E–R functions would be somewhat below 6% (80 FR 65406–07, October 26, 2015). In so doing, she noted that the median RBL estimate was 6% for a cumulative seasonal W126 exposure index of 19 ppm-hrs (80 FR 65391–92, Table 4, October 26, 2015).[166] Given the information on median RBL at different W126 exposure levels, using a 3-year cumulative exposure index for assessing vegetation effects,[167] the potential for single-season effects of concern, and CASAC comments on the appropriateness of a lower value for a 3-year average W126 index, the Administrator concluded it was appropriate to identify a standard that would restrict cumulative seasonal exposures to 17 ppm-hrs or lower, in terms of a 3-year W126 index, in nearly all instances (80 FR 65407, October 26, 2015). Based on such information, available at that time, to inform consideration of vegetation effects and their potential adversity to public welfare, the Administrator additionally judged that the RBL estimates associated with marginally higher exposures in isolated, rare instances were not indicative of effects that would be adverse to the public welfare, particularly in light of variability in the array of environmental factors that can influence O_3 effects in different systems and uncertainties associated with estimates of effects associated with this magnitude of cumulative exposure in the natural environment (80 FR 65407, October 26, 2015).

Using these objectives, the Administrator's decision regarding a revised standard was based on extensive air quality analyses that included the most recently available data (monitoring year 2013) and extended back more than a decade (80 FR 65408, October 26, 2015; Wells, 2015). These analyses evaluated the cumulative seasonal exposure levels in locations meeting different alternative levels for a standard of the existing form and averaging time. Based on these analyses, the Administrator judged that the desired level of public welfare protection, considered in terms of cumulative exposure (quantified as the W126 index), could be achieved by a standard with a revised level in combination with the existing form and averaging time (80 FR 65408, October 26, 2015).

In the most recent period of air quality data (2011–2013), across the more than 800 monitor locations meeting the existing standard (with its level of 75 ppb), the 3-year average W126 index values were above 17 ppm-hrs in 25 sites distributed across different NOAA climatic regions, and

[164] These limitations included the lack of established E–R functions that would allow prediction of visible foliar injury severity and incidence under varying air quality and environmental conditions, a lack of consistent quantitative relationships linking visible foliar injury with other O_3-induced vegetation effects, such as growth or related ecosystem effects, and a lack of established criteria or objectives relating reports of foliar injury with public welfare impacts (80 FR 65407, October 26, 2015).

[165] With respect to commercial production of commodities, the Administrator noted the difficulty in discerning the extent to which O_3-related effects on commercially managed vegetation are adverse from a public welfare perspective, given that the extensive management of such vegetation (which, as the CASAC noted, may reduce yield variability) may also to some degree mitigate potential O_3-related effects. Management practices are highly variable and are designed to achieve optimal yields, taking into consideration various environmental conditions. Further, changes in yield of commercial crops and commercial commodities, such as timber, may affect producers and consumers differently, complicating the assessment of overall public welfare effects still further (80 FR 65405, October 26, 2015).

[166] When stated to the first decimal place, the median RBL was 6.0% for a cumulative seasonal W126 exposure index of 19 ppm-hrs. For 18 ppm-hrs, the median RBL estimate was 5.7%, which rounds to 6%, and for 17 ppm-hrs, the median RBL estimate was 5.3%, which rounds to 5% (80 FR 65407, October 26, 2015).

[167] Based on a number of considerations, the Administrator recognized greater confidence in judgments related to public welfare impacts based on a 3-year average metric than a single-year metric, and consequently concluded it to be appropriate to use a seasonal W126 index averaged across three years for judging public welfare protection afforded by a revised secondary standard. For example, she recognized uncertainties associated with interpretation of the public welfare significance of effects resulting from a single-year exposure, and that the public welfare significance of effects associated with multiple years of critical exposures are potentially greater than those associated with a single year of such exposure. She additionally concluded that use of a 3-year average metric could address the potential for adverse effects to public welfare that may relate to shorter exposure periods, including a single year (80 FR 65404, October 26, 2015).

above 19 ppm-hrs at nearly half of these sites, with some well above (Wells, 2015). In comparison, among the more than 500 sites meeting an alternative standard of 70 ppb across 46 of the 50 states, there were no occurrences of a W126 value above 17 ppm-hrs and fewer than five occurrences that equaled 17 ppm-hrs (Wells, 2015 and associated dataset [document identifier, EPA–HQ–OAR–2008–0699–4325]). For the full air quality dataset (extending back to 2001), among the nearly 4000 instances where a monitoring site met a standard level of 70 ppb, the Administrator noted that there was only ''a handful of isolated occurrences'' of 3-year W126 index values above 17 ppm-hrs, ''all but one of which were below 19 ppm-hrs'' (80 FR 65409, October 26, 2015). The Administrator concluded that that single value of 19.1 ppm-hrs (just equaling 19, when rounded), observed at a monitor for the 3-year period of 2006–2008, was reasonably regarded as an extremely rare and isolated occurrence, and, as such, it was unclear whether it would recur, particularly as areas across the U.S. took further steps to reduce O_3 to meet revised primary and secondary standards. Further, based on all of the then available information, as noted above, the Administrator did not judge RBL estimates associated with marginally higher exposures in isolated, rare instances to be indicative of adverse effects to the public welfare. The Administrator concluded that a standard with a level of 70 ppb and the existing form and averaging time would be expected to limit cumulative exposures, in terms of a 3-year average W126 exposure index, to values at or below 17 ppm-hrs, in nearly all instances, and accordingly, to eliminate or virtually eliminate cumulative exposures associated with a median RBL of 6% or greater (80 FR 65409, October 26, 2015). Thus, using RBL as a proxy in judging effects to public welfare, the Administrator judged that such a standard with a level of 70 ppb would provide the requisite protection from adverse effects to public welfare by limiting cumulative seasonal exposures to 17 ppm-hrs or lower, in terms of a 3-year W126 index, in nearly all instances, and decided to revise the standard level to 70 ppb.

In summary, the Administrator judged that the revised standard would protect natural forests in Class I and other similarly protected areas against an array of adverse vegetation effects, most notably including those related to effects on growth and productivity in sensitive tree species. The Administrator additionally judged that the revised standard would be sufficient to protect public welfare from known or anticipated adverse effects. This judgment by the Administrator appropriately recognized that the CAA does not require that standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects. Thus, based on the conclusions drawn from the air quality analyses which demonstrated a strong, positive relationship between the 8-hour and W126 metrics and the findings that indicated the significant amount of control provided by the fourth-high metric, the evidence base of O_3 effects on vegetation and her public welfare policy judgments, as well as public comments and CASAC advice, the Administrator decided to retain the existing form and averaging time and revise the level to 0.070 ppm, judging that such a standard would provide the requisite protection to the public welfare from any known or anticipated adverse effects associated with the presence of O_3 in ambient air (80 FR 65409–10, October 26, 2015).

2. Overview of Welfare Effects Information

The information summarized here is an overview of the scientific assessment of the welfare effects evidence available in this review; this assessment is documented in the ISA and its policy implications are further discussed in the PA. As in past reviews, the welfare effects evidence evaluated in the ISA for O_3 and related photochemical oxidants is focused on O_3 (ISA, p. IS–3). Ozone is the most prevalent photochemical oxidant present in the atmosphere and the one for which there is a very large, well-established evidence base of its health and welfare effects (ISA, p. IS–3). Thus, the current welfare effects evidence and the Agency's review of the evidence, including the evidence newly available in this review,[168] continues to focus on O_3. The subsections below briefly summarize the following aspects of the evidence: the nature of O_3-related welfare effects, the potential public welfare implications, and exposure concentrations associated with effects.

a. Nature of Effects

The welfare effects evidence base available in the current review includes more than sixty years of extensive research on the phytotoxic effects of O_3 and subsequent effects on associated ecosystems (1978 AQCD, 1986 AQCD, 1996 AQCD, 2006 AQCD, 2013 ISA, 2020 ISA). As described in past reviews, O_3 can interfere with carbon gain (photosynthesis) and allocation of carbon within the plant, making fewer carbohydrates available for plant growth, reproduction, and/or yield (2013 ISA, p. 1–10; 1996 AQCD, pp. 5–28 and 5–29). As described in the 2013 ISA, the strongest evidence for effects from O_3 exposure on vegetation is from controlled exposure studies, which ''have clearly shown that exposure to O_3 is causally linked to visible foliar injury, decreased photosynthesis, changes in reproduction, and decreased growth'' in many species of vegetation (2013 ISA, p. 1–15). Such effects at the plant scale can also be linked to an array of effects at larger spatial scales (and higher levels of biological organization), with the evidence available in the last review indicating that ''O_3 exposures can affect ecosystem productivity, crop yield, water cycling, and ecosystem community composition'' (2013 ISA, p. 1–15, Chapter 9, section 9.4). Beyond its effects on plants, the 2013 ISA also recognized O_3 in the troposphere as a major greenhouse gas (ranking behind carbon dioxide and methane in importance), with associated radiative forcing and effects on climate, and recognized the accompanying ''large uncertainties in the magnitude of the radiative forcing estimate . . . making the impact of tropospheric O_3 on climate more uncertain than the effect of the longer-lived greenhouse gases'' (2013 ISA, sections 10.3.4 and 10.5.1 [p. 10–30]).

The evidence newly available in this review supports, sharpens and expands somewhat on the conclusions reached in the last review (ISA, Appendices 8 and 9). Consistent with the evidence in the last review, the currently available evidence describes an array of O_3 effects on vegetation and related ecosystem effects, as well as the role of O_3 in radiative forcing and subsequent climate-related effects. The ISA concludes there to be causal relationships between O_3 and visible foliar injury,[169] reduced vegetation growth and reduced plant reproduction,[170] as well as reduced

[168] More than 1600 studies are newly available and considered in the ISA, including nearly 600 studies on welfare effects (ISA, Appendix 10, Figure 10–2).

[169] Evidence continues to indicate that ''visible foliar injury usually occurs when sensitive plants are exposed to elevated ozone concentrations in a predisposing environment,'' with a major factor for such an environment being the amount of soil moisture available to the plant (ISA, Appendix 8, p. 8–23; 2013 ISA, section 9.4.2).

[170] The 2013 ISA did not include a separate causality determination for reduced plant reproduction. Rather, it was included with the

yield and quality of agricultural crops, reduced productivity in terrestrial ecosystems, alteration of terrestrial community composition,[171] and alteration of belowground biogeochemical cycles (ISA, section IS.5). The current ISA also concludes there likely to be a causal relationship between O_3 and alteration of ecosystem water cycling, reduced carbon sequestration in terrestrial ecosystems, and with increased tree mortality (ISA, section IS.5). Additionally, evidence newly available in this review augments more limited previously available evidence related to insect interactions with vegetation, contributing to the ISA conclusion that the evidence is sufficient to infer that there are likely to be causal relationships between O_3 exposure and alteration of plant-insect signaling (ISA, Appendix 8, section 8.7) and of insect herbivore growth and reproduction (ISA, Appendix 8, section 8.6). Thus, conclusions reached in the last review continue to be supported by the current evidence base and conclusions are also reached in a few new areas based on the now expanded evidence.

As in the last review, the strongest evidence and the associated findings of causal or likely causal relationships with O_3 in ambient air, and the quantitative characterizations of relationships between O_3 exposure and occurrence and magnitude of effects are for vegetation effects. Visible foliar injury has long been used as a bioindicator of O_3 exposure, although it is not always a reliable indicator of other negative effects on vegetation (ISA, sections IS.5.1.2 and 8.2). Effects of O_3 on physiology of individual plants at the cellular level, such as through photosynthesis and carbon allocation, can impact plant growth and reproduction (ISA, section IS.5.1.2). The scales of these effects range from the individual plant scale to the ecosystem scale, with potential for impacts on the public welfare (as discussed in section III.A.2.b below). The effects of O_3 on plants and plant populations have implications for ecosystems. Effects at the ecosystem scale include reduced terrestrial productivity and carbon storage, and altered terrestrial community composition, as well as impacts on ecosystem functions, such as belowground biogeochemical cycles and ecosystem water cycling (ISA, Appendix 8, sections 8.11 and 8.9).

Ozone welfare effects also extend beyond effects on vegetation and associated biota due to it being a major greenhouse gas and radiative forcing agent.[172] The current evidence, augmented since the 2013 ISA, continues to support a causal relationship between the global abundance of O_3 in the troposphere and radiative forcing, and a likely causal relationship between the global abundance of O_3 in the troposphere and effects on temperature, precipitation, and related climate variables[173] (ISA, section IS.5.2 and Appendix 9; Myhre et al., 2013). Uncertainty in the magnitude of radiative forcing estimated to be attributed to tropospheric O_3 contributes to the relatively greater uncertainty associated with climate effects of tropospheric O_3 compared to such effects of the well mixed greenhouse gases, such as carbon dioxide and methane (ISA, section IS.6.2.2).

Lastly, the evidence regarding tropospheric O_3 and UV–B shielding (shielding of ultraviolet radiation at wavelengths of 280 to 320 nanometers) was evaluated in the 2013 ISA and determined to be inadequate to draw a causal conclusion (2013 ISA, section 10.5.2). The current ISA concludes there to be no new evidence since the 2013 ISA relevant to the question of UV–B shielding by tropospheric O_3 (ISA, IS.1.2.1 and Appendix 9, section 9.1.3.4).

b. Public Welfare Implications

The secondary standard is to ''specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator . . . is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air'' (CAA, section 109(b)(2)). As recognized in prior reviews of secondary standards, the secondary standard is not meant to protect against all known or anticipated O_3-related welfare effects, but rather those that are judged to be adverse to the public welfare, and a bright line determination of adversity is not required in judging what is requisite (78 FR 3212, January 15, 2013; 80 FR 65376, October 26, 2015; see also 73 FR 16496, March 27, 2008). The significance of each type of welfare effect with regard to potential effects on the public welfare depends on the type and severity of effects, as well as the extent of such effects on the affected environmental entity, and on the societal use of the affected entity and the entity's significance to the public welfare. Such factors have been considered in the context of judgments and conclusions made in some prior reviews regarding public welfare effects. For example, judgments regarding public welfare significance in the last two O_3 NAAQS decisions gave particular attention to O_3 effects in areas with special federal protections (such as Class I areas), and lands set aside by states, tribes and public interest groups to provide similar benefits to the public welfare (73 FR 16496, March 27, 2008; 80 FR 65292, October 26, 2015).[174] In the 2015 review, the EPA recognized the ''clear public interest in and value of maintaining these areas in a condition that does not impair their intended use and the fact that many of these lands contain O_3-sensitive species'' (73 FR 16496, March 27, 2008).

Judgments regarding effects on the public welfare can depend on the intended use for, or service (and value) of, the affected vegetation, ecological receptors, ecosystems and resources and the importance of that use to the public welfare (73 FR 16496, March 27, 2008; 80 FR 65377, October 26, 2015). Uses or services provided by areas that have been afforded special protection can flow in part or entirely from the vegetation that grows there. Ecosystem services range from those directly related to the natural functioning of the ecosystem to ecosystem uses for human recreation or profit, such as through the production of lumber or fuel (Costanza et al., 2017; ISA, section IS.5.1). Services of aesthetic value and outdoor recreation depend, at least in part, on

conclusion of a causal relationship with reduced vegetation growth (ISA, Table IS–12).

[171] The 2013 ISA had concluded alteration of terrestrial community composition to be likely causally related to O_3 based on the then available information (ISA, Table IS–12).

[172] Radiative forcing is a metric used to quantify the change in balance between radiation coming into and going out of the atmosphere caused by the presence of a particular substance (ISA, Appendix 9, section 9.1.3.3).

[173] Effects on temperature, precipitation, and related climate variables were referred to as ''climate change'' or ''effects on climate'' in the 2013 ISA (ISA, p. IS–82; 2013 ISA, pp. 1–14 and 10–31).

[174] For example, the fundamental purpose of parks in the National Park System ''is to conserve the scenery, natural and historic objects, and wild life in the System units and to provide for the enjoyment of the scenery, natural and historic objects, and wild life in such manner and by such means as will leave them unimpaired for the enjoyment of future generations'' (54 U.S.C. 100101). Additionally, the Wilderness Act of 1964 defines designated ''wilderness areas'' in part as areas ''protected and managed so as to preserve [their] natural conditions'' and requires that these areas ''shall be administered for the use and enjoyment of the American people in such manner as will leave them unimpaired for future use and enjoyment as wilderness, and so as to provide for the protection of these areas, [and] the preservation of their wilderness character . . .'' (16 U.S.C. 1131(a) and (c)). Other lands that benefit the public welfare include national forests which are managed for multiple uses including sustained yield management in accordance with land management plans (see 16 U.S.C. 1600(1)–(3); 16 U.S.C. 1601(d)(1)).

the perceived scenic beauty of the environment. Additionally, public surveys have indicated that Americans rank as very important the existence of resources, the option or availability of the resource and the ability to bequest or pass it on to future generations (Cordell et al., 2008).

The different types of O_3 effects on vegetation recognized in section III.A.2.a above differ with regard to aspects important to judging their public welfare significance. For example, in the case of effects on crop yield, such judgments may consider aspects such as the heavy management of agriculture in the U.S., while judgments for other categories of effects may generally relate to considerations regarding natural areas, including specifically those areas that are not managed for harvest. In this context, it may be important to consider that O_3 effects on tree growth and reproduction could, depending on severity, extent and other factors, lead to effects on a larger scale including reduced productivity, altered forest and forest community (plant, insect and microbe) composition, reduced carbon storage and altered ecosystem water cycling (ISA, section IS.5.1.8.1; 2013 ISA, Figure 9–1, sections 9.4.1.1 and 9.4.1.2). For example, the composition of vegetation or of terrestrial community composition can be affected through O_3 effects on growth and reproductive success of sensitive species in the community, with the extent of compositional changes dependent on factors such as competitive interactions (ISA, section IS.5.1.8.1; 2013 ISA, sections 9.4.3 and 9.4.3.1). Impacts on some of these characteristics (*e.g.,* forest or forest community composition) may be considered of greater public welfare significance when occurring in Class I or other protected areas, due to value for particular services that the public places on such areas.

Agriculture and silviculture provide ecosystem services with clear public welfare benefits. With regard to agriculture-related effects of O_3, however, there are complexities in this consideration related to areas and plant species that are heavily managed to obtain a particular output (such as commodity crops or commercial timber production). In light of this, the degree to which O_3 impacts on agriculturally important vegetation would impair the intended use at a level that might be judged adverse to the public welfare has been less clear (80 FR 65379, October 26, 2015; 73 FR 16497, March 27, 2008). While having sufficient crop yields is of high public welfare value, important commodity crops are typically heavily managed to produce optimum yields. Moreover, based on the economic theory of supply and demand, increases in crop yields would be expected to result in lower prices for affected crops and their associated goods, which would primarily benefit consumers. Analyses in past reviews have described how these competing impacts on producers and consumers complicate consideration of these effects in terms of potential adversity to the public welfare (2014 WREA, sections 5.3.2 and 5.7).

Other ecosystem services valued by people that can be affected by reduced tree growth, productivity and associated forest effects include aesthetic value; provision of food, fiber, timber, other forest products, habitat, and recreational opportunities; climate and water regulation; erosion control; air pollution removal, and desired fire regimes (PA, Figure 4–2; ISA, section IS.5.1; 2013 ISA, sections 9.4.1.1 and 9.4.1.2). In considering such services in past reviews, the Agency has given particular attention to effects in natural ecosystems, indicating that a protective standard, based on consideration of effects in natural ecosystems in areas afforded special protection, would also ''provide a level of protection for other vegetation that is used by the public and potentially affected by O_3 including timber, produce grown for consumption and horticultural plants used for landscaping'' (80 FR 65403, October 26, 2015). For example, locations potentially vulnerable to O_3-related impacts might include forested lands, both public and private, where trees are grown for timber production. Forests in urbanized areas also provide a number of services that are important to the public in those areas, such as air pollution removal, cooling, and beautification. There are also many other tree species, such as various ornamental and agricultural species (*e.g.,* Christmas trees, fruit and nut trees), that provide ecosystem services that may be judged important to the public welfare.

With its effect on the physical appearance of plants, visible foliar injury has the potential to be significant to the public welfare, depending on its severity and spatial extent, by impacting aesthetic or scenic values and outdoor recreation in Class I and other similarly protected areas valued by the public. To assess evidence of injury to plants in forested areas on national and regional scales, the U.S. Forest Service (USFS) conducted surveys of the occurrence and severity of visible foliar injury on sensitive (bioindicator) species at biomonitoring sites across most of the U.S., beginning in 1994 (in eastern U.S.) and extending through 2011 (Smith et al., 2003; Coulston et al., 2003). At these sites (biosites), a national protocol, including verification and quality assurance procedures and a scoring system, was implemented. The resultant biosite index (BI) scores may be described with regard to one of several categories ranging from little or no foliar injury to severe injury (*e.g.,* Smith et al., 2003; Campbell et al., 2007; Smith et al., 2007; Smith, 2012).[175] However, the available information does not yet address or describe the relationships expected to exist between some level of injury severity (*e.g.,* little, low/light, moderate or severe) and/or spatial extent affected and scenic or aesthetic values. This gap impedes consideration of the public welfare implications of different injury severities, and accordingly judgments on the potential for public welfare significance. That notwithstanding, while minor spotting on a few leaves of a plant may easily be concluded to be of little public welfare significance, some level of severity and widespread occurrence of visible foliar injury, particularly if occurring in specially protected areas, where the public can be expected to place value (*e.g.,* for recreational uses), might reasonably be concluded to impact the public welfare.

The tropospheric O_3-related effects of radiative forcing and subsequent effects on temperature, precipitation and related climate also have important public welfare implications, although their quantitative evaluation in response to O_3 concentrations in the U.S. is complicated by ''[c]urrent limitations in climate modeling tools, variation across models, and the need for more comprehensive observational data on these effects'' (ISA, section IS.6.2.2). An ecosystem service provided by forested lands is carbon sequestration or storage (ISA, section IS.5.1.4 and Appendix 8, section 8.8.3; 2013 ISA, section 2.6.2.1 and p. 9–37)[176], which has an extremely valuable role in counteracting the impact of greenhouse gases on radiative forcing and related climate effects on the public welfare. Accordingly, the

[175] Authors of studies presenting USFS biomonitoring program data have suggested what might be ''assumptions of risk'' (*e.g.,* for the forest resource) related to scores in these categories, *e.g.,* none, low, moderate and high for BI scores of zero to five, five to 15, 15 to 25 and above 25, respectively (*e.g.,* Smith et al., 2003; Smith et al., 2012. For example, maps of localized moderate to high risk areas may be used to identify areas where more detailed evaluations are warranted (Smith et al., 2012).

[176] While carbon sequestration or storage also occurs for vegetated ecosystems other than forests, it is relatively larger in forests given the relatively greater biomass for trees compared to other plants.

service of carbon storage can be of paramount importance to the public welfare no matter in what location the trees are growing or what their intended current or future use (*e.g.,* 2013 ISA, section 9.4.1.2). This benefit exists as long as the trees are growing, regardless of what additional functions and services it provides.

Categories of effects newly identified as likely causally related to O_3 in ambient air, such as alteration of plant-insect signaling and insect herbivore growth and reproduction, also have potential public welfare implications (*e.g.,* given the role of the plant-insect signaling process in pollination and seed dispersal). Uncertainties and limitations in the current evidence (*e.g.,* summarized in sections III.B.3.c and III.D.1 of the proposal) preclude an assessment of the extent and magnitude of O_3 effects on these endpoints, which thus also precludes an evaluation of the potential for associated public welfare implications.

In summary, several considerations are recognized as important to judgments on the public welfare significance of the array of welfare effects of different O_3 exposure conditions. These include uncertainties and limitations associated with the magnitude of key welfare effects that might be concluded to be adverse to ecosystems and associated services. Additionally, the presence of O_3-sensitive tree species may contribute to a vulnerability of numerous locations to public welfare impacts from O_3 related to tree growth, productivity and carbon storage and their associated ecosystems and services. Other important considerations include the exposure circumstances that may elicit effects and the potential for the significance of the effects to vary in specific situations due to differences in sensitivity of the exposed species, the severity and associated significance of the observed or predicted O_3-induced effect, the role that the species plays in the ecosystem, the intended use of the affected species and its associated ecosystem and services, the presence of other co-occurring predisposing or mitigating factors, and associated uncertainties and limitations.

c. Exposures Associated With Effects

The welfare effects identified in section III.A.2.a above vary widely with regard to the extent and level of detail of the available information that describes the O_3 exposure circumstances that may elicit the effects. The information on exposure metric and E–R relationships for effects related to vegetation growth is long-standing, having been first described in the 1997 review, while such information is much less established for visible foliar injury. The evidence base for other categories of effects is also lacking in information that might support characterization of potential impacts of changes in O_3 concentrations.

(i) Growth-Related Effects

The long-standing body of vegetation effects evidence includes a wealth of information on aspects of O_3 exposure that influence its effects on plant growth and yield, and that has been described in the scientific assessments across the last several decades (1996 AQCD; 2006 AQCD; 2013 ISA; 2020 ISA). A variety of factors have been investigated, and a number of mathematical approaches have been developed for summarizing O_3 exposure for the purpose of assessing effects on vegetation, including several that cumulate exposures over some specified period while weighting higher more than lower concentrations (2013 ISA, sections 9.5.2 and 9.5.3; ISA, Appendix 8, section 8.2.2.2). Over this period, the EPA's scientific assessments have focused on the use of a cumulative, seasonal [177] concentration-weighted index when considering the growth-related effects evidence and when analyzing exposures for purposes of reaching conclusions on the secondary standard. Such metrics have included SUM06,[178] in the past, and more recently (since the 2008 review), the focus has been on the W126-based, seasonal metric, termed the ''W126 index'' [179] (ISA, section IS.3.2, Appendix 8, sections 8.1 and 8.13).

Quantifying exposure using cumulative, concentration-weighted indices of exposure, such as the W126 index, has been found to improve the explanatory power of E–R models for growth and yield over using indices based only on mean and peak exposure values (ISA, section IS.5.1.9, p. IS–79; 2013 ISA, section 2.6.6.1, p. 2–44). The most well-analyzed datasets in such evaluations are two detailed datasets established two decades ago, one for seedlings of 11 tree species [180] and one for 10 crops (*e.g.,* Lee and Hogsett, 1996, Hogsett et al., 1997). These datasets, which include species-specific seedling growth and crop yield response information across multiple seasonal cumulative exposures, were used to develop robust quantitative E–R functions to predict growth reduction relative to a zero-O_3 setting (RBL) in seedlings of the tree species [181] and similarly, E–R functions for predicting RYL for a set of 10 common crops (ISA, Appendix 8, section 8.13.2; 2013 ISA, section 9.6.2).

The tree seedling E–R functions were derived from data for multiple studies documenting effects on tree seedling growth under a variety of O_3 exposures [182] and growing conditions. Importantly the data included hourly concentrations recorded across the duration of the exposure, which allowed for derivation of various metrics that were analyzed for association with reduced growth (2013 ISA, section 9.6.2; Lee and Hogsett, 1996). In producing E–R functions of consistent duration across the experiments, the E–R functions were derived first based on the exposure duration of the experiment [183] and then normalized to 3-month (seasonal) periods [184] (see Lee and Hogsett, 1996, section I.3; PA, Appendix 4A). The species-specific composite E–R functions developed from the experiment-specific functions indicate the wide variation in growth

[177] The ''seasonal'' descriptor refers to the duration of the period quantified (3 months) rather than a specific season of the year.

[178] The SUM06 index received attention across past O_3 NAAQS reviews. It is the seasonal sum of hourly concentrations at or above 0.06 ppm during a specified daily time window (2006 AQCD, p. AX9–161; 2013 ISA, section 9.5.2).

[179] The W126 index is described in section III.B.3.a(i) of the proposal (85 FR 49887, August 14, 2020) and in the PA (PA, Appendix 4D, section 4D.2.2).

[180] In total, the 11 species-specific composite E–R functions are based on 51 tree seedling studies or experiments, many of which employed open top chambers, an established experimental approach (PA, Appendix 4A, section 4A.1.1; ISA, section 8.1.2.1.2). For six of the 11 species, this function is based on just one or two studies, while for other species there were as many as 11 studies available.

[181] While the 11 species represent only a small fraction of the total number of native tree species in the contiguous U.S., this subset includes eastern and western species, deciduous and coniferous species, and species that grow in a variety of ecosystems and represent a range of tolerance to O_3 (PA, Appendix 4B; 2013 ISA, section 9.6.2).

[182] Across the experiments for the 11 tree species, the exposure levels assessed are more extensive for relatively higher seasonal exposures (*e.g.,* at/above a SUM06 of 30 ppm-hrs). Across these experiments, there is more limited representation of lower cumulative exposure levels, such as SUM06 values below those that may correspond to a W126 index of 20 ppm-hrs. These lowest levels did not always yield a statistically significant effect (PA, section 4.5.1.2 and Appendix 4A; 85 FR 49901, August 14, 2020).

[183] The exposure durations varied from periods of 82 to 140 days over a single year to periods of 180 to 555 days across two years (Lee and Hogsett, 1996; PA, Appendix 4A, Table 4A–5).

[184] Underlying the adjustment is a simplifying assumption of uniform W126 distribution across the exposure periods and of a linear relationship between duration of cumulative exposure in terms of the W126 index and plant growth response (85 FR 49901; August 14, 2020; PA). Some functions for experiments that extended over two seasons were derived by distributing responses observed at the end of two seasons of varying exposures equally across the two seasons (*e.g.,* essentially applying the average to both seasons).

sensitivity of the studied tree species at the seedling stage (PA, Appendix 4A, section 4A.1.1).

Since the initial set of tree seedling growth studies were completed, several additional studies, focused on aspen, have been published based on the Aspen FACE experiment in a planted forest in Wisconsin; the findings were consistent with earlier open top chamber (OTC) studies [185] (ISA, Appendix 8, section 8.13.2). Newly available studies that investigated growth effects of O_3 exposures are also consistent with the existing evidence base, and generally involve particular aspects of the effect rather than expanding the conditions under which plant species, particularly tree species, have been assessed (ISA, section IS.5.1.2). These publications include a compilation of previously available studies on plant biomass response to O_3; the compilation reports linear regressions conducted on the associated varying datasets. Based on these regressions, this study describes distributions of sensitivity to O_3 effects on biomass across many tree and grassland species, including 17 species native to the U.S. and 65 introduced species (ISA, Appendix 8, section 8.13.2; van Goethem et al., 2013). Additional information is needed to more completely describe O_3 exposure response relationships for these species in the U.S.[186]

(ii) Visible Foliar Injury

Current evidence ''continues to show a consistent association between visible injury and ozone exposure,'' while also recognizing the role of modifying factors such as soil moisture and time of day (ISA, section IS.5.1.1). The ISA summarizes several recently available studies that continue to document that O_3 elicits visible foliar injury in many plant species. As in the prior review, the evidence in the current review, while documenting that elevated O_3 conditions in ambient air generally results in visible foliar injury in sensitive species (when in a predisposing environment),[187] does not include a quantitative description of the relationship of incidence or severity of visible foliar injury in natural areas of the U.S. with specific metrics of seasonal O_3 exposure.

Although studies of the incidence of visible foliar injury in national forests, wildlife refuges, and similar areas have often used cumulative indices (*e.g.,* SUM06) to investigate variations in incidence of foliar injury, studies also suggest an additional role for metrics focused on peak concentrations (ISA; 2013 ISA; 2006 AQCD; Hildebrand et al., 1996; Smith, 2012). Other studies have indicated this uncertainty regarding the influential metric(s), *e.g.,* by recognizing the need for research to help develop a ''better linkage between air levels and visible injury'' (Campbell et al., 2007).[188] Some studies of visible foliar injury incidence data have investigated such a role for peak concentrations quantified by an O_3 exposure index that is a count of hourly concentrations (*e.g.,* in a growing season) above a threshold concentration of 100 ppb, N100 (*e.g.,* Smith, 2012; Smith et al., 2012). For example, a study describing injury patterns over 16 years at USFS biosites in 24 states in the Northeast and North Central regions, in the context of the SUM06 index and N100 metrics, suggested that there may be a threshold exposure needed for injury to occur, and that the number of hours of elevated O_3 concentrations during the growing season (such as what is captured by a metric like N100) may be more important than cumulative exposure in determining the occurrence of foliar injury (Smith, 2012).[189] This finding is consistent with statistical analyses of seven years of visible foliar injury data from a wildlife refuge in the mid-Atlantic area (Davis and Orendovici, 2006).[190]

The established significant role of higher or peak O_3 concentrations, as well as pattern of their occurrence, in plant responses has also been noted in prior ISAs or AQCDs. The evidence has included studies that use indices to summarize the incidence of injury on bioindicator species present at specific monitored sites, as well as experimental studies that assess varying O_3 treatments on cultured stands of different tree species (2013 ISA, section 9.5.3.1; 2006 AQCD, p. AX9–169; Oksanen and Holopainen, 2001; Yun and Laurence, 1999). In identifying support for such O_3 metrics with regard to foliar injury as the response, the 2013 ISA and 2006 AQCD both cite studies that support the ''important role that peak concentrations, as well as the pattern of occurrence, plays in plant response to O_3'' (2013 ISA, p. 9–105; 2006 AQCD, p. AX9–169).

A recent study (by Wang et al. [2012]) involved a statistical modeling analysis on a subset of the years of USFS BI data that were described in Smith (2012). This analysis tested a number of models for their ability to predict the presence of visible foliar injury (a nonzero biosite score), regardless of severity, and generally found that the type of O_3 exposure metric (*e.g.,* SUM06 *versus* N100) made only a small difference, although the models that included both a cumulative index (SUM06) and N100 had a just slightly better fit (Wang et al., 2012). Based on their investigation of 15 different models, using differing combinations of several types of potential predictors, the study authors concluded that they were not able to identify environmental conditions under which they ''could reliably expect plants to be damaged'' (Wang et al., 2012). This is indicative of the current state of knowledge, in which there remains a lack of established quantitative functions describing E–R relationships that would allow prediction of visible foliar injury severity and incidence under varying air quality and other environmental conditions.

The information related to O_3 exposures associated with visible foliar injury of varying severity available in this review also includes quantitative

[185] These studies included experiments that used OTCs to investigate tree seedling growth response and crop yield over a growing season under a variety of O_3 exposures and growing conditions (2013 ISA, section 9.6.2; Lee and Hogsett, 1996).

[186] The studies compiled in this publication included at least 21 days exposure above 40 ppb O_3 (expressed as AOT40 [seasonal sum of the difference between an hourly concentration above 40 ppb and 40 ppb]); and had a maximum hourly concentration that was no higher than 100 ppb (van Goethem et al., 2013). The publication does not report study-specific exposure durations, details of biomass response measurements or hourly O_3 concentrations, making it less useful for describing E–R relationships that might support estimation of specific impacts associated with air quality conditions meeting the current standard (*e.g.,* 2013 ISA, p. 9–118).

[187] As a major modifying factor is the amount of soil moisture available to a plant, dry periods decrease the incidence and severity of ozone-induced visible foliar injury, such that the incidence of visible foliar injury is not always higher in years and areas with higher ozone, especially with co-occurring drought (ISA, Appendix 8, p. 8–23; Smith, 2012; Smith et al., 2003).

[188] In considering their findings, the authors expressed the view that ''[a]lthough the number of sites or species with injury is informative, the average biosite injury index (which takes into account both severity and amount of injury on multiple species at a site) provides a more meaningful measure of injury'' for their assessment at a statewide scale (Campbell et al., 2007).

[189] Although the ISA and past assessments have not described extensive evaluations of specific peak concentration metrics such as the N100, in summarizing this study in the last review, the ISA observed that ''[o]verall, there was a declining trend in the incidence of foliar injury as peak O3 concentrations declined'' (2013 ISA, p. 9–40).

[190] The models evaluated included several with cumulative exposure indices alone. These included SUM60 (*i.e.,* SUM06 in ppb), SUM0, and SUM80 (SUM08 in ppb), but not W126. They did not include a model with W126 that did not also include N100. Across all of the models evaluated, the model with the best fit to the data was found to be the one that included N100 and W126, along with the drought index (Davis and Orendovici, 2006).

presentations of the dataset (developed by the EPA in the last review) of USFS BI scores, collected during the years 2006 through 2010 at locations in 37 states. In developing this dataset, the BI scores were combined with estimates of soil moisture [191] and estimates of seasonal cumulative O_3 exposure in terms of W126 index [192] (PA, Appendix 4C). This dataset includes more than 5,000 records of which more than 80 percent have a BI score of zero (indicating a lack of visible foliar injury). While the estimated W126 index assigned to records in this dataset ranges from zero to somewhat above 50 ppm-hrs, more than a third of all the records (and also of records with BI scores above zero or five) [193] are at sites with W126 index estimates below 7 ppm-hrs. In an extension of analyses developed in the last review, the presentation in the PA [194] describes the BI scores for the records in this dataset in relation to the W126 index estimate for each record, using ''bins'' of increasing W126 index values. The PA presentation utilizes the BI score breakpoints in the scheme used by the USFS to categorize severity. This presentation indicates that, across the W126 bins, there is variation in both the incidence of particular magnitude BI scores and in the average score per bin. In general, however, the greatest incidence of records with BI scores above zero, five, or higher—and the highest average BI score—occurs with the highest W126 bin, *i.e.,* the bin for W126 index estimates greater than 25 ppm-hrs (PA, Appendix 4C, Table 4C–6).

Overall, the dataset described in the PA generally indicates the risk of injury, and particularly injury considered at least light, moderate or severe, to be higher at the highest W126 index values, with appreciable variability in the data for the lower bins (PA, Appendix 4C). This appears to be consistent with the conclusions of the detailed quantitative analysis studies, summarized above, that the pattern is stronger at higher O_3 concentrations. A number of factors may contribute to the observed variability in BI scores and lack of a clear pattern with W126 index bin; among other factors, these may include uncertainties in assignment of W126 estimates and soil moisture categories to biosite locations, variability in biological response among the sensitive species monitored, and the potential role of other aspects of O_3 air quality not captured by the W126 index. Thus, the dataset has limitations affecting associated conclusions, and uncertainty remains regarding the tools for and the appropriate metric (or metrics) for quantifying O_3 exposures, as well as perhaps for quantifying soil moisture conditions, with regard to their influence on extent and/or severity of injury in sensitive species in natural areas, as quantified via BI scores (Davis and Orendovici, 2006, Smith et al., 2012; Wang et al., 2012).

(iii) Other Effects

With regard to radiative forcing and subsequent climate effects associated with the global tropospheric abundance of O_3, the newly available evidence in this review does not provide more detailed quantitative information regarding response to O_3 concentrations at the national scale. Rather, it is noted that ''the heterogeneous distribution of ozone in the troposphere complicates the direct attribution of spatial patterns of temperature change to ozone induced [radiative forcing]'' and there are ''ozone climate feedbacks that further alter the relationship between ozone [radiative forcing] and temperature (and other climate variables) in complex ways'' (ISA, Appendix 9, section 9.3.1, p. 9–19). Further, ''precisely quantifying the change in surface temperature (and other climate variables) due to tropospheric ozone changes requires complex climate simulations that include all relevant feedbacks and interactions'' (ISA, section 9.3.3, p. 9–22). Yet, there are limitations in current climate modeling capabilities for O_3; an important one is representation of important urban- or regional-scale physical and chemical processes, such as O_3 enhancement in high-temperature urban situations or O_3 chemistry in city centers where NO_X is abundant. Such limitations impede our ability to quantify the impact of incremental changes in O_3 concentrations in the U.S. on radiative forcing and subsequent climate effects.

With regard to tree mortality, the evidence available in the last several reviews included field studies of pollution gradients that concluded O_3 damage to be an important contributor to tree mortality although ''several confounding factors such as drought, insect outbreak and forest management'' were identified as potential contributors (2013 ISA, p. 9–81, section 9.4.7.1). Among the newly available studies, there is only limited experimental evidence that isolates the effect of O_3 on tree mortality [195] and might be informative regarding O_3 concentrations of interest in the review, and evidence is lacking regarding exposure conditions closer to those occurring under the current standard and any contribution to tree mortality.

With regard to alteration of herbivore growth and reproduction, although ''[t]here are multiple studies demonstrating ozone effects on fecundity and growth in insects that feed on ozone-exposed vegetation'', ''no consistent directionality of response is observed across studies and uncertainties remain in regard to different plant consumption methods across species and the exposure conditions associated with particular severities of effects'' (ISA, pp. ES–18). The evidence for alteration of plant-insect signaling draws on new research yielding clear evidence of O_3 modification of volatile plant signaling compounds and behavioral responses of insects to the modified chemical signals (ISA, section IS.6.2.1). The evidence includes a relatively small number of plant species and plant-insect associations and is limited to short controlled exposures, posing limitations for consideration of the potential for associated impacts to be elicited by air quality conditions that meet the current standard (ISA, section IS.6.2.1 and Appendix 8, section 8.7).

For categories of vegetation-related effects that were recognized in past reviews, other than growth and visible foliar injury (*e.g.,* reduced plant reproduction, reduced productivity in terrestrial ecosystems, alteration of terrestrial community composition and alteration of below-ground biogeochemical cycles), the newly available evidence includes a variety of studies that quantify exposure of varying duration in various countries using a variety of metrics (ISA, Appendix 8, sections 8.4, 8.8 and 8.10).

[191] This dataset, including associated uncertainties and limitations in the assignment of soil moisture categories (dry, wet or normal), such as the substantial spatial variation in soil moisture and large size of NOAA climate divisions, is described in the PA, Appendix 4C.

[192] The W126 index estimates assigned to the biosite locations were developed for 12 kilometer (km) by 12 km cells in a national-scale spatial grid for each year. A spatial interpolation technique was applied to annual W126 values derived from O_3 measurements at ambient air monitoring locations for the years of the BI data (PA, Appendix 4C, sections 4.C.2 and 4C.5).

[193] One third (33%) of scores above 15 are at sites with W126 below 7 ppm-hrs (PA, Appendix 4C, Table 4C–3).

[194] Beyond the presentation of a statistical analysis developed in the last review, the PA presentations are primarily descriptive (as compared to statistical) in recognition of the limitations and uncertainties of the dataset (PA, Appendix 4C, section 4C.5).

[195] Of the three new studies on tree mortality described in the ISA is another field study of a pollution gradient that, like such studies in prior reviews, recognizes O_3 exposures as one of several contributing environmental and anthropogenic stressors (ISA, p. 8–55).

The ISA also describes publications that analyze and summarize previously published studies. For example, a meta-analysis of reproduction studies categorized the reported O_3 exposures into bins of differing magnitude, grouping differing concentration metrics and exposure durations together, and performed statistical analyses investigating associations with an O_3-related effect (ISA, Appendix 8, section 8.4.1). While such studies continue to support conclusions of O_3 ecological hazards, they do not improve capabilities for characterizing the likelihood of such effects under patterns of environmental O_3 concentrations occuring with air quality conditions that meet the current standard (*e.g.,* factors such as variation in exposure assessments and limitations in response information preclude detailed analysis for such conditions), as discussed further in the PA.

As at the time of the last review, growth impacts, most specifically as evaluated by RBL for tree seedlings and RYL for crops, remain the type of vegetation-related effects for which we have the best understanding of exposure conditions likely to elicit them. Accordingly, as was the case in the last review, the quantitative analyses of exposures occurring under air quality that meets the current standard, summarized below, are focused primarily on the W126 index, given its established relationship with growth effects.

3. Overview of Air Quality and Exposure Information

The air quality and exposure analyses developed in this review, like those in the last review, are of two types: (1) W126-based cumulative exposure estimates in Class I areas; and (2) analyses of W126-based exposures and their relationship with the current standard for all U.S. monitoring locations (PA, Appendix 4D). We recognize relatively lower uncertainty associated with the use of these types of analyses (compared to the national or regional-scale modeling analyses performed in the last review) to inform a characterization of cumulative O_3 exposure (in terms of the W126 index) associated with air quality just meeting the current standard (IRP, section 5.2.2). As in the last review, the lower uncertainty of these air quality monitoring-based analyses contributes to their value in informing the current review.

The analyses conducted in this review focus on design values (3-year average annual fourth-highest 8-hour daily maximum concentration, also termed the ''4th max metric'') and W126 index values (in terms of the 3-year average) for the recent 2016 to 2018 period and across the historical record back to 2000 (PA, Section 4.3). These analyses are based primarily on the hourly air monitoring data that were reported to EPA from O_3 monitoring sites nationwide and in or near Class 1 areas.[196]

a. Influence of Form and Averaging Time of Current Standard on Environmental Exposure

The findings of the quantitative analyses in this review of relationships between air quality in terms of the form and averaging time of the current standard and environmental exposures in terms of the W126 index are similar to those based on the data available during the last review (PA, Appendix 4D, section 4D.2.2).[197] As previously, the current analysis of data spanning 19 years and including seventeen 3-year periods documented a positive nonlinear relationship between cumulative seasonal exposure (quantified using the W126 index) and design values (based on the form and averaging time of the current standard). In the current analysis, which revealed the variability in the annual W126 index values across a 3-year period to be relatively low,[198] the positive nonlinear relationship is shown for both the average W126 index across the 3-year design value period and for W126 index values for individual years within the period (PA, Figure 4–7; Appendix 4D, section 4D.3.1.2). That is, W126 index values (in a single year or averaged across years) are lower at monitoring sites with lower design values. This is seen both for design values above the standard and across lower design values, indicating the effectiveness of the averaging time and form of the current standard at controlling W126-based cumulative exposures.

Further, analysis of the relationship between trends or long-term changes in design value and long-term changes in W126 index shows there to be a positive, linear relationship at monitoring sites across the U.S. (PA, Appendix 4D, section 4D.3.2.3). The existence of this relationship means that a change in the design value at a monitoring site was generally accompanied by a similar change in the W126 index. The relationship varies across the NOAA climate regions, with the greatest change in W126 index per unit change in design value observed in the Southwest and West regions, the regions which had the highest W126 index values at sites meeting the current standard (PA, Appendix 4D, Figures 4D–6 and 4D–14, Table 4D–12). Thus, this analysis indicates that going forward, as design values are reduced in areas that are presently not meeting the current standard, the W126 index in those areas would also be expected to decline and the greatest improvement in W126 index per unit decrease in design value would be expected in the Southwest and West regions (PA, Appendix 4D, section 4D.3.2.3 and 4D.5). The overall trend showing reductions in the W126 index concurrent with reductions in the design value metric for the current standard is positive whether the W126 index is expressed in terms of the average across the 3-year design value period or the annual value (PA, Appendix 4D, section 4D.3.2.3).

The available air quality information also indicates that the current standard's form and averaging time exerts control on other vegetation exposures of potential concern, such as days with particularly high O_3 concentrations that may contribute to visible foliar injury. The current form and averaging time, by their very definition, limit occurrences of such concentrations. This is demonstrated by reductions in daily maximum 8-hour concentrations, as well as in the frequency of elevated 1-hour concentrations, including concentrations at or above 100 ppb, with decreasing design values (PA, Figure 2–11, Appendix 2A, section 2A.2). As the form and averaging time of the secondary standard have not changed since 1997, the analyses have been able to assess the amount of control exerted by these aspects of the standard, in combination with reductions in the standard level (*i.e.,*

[196] Across the seventeen 3-year periods from 2000–2002 to 2016–2018, the number of monitoring sites with sufficient data for calculation of valid design values and W126 index values (across the 3-year design value period) ranged from a low of 992 in 2000–2002 to a high of 1119 in 2015–2017 (PA, Section 4.3).

[197] In 2015 the Administrator concluded that, with revision of the standard level, the existing form and averaging time provided the control of cumulative seasonal exposure circumstances needed for the public welfare protection desired (80 FR 65408, October 26, 2015).

[198] This evaluation, performed for all U.S. monitoring sites with sufficient data available in the most recent 3-year period, 2016 to 2018, indicates the extent to which the three single-year W126 index values within a 3-year period deviate from the average for the period. Across the full set of sites, regardless of W126 index magnitude (or whether or not the current standard is met), single-year W126 index values differ less than 15 ppm-hrs from the average for the 3-year period (PA, Appendix 4D, Figure 4D–6). For the approximately 850 sites meeting the current standard, over 99% of single-year W126 index values differ from the 3-year average by no more than 5 ppm-hrs, and 87% by no more than 2 ppm-hrs (PA, Appendix 4D, Figure 4D–7).

from 0.08 ppm in 1997 to 0.075 ppm in 2008 to 0.070 ppm in 2015), on cumulative seasonal exposures in terms of W126 index, and on the magnitude of short-term peak concentrations. These analyses indicate that the long-term reductions in the design values, presumably associated with implementation of the revised standards, were accompanied by reductions in W126 index, as well as in short-term peak concentrations.

b. Environmental Exposures in Terms of W126 Index

The analyses summarized here describe the nature and magnitude of vegetation exposures associated with conditions meeting the current standard at sites across the U.S., particularly in specially protected areas, such as Class I areas. Given the evidence indicating the W126 index to be strongly related to growth effects and its use in the E–R functions for tree seedling RBL (as summarized in section III.A.2.c above), exposure is quantified using the W126 metric. These analyses include a particular focus on monitoring sites in or near Class I areas,[199] in light of the greater public welfare significance of many O_3 related impacts in such areas, as described in section III.A.2.b above, and consider both recent air quality (2016–2018) and the air quality record since 2000 (PA, Appendix 4D). As was the case in the last review, the currently available quantitative information continues to indicate appreciable control of seasonal W126 index-based cumulative exposure at all sites with air quality meeting the current standard.

Among sites nationwide meeting the current standard in the recent period of 2016 to 2018, there are none with a W126 index, based on the 3-year average, above 19 ppm-hrs, and just one with such a value above 17 ppm-hrs (Table 4).[200] Additionally, the full historical dataset includes no occurrences of a 3-year average W126 index above 19 ppm-hrs for sites meeting the current standard, and just eight occurrences of a W126 index above 17 ppm-hrs (less than 0.1% of the dataset), with the highest such occurrence just equaling 19 ppm-hrs (Table 4; PA, Appendix 4D, section 4D.3.2.1).

With regard to Class I areas, the updated air quality analyses include data from sites in or near 65 Class I areas. The findings for these sites, which are distributed across all nine NOAA climate regions in the contiguous U.S., as well as Alaska and Hawaii, mirror the findings for the analysis of all U.S. sites in the dataset. Among the Class I area sites meeting the current standard (*i.e.,* having a design value at or below 70 ppb) in the most recent period of 2016 to 2018, there are none with a W126 index (averaged over the design value period) above 17 ppm-hrs (Table 4). The historical dataset includes just seven occurrences (all dating from the 2000–2010 period) of a Class I area site meeting the current standard and having a 3-year average W126 index above 17 ppm-hrs, and no such occurrences above 19 ppm-hrs (Table 4).

The W126 index values at sites that do not meet the current standard are much higher, with values at such sites ranging as high as approximately 60 ppm-hrs (PA, Appendix 4D, Figure 4D–3). Among all sites across the U.S. that do not meet the current standard in the 2016 to 2018 period, more than a quarter have average W126 index values above 19 ppm-hrs and a third exceed 17 ppm-hrs (Table 4). A similar situation exists for Class I area sites (Table 4). For example, out of the 11 Class I area sites with design values above 70 ppb during the most recent period, eight sites had a 3-year average W126 index above 19 ppm-hrs (with a maximum value of 47 ppm-hrs) and for nine, it was above 17 ppm-hrs (Table 4; PA, Appendix 4D, Table 4D–17).

TABLE 4—DISTRIBUTION OF 3-YR AVERAGE SEASONAL W126 INDEX FOR SITES IN CLASS I AREAS AND ACROSS U.S. THAT MEET THE CURRENT STANDARD AND FOR THOSE THAT DO NOT

3-year periods	Number of occurrences or site-DVs [A]							
	In Class I areas				Across all monitoring sites (urban and rural)			
	Total	W126 (ppm-hrs)			Total	W126 (ppm-hrs)		
		>19	>17	≤17		>19	>17	≤17
At sites that meet the current standard (design value at or below 70 ppb)								
2016–2018	47	0	0	47	849	0	1	848
All from 2000 to 2018	498	0	7	491	8,292	0	8	8,284
At sites that exceed the current standard (design value above 70 ppb)								
2016–2018	11	8	9	2	273	78	91	182
All from 2000 to 2018	362	159	197	165	10,695	2,317	3,174	7,521

[A] Counts presented here are drawn from the PA, Appendix D, Tables 4D–1, 4D–4, 4D–5, 4D–6, 4D–9, 4D–10 and 4D–13 through 16.

B. Conclusions on the Secondary Standard

In drawing conclusions on the adequacy of the current secondary standard, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the currently available welfare effects evidence and air quality and ecological exposure information. He additionally has considered the evidence base, information, and policy judgments that were the foundation of the last review, to the extent they remain relevant in light of the currently available information. The Administrator has taken into account both evidence-based and air quality and exposure-based considerations discussed in the PA, as well as advice from the CASAC and

[199] This includes monitors sited within Class I areas or the closest monitoring site within 15 km of the area boundary.

[200] Rounding conventions are described in detail in the PA, Appendix 4D, section 4D.2.2.

public comments. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence as presented in the ISA, with a focus on policy-relevant considerations as discussed in the PA (summarized in sections III.B and III.D.1 of the proposal and section III.A.2 above). The air quality and exposure-based considerations draw from the results of the quantitative air quality analyses presented and considered in the PA (as summarized in section III.C of the proposal and section III.A.3 above). The Administrator additionally considered the August 2019 decision of the D.C. Circuit remanding the 2015 secondary standard for further justification or reconsideration.

The consideration of the evidence and air quality/exposure information in the PA informed the Administrator's proposed conclusions and judgments in this review, and his associated proposed decision. Section III.B.1 below briefly summarizes the basis for the Administrator's proposed decision, drawing from section III.D of the proposal. Section III.B.1.a provides a brief overview of key aspects of the policy evaluations presented in the PA, and the advice and recommendations of the CASAC are summarized in III.B.1.b. An overview of the Administrator's proposed conclusions is presented in section III.B.1.c. Public comments on the proposed decision are addressed below in sections III.B.2 and the Administrator's conclusions and decision in this review regarding the adequacy of the current secondary standard and whether any revisions are appropriate are described in section III.B.3.

1. Basis for Proposed Decision

a. Policy-Relevant Evaluations in the PA

The main focus of the policy-relevant considerations in the PA is consideration of the question: Does the currently available scientific evidence- and air quality and environmental exposure-based information support or call into question the adequacy of the protection afforded by the current secondary O_3 standard? The PA response to this overarching question takes into account discussions that address the specific policy-relevant questions for this review, focusing first on consideration of the evidence, as evaluated in the ISA, including that newly available in this review. The PA also considers the quantitative information available in this review that relates O_3 environmental exposures to vegetation responses (presented in Appendices 4A and 4C of the PA) and the air quality analyses that investigate relationships between air quality that meets the current standard and cumulative and peak exposures (presented in detail in Appendix 4D of the PA). The PA additionally discusses the key aspects of the evidence and exposure/risk estimates that were emphasized in establishing the current standard, and key aspects of the 2019 court remand on the standard. In so doing, the PA also considers associated public welfare policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to the Administrator's consideration of whether the currently available information supports or calls into question the adequacy of the current secondary O_3 standard (PA, section 3.5).

Key policy-relevant considerations identified by the PA included the following. The new information available is consistent with that available in the last review for the principal effects for which the evidence is strongest (*e.g.,* growth, reproduction, and related larger-scale effects, as well as, visible foliar injury) and for key aspects of the decision in that review. The currently available information does not provide established quantitative relationships and tools for estimating incidence and severity of visible foliar injury in protected areas across the U.S. or provide information linking extent and severity of injury to aesthetic values that might be useful for considering public welfare implications. Further, the currently available evidence for forested locations across the U.S., such as studies of USFS biosites, does not indicate widespread incidence of significant visible foliar injury. Additionally, the evidence regarding RBL and air quality in areas meeting the current standard does not appear to call into question the adequacy of protection. For other vegetation-related effects that the ISA newly concludes likely to be causally related to O_3, the new information does not provide us an indication of the extent to which such effects might be anticipated to occur in areas that meet the current standard of a significance reasonably judged significant to public welfare. Thus, the PA does not find the current information for these newly identified categories to call into question the adequacy of the current standard. Similarly, the current information regarding O_3 contribution to radiative forcing or effects on temperature, precipitation and related climate variables is not strengthened from that available in the last review, including with regard to uncertainties that limit quantitative evaluations. Based on such considerations, discussed in detail in the PA, it concludes that the currently available evidence and quantitative exposure/risk information does not call into question the adequacy of the current secondary standard such that it is appropriate to consider retaining the current standard without revision. In so doing, it recognized that, as is the case in NAAQS reviews in general, the extent to which the Administrator judges the current secondary O_3 standard to be adequate will depend on a variety of factors, including science policy judgments and public welfare policy judgments.

b. CASAC Advice in This Review

In comments on the draft PA, the CASAC concurred with the PA conclusions, stating that it ''finds, in agreement with the EPA, that the available evidence does not reasonably call into question the adequacy of the current secondary ozone standard and concurs that it should be retained'' (Cox, 2020a, p. 1). The CASAC additionally stated that it ''commends the EPA for the thorough discussion and rationale for the secondary standard'' (Cox, 2020a, p. 2). The CASAC also provided comments particular to the consideration of climate and growth-related effects.

With regard to O_3 effects on climate, the CASAC recommended quantitative uncertainty and variability analyses, with associated discussion (Cox, 2020a, p. 2 and Consensus Responses to Charge Questions p. 22).[201] With regard to growth-related effects and consideration of the evidence in quantitative exposure analyses, it stated that the W126 index ''appears reasonable and scientifically sound,'' ''particularly [as] related to growth effects'' (Cox, 2020a, Consensus Responses to Charge Questions p. 16). Additionally, with regard to the prior Administrator's expression of greater confidence in judgments related to public welfare impacts based on a seasonal W126 index estimated by a three-year average and accordingly relying on that metric the CASAC expressed the view that this ''appears of reasonable thought and scientifically

[201] As recognized in the ISA, ''[c]urrent limitations in climate modeling tools, variation across models, and the need for more comprehensive observational data on these effects represent sources of uncertainty in quantifying the precise magnitude of climate responses to ozone changes, particularly at regional scales'' (ISA, section IS.6.2.2, Appendix 9, section 9.3.3, p. 9–22). These complexities impede our ability to consider specific O_3 concentrations in the U.S. with regard to specific magnitudes of impact on radiative forcing and subsequent climate effects.

sound'' (Cox, 2020a, Consensus Responses to Charge Questions p. 19). Further, the CASAC stated that ''RBL appears to be appropriately considered as a surrogate for an array of adverse welfare effects and based on consideration of ecosystem services and potential for impact to the public as well as conceptual relationships between vegetation growth effects and ecosystem scale effects'' and that it agrees ''that biomass loss, as reported in RBL, is a scientifically-sound surrogate of a variety of adverse effects that could be exerted to public welfare,'' concurring that this approach is not called into question by the current evidence which continues to support ''the use of tree seedling RBL as a proxy for the broader array of vegetation related effects, most particularly those related to growth that could be impacted by ozone'' (Cox, 2020a, Consensus Responses to Charge Questions p. 21). The CASAC additionally concurred that the strategy of a secondary standard that generally limits 3-year average W126 index values somewhat below those associated with a 6% RBL in the median species is ''scientifically reasonable'' and that, accordingly, a W126 index target value of 17 ppm-hrs for generally restricting cumulative exposures ''is still effective in particularly protecting the public welfare in light of vegetation impacts from ozone'' (Cox, 2020a, Consensus Responses to Charge Questions p. 21).

With regard to the court's remand of the 2015 secondary standard to the EPA for further justification or reconsideration (''particularly in relation to its decision to focus on a 3-year average for consideration of the cumulative exposure, in terms of W126, identified as providing requisite public welfare protection, and its decision to not identify a specific level of air quality related to visible foliar injury''), while the CASAC stated that it was not clear whether the draft PA had fully addressed this concern (Cox, 2020a, Consensus Responses to Charge Questions p. 21), it described there to be a solid scientific foundation for the current secondary standard and also commented on areas related to the remand. With regard to support in the information available in the current review for the focus on the 3-year average W126 index in assessing different patterns of air quality using median tree seedling RBL, in addition to the comments summarized above, the CASAC concluded, in considering the approach used in the last review, that reliance on the 3-year average and associated judgments in doing so ''appears of reasonable thought and scientifically sound'' (Cox, 2020a, Consensus Responses to Charge Questions p. 19). Further, while recognizing the existence of established E–R functions that relate cumulative seasonal exposure of varying magnitudes to various incremental reductions in expected tree seedling growth (in terms of RBL) and in expected crop yield, the CASAC letter also noted that while decades of research also recognizes visible foliar injury as an effect of O_3, ''uncertainties continue to hamper efforts to quantitatively characterize the relationship of its occurrence and relative severity with ozone exposures'' (Cox, 2020a, Consensus Responses to Charge Questions p. 20). In summary, the CASAC stated that the approach described in the draft PA to considering the evidence for welfare effects ''is laid out very clearly, thoroughly discussed and documented, and provided a solid scientific underpinning for the EPA conclusion leaving the current secondary standard in place'' (Cox, 2020a, Consensus Responses to Charge Questions p. 22).

c. Administrator's Proposed Conclusions

In reaching conclusions on the adequacy and appropriateness of protection provided by the current secondary standard and his proposed decision to retain the standard, the Administrator carefully considered: (1) The assessment of the available welfare effects evidence and conclusions contained in the ISA, with supporting details in the 2013 ISA and past AQCDs; (2) the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA; (3) the advice and recommendations from the CASAC; (4) the August 2019 decision of the D.C. Circuit remanding the secondary standard established in the last review to the EPA for further justification or reconsideration; and (5) public comments that had been received up to that point (85 FR 49830, August 14, 2020). In considering the evidence base on welfare effects associated with exposure to photochemical oxidants, including O_3, in ambient air, he noted the newly available evidence, and the extent to which it alters key scientific conclusions from the last review. He additionally considered the quantitative analyses developed in this review, and their associated limitations and uncertainties, with regard to what they indicate regarding the protection provided by the current standard. Key aspects of the evidence and air quality and exposure information emphasized in establishing the current standard were also considered. Further, he considered uncertainties in the evidence and quantitative information as a part of public welfare policy judgments that are essential and integral to his decision on the adequacy of protection provided by the standard. In considering the CASAC advice, he noted the CASAC characterization of the ''thorough discussion and rationale for the secondary standard'' presented in the PA (Cox, 2020a, p. 2), and also considered the Committee's overall agreement that the currently available evidence does not call into question the adequacy of the current standard and that it should be retained (Cox, 2020a, p. 1).

As an initial matter, the Administrator recognized the continued support in the current evidence for O_3 as the indicator for photochemical oxidants, noting that no newly available evidence has been identified in this review on the importance of photochemical oxidants other than O_3 with regard to abundance in ambient air and potential for welfare effects. For such reasons, described with more specificity in the ISA and PA and summarized in the proposal, he proposed to conclude it to be appropriate to retain O_3 as the indicator for the secondary NAAQS for photochemical oxidants and he focused on the current information for O_3.

With regard to the currently available welfare effects evidence, the Administrator recognized that, consistent with the evidence in the last review, the currently available evidence describes an array of effects on vegetation and related ecosystem effects causally or likely to be causally related to O_3 in ambient air, as well as the causal relationship of tropospheric O_3 in radiative forcing and subsequent likely causally related effects on temperature, precipitation and related climate variables. The evidence for three additional categories of effects was newly determined in this review to be sufficient to infer likely causal relationships with O_3. However, the Administrator did not find the evidence for these effects to be informative to his proposed decision in review of the standard. For example, the Administrator noted the PA did not find the current evidence to indicate air quality under the current standard to cause increased tree mortality, and, accordingly, he found it appropriate to focus on more sensitive effects, such as tree seedling growth, in his review of the standard. With regard to the two insect-related categories of effects with new ISA determinations (alteration of plant-insect signaling and alteration of

insect herbivore growth and reproduction), the Administrator noted the associated uncertainties in the evidence that preclude a full understanding of key aspects of the effects and indicate there to be insufficient information to judge the current standard inadequate based on these effects as described in the proposal.

In considering the evidence documenting tropospheric O_3 as a greenhouse gas causally related to radiative forcing, and likely causally related to subsequent effects on variables such as temperature and precipitation, the Administrator took note of the limitations and uncertainties in the evidence base that affect characterization of the extent of any relationships between O_3 concentrations in ambient air in the U.S. and climate-related effects. He found this to preclude quantitative characterization of climate responses to changes in O_3 concentrations in ambient air at regional (*versus* global) scales. This lack of quantitative tools precluding important analyses and the resulting uncertainty led the Administrator to conclude there to be insufficient information available for these effects in the current review to support judging the existing standard inadequate or to identify an appropriate revision.

With regard to visible foliar injury, the Administrator recognized that, depending on its severity and spatial extent, as well as the location(s) and intended use(s), the impact of visible foliar injury on the physical appearance of plants has the potential to be significant to the public welfare. For example, depending on its extent and severity, its occurrence in specially protected natural areas may affect aesthetic and recreational values, such as the aesthetic value of scenic vistas in protected natural areas (*e.g.,* national parks and wilderness areas). While recognizing there to be a paucity of information that relates incidence or severity of injury on vegetation in public lands to impacts on the public welfare (*e.g.,* related to recreational services), the Administrator noted the USFS BI scoring scheme, and proposed to judge that occurrence of the lower categories of BI scores does not pose concern for the public welfare, but that findings of BI scores categorized as ''moderate to severe'' injury by the USFS scheme would be an indication of visible foliar injury occurrence that, depending on extend and severity, may raise public welfare concerns.

While recognizing that important uncertainties remain in the understanding of the O_3 exposure conditions that will elicit visible foliar injury of varying severity and extent in natural areas, the Administrator took note of the evidence indicating a general association of injury incidence and severity with cumulative exposure metrics, including the W126 index, and also an influence of peak concentrations, as well as the quantitative analyses in the PA of USFS biosite data and of air quality monitoring data. In the PA analysis of biosite scores, the incidence of nonzero BI scores, and particularly of relatively higher scores, such as those indicative of ''moderate to severe'' injury in the USFS scheme, appear to markedly increase only with W126 index values above 25 ppm-hrs. The Administrator noted that such a magnitude of W126 index (either as a 3-year average or in a single year) is not seen to occur at monitoring locations in or near Class I areas where the current standard is met (and such a W126 index, in a single year, has occurred only once in 19 years of monitoring data at sites across the U.S.), and that values above 17 or 19 ppm-hrs are rare (PA, Appendix 4C, section 4C.3; Appendix 4D, section 4D.3.2.3; 85 FR 49911, August 14, 2020). The Administrator further took note of the PA consideration of the USFS publications that identify an influence of peak concentrations on BI scores (beyond an influence of cumulative exposure) and the PA observation of the appreciable control of peak concentrations exerted by the form and averaging time of the current standard, as evidenced by the air quality analyses which document reductions in 1-hour daily maximum concentrations with declining design values. Based on these considerations, the Administrator agreed with the PA finding that the current standard provides control of air quality conditions that contribute to increased BI scores and to scores of a magnitude indicative of ''moderate to severe'' foliar injury. Based on his consideration of PA findings that areas that meet the current standard are unlikely to have BI scores reasonably considered to be impacts of public welfare significance, the Administrator further proposed to conclude that the current standard provides sufficient protection of natural areas, including particularly protected areas such as Class I areas, from O_3 concentrations in the ambient air that might be expected to elicit visible foliar injury of such an incidence and severity as would reasonably be judged adverse to the public welfare.

With regard to the welfare effects of reduced plant growth or yield, the Administrator recognized that the evidence base continues to indicate growth-related effects as sensitive welfare effects, with the potential for ecosystem-scale ramifications. While recognizing associated uncertainties, the Administrator took note of the PA conclusion and CASAC advice that the approach taken in the last review of using estimates of O_3 impacts on tree seedling growth (in terms of RBL) as a surrogate for comparable information on other species and lifestages, as well as a proxy or surrogate for other vegetation-related effects, including larger-scale effects, continues to appear to be a reasonable judgment in the current review (85 FR 49910, August 14, 2020; PA, section 4.5.3). These estimates were medians based on the established E–R functions for 11 tree species. In light of this and the lack of an alternative metric or approach being indicated by the current evidence, the Administrator found it appropriate to adopt this approach in the current review.

The Administrator additionally took note of considerations in the PA regarding aspects of the derivation of the tree seedling E–R functions that he found informative to his consideration of issues discussed in the court's remand of the 2015 secondary standard with respect to use of a 3-year average W126. In this context, the Administrator considered whether aspects of this evidence support making judgments using the E–R functions with W126 index derived as an average across multiple years. He noted that such averaging would have some conceptual similarity to the assumptions underlying the adjustment made to develop seasonal W126 E–R functions from exposures that extended over multiple seasons (or less than a single season).[202] The Administrator also noted uncertainties in regard to estimated RBL at lower cumulative exposure levels, given the more limited data and fewer findings of statistical significance supporting the functions at the relatively lower cumulative exposure levels most commonly

[202] The E–R functions for the 11 species were derived in terms of a seasonal W126 index from experiments that varied in duration from less than three months to many more. Underlying the adjustments made to derive the functions for a 3-month season duration are simplifying assumptions of uniform W126 distribution over the exposure period and linear relationship between cumulative exposure duration and response. Averaging of seasonal W126 across three years, with its reduction of the influence of annual variations in seasonal W126, would give less influence to RBL estimates derived from such potentially variable representations of W126, thus providing an estimate of W126 considered more suitably paired with the E–R functions.

associated with the current standard (*e.g.,* at or below 17 ppm-hrs). The Administrator additionally took note of the PA summary of different comparisons that had been performed in the 2013 ISA and the current ISA of RBL estimated via the aspen E–R function using either a cumulative average multi-year W126 index (2013 ISA) or a single-year W126 index (current ISA) with RBL estimates derived directly from aspen growth information in a multi-year O_3 exposure study. In this context, he noted the PA finding that consideration of these two different comparisons illustrate the variability inherent in the magnitude of growth impacts of O_3 and in the quantitative relationship of O_3 exposure and RBL,[203] while also providing general agreement of predictions (based on either metric) with observations. In light of these considerations, the Administrator recognized that such factors as identified in the proposal, including the currently available evidence and its recognized limitations, variability and uncertainties, support a conclusion that it is reasonable to use a seasonal RBL averaged over multiple years, such as a 3-year average (85 FR 49910, August 14, 2020). The Administrator additionally took note of the CASAC advice reaffirming the EPA's focus on a 3-year average W126, concluding such a focus to be reasonable and scientifically sound. In light of these considerations, the Administrator found there to be support for use of an average seasonal W126 index derived from multiple years (with their representation of variability in environmental factors), concluding the use of such averaging to provide an appropriate representation of the evidence and attention to considerations summarized above. In so doing, he found that a reliance on single year W126 estimates for reaching judgments with regard to magnitude of O_3-related RBL and associated judgments of public welfare protection would ascribe a greater specificity and certainty to such estimates than supported by the current evidence. Thus, he proposed to conclude that it is appropriate to use a seasonal W126 averaged over a 3-year period, which is the design value period for the current standard, to estimate median RBL using the established E–R functions for purposes in this review of considering the public welfare protection provided by the standard.

[203] For example, there is variability associated with tree growth in the natural environment (*e.g.,* related to variability in plant, soil, meteorological and other factors), as well as variability associated with plant responses to O_3 exposures in the natural environment (85 FR 49910, August 14, 2020).

In reaching his proposed conclusions and judgments related to the use of RBL as a surrogate for the broad array of vegetation-related effects, the Administrator recognized a number of important public welfare policy judgments. The Administrator proposed to conclude that the current evidence base and available information (qualitative and quantitative) continue to support consideration of the potential for O_3-related vegetation impacts in terms of the RBL estimates from established E–R functions as a quantitative tool within a larger framework of considerations pertaining to the public welfare significance of O_3 effects. He judged the framework to include consideration of effects that are associated with effects on vegetation, and particularly those that conceptually relate to growth, and that are causally or likely causally related to O_3 in ambient air, yet for which there are greater uncertainties affecting estimates of impacts on public welfare. In his consideration of the adequacy of protection provided by the current standard, the Administrator also noted judgments of the prior Administrator in considering the public welfare significance of small magnitude estimates of RBL and associated unquantified potential for larger-scale related effects. In light of CASAC advice and based on the current evidence as evaluated in the PA, the Administrator proposed to conclude that the approach or framework initially described with the 2015 decision, with its focus on controlling air quality such that cumulative exposures at or above 19 ppm-hrs, in terms of a 3-year average W126 index, are isolated and rare, is appropriate for a secondary standard that provides the requisite public welfare protection and proposed to use such an approach in this review (85 FR 49911, August 14, 2020).

With this approach and protection target in mind, the Administrator considered the analyses of air quality at sites across the U.S., particularly including those sites in or near Class I areas. In virtually all design value periods and all locations at which the current standard was met (*i.e.,* in more than 99.9% of such instances) across the 19 years of the data analyzed, the 3-year average W126 metric was at or below 17 ppm-hrs. Further, in all such design value periods and locations the 3-year average W126 index was at or below 19 ppm-hrs. The Administrator additionally considered the protection provided by the current standard from the occurrence of O_3 exposures within a single year with potentially damaging consequences, such as a significantly increased incidence of areas with visible foliar injury that might be judged moderate to severe. In so doing, he noted the PA findings that incidence of sites with BI scores above 15 (termed ''moderate to severe injury'' by the USFS categorization scheme) markedly increases with W126 index estimates above 25 ppm-hrs, and the scarcity of single-year W126 index values above 25 ppm-hrs at sites that meet the current standard, with just a single occurrence across all U.S. sites with design values meeting the current standard in the 19-year historical dataset dating back to 2000 (PA, section 4.4 and Appendix 4D). In light of the evidence indicating that peak short-term concentrations (*e.g.,* of durations as short as one hour) may also play a role in the occurrence of visible foliar injury, the Administrator additionally recognized the control of peak 1-hour concentrations provided by the form and averaging time of the current standard and noted there to be less than one day per site with a maximum hourly concentration at or above 100 ppb (PA, Appendix 2A, section 2A.2). In consideration of these findings, the Administrator proposed to judge that the current standard provides adequate protection from air quality conditions with the potential to be adverse to the public welfare (85 FR 49912, August 14, 2020).

In reaching his proposed decision, the Administrator gave primary attention to the principal effects of O_3 as recognized in the current ISA, the 2013 ISA and past AQCDs, and for which the evidence is strongest (*e.g.,* growth, reproduction, and related larger-scale effects, as well as visible foliar injury). With respect to the currently available information related to O_3-related visible foliar injury, the Administrator considered air quality analyses that may be informative with regard to air quality conditions associated with appreciably increased incidence and severity of BI scores at USFS biomonitoring sites, noting that this information does not indicate a potential for public welfare impacts of concern under air quality conditions that meet the current standard. In light of these and other considerations discussed more completely in the proposal, and with particular attention to Class I and other areas afforded special protection, the Administrator proposed to conclude that the evidence regarding visible foliar injury and air quality in areas meeting the current standard indicates that the current standard provides adequate protection for this effect.

The Administrator additionally considered O_3 effects on crop yield, taking note of the long-standing evidence, qualitative and quantitative, of the reducing effect of O_3 on the yield of many crops, as summarized in the PA and current ISA and characterized in detail in past reviews (*e.g.,* 2013 ISA, 2006 AQCD, 1997 AQCD, 2014 WREA). In so doing, he recognized that not every effect on crop yield will be adverse to public welfare and in the case of crop yield effects in particular there are a number of complexities related to the heavy management of many crops to obtain a particular output for commercial purposes, and to other factors, that contribute uncertainty to predictions of potential O_3-related public welfare impacts, as summarized in sections III.B.2 and III.D.1 of the proposal (PA, sections 4.5.1.3 and 4.5.3). Thus, in judging the extent to which the median RYL estimated for the W126 index values generally occurring in areas meeting the current standard would be expected to be of public welfare significance, he recognized the potential for a much larger influence of extensive management of such crops, and also considered other factors recognized in the PA and proposal, including similarities in median estimates of RYL and RBL (PA, sections 4.5.1.3 and 4.5.3). With this context, the information for crop yield effects did not lead the Administrator to identify this endpoint as requiring separate consideration or to provide a more appropriate focus for the standard than RBL, in its role as a proxy or surrogate for the broader array of vegetation-related effects, as discussed above. Rather, in light of these considerations, he proposed to judge that a decision based on RBL as a proxy for other vegetation-related effects will provide adequate protection against crop related effects. In light of the current information and considerations discussed more completely in the proposal, the Administrator further proposed to conclude that the evidence regarding RBL, and its use as a proxy or surrogate for the broader array of vegetation-related effects, in combination with air quality in areas meeting the current standard, provide adequate protection for these effects (85 FR 49912, August 14, 2020).

In reaching his proposed conclusion on the current standard, the Administrator also considered the extent to which the current information may provide support for an alternative standard, proposing to conclude that the appreciably greater occurrence of higher levels of cumulative exposure, in terms of the W126 index, as well as an appreciably greater occurrence of peak concentrations (both hourly and 8-hour average concentrations) in areas that do not meet the current standard (*e.g.,* areas meeting a higher standard level), would not provide the appropriate protection of public welfare in light of the potential for adverse effects on the public welfare. The Administrator also considered an alternative based solely on the W126 metric, as was considered in the last review, based on such a concentration-weighted, cumulative exposure metric having been identified as quantifying exposure in a way that relates to reduced plant growth (ISA, Appendix 8, section 8.13.1). While recognizing a role for W126 index in quantifying exposure to develop estimates of RBL that the Administrator considers appropriately used as a proxy or surrogate for the broader array of vegetation-related effects, he notes that the evidence indicates there to be aspects of O_3 air quality not captured by measures of cumulative exposure like W126 index that may pose a risk of harm to the public welfare (*e.g.,* risk of visible foliar injury related to peak concentrations). Thus, in light of the information available in this review, the Administrator proposed to conclude that such an alternative standard in terms of a W126 index would be less likely to provide sufficient protection against such occurrences and accordingly would not provide the requisite control of aspects of air quality that pose risk to the public welfare.

In summary, the Administrator recognized that his proposed decision on the public welfare protection afforded by the current secondary O_3 standard from identified O_3-related welfare effects, and from their potential to present adverse effects to the public welfare, is based in part on judgments regarding uncertainties and limitations in the available information, such as those identified above. In this context, he considered what the available evidence and quantitative information indicated with regard to the protection provided from the array of O_3 welfare effects, finding it to not indicate the current standard to allow air quality conditions with implications of concern for the public welfare. He additionally took note of the advice from the CASAC in this review. Based on all of the above considerations, described in more detail in the proposal, including his consideration of the currently available evidence and quantitative exposure/risk information, the Administrator proposed to conclude that the current secondary standard provides the requisite protection against known or anticipated effects to the public welfare, and thus that the current standard should be retained, without revision.

3. Comments on the Proposed Decision

Over 50,000 individuals and organizations indicated their views in public comments on the proposed decision. Most of these are associated with mass mail campaigns or petitions. Approximately 40 separate submissions were also received from individuals, and 75 from organizations and groups of organizations; 40 elected officials also submitted comments. Among the organizations commenting were state and local agencies and organizations of state agencies, organizations of health professionals and scientists, environmental and health protection advocacy organizations, industry organizations and regulatory policy-focused organizations. The comments on the proposed decision to retain the current secondary standard are addressed here. Those in support of the proposed decision are addressed in section III.B.2.a and those in disagreement are addressed in section III.B.2.b. Comments related to aspects of the process followed in this review of the O_3 NAAQS (described in section I.D above), as well as comments related to other legal, procedural or administrative issues, and those related to issues not germane to this review are addressed in the separate Response to Comments document.

a. Comments in Support of Proposed Decision

Of the comments supporting the Administrator's proposed decision to retain the current secondary standard without revision, all generally state that the record supports the proposed decision, and note the CASAC conclusion that the current evidence is generally consistent with that available in the last review, and the CASAC conclusion that the evidence does not call into question the adequacy of the current standard and should be retained. In support of their views, some of these commenters state that new evidence is lacking that might call into question the objective for the standard to generally protect against cumulative exposures associated with median RBL estimates above 6%. They additionally state that the proposed decision appropriately addresses the *Murray Energy* remand issues. Further, these commenters conclude that the available evidence with regard to areas meeting the current standard does not call into question the adequacy of protection provided by the current standard from

the array of vegetation effects, including in Class I areas. Lastly, these commenters find the EPA's proposed judgments regarding the uncertainties associated with predicting responses of climate-related effects to changes in O_3 concentrations across the U.S., as well as the limitations in the availability of tools for such purposes, to be appropriate and well supported. The EPA agrees with these comments.

Some of these comments also express the view that welfare benefits of a more restrictive O_3 standard are highly uncertain, while such a standard would likely cause socioeconomic impacts that the EPA should consider and find to outweigh the uncertain benefits. While as discussed in section III.B.3 below, the Administrator does not find a more stringent secondary standard requisite to protect the public welfare, he does not consider economic impacts of alternate standards in reaching this judgment. As summarized in section I.A. above, in setting primary and secondary standards that are ''requisite'' to protect public health and welfare, respectively, as provided in section 109(b), the EPA may not consider the costs of implementing the standards. See generally *Whitman* v. *American Trucking Ass'ns,* 531 U.S. 457, 465–472, 475–76 (2001). Likewise, ''[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.'' See *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1185 (D.C. Cir. 1981); *accord Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 623–24 (D.C. Cir. 2019). Arguments such as the views on socioeconomic impacts expressed by these commenters have been rejected by the courts, as summarized in section I.A above, including in the recent *Murray Energy* decision, with the reasoning that consideration of such impacts was precluded by *Whitman's* holding that the ''plain text of the Act unambiguously bars cost considerations from the NAAQS-setting process'' (*Murray Energy Corp.* v. *EPA,* 936 F.3d at 621, quoting *Whitman* [531 U.S. at 471]).

b. Comments in Disagreement With Proposed Decision

Among those submitting comments that disagreed with the proposed decision to retain the current secondary standard, or that raised concerns with the basis for the decision, most of these commenters expressed concerns regarding the process for reviewing the criteria and standards and state that the proposal must be withdrawn, and a new review conducted. Most of these commenters also disagree with the EPA's proposed conclusion that the current standard, with its current averaging time and form, provides the requisite public welfare protection from known or anticipated adverse public welfare effects associated with the array of O_3-related effects, and generally state that the standard should be revised to be in terms of a single-year W126 index. Among the claims made in describing the basis for their view, these commenters claim that EPA failed to describe the basis for its proposed conclusion; to explain why a standard using the W126 index was not proposed, consistent with 2014 advice from the former CASAC, and to address the issues raised by court remand of the 2015 standard. Some commenters expressing the view that the standard should be revised also express the view that an additional standard should be established to protect from O_3 effects on climate.

With regard to the process by which this review has been conducted, we disagree with the commenters that claim that it is arbitrary and capricious or that it does not comport with legislative requirements. The review process, summarized in section I.D, implemented a number of features, some of which have been employed in past reviews and others which have not, and several which represent efficiencies in consideration of the statutorily required time frame for completion of the review. The comments received that raise concerns regarding specific aspects of the process are addressed in the separate Response to Comments document. As indicated there, the EPA disagrees with these comments. The EPA finds the review to have been lawfully conducted and the process reasonably explained. Accordingly, the EPA is not withdrawing the proposal and restarting the review.

(i) Metric for Standard

The premise of many of the comments expressing disagreement with the proposed decision is that the secondary standard must be a ''biologically relevant'' metric, which they identify to be the W126 index. Similarly, some commenters assert that EPA cannot lawfully or rationally set a secondary standard using the metric of the current standard, which is also the metric used for the primary standard, claiming that this contradicts EPA's recognition of the relevance of the W126 index as an exposure metric for assessing the level of protection from welfare effects, such as RBL. These commenters also claim that this approach arbitrarily disregards the recommendations of the prior CASAC, and, in doing so, imply that EPA must establish a W126 based standard because of prior CASAC advice.

We disagree with these commenters. The Clean Air Act includes no requirements with respect to what metrics should be used to establish the secondary standards. As is clear from the text of Section 109(b)(2) of the CAA, the critical test for NAAQS is whether they achieve the requisite protection. In so doing, it is not uncommon for the form and averaging time of a NAAQS to differ from exposure metrics most relevant to assessment of particular effects. These exposure metrics are based on the health or welfare effects evidence for the specific pollutant and commonly, in assessments for primary standards, on established exposure-response relationships or health-based benchmarks (doses or exposures of concern) for effects associated with specific exposure circumstances. Evidence for this is found in the common use, in assessments conducted for NAAQS reviews, of exposure metrics that differ in a variety of ways from the ambient air concentration metrics of those standards.[204] Across reviews for the various NAAQS pollutants over the years, the EPA has used a variety of exposure metrics to evaluate the protection afforded by the standards (see examples identified at 80 FR 65399–65400, October 26, 2015). Further, a single standard may provide protection from multiple different effects, the protection for which may be assessed using different exposure metrics. One standard may also provide protection from multiple pathways of exposure. Both the primary and secondary Pb standards provide examples of this. While these standards are expressed in terms of the concentration of lead in particles suspended in air, different exposure metrics have been used to evaluate the protection provided by the Pb standards. The salient exposure metric for assessment of protection provided by the primary standard has been blood Pb, while for the secondary standard, concentrations of lead in soil, surface water and sediment are pertinent, and have been evaluated to assess the potential for welfare effects related to lead deposition from air (73 FR 67009, November 12, 2008). In somewhat similar manner, the exposure metric used to evaluate health impacts in the primary sulfur dioxide standard review includes a 5-minute exposure

[204] The term design value, defined above, is used in this discussion to refer to the metric for the standard.

concentration. In contrast, the health-based standard for this pollutant is the average across three years of the 99th percentile of 1-hour daily maximum concentration of sulfur dioxide in ambient air (75 FR 35520, June 22, 2010; 84 FR 9866, March 18, 2019).

We disagree with the comment that a secondary standard with the same form and averaging time as the primary standard does not comply with the CAA. The CAA does not require that the secondary standard be established in a specific form or averaging time. The Act, at Section 109(b)(2), provides only that any secondary NAAQS ''shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. . . . [S]econdary standards may be revised in the same manner as promulgated.'' The EPA interprets this provision to leave it considerable discretion to determine whether a particular form and averaging time are appropriate, in combination with the other aspects of the standard (level and indicator), for specifying the air quality that provides the requisite protection, and to determine whether, once a standard has been established in a particular form, that form must be revised. Moreover, nothing in the Act or the relevant case law precludes the EPA from establishing a secondary standard equivalent to the primary standard in some or all respects, as long as the Agency has engaged in reasoned decision-making.[205]

Thus, we note that particular metrics may logically, reasonably, and for technically or scientifically sound reasons, be used in assessing exposures of concern or characterizing risk. The purpose, and use, of exposure metrics is different from the purpose, and use, of metrics for the standard, and as a result the metrics may differ from one use to the other. Exposure metrics are used to assess the likely occurrence and/or frequency and extent of effects under different air quality conditions, while the air quality standards are intended to control air quality to the extent requisite to protect from the occurrence of public health or welfare effects judged to be adverse. In this review of the O_3 secondary standard, the EPA agrees that based on evidence summarized in section III.A above, metrics such as the W126 index are appropriate for assessing exposures of concern for vegetation, characterizing risk to public welfare, and evaluating what air quality conditions might provide the appropriate degree of public welfare protection. We disagree, however, that the secondary standard must be established using those same metrics. Rather, when the Administrator judges that a standard using a different metric provides the requisite protection, in light of his consideration of all the elements of the standard together, he may reasonably establish or retain such a standard.

With regard to the commenter's emphasis on recommendations from the CASAC on the form of the secondary standard, the EPA generally agrees with the importance of giving such recommendations careful consideration. However, it is not necessary for EPA to address in this review each statement a prior CASAC made in a prior review. In addition, if a recommendation of a prior CASAC is raised in a subsequent review (*e.g.,* in public comments or as a focus in court decision being addressed), it is reasonable for the Agency to consider it in the context both of the current review and of consideration of all the other now available scientific, technical and policy-relevant information, including advice from the current CASAC. We note that in this review of the secondary standard, the current CASAC, based on its review of the information and analyses available in the current review, concurs with retention of a secondary standard with a metric that differs from commonly used vegetation exposure metrics, such as the W126 index (Cox, 2020a). We further note, under the relevant provisions of the CAA and case law interpreting them, the Administrator is never bound by the CASAC's conclusions but rather may depart from them when he has provided an explanation of the reasons for such differences.[206] While the EPA does not interpret the requirements of CAA sections 307(d)(3) and 307(d)(6)(A) to apply to every recommendation it has received from a prior CASAC, even assuming there are some circumstances in which EPA were required to comply with the requirements of CAA section 307(d)(3) and (6)(A) with respect to particular recommendations from a prior CASAC, these same principles would apply. Thus, the Administrator would not be bound to follow those recommendations, but rather could depart from them when he had explained his reasons for doing so. Accordingly, in reaching conclusions on the revised secondary standard in this review, the Administrator has given careful consideration to the current CASAC advice in this review and to issues raised by the prior CASAC that are subject to the *Murray Energy* remand. When he has differed from those CASAC recommendations, the reasons and judgments that led to a different conclusion are explained, as summarized in this section and in section III.B.3 below. Consistent with his consideration of all significant issues raised in public comments, the Administrator has also considered the issues raised by commenters that have also been raised by a prior CASAC, together with the Agency's responses to those comments, as summarized in this section and in section III.B.3 below.

The current air quality analyses demonstrate the successfulness of the current form and averaging time in controlling cumulative exposures, in terms of W126. These extensive air quality analyses, presented in the PA and summarized in the proposal, are based on data collected across the U.S. over a time span of nearly 20 years (85 FR 49892–49895, 49903–49904, August 14, 2020). One of these analyses describes the positive, linear relationship between long-term changes in the O_3 design value and long-term changes in the W126 index at monitoring sites across the U.S.[207] This positive, linear relationship exists for the O_3 design value with both a 3-year average and single-year W126 index (PA, Appendix 4D, Figure 4D–11). The existence of this relationship means that a change (*e.g.,* reduction) in the design value at a monitoring site was generally accompanied by a similar change (*e.g.,* reduction) in the W126 index, both in the 3-year average and in the single-year values. As the form and averaging time of the secondary standard have not changed since 1997, the analyses performed have been able to assess the amount of control exerted by these aspects of the standard, in combination

[205] In fact, the D.C. Circuit has upheld secondary NAAQS that were identical to the corresponding primary standard for the pollutant (*e.g., ATA III,* 283 F.3d at 375, 380 [D.C. Cir. 2002, upholding secondary standards for $PM_{2.5}$ and O_3 that were identical to primary standards]).

[206] See CAA sections 307(d)(3) and 307(d)(6)(A); see also *Mississippi* v. *EPA,* 744 F.3d 1334, 1354 (D.C. Cir. 2013) (''Although EPA is not bound by CASAC's recommendations, it must fully explain its reasons for any departure from them''); *id.* at 1358 (noting CASAC, like EPA, exercises both scientific judgment and public health policy judgment). Selection of a metric for the standard is a public health or public welfare policy judgment about what standards will control air quality to the extent judged requisite to protect from adverse public health or welfare effects.

[207] This analysis focuses on the relationship between changes (at each monitoring site) in the 3-year design value across the 17 design value periods from 2000–2002 to 2016–2018 and changes in the W126 index over the same period (PA, Appendix 4D, section 4D.3.2.3).

with reductions in the level (*i.e.,* from 80 ppb in 1997 to 75 ppb in 2008 to 70 ppb in 2015) on cumulative seasonal exposures in terms of W126 index. The analyses have found that the reductions in design value, presumably associated with implementation of the revised standards, have been accompanied by reductions in cumulative seasonal exposures in terms of W126 index (PA, section 4.4.1). Further, while the formulation of the W126 metric gives more weight to higher concentrations (in the context of its focus on cumulative exposure), it is much less effective at curbing elevated hourly concentrations (that can be important in altering plant growth and yield) than the current design value metric, as discussed in section III.B.2.b(ii) below.

In expressing the view that the secondary standard should be in terms of a W126 index, some commenters describe the EPA's statements regarding the protection from cumulative exposures that is provided by the current form and averaging time to be ''incidental'' and ''happenstance,'' which leads them to claim the EPA's findings of protection to be arbitrary. In support of their view, the commenters quote a statement of the prior CASAC cautioning against interpreting the W126 index levels in the W126 index scenario created for the 2014 WREA, by first adjusting air quality to meet the then-existing fourth maximum standard of 75 ppb, to be representative of implementation of a W126 index standard. The issue described by the prior CASAC related to the application to all monitoring sites of the precursor reduction necessary for the highest monitoring site in a region to just meet the scenario target; the prior CASAC's concern was that actual implementation of the target as a standard would not necessarily yield such reductions. We disagree with the commenters that this is relevant to the air quality analysis in the current review, in which we simply observe the W126 index values that exist in reality at sites that have met the existing secondary standard. Contrary to the context for the prior CASAC's caution, the analysis in the current review is not showing the results of a theoretical scenario created by modeling theoretical precursor reductions estimated for attaining a particular W126-based or fourth high standard. Rather, we are observing what the W126-based cumulative exposure is at ambient air monitoring sites that meet the current secondary standard. Thus, regardless of the labels assigned by the commenter to the findings of the air quality analyses in the current review, these analyses clearly document the success of the existing standard (with its fourth maximum form and 8-hour averaging time) in controlling exposure in terms of the W126 index.

Thus, in light of this evidence, the EPA disagrees with the commenters who express the view that to provide the requisite protection the secondary standard must be a W126 index standard. In assessing the air quality necessary to provide the requisite degree of protection, particularly for growth and related vegetation and ecosystem effects, the Agency has recognized the importance of cumulative exposures, but also the significance of higher peak exposures (as summarized in section III.B.2.b(ii) below) that can be characterized through other metrics (*e.g.,* N100). As a result, in assessing the protection provided by the current standard, the Agency has focused on the W126 index, expressed in terms of the average of three consecutive years (in light of considerations discussed below), as a metric for cumulative exposure, but has also considered the frequency and magnitude of elevated single-year W126 index values, and of elevated hourly O_3 concentrations (as discussed further below).

(ii) Protection Against Unusually Damaging Years

In the last review, the Administrator relied on the 70 ppb standard (as the fourth highest daily maximum 8-hour average concentration averaged over three consecutive years) to achieve a level of air quality that would restrict cumulative seasonal exposures to 17 ppm-hrs or lower, in terms of a 3-year average W126 value, in nearly all instances. The *Murray Energy* court found in relevant part that the EPA had not explained why that level of protection was requisite, in light of certain comments from the CASAC in 2014 recommending that EPA base a standard on a one-year W126 metric, in part to limit exposures in single unusually damaging years.[208] In responding to the remand,[209] we are explaining in this document that the EPA is looking to prevent the damaging effects of O_3 on tree growth as a proxy for public welfare effects related to the broad array of O_3's vegetation-related effects conceptually related to growth effects, including ecosystem-level effects (as discussed in section III.B.2.b(v) below). In this review, in assessing the air quality requisite to prevent adverse effects on public welfare from these effects, the EPA is not relying solely on maintaining a particular 3-year W126 value. Rather, we are considering air quality patterns that are associated with meeting the current standard, including control of peak hourly concentrations, and the exposures that would be expected under the current standard, including in terms of W126 values, particularly those averaged over a 3-year period. The EPA is explaining the grounds for our conclusion that use of the 3-year average W126 index is a reasonable basis for assessing protection from RBL, but also that the Administrator is using other exposure information in reaching the conclusion that retention of the existing standard (with its form and averaging time of the fourth highest annual daily maximum 8-hour average concentration, averaged over three years) provides the needed protection of RBL, including from what the *Murray Energy* court noted that the prior CASAC termed ''unusually damaging years.''

In disagreeing with the EPA's proposed decision, some commenters object to the EPA's use of a 3-year average W126 index in assessing different patterns of air quality using median tree seedling RBL as a surrogate for an array of vegetation-related effects, particularly those related to growth and productivity. In so doing, these commenters variously claim that this use of a 3-year average W126 index (rather than a single-year W126 index) is inconsistent with recommendations from the prior CASAC, does not address the court remand on this point, and that it is inadequate to protect vegetation from high years or years with hourly O_3 concentrations that can be most important in eliciting adverse effects.

The EPA disagrees with these commenters and notes that it has taken such concerns, as well as the court's remand, into account in the final decision. In evaluating the air quality

[208] The prior CASAC comments on this matter were in the context of its recommendation for a secondary standard in the form of a single-year W126 index, which as discussed below would be expected to provide relatively less control against high-concentration years compared with the current secondary standard. The prior CASAC additionally commented that it ''favor[ed] a single-year period'' which it stated would ''provide more protection for annual crops and for the anticipated cumulative effects on perennial species.'' The prior CASAC continued on to state that if the Administrator preferred, instead, to establish a secondary standard as a 3-year average W126 index, as a policy matter, the level should be revised downward (Frey, 2014b, p. iii). The prior CASAC stated the purpose for this step would be to be protecting ''against single unusually damaging years that will be obscured in the average'' (Frey, 2014b, p. 13).

[209] The Agency intends this decision, associated analyses conducted for this review in consideration of issues raised by the court's remand, and the discussions herein to constitute its response to the Murray Energy remand on this issue.

conditions allowed by the current standard, the EPA has focused on the W126 metric averaged over 3 years as the most appropriate measure of cumulative exposure for consideration of adverse effects on public welfare, but EPA has also considered other relevant exposure information, including higher exposures that might be expected to occur in an ''unusually damaging year.'' The Administrator's decision on the adequacy of protection provided by the current standards is based on the full scope of exposure information he has considered.

The EPA concludes that the 3-year average W126 index is a reasonable metric for assessing the level of protection provided by the current standard from cumulative seasonal exposures related to RBL, while noting that our evaluation for the protection provided by the current standard has also been informed by our consideration of other metrics (as described further below). In reaching this conclusion, we have taken into account the available evidence base and air quality analyses, with a focus on two types of considerations, as well as consideration of the context for RBL as a proxy for an array of other vegetation effects (discussed in section III.B.2.b(v) below). The first of the two consideration types concerns the E–R functions and their use with a 3-year average W126 index, and the second concerns the control by the W126 index metric of exposures that might be termed ''unusually damaging.'' With regard to the first, we find our use of the 3-year average W126 index appropriate in light of the approach used in deriving the E–R functions from the underlying data (from exposures of varying durations, including of multiple years), and the evidence available for evaluating these functions across multiyear exposures.[210] Additionally, with regard to the second consideration, we recognize limitations associated with a reliance solely on W126 index as a metric to control exposures that might be termed ''unusually damaging.'' For example, two different air quality patterns for which the associated W126 index is the same may have very different incidence of elevated O_3 concentrations, and accordingly pose different risks to vegetation. As discussed below, however, the occurrence of such concentrations (and any associated risk of damage) are controlled by the current secondary standard.

In light of this evidence, and recognizing the role for both peak and cumulative exposures in eliciting growth and related vegetation and ecosystem effects, the EPA concludes that focusing solely on W126 index (either in terms of a single year or 3-year average) in considering the public welfare protection provided by the current standard would not be considering all the relevant scientific information. To the extent that the prior CASAC advised that the EPA should focus solely on single-year W126 index values in evaluating the protection provided by the secondary standard, the EPA disagrees that this would provide the needed protection, for the reasons explained more fully below. In this regard, we additionally note that the current CASAC concluded that focusing on three-year average W126 index values in considering the public welfare protection offered by the secondary standard ''appears of reasonable thought and scientifically sound'' (Cox, 2020a, p. 19).

With regard to the established tree seedling E–R functions, we note there are aspects of the datasets and methodology on which the E–R functions are based which provide support for a 3-year average approach. As summarized in section III.A.2.c(i) above, in deriving the E–R functions from studies of durations that varied from shorter than 90 days to multiple years or growing seasons, the results were normalized to the duration of a single 90-day seasonal period (PA, section 4.5.1.2 and Appendix 4A, pp. 4A–28 to 4A–29 and footnote 17). Inherent in this approach is an assumption that the growth impacts relate generally to the cumulative O_3 exposure across the multiple growing seasons, *i.e.,* with little additional influence related to any year to year differences in the exposures. As discussed in the proposal, the use of a 3-year average in assessing RBL using the established tree seedling E–R functions is compatible with the normalization step taken to derive functions for a seasonal 90-day period from the underlying data with its varying exposure durations (85 FR 49901, August 14, 2020).

This concept of the importance of cumulative multiyear O_3 exposure to multiyear impacts, and its representation as an average, is also reflected in the evaluation of the predicted growth impacts compared to observations from the multiyear study of O_3 impacts on aspen by King et al (2005), as presented in the 2013 and 2020 ISAs and summarized in the PA (PA, Section 4.5.1.2). The ISAs considered the 6-year experimental dataset of O_3 exposures and aspen growth effects with regard to correspondence of E–R function predictions with study observations (2020 ISA, Appendix 8, section 8.13.2 and Figure 8–17; 2013 ISA, section 9.6.3.2, Table 9–15, Figure 9–20). The analysis in the 2013 ISA compared observed reductions in growth for each of the six years to those predicted by applying the established E–R function for Aspen to cumulative multi-year average W126 index values (2013 ISA, section 9.6.3.2).[211] [212] The evaluation in the 2020 ISA applied the E–R functions to the single-year W126 index for each year rather than the cumulative multi-year W126 (2020 ISA, Appendix 8, Figure 8–17), with this approach indicating a somewhat less tight fit to the experimental observations (2020 ISA, Appendix 8, p. 8–192),[213] Both ISAs reach similar conclusions regarding general support for the E–R functions across a multiyear study of trees in naturalistic settings (ISA, Appendix 8, section 8.13.3 and p. 8–192; 2013 ISA, p. 9–135).

Based on all of the above considerations, the EPA finds the evidence to support a 3-year average W126 index for use in assessing the level of protection provided by the current standard from cumulative seasonal exposures related to RBL of concern based on the established E–R functions. As discussed in section III.B.3 below, the EPA additionally finds the 3-year average metric to be reasonable in the context of the use of RBL as a proxy to represent an array of vegetation-related effects. In the discussion immediately below, we additionally and specifically address the issue of protection from ''unusually damaging years'' of vegetation exposure.

With regard to the comment that cited a recommendation from the prior CASAC on protection of vegetation

[210] Additionally, as described in section III.B.1.c above and III.B.2.b(v) below, the EPA's identification of 17 ppm-hrs for a target W126 index of 17 ppm-hrs (*e.g.,* versus 18 ppm-hrs) was in consideration of the prior CASAC recommendation for considering a ''lower'' level ppm-hrs.

[211] For example, the growth impact estimate for year 1 used the W126 index for year 1; the estimate for year 2 used the average of W126 index in year 1 and W126 index in year 2; the estimate for year 3 used the average of W126 index in years 1, 2 and 3; and so on.

[212] One finding of this evaluation was that ''the function based on one year of growth was shown to be applicable to subsequent years'' (2013 ISA, p. 9–135).

[213] Based on information drawn from Figure 8–17 in the 2020 ISA, the correlation metric (r^2) for the percent difference (estimated vs observed biomass) and year of growth can be estimated to be approximately 0.7, while using values reported in Table 9–15 of the 2013 ISA (which are plotted in Figure 9–20), the r^2 for predicted O_3 impact *versus* observed impact is 0.99 and for the percent difference *versus* year is approximately 0.85.

against ''unusually damaging years'' and the part of the court remand referencing that CASAC recommendation, we have considered the CASAC discussion using this term, in the context of the court remand. Use of this term by the prior CASAC occurs in the 2014 letter on the second draft PA in the 2015 review (Frey, 2014b). Most prominently, the prior CASAC defined as damage ''injury effects that reach sufficient magnitude as to reduce or impair the intended use or value of the plant to the public, and thus are adverse to public welfare'' (Frey, 2014b, p. 9). The prior CASAC additionally provided advice with regard to surrogate metrics for judging such ''damage,'' *e.g.,* use of RBL for judging effects on trees and their related functions and ecosystem services, use of crop RYL for judging public welfare effects of crop effects (Frey, 2014b, p. 10). We also note that the context for the prior CASAC's use of the phrase ''unusually damaging years'' is in considering the form and averaging time for a revised secondary standard in terms of a W126 index (Frey, 2014b, p. 13), which as discussed below is relatively less controlling of high-concentration years, rather than in the context of the current secondary standard and its fourth highest daily maximum 8-hour metric.

While the prior CASAC did not provide any specificity or details as to the exposure circumstances and damage intended by its more general phrasing, nor did it cite to specific evidence in scientific publications, we agree with the general concept that particular air quality patterns in a year may pose particular risk of vegetation damage, in terms of both or either growth-related effects or visible foliar injury (discussed in section III.B.2(iii) below). Across past O_3 NAAQS reviews, the air quality criteria for vegetation effects have emphasized the risk posed to vegetation from higher hourly average O_3 concentrations (*e.g.,* ''[h]igher concentrations appear to be more important than lower concentrations in eliciting a response'' [ISA, p. 8–180]; ''higher hourly concentrations have greater effects on vegetation than lower concentrations'' [2013 ISA, p. 91–4] ''studies published since the 2006 O_3 AQCD do not change earlier conclusions, including the importance of peak concentrations, . . . in altering plant growth and yield'' [2013 ISA, p. 9–117]). In fact, the EPA has recognized the W126 index for E–R models for growth and yield (in the current and prior ISA and prior AQCD) in part due to its preferential weighting of higher concentrations (ISA, p. 8–130).

We note, however, that while the W126 index weights higher hourly concentrations, it cannot, given its definition as an index that sums three months of weighted hourly concentrations into a single value, always differentiate between air quality patterns with high peak concentrations and those without such concentrations. This is illustrated by the following two hypothetical examples. In the first example, two air quality monitors have a similar pattern of generally lower average hourly concentrations, but differ in the occurrence of higher concentrations (*e.g.,* hourly concentrations at or above 100 ppb). The W126 index describing these two monitors would differ. In the second example, one monitor has appreciably more hourly concentrations above 100 ppb compared to a second monitor; but the second monitor has higher average hourly concentrations than the first. In the second example, the two monitors may have the same W126 index, even though the air quality patterns observed at those monitors are quite different, particularly with regard to the higher concentrations, which have been recognized to be important in eliciting responses (as noted above).

Thus, the EPA disagrees with a view implied by many of the commenters (who object to the EPA's proposed decision) that the sole focus for assessing public welfare protection, related to vegetation damage, and air quality control provided by the secondary standard should be on the W126 index. This view ignores both the limitations of the W126 index itself in distinguishing among different patterns of hourly O_3 concentrations and the fact that the current secondary standard has, by virtue of its form, a metric that does. With regard to these limitations of the W126 index, as described above, two different locations or years may have different patterns of hourly concentrations but the same W126 index value. This was recognized in the study by Lefohn et al. (1997), which observed the appreciable differences between the prevalence of hourly concentrations at or above 100 ppb in exposures on which the E–R functions are based and those common in ambient air.[214]

This potential for such a difference in peak concentrations between two different locations with the same W126 index was noted by one commenter who objected to the EPA's focus on a 3-year average W126 index in assessing RBL and advocated use of a single-year W126 index. This commenter stated that the same 3-year average could be maintained in two different locations in which the annual exposure may differ due to ''variability of the higher hourly average concentrations associated with vegetation effects.'' In emphasizing the higher hourly average concentrations associated with effects, the commenter cited the support provided by the evidence for the San Bernardino National Forest, described in the 2013 ISA and prior CDs (*e.g.,* 2013 ISA, section 9.5.3.1). We agree with this point and additionally note that this point also applies to two locations with the same single-year W126 index, given its definition (as noted above).

Given the mathematics inherent in calculation of the W126 index, while the metric is useful for comparing cumulative exposures, it can conceal peak concentrations that can be of concern (as described above). More specifically, one year or location could have few, or even no, hourly concentrations above 100 ppb[215] and the second could have many such concentrations; yet each of the two years or locations could have the identical W126 index (*e.g.,* equal to 25 or 17 or 10 ppm-hrs, or some other value). However, as can be seen by the historical ambient air monitoring dataset of O_3 concentrations, the form of the current standard limits the occurrence of such elevated concentrations, *e.g.,* at or above 100 ppb (PA, Appendix 2A, section 2A.2; Wells, 2020).

Analyses of hourly concentrations for different air quality scenarios developed in consideration of the remand and such comments (and documented in a technical memorandum to the docket) show the form and averaging time of the existing standard to be much more effective than the W126 index in limiting the number of hours with O_3 concentrations at or above 100 ppb (N100) and in limiting the number of days with any such hours (Wells,

[214] For example, many of the experimental exposures of elevated O_3 on which the established E–R functions for the 11 tree seedling species are based, had hundreds of hours of O_3 concentrations above 100 ppb, far more than are common in (unadjusted) ambient air, including in areas that meet the current standard (Lefohn et al. 1997; PA, Appendix 2A, section 2A.2; Wells, 2020). Similarly, the experimental exposures in studies supporting some of the established E–R functions for 10 crop species also include many hours with hourly O_3 concentrations at or above 100 ppb (Lefohn and Foley, 1992).

[215] The value of 100 ppb is used here as it has been in some studies focused on O_3 effects on vegetation, simply as an indicator of elevated or peak hourly O_3 concentrations (*e.g.,* Lefohn et al. 1997, Smith, 2012; Davis and Orendovici, 2006; Kohut, 2007a). Values of 95 ppb and 110 ppb have also been considered in this way (2013 ISA, section 9.5.3.1).

2020).[216] For example, during the recent design value period (2016–2018), across all sites that met the current standard, few sites had any hours at or above 100 ppb in a year (6% in the highest year, Wells, 2020, Table 2).[217] Among the sites with any such hours, the vast majority had fewer than five such hours (99.5% in the highest year, Wells, 2020, Table 2), with none having more than ten such hours,[218] and no site having more than three days in any one year with any such concentrations (Wells, 2020, Figures 4 and 5). In comparison, sites with an annual W126 index below 15 ppm-hrs recorded nearly 40 hourly concentrations at or above 100 ppb, and as many as seven days with such a concentration (Wells, 2020, *e.g.,* Figures 10 and 11).[219] A similar pattern is seen using the historical dataset extending back to 2000. This historical dataset also shows the appreciable reductions in peak concentrations (via either the N100 or D100 metric) that have been achieved in the U.S. as air quality has improved under O_3 standards of the existing form and averaging time (Wells, 2020, Figures 12 and 13). Thus, based on the findings of both the analyses in the PA (PA, Appendix 2A) and the additional analyses (Wells, 2020), the EPA disagrees with the commenter that the proposed decision ignores the importance of elevated hourly O_3 concentrations in eliciting effects on vegetation. Rather, the proposed decision, and final decision to retain the existing standard, which controls peak concentrations and also cumulative seasonal exposure in terms of W126 index, explicitly considers this importance and address it in a way that is more effective than a standard expressed in terms of the W126 index would be, even based on a single-year W126 well below 17 ppm-hrs (as shown in the additional air quality analyses [Wells, 2020]).

In summary, we find that a 3-year average is appropriate for use in assessing protection for RBL based on the established tree seedling E–R functions, in light of the discussion above, while also finding it important to consider additional aspects of O_3 air quality, that influence vegetation exposures of potential concern, in reaching conclusions about the adequacy of the current standard. We disagree with the commenters and the prior CASAC that focus on a single year W126 index is needed to protect against years with O_3 concentrations with the potential to be ''unusually damaging,'' Rather, as described here, the metric of the current standard provides strong protection against elevated hourly concentrations that might contribute to ''unusually damaging'' years with the potential to be adverse to the public welfare, as well as providing protection against effects of cumulative exposures seen in experimental studies. Accordingly, we disagree with those commenters that express the view that the current standard does not provide such protection.

(iii) Visible Foliar Injury

In support of their disagreement with the EPA's proposed decision, some commenters express the view that the EPA's proposed conclusion that the current standard provides sufficient protection from an incidence and severity of visible foliar injury that would reasonably be judged adverse to the public welfare is unlawful. These commenters variously claim that EPA analyses are flawed, arbitrary, and ignore conclusions and judgments of the prior CASAC; cite some studies that they state indicate a threshold for foliar injury lower than 25 or 17 ppm-hrs; claim that the EPA must, yet does not, identify a level of injury that is adverse; state that the EPA does not explain its use of USFS biosite scores in this regard, and state that the EPA does not adequately address the *Murray Energy* remand related to these effects. With regard to the latter, the Agency intends this decision, associated analyses conducted for this review in consideration of issues raised by the court remand, and the discussions herein to constitute its response to the *Murray Energy* remand on these effects.

With regard to EPA's analyses of the current information on O_3-related visible foliar injury, some commenters claim that the EPA needs to and has not adequately explained why it disagrees with the conclusions and judgments of the prior CASAC in comments on the 2014 draft PA regarding a W126 index value of 10 ppm-hrs. As an initial matter, we note that in discussing this topic, these commenters conflate the prior CASAC's scientific evidence-based recommendations on the secondary standard with its judgments of scientific information in the context of its policy recommendations. In its letter on the draft PA, the prior CASAC explicitly separates into two separate paragraphs its scientific judgment based recommendations to the Administrator on the standard from its additional policy recommendations, with this statement regarding visible foliar injury occurring in the second paragraph (that addresses policy recommendations) (Frey, 2014b, p. iii).[220] Thus, we

[216] The impact of the current form of the standard on occurrence of elevated hourly concentrations is also seen by a recent study submitted with comments (Neufeld et al., 2019). For example, the frequency of episodes defined by three consecutive hours at or above 60 ppb, as well as the magnitude of W126 index, has appreciably declined at locations within and immediately adjacent to the Smoky Mountains National Park, and the periods of respite from elevated episodes has appreciably increased (Neufeld et al., 2019). This was found for low elevation sites, and also high elevation Park sites, which generally have higher levels (Neufeld et al., 2019).

[217] In these analyses the N100 and D100 metrics are based on counts of hourly O_3 concentrations at or above 100 ppb across the consecutive 3-month period with the highest total (Wells, 2020). The metric D100 is the count of days with an hour at or above 100 ppb.

[218] We note that we are not intending to ascribe specific significance to five days with an hour at or above 100 ppb or ten hours such, *per se.* Rather, these are used simply as reference points to facilitate comparison to illustrate the point that such high concentrations, which based on toxicological principles, pose greater risk to biota than lower concentrations (*e.g.,* ''[h]igher concentrations appear to be more important than lower concentrations in eliciting a response'' [ISA, p. 8–180]; ''higher hourly concentrations have greater effects on vegetation than lower concentrations'' [2013 ISA, p. 91–4] ''studies published since the 2006 O_3 AQCD do not change earlier conclusions, including the importance of peak concentrations, . . . in altering plant growth and yield'' [2013 ISA, p. 9–117]).

[219] We also note the higher percentages of sites with an N100 above five among sites meeting a single-year W126 index of 7 ppm-hrs than sites meeting the current standard (Wells, 2020, Table 2). Sites with an annual W126 index of 7 ppm-hrs also record a greater percentage of sites with more than two days with an hour at or above 100 ppb (Wells, 2020, Table 2).

[220] The first paragraph, conveying scientific judgment provides a range of levels for a revised standard (Frey, 2014b, p. iii). The second begins by noting that the ''scientific judgment'' regarding a revised secondary standard, in prior paragraph, are based on the scientific evidence. Midway through that paragraph, as shown below, the prior CASAC turns to its policy recommendations, in which it relates various W126 index values in different ways to various effect categories, including crop yield loss, foliar injury, and relative biomass loss (Frey, 2014b, p. iii). Given that the prior CASAC recommended multiple times in this letter a standard level range that extends higher than 10 ppm-hrs (to 15 ppm-hrs), the fact that the sentence regarding visible foliar injury in the version of this second paragraph that appears within the attachment to the letter begins with the phrase ''[b]ased on its scientific judgment'' cannot reasonably be interpreted to be overriding the Committee's scientific advice on the standard. Rather, the prior CASAC appears to be implying that to the extent the Administrator judges, as a matter of public welfare policy, it important to consider such a focus on foliar injury, the prior CASAC's scientific judgment is that 10 ppm-hrs is required to reduce it (Frey, 2014b, pp. iii and 15). In relevant part, the second paragraph reads:

In reaching its scientific judgment regarding the indicator, form, summation time, and range of levels for a revised secondary standard, the CASAC has focused on the scientific evidence for the identification of the kind and extent of adverse effects on public welfare. The CASAC acknowledges that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act. . . . *As a policy recommendation,* separate from its advice above regarding scientific findings, the CASAC advises

reasonably interpreted the statement by the prior CASAC as simply indicating a consideration of the prior CASAC in reaching its decision on the recommended range of levels, stated multiple times in the same letter and including levels higher than 10 ppm-hrs, that the Committee thought might be useful (*e.g.,* as a ''policy recommendation'') to the Administrator in exercising the discretion granted him under the Act for specifying a secondary standard (Frey, 2014b, p. iii). The prior CASAC statement regarding a W126 index value of 10 ppm-hrs, is related to visible foliar injury at biosites, and, more specifically, is based on its consideration of an EPA cumulative analysis of a biomonitoring dataset presented in the 2013 draft WREA.[221] This analysis, the dataset for which is further described in Appendix 3C of the PA for the current review, does not show, as implied by the 2014 CASAC comments, that, in considering sites with W126 index values from highest to lowest, there is no reduction in prevalence of sites with visible foliar injury above a W126 index of 10 ppm-hrs (*i.e.,* there are not differences in the occurrence of injury across higher values).[222] The 2014 WREA analysis could not and was not addressing this issue.

The 2014 WREA analysis is a cumulative analysis of the proportion of records with nonzero BI scores; each point graphed in the analysis includes the records for the same and lower W126 index values. Not only is the analysis silent with regard to severity of injury, but it also does not compare the incidence of visible foliar injury for records of differing W126 index values. Rather, each point in the cumulative frequency figure represents all the records included in the group (thus far), which increase by one with each new point (moving through dataset). Where the record added to the group has the same W126 index value as the prior included record, the point is at the same location along the x-axis, but at a slightly higher location along the y-axis (if it has a nonzero BI), thus contributing to an increase in the proportion of sites (the metric assessed on the y-axis). Thus, where there are many records with quite similar W126 index values, the points do not appreciably move along the x-axis, yet when they have a nonzero BI score, they are placed higher along the y-axis (as each represents another nonzero record in the dataset, thus increasing the proportion of records). At such a location along the x-axis, an inflection occurs (*i.e.,* a location along the x-axis for which each additional record had the same or quite similar W126 index as the prior record such that the point is at a similar location on the x-axis but contributes to increasing values along the y-axis). As the addition of each new record makes the dataset larger, such increases (or decreases for zero BI records) become progressively smaller (along the y-axis), making such changes or inflections less pronounced at higher W126 index values. Accordingly, given the much greater representation in the dataset of relatively lower W126 index records (some two thirds of the dataset has W126 index values at/below 11 ppm-hrs), the prominent inflection point noted by the prior CASAC on the cumulative frequency graph occurs around 11 ppm-hrs, and the figure from the 2014 WREA shows only small changes in the height of the line with increasing W126 index. This does not mean that records with higher W126 index values have no greater occurrence of foliar injury than values below 11 ppm-hrs; in fact, they do, most particularly the records with W126 index values above 25 ppm-hrs (PA, Figure 4–5). Thus, we disagree with the prior CASAC statement that W126 index values below 10 ppm-hrs are required for any reduction in visible foliar injury and with the suggestion that the WREA cumulative analysis supports such a conclusion. Given that the statement by the prior CASAC did not provide any information to indicate another basis for its statement and because the 2014 WREA analysis cannot and does not address this issue, we conclude that the prior CASAC's statement lacks scientific support. Based on this conclusion, the Administrator does not find this statement from the prior CASAC informative to his consideration of the adequacy of the protection provided by the current standard for adverse public welfare effects related to visible foliar injury (discussed in section III.B.3 below).

Unlike the 2014 WREA cumulative frequency analysis, the presentations in the PA for this review allow for comparison of injury incidence, and severity, at distinctly different exposures. As can be seen by graphs of the distribution of nonzero BI scores for bins of increasing W126 index estimates, the greatest representation of nonzero BI scores occurs in the bin with the highest W126 index estimates, which for the normal soil moisture category is above 25 ppm-hrs (PA, Figure 4–5). In disagreeing with the EPA's observations from this analysis, these commenters express the view that the higher percentage at the higher W126 index level is not meaningful because there are fewer records for the higher W126 index levels. While we agree that there are fewer records in the higher W126 index bins, as noted above, we disagree that there are too few records in those bins to support some interpretation for some soil moisture categories (such as the normal or dry categories), although for other soil moisture categories (*i.e.,* wet), the small sample size does limit interpretation. Sample size in each bin was considered in the PA analysis and was recognized as placing a limitation on interpretation of patterns for the wet soil moisture category. Contrary to these commenters' view that EPA provides no reason for giving little focus to the higher W126 index bins for the wet soil moisture category, the PA explains that interpretations of patterns across the higher W126 bins are limited for the wet soil moisture category, noting that the number of records in each of the W126 bins above 13 ppm-hrs comprise less than 1% of the records available for that soil moisture category (PA, Appendix 4C, section 4C.6). Thus, we agree with these commenters that sample size is an important consideration in reaching conclusions from this dataset, and, contrary to the commenters' assertion of providing no valid reasons with regard to the EPA's lesser emphasis on the wet soil moisture category, the proposal stated that the PA observations focused primarily on the records for the normal or dry soil moisture categories explicitly in recognition of those categories having adequate sample size which the bins above 13 ppm-hrs did not for the wet soil moisture category (85 FR 49890, August 14, 2020). While the dataset includes an extremely small number of records in the wet soil moisture category that fall into the higher W126 index bins

that a level . . . below 10 ppm-hrs is required to reduce foliar injury. A level of 7 ppm-hrs . . . offers additional protection against crop yield loss and foliar injury. . . . Thus, lower levels within the recommended range offer a greater degree of protection of more endpoints than do higher levels within the range. (Frey, 2014b, p. iii, [emphasis added]).

[221] In reference to the 2013 draft WREA cumulative frequency analysis (*e.g.,* 2013 draft WREA, Figures 7–9 to 7–12), a 2014 CASAC comment cited by commenters states that ''W126 values below 10 ppm-hrs [are] required to reduce the number of sites showing visible foliar symptoms'' (Frey, 2014b, p. 14).

[222] We note that in light of, and subsequent to, the prior CASAC's 2014 letter in the last review, the EPA had considered the extensive evidence documented in the 2013 ISA, as well as analyses of USFS data in the 2008 and 2015 reviews, including technical memos developed after the prior CASAC provided its 2014 advice (80 FR 65376, 65395–96, October 26, 2015). In the current review, the now expanded available data and analyses augment the support for EPA's conclusions in this regard.

(just 18 distributed across the three W126 index bins above 13 ppm-hrs),[223] there are more than 550 records categorized as normal soil moisture distributed across all five bins for W126 index above 13 ppm-hrs, more than 40 in each bin (PA, Appendix 4C, Table 4C–4). To the extent that the commenters are suggesting that the EPA is disregarding data for sites categorized as wet soil moisture, we disagree. In recognition of the role of soil moisture in contributing to a condition ''necessary for visible foliar injury to occur,'' the PA analysis presents BI scores separated into groups based on categorization related to soil moisture (ISA, Appendix 8, p. 8–13; 85 FR 49881; PA, pp. 4–40 to 4–41). The EPA thus considered the available evidence for all of the soil moisture categories, but with regard to any patterns evidenced for the higher W126 index bins (above 13 ppm-hrs), the EPA reasonably explained its focus on two of the three categories (the normal or dry soil moisture categories), and lesser attention to the third category (wet soil moisture) due to the extremely small number of records in that category that fall into the higher W126 index bins.

Further, in addition to incidence of sites with any injury, the PA presentations indicate that the severity of injury is also highest in records for the highest W126 index values, appreciably higher that it is in all of the lower W126 index bins. For normal soil moisture category, the median BI score across the nonzero records in the highest W126 bin (greater than 25 ppm-hrs) is just over 10 (with an average over 15), compared to well below 5 (averages below 7) for each of the lower W126 bins (PA, Figure 4–5, Appendix 4C, Table 4C–5). Both of these observations are consistent with an E–R relationship of O_3 with visible foliar injury, while the variability observed across the full dataset, in addition to perhaps indicating limitations in some aspects of the dataset (*e.g.,* categorization by soil moisture, among others [PA, Appendix 4C, section 4C.5]), no doubt also indicates the role of other factors that have not been completely accounted for. Given the evidence from controlled experiments documented across many years, the lack of noticeable change in incidence or severity across lower W126 index values may, as recognized in the PA, relate to a number of factors, including uncertainties in the assignment of W126 index estimates to the biosite locations and the soil moisture categorization of sites, as well as potential for differences in individual plant responses in controlled experiments from plant communities in natural environmental settings. Although such factors may contribute to an unclear pattern at lower exposures, precluding reaching conclusions regarding O_3-related response across the lower W126 index bins, the observed response for the highest bin clearly indicates an O_3-related response for W126 index values above 25 ppm-hrs.

Some commenters question the significance EPA ascribes to its observation that the BI scores are appreciably higher for records in the highest W126 index bin, cryptically characterizing the observation as describing a ''derivative of a derivative.'' Yet, this observation is simply focused on the response (*e.g.,* incidence of BI score greater than 0 or 5 or 15) exhibited across the range of exposure levels evaluated. The EPA makes this observation in assessing the dataset as to whether an E–R relationship is exhibited and if so, at what part of the exposure range is there a noticeable increase in response. This assessment, in combination with related evidence, then informs the Agency's conclusions regarding O_3 exposure circumstances that influence BI scores, as well as levels of W126 for which such an influence is indicated.[224] The commenters quote the prior CASAC as characterizing the 2014 WREA analysis as ''a change in the E–R slope,''[225] but, as discussed in detail above, the 2014 WREA figure is presenting a cumulative frequency analysis, which, by its design, does not show ''a change in the E–R slope.'' Such an analysis, because responses are not compared among distinct and discrete exposures, as explained above, is not well described as an exposure-response assessment (*i.e.,* an analysis of responses occurring across a range of different exposures). This is in contrast to the current PA presentation of BI scores across bins of increasing W126 index, which presents the occurrence of responses, quantified by magnitude of BI score, associated with multiple different exposures (presented as bins). Thus, the EPA finds the current analyses in the PA, and not the cumulative frequency analysis in the 2014 WREA, to be informative to the consideration of relationships between extent of visible foliar injury and W126 index, and finds the 2014 WREA analysis to be mistakenly interpreted by the commenters.

Further some commenters, who object to the Administrator's proposed focus on BI scores above 15 for his consideration of visible foliar injury that may be adverse to the public welfare, additionally suggest that EPA should give weight to all nonzero BI scores in considering the appropriate protection against this effect for the standard. As an initial matter, contrary to the implication of the commenters that any amount of visible foliar injury is adverse to the affected plant, we note the long-standing conclusions that visible foliar injury ''is not always a reliable indicator of other negative effects on vegetation,'' such as growth and reproduction, and the ''significance of ozone injury at the leaf and whole-plant levels depends on how much of the total leaf area of the plant has been affected, as well as the plant's age, size, developmental stage, and degree of functional redundancy, among the existing leaf area'' (ISA, p. 8–24; 2013 ISA, section 9.4.2). Further, we disagree with the further implication of these commenters that any occurrence of a nonzero BI score in the PA dataset can be used to identify O_3 exposure conditions that are adverse to the public

[223] The records for the wet soil moisture category in the higher W126 bins are more limited than the other categories, with nearly 90% of the wet soil moisture records falling into the bins for W126 index at or below 9 ppm-hrs, limiting interpretations for higher W126 bins (PA, Appendix 4C, Table 4C.4 and section 4C.6). The number of records in each of the W126 bins above 13 ppm-hrs (sample size ranging from zero to 9) comprise less than 1% of the wet soil moisture category. Accordingly, the PA observations focused primarily on the records for the normal or dry soil moisture categories, for which all W126 index in the analysis, including those above 13 ppm-hrs, are better represented (85 FR 49890, August 14, 2020). For the wet soil moisture category, we agree with the commenter's statement that ''higher percentage at higher levels isn't necessarily meaningful, because there are fewer sites with any data at those levels,'' however note that there is much greater representation of the normal and dry soil moisture categories in each of the higher bins, extending to the highest bins, than is the case for the wet soil moisture category bins.

[224] Such information informs the Administrator's consideration of the currently available evidence and the extent to which it can inform his judgments on O_3 air quality associated with visible foliar injury of such an extent and severity in the environment as to indicate adverse effects to the public welfare. Such judgments, as discussed further below, rely on information on relationships between different O_3 air quality metrics and injury incidence and severity as well as factors influencing the public welfare significance of different incidence and severity of foliar injury in vegetated areas valued by the public (*e.g.,* as summarized in section III.A.2.b).

[225] This characterization was made in the 2014 letter providing the prior CASAC's review of the second draft WREA. As noted by some commenters, the letter goes on to state, ''[b]ased on this E–R slope change, 10 ppm-hrs is a reasonable candidate level for consideration in the WREA, along with other levels'' (Frey, 2014c, p. 7). Although the EPA did not examine the specific value of 10 ppm-hrs in the 2014 WREA, as observed by these commenters, the EPA did consider this recommendation in the 2015 decision, contrary to the claim of the commenters (80 FR 65395–96, October 26, 2020).

welfare. As discussed in section III.A.2.b above, a number of factors influence the public welfare implications of visible foliar injury, and as discussed further below, the Administrator has taken these into account in his decision making regarding the protection from such effects that should be afforded by the secondary standard.

These commenters additionally claim that the USFS dataset indicates a clear relationship between the W126 metric and foliar injury. While we agree that the dataset provides some support for the conclusion of a greater incidence of nonzero BI scores and higher scores for the highest W126 bin, a change in response is not evident across the full range of W126 index levels (for records of similar soil moisture category), thus suggesting a limitation of the dataset in its ability to describe the E–R relationship of BI scores with W126 index. As discussed in the PA, limitations in the dataset (*e.g.,* with regard to assignment of W126 index estimates to biosite records and the approach for accounting for the role of soil moisture) may be contributing to the lack of a clearly delineated E–R relationship of injury occurrence and BI score with W126 index across a range of W126 index values, such that a clear shape for a relationship between these variables is not evident with this dataset, and may be contributing to uncertainties in this regard. It is with the increase in W126 for the last bin (>25 ppm-hrs) that the accompanying noticeable increase in response provides increased confidence in that response (BI scores) being related to a particular magnitude of the O_3 metric. It is this consideration which leads to the emphasis that EPA's conclusions from this analysis place on W126 index above 25 ppm-hrs, albeit with a recognition of some associated uncertainty.

Regarding the Administrator's judgment of the extent and severity of visible foliar injury that may be adverse to the public welfare, some commenters state that the EPA must, and has not, considered the full USFS dataset, including records for which the BI scores are below 5, and they express the view that the USFS data indicate injury (*i.e.,* a nonzero BI score) to be occurring at W126 index values as low as 3 ppm-hrs. In so doing, they note the occurrence of scores above 15 in the lowest bin (W126 index below 7 ppm-hrs). These commenters note that a third of all records with a BI above 15 are in the lowest W126 index bin (W126 <7 ppm-hrs) and more than 500 records with nonzero BI are in higher bins, seemingly intending this as support of their view that the EPA should identify a W126 of 7 ppm-hrs as a target level for visible foliar protection. However, this line of logic seems to ignore the fact that this bin also has over a third of the records with a BI above zero (PA, Table 4C–4), a fact which would seem contrary to these commenters' position that 7 ppm-hrs would protect against such scores. All three of these observations are likely due to the fact that this bin contains 42% of all records and the most records of any bin, by far (PA, Appendix 4C, Table 4C–4). Accordingly, the more important observation with regard to the extent of conclusions supported by the dataset on the role of W126 index in influencing BI scores is that the proportion of records in the lowest W126 bin that have scores above 15, 5 or 0 is appreciably less that in the highest W126 index bin (PA, Appendix 4C, Table 4C–6). The fact that there is not a clear pattern of increasing proportion across the intervening (and full set of) bins indicates there to be factors unaccounted-for in this dataset with regard to the O_3 exposure circumstances and the environmental circumstances that together elicit increased scores in vegetated areas.

In considering the PA analyses of the biosite dataset in light of these comments, we first note that, as described in the PA, the USFS dataset includes a broad assortment of BI scores, extending down to zero, occurring across the range of W126 estimates applied to the records (PA, Appendix 4C, Figure 4C–3). Contrary to the statement by these commenters, the EPA *has* considered the full dataset. The PA documents the various ways in which this is done, and the proposal discusses key observations from this dataset to inform the Administrator's judgment on adversity to public welfare (PA, section 4.3.3.2, 4.5.1.2 and Appendix 4C; 85 FR 49889–90, 49903, August 14, 2020). For example, the lack of clear BI score response to W126 across the range of lower values is consistent with findings of published studies of the USFS biomonitoring data which find that W126 index alone may not be sufficient to characterize the O_3 conditions contributing to injury levels that may be of interest (*e.g.,* Smith et al., 2012; Smith, 2012; 85 FR 49888–49889, August 14, 2020). Similar to the discussion above, these studies suggest a role for the occurrence of elevated hourly concentrations and a focus solely on W126 index may miss this. This consideration of the larger evidence base for visible foliar injury and associated USFS biomonitoring findings is important to judging the findings of analyses of the BI dataset and their informativeness to the Administrator's needs in judging public welfare adversity. Based on a detailed evaluation of the currently available record regarding such data, the EPA recognizes the need to consider factors beyond just W126 index in considering O_3 conditions most influential in the incidence and extent of visible foliar injury.

With regard to lower ''thresholds,'' the commenters simply cite a set of studies that describe visible foliar injury observations in bioindicator species and for which estimates of W126 index for a prior time period are below 25 ppm-hrs. The first group of these studies focus on naturally occurring plants in locations during which the current standard (with its level of 70 ppb) is not met.[226] As discussed above, the current standard limits the occurrence of elevated concentrations which, as discussed above, is suggested to be important in the occurrence of visible foliar injury in sites of the USFS biosite monitoring program, and such elevated concentrations are much more prevalent in areas that do not meet the current standard (*e.g.,* PA, Appendix 4A, section 2A.2; Wells [2020]). Thus, this group of studies do not provide sufficient information to characterize the O_3 exposure circumstances that may be eliciting the observed responses. Nor are they informative with regard to consideration of the incidence and extent or severity of injury that may occur under air quality conditions allowed by the current standard. Two other examples raised by commenters (but without complete study citations), appear to relate to leaf injury assessed in potted plants either outdoors but watered daily or maintained in greenhouse conditions. The injury assessed is at the individual plant level, making implications with regard to natural vegetation communities unclear, and the extent to which either finding in artificial conditions might represent such plant responses in natural environmental conditions is unknown. These commenters additionally note what they describe as ''threshold values'' reported in a National Park Service publication (Kohut, 2020). This publication includes three ''injury thresholds'' in terms of three assessment metrics, with one being a 3-month W126 index and a second in terms of

[226] For example, valid design values include: (1) 73 (2002) and 72 (2003) at monitoring site 450190046, (2) 91 (2002), 94 (2003), and 88 (2004) at 230090102; (3) 77 ppb (2004) at 261530001, and (4) 90 (2002 and 2003) at 340010005.

SUM06.[227] For each metric, three ranges of ''thresholds'' are presented (for different purposes). The ranges for SUM06 come from a 1996 workshop report (Heck and Cowling, 1997). The ranges for W126 index are based on a W126 index conversion of the SUM06 ranges. One of the ranges is labeled as pertaining to foliar injury as a response, yet, the publication cited does not provide data on foliar injury in relation to that range, nor do publications cited by the former publication. As we can best discern based on cited and related publications, it appears to at the lower end relate to a benchmark derived for growth effects (10% RBL) in the highly sensitive species, black cherry, rather than visible foliar injury (Kohut, 2007b; Lefohn et al., 1997; 80 FR 65378, October 26, 2015). Thus, contrary to the commenters' assertion, the range for W126 index (labeled as pertaining to foliar injury) does not appear to provide a threshold based on evidence for visible foliar injury.

Some commenters (citing page 4C–18 of the PA), express confusion over how EPA can state there to be an incomplete understanding of the relationships influencing severity of visible foliar injury while also using the USFS scores to inform the Administrator's judgments regarding conditions that may be adverse to the public welfare. We see no contradiction in this. Rather, it is this recognition of an incomplete understanding, including the recognition of uncertainty in ''specific aspects of [the influences of environmental/genetic factors] on the relationship between O_3 exposures, the most appropriate exposure metrics, and the occurrence or severity of visible foliar injury'' (PA, Appendix 4C, p. 4C–18), that leads the EPA to place greatest weight on the most clear findings from the USFS data. With regard to the PA presentation, with its recognized uncertainties and limitations, such a finding is the obviously increased prevalence and severity of visible foliar injury for records with W126 index estimates above 25 ppm-hrs.

Further, in considering public welfare implications of O_3 related visible foliar injury, the EPA continues to recognize that the occurrence of visible foliar injury has the potential to be adverse to the public welfare (*e.g.,* as summarized in section III.A.2.b above and section III.B.2 of the proposal). However, as noted in the proposal, the EPA does not find that any small discoloring on a single leaf of a plant (which might yield a quite low, nonzero BI score in the USFS system) is reasonably considered adverse to the public welfare. Thus, findings such as those raised by commenters of injury on individual plants in controlled conditions, while providing support to the conclusion of a causal relationship between O_3 exposure and visible foliar injury (ISA, Appendix 8, Table 8–3), are less informative to the Administrator's judgment on adequacy of the protection provided by the current standard from adverse effects to the public welfare. Rather, the USFS biosite monitoring data provide information that is more useful for such a judgment because this monitoring program, as summarized in section III.A.2.b above (and III.B.3.b of the proposal), and the scale of its objectives which focus on natural settings in the U.S. and forests as opposed to individual plants is better suited for the Administrator's consideration with regard to the public welfare protection afforded by the current standard. In this context, as described in section III.B.3 below, the Administrator judges that very low BI scores, such as those less than 5, described by the USFS scheme as ''little or no foliar injury'' do not pose concern for the public welfare.[228]

Lastly, we disagree with the comment that the Act requires the EPA to specify ''a level'' of injury that is adverse. The Court of Appeals for the D.C. Circuit has held that ''the Agency may sometimes need to articulate the level of threat to the population it considers tolerable; but there is no separate methodological requirement under § 109 that the Administrator establish a measure of the risk to safety it considers adequate to protect public health every time it establishes a standard pursuant to § 109.'' See *Nat. Res. Def. Council, Inc.* v. *EPA,* 902 F.2d 962, 973 (D.C. Cir. 1990), opinion vacated in part on other grounds, 921 F.2d 326 (D.C. Cir. 1991). The same principle applies for consideration of the protection of public welfare in the context of establishing or reviewing secondary standards. The court later confirmed that it ''expressly rejected the notion that the Agency must 'establish a measure of the risk to safety it considers adequate to protect public health every time it establishes a [NAAQS].'' See *ATA III,* 283 F.3d at 369 (D.C. Cir. 2002) (quoting *Natural Res. Def. Council, Inc.* v. *EPA,* 902 F.2d 962, 973 [D.C. Cir. 1990]). As is recognized by the courts and by EPA and CASAC across NAAQS reviews, the judgment of the Administrator, in addition to being based on the scientific evidence, depends on a variety of factors, including science policy judgments and public welfare policy judgments. As noted by the case law and also in section III.B.2.b(iv) below, the EPA is not required under the Act to identify individual levels of adversity or set separate standards for every type of effect that may be caused by a pollutant in ambient air, as long as it has engaged in reasoned decision making in determining that a particular standard provides the requisite protection. Thus, it is common for one NAAQS to provide protection for multiple effects, with the most sensitive effect influencing the stringency of the standard and accordingly leading to protection that is adequate for other, less sensitive effects. Given the significant uncertainties which are present in every NAAQS review, it is enough for the Administrator to set standards that specify a level of air quality that will be ''tolerable,'' (*NRDC,* 902 F.2d at 973), and ''qualitatively to describe the standard governing its selection of particular NAAQS'' (*ATA III,* 283 F.3d at 369). In reviewing each standard, the EPA gives due consideration to each of the effects that are relevant for that standard in considering whether the standard provides adequate protection from the type, magnitude or extent of such effects known or anticipated to be adverse to the public welfare. In the case of visible foliar injury, as discussed in section III.B.3 below, the Administrator has considered the available scientific evidence, with associated uncertainties and limitations, in reaching his decision that the current secondary standard provides adequate public welfare protection for this effect.

(iv) Crop Yield Effects

Some commenters object to the proposed conclusions with regard to the protection provided by the existing secondary standard from adverse effects on the public welfare related to O_3 effects on crop yield, expressing the view that the EPA must specify ''a level'' to protect the public welfare against crop yield reductions and that not doing so is unlawful and arbitrary. These commenters' additionally object to the Administrator's proposed judgment that a decision based on RBL as a proxy for other vegetation-related effects will also provide adequate protection against crop related effects, indicating their view that EPA does not

[227] We note that the third assessment approach utilizes a combination of a W126 index metric with the N100 metric, illustrating the consideration by the National Park Service of the role of peak concentrations in posing risk of visible foliar injury (Kohut, 2020).

[228] Studies that consider such data for purposes of identifying areas of potential impact to the forest resource suggest this category corresponds to ''none'' with regard to ''assumption of risk'' (Smith et al., 2007; Smith et al., 2012).

adequately explain the basis for this judgment. These commenters additionally claim that the prior CASAC described 5.1% RYL as constituting an adverse welfare effect and express the view that the EPA arbitrarily and unlawfully does not ''give effect to'' the prior CASAC's recommendation.

We disagree with the implication of these commenters that, in judging adequacy of protection provided by the current standard for a particular effect, it is *per se* unlawful to conclude that the air quality achieved by the current standard provides adequate protection for that particular effect, even if the greater attention in reviewing the current standard is on another effect. The EPA is not precluded from reaching such a conclusion as long as the Agency has engaged in reasoned decision-making in doing so.[229] In reaching his proposed conclusions regarding the extent to which the current standard provides appropriate protection from O_3 effects on crop yield that may be adverse to the public welfare, as in his conclusions described in section III.B.3 below, the Administrator recognizes the long-standing evidence of O_3 effects on crop yield and the established E–R functions for which RYL estimates for the median crop species are presented in the PA (PA, Appendix 3A). He also considers factors that might be important to his judgments related to the requisite protection for a secondary standard that protects against adverse effects to the public welfare. In this context he judges that the median RYL estimated for air quality that achieves his RBL-related objectives for the current standard does not constitute an adverse effect on public welfare and thus concludes that the current standard also provides adequate protection for crop yield-related effects. Given that the decision on adequacy of protection is a judgment of the Administrator and that the Clean Air Act does not require a particular approach for reaching such judgments, we disagree with the commenters to the extent that they suggest that it is *per se* unlawful for the Administrator to use such an approach. The circumstances for his use of this approach include particular aspects of the information available on O_3-related crop yield effects and other factors important to judgments on public welfare effects related to crop yield effects.

In reaching his decision in this review, as described in section III.B.3 below, the Administrator has also considered public comments on these issues, including that regarding a prior CASAC statement. The comment regarding the prior CASAC appears to draw on a judgment of the prior CASAC that a median RYL of 5% ''represents an adverse impact'' (Frey, 2014b, p. 14). The prior CASAC provided no clear scientific foundation for this judgment. While we infer this judgment to draw on discussion at a 1996 workshop,[230] neither the prior CASAC nor the workshop summary provides any explicit rationale for identification of 5% (with regard to RYL), or any description of a connection of an estimated 5% RYL to broader impacts of a specific magnitude or type, or to judgments on significance of a 5% RYL to the public welfare. Thus the EPA disagrees with the commenters regarding the weight to give the prior CASAC statement and, as described below, respectfully disagrees with the prior CASAC on this statement.

In reaching his judgment regarding whether the current standard provides the requisite public welfare protection, as described in section III.B.3 below, the Administrator considers the extent to which a specific estimate of RYL may be indicative of adverse effects to the public welfare. In so doing, he notes that the secondary standard is not intended to protect against all known or anticipated O_3-related effects, but rather those that are judged to be adverse to the public welfare, and that a bright-line determination of adversity is not required in judging what is requisite. In his decision described below, the Administrator also notes that the determination of the extent of RYL estimated from experimental O_3 exposures that should be judged adverse to the public welfare is not clear, in light of the extensive management of agricultural crops that occurs to elicit optimum yields (*e.g.,* through irrigation and usage of soil amendments, such as fertilizer). Further, in considering effects on the public welfare that may relate to agricultural markets, we note that detrimental impacts on crops, as well as beneficial impacts, can be unevenly distributed between producers and consumers, complicating conclusions with regard to relative adversity. In light of such considerations, the Administrator, while finding consideration of the RYL estimate for the median crop species informative to his judgment on the adequacy of the protection provided by the current standard for this effect, does not find such an RYL estimate of 5% to represent an adverse effect to the public welfare, as described more fully in section III.B.3 below. For these reasons, and for the reasons discussed earlier in this section, including those regarding advice from a prior CASAC, the EPA also disagrees with the commenters' assertion that the Administrator is arbitrarily and unlawfully failing to ''give effect to'' the prior CASAC's recommendation.

Further, we disagree with the comment that the Act requires the EPA to specify ''a level'' to protect the public welfare against crop yield reductions. As discussed in greater detail in section III.B.2.b(iii) above, the EPA is not required under the Act to set separate standards for every type of effect that may be caused by a pollutant in ambient air, as long as it has engaged in reasoned decision making in determining that a particular standard provides the requisite protection. Thus, it is common for one NAAQS to provide protection for multiple effects, with the most sensitive effect influencing the stringency of the standard and accordingly leading to protection that is adequate for other less sensitive effects. As discussed further in section III.B.2.b(iii) above, in reviewing each standard, the EPA gives due consideration to each effect relevant for that standard in considering whether the standard provides adequate protection from the type, magnitude or extent of such effects known or anticipated to be adverse to the public welfare. In the case of crop yield loss, as discussed in section III.B.3 below, the Administrator has considered the magnitude of RYL that may be

[229] Section 109(b)(2) of the CAA provides only that any secondary standard ''shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.''

[230] The first reference to 5% RYL by the prior CASAC (in the 2015 O_3 NAAQS review) appears to be in its letter on the first draft PA (Frey and Samet, 2012). In that letter, the prior CASAC identifies 5% RYL as a factor on which levels for a W126 index secondary standard should be based, although no rationale is provided for this recommendation. In a letter attachment, comments from an individual member point to a 1996 workshop (2014 PA, pp. 6–15 through 6–17; Heck and Cowling, 1997). As summarized in the 2015 O_3 decision, the 1996 workshop participants (16 leading scientists, discussing their views for a secondary O_3 standard) indicated an interest in protecting against crop yield reductions of 5% yet noted uncertainties surrounding such a percentage which led them to identify 10% RYL (80 FR 65378, October 26, 2015). In their emphasis on 5%, the 2012 comments from the individual prior CASAC member expressed the view that the ability to estimate 5% RYL has improved (Frey and Samet, 2012, p. A–54). Neither the individual prior CASAC member nor the 1997 workshop report provide any explicit rationale for the percentages identified or any description of their connection to ecosystem impacts of a specific magnitude or type, or to judgments on significance of the identified effects for public welfare (80 FR 65378, October 26, 2015; Heck and Cowling, 1997).

associated with W126 index values that occur under the current standard and, based on the current information with regard to the RYL estimates, notes that these estimates are generally no higher than 5.1% and predominantly well below that. In so doing, he has also considered factors such as those raised above, and in light of all of these considerations, he judges that a RYL of 5.1% does not represent an adverse effect to the public welfare. Thus, the Administrator judges that the current standard provides adequate protection of the public welfare for crop yield loss related effects.

(v) RBL

In objecting to the EPA's proposed decision, some commenters disagree with the target level of protection identified based on use of RBL. In so doing, such commenters variously claim that a 3-year average of 17 ppm-hrs is ''ill-suited'' to protect against adverse impacts to the public welfare; that 6% RBL is too high to protect the public welfare; that use of a 3-year average instead of a single year W126 index is needed; and, that EPA must focus a target on exposures that would avoid 2% RBL, citing comments from the prior CASAC on the second draft PA in the 2015 review, and claiming that a focus on a W126 index of 7 ppm-hrs is needed for that. With regard to the EPA's use of 6% in considering the adequacy of protection related to RBL, these commenters recognize that *Murray Energy* rejected an argument that EPA's prior reliance on 6% (in the 2015 decision) was arbitrary based on the record in that case (*Murray Energy,* 936 F.3d at 615–16). In pressing their views, however, the commenters state that nothing in *Murray Energy* prevents EPA from revising its prior determination based on the scientific evidence and CASAC advice.

With respect to the latter point, the EPA agrees that the Administrator's decision in this review must take into account the currently available scientific evidence and advice from the CASAC, and that the Agency is not bound by the Administrator's conclusions in the prior review. As summarized in the proposal for the current review, in the proposal, the Administrator took the currently available scientific evidence and advice from the CASAC into account, while also choosing to consider the judgments and decision made by the prior Administrator in that Administrator's consideration of RBL related targets for cumulative seasonal exposure. He did so, in light of the welfare effects evidence and air quality information now available, as well as the advice from the current CASAC reflecting its concurrence that implementation of the prior Administrator's approach or framework is ''still effective'' in protecting the public welfare from vegetation effects of O_3 (Cox, 2020a, Consensus Responses to Charge Questions p. 21). As described in section III.B.3 below, after considering the public comments on this point, he is taking a similar approach in reaching his decision in this review.

With regard to the commenters' objection to the EPA's use of a 3-year average in assessing RBL, we note, as an initial matter, that the EPA's focus on a 3-year average of 17 ppm-hrs as a target level relates to an RBL estimate of 5.3%, a value that was also chosen in 2015 in recognition of the prior CASAC advice both with regard to 6% RBL and about considering a lower W126 index target for a 3-year average due to the prior CASAC's concern about ''unusually damaging years.'' In the current review, the CASAC has explicitly considered the EPA's interpretation of 6% in identifying a target of 17 ppm-hrs as a 3-year average, and expressed its view that this target ''is still effective in particularly protecting the public welfare in light of vegetation impacts from ozone'' (Cox, 2020a, Consensus Responses to Charge Questions p. 21). Accordingly, the EPA disagrees with the comments that 6% RBL and a 3-year average W126 index target of 17 ppm-hrs are too high to inform the Administrator's judgments on O_3 air quality that protects the public welfare; rather, the Administrator continues to find this useful in informing his judgments regarding the public welfare protection provided by the standard, together with a broader consideration of air quality patterns associated with meeting the current standard, such as control of peak hourly concentrations, as described in section III.B.3 below. Further, we refer to the discussion above of how the existing standard, with its current averaging time and form provides the protection from the occurrence of elevated hourly concentrations that may characterize what the prior CASAC described as ''unusually damaging years.'' As discussed above, the available air quality data demonstrate the strong protection provided by the current standard from elevated concentrations that may occur in some years. As noted above, these analyses indicate that while the current form and averaging time of the existing standard provides control of these concentrations and the associated peak exposures, reliance solely on a standard in the form of the W126 index based standard, as advocated by the commenters, even with a level as low as 7 ppm-hrs cannot be relied on to provide it.

In support of their view that the EPA must focus on avoiding 2% RBL with a W126 index of 7 ppm-hrs, these commenters provide little rationale beyond citing a comment by the prior CASAC made in the last review. In so doing, the commenters assert that because the prior CASAC had noted that 7 ppm-hrs was the only W126 index level for which the E–R functions yielded a RBL for the median tree species that was less than or equal to 2%, the EPA must protect against 2% RBL and adopt a W126 index level of 7 ppm-hrs. We disagree. As an initial matter, we note our discussion above regarding the EPA's consideration in this review of advice from a prior CASAC, including prior CASAC statements that are raised by commenters, such as those noted here. Further, in making the statement that the commenters' cite, the prior CASAC did not reach the same conclusion as the commenters with regard to the extent to which a revised secondary standard should limit cumulative exposures and associated estimates of RBL, such that the prior CASAC did not recommend that the EPA consider only W126 index levels associated with median RBL estimates at or below 2%.[231] See *Murray Energy,* 936 F.36 at 615–16 (noting that ''CASAC did not identify 2% growth loss as the only sufficiently protective level'' but merely recommended ''2% as the lower end of a range of permissible target levels'' to be considered). In fact, seven of the nine W126 index levels in the range recommended by the prior CASAC (7 to 15 ppm-hrs [Frey, 2014b]) are associated with RBL estimates higher than 2% (PA, Appendix 4A). As a basis for their assertion that the secondary standard should protect against a median RBL of 2%, these commenters additionally oddly declare that after three years, a 2% RBL per year ''becomes 6%.'' There is no evidence in the record, and the commenter provides no evidence, that would support their declaration that without a tripling in exposure, the O_3-attributable reduction in annual growth (the RBL) would triple.[232] Nor is there

[231] Additionally, an explicit scientific rationale for 2% is not provided by the former CASAC. Nor is it provided in the workshop report referenced by the prior CASAC in its discussion, as further discussed in the 2015 decision (80 FR 65394, October 26, 2015; Frey, 2014b, p. 14).

[232] It is unclear by what logic the commenters conclude that RBL, a metric describing the effect of

evidence that would support an alternative interpretation of the commenters' statement as a claim that a tree experiencing a 2% RBL per year is reduced in absolute biomass by 6% after three years.[233]

Some commenters who disagree with the proposed decision also express the view that the EPA has ''proposed'' to use RBL functions for trees as a proxy for all vegetation effects. Based on this view, these commenters variously assert that the EPA is failing to comply with its obligation under the Clean Air Act that a secondary standard protect the public welfare from ''any known or anticipated adverse effects''; that the EPA's approach is not the same as the prior CASAC's discussion of RBL as a surrogate; that the EPA is contravening its statutory obligation by using one adverse effect as a surrogate for another without showing that prevention of the former will prevent the latter; and that, based on the commenters' interpretation of a statement made by the prior CASAC, a standard that allows tree growth loss above 2% cannot protect against visible foliar injury. As an initial matter, we note that the citation provided by the commenters for their statement that the ''EPA proposes'' to use RBL functions as a proxy for the broad array of O_3 vegetation-related effects does not include such a ''proposal.'' Rather the commenters' citation points to the background section of the proposal which simply summarizes the concept of RBL as a proxy or surrogate which was employed in the last review and which was described by the prior CASAC (85 FR 49899, August 14, 2020). In describing use of RBL as a proxy or surrogate, the proposal (and the PA) use several phrases, ranging from ''for consideration of the broader array of vegetation-related effects of potential public welfare significance, that included effects on growth of individual sensitive species and extended to ecosystem-level effects, such as community composition in natural forests, particularly in protected public lands, as well as forest productivity'' (85 FR 49878, August 14, 2020), to shorter phrases, such as ''for the broad array of vegetation related effects that extend to the ecosystem scale'' (85 FR 49911, August 14, 2020).

We disagree with these commenters that the way the EPA uses RBL as a ''proxy'' or ''surrogate'' is contrary to law, and with their contention that the EPA uses one adverse effect as a surrogate for another without showing that prevention of the former will prevent the latter. As described in the Administrator's decision below, the most precise use of RBL as a surrogate or proxy is in the target level of protection for cumulative seasonal exposure (17 ppm-hrs as a 3-year average W126 index). This use relates specifically to public welfare effects related to O_3 effects on growth of individual sensitive species and related effects, including ecosystem-level effects, such as community composition in natural forests, particularly in protected public lands, as well as forest productivity (as discussed in the PA, section 4.5.1.2). In fact, the ISA describes (or relies on) conceptual relationships among such effects in considering causality determinations for ecosystem-scale effects such as altered terrestrial community composition and reduced productivity, as well as reduced carbon sequestration, in terrestrial ecosystems (ISA, Appendix 8, sections 8.8 and 8.10). Beyond these relationships of plant-level effects and ecosystem-level effects,[234] RBL can be appropriately described as a scientifically valid surrogate of a variety of welfare effects based on consideration of ecosystem services and the potential for adverse impacts on public welfare, as well as conceptual relationships between vegetation growth-related effects (including carbon allocation) and ecosystem-scale effects (PA, pp. 4–75 and 4–76). Both the prior CASAC and the current CASAC recognized this (Frey, 2014b, pp. iii, 9–10;[235] Cox, 2020a, Consensus Responses to Charge Questions pp. 18 and 21[236]). As was discussed in the proposal, the information available in this review provides continued support for the use of tree seedling RBL as a proxy for the broad array of vegetation-related effects conceptually related to growth effects, a conclusion with which the CASAC agreed (85 FR 49899,49906, August 14, 20202).[237]

As recognized in the proposal (and PA) there are two other vegetation effect categories with extensive evidence bases (which include analyses that assess the influence of cumulative seasonal exposure); these are crop yield loss and visible foliar injury. As discussed above, the consideration of protection provided by the current standard for the former goes beyond the target focused on RBL and includes aspects of the evidence specific to those effects. As described above and in section III.B.3 below, the EPA is concluding that the level of protection is adequate to protect the public welfare from effects related to crop yield loss. With regard to the latter, contrary to the commenter's assertion, the EPA is not claiming that protection focused on RBL provides protection for visible foliar injury. The EPA's consideration of visible foliar injury is described earlier in this section and in section III.B.3 below.

the O_3 exposure in a single year, can be modified by the RBL in a prior year.

[233] The fallacy of such interpretations can be seen in the presentation of above-ground biomass from a multiyear study of O_3 exposure of aspen that varies little over six years. Across the six years, the above-ground biomass of the trees receiving elevated O_3 exposure is 25%, 30%, 29%, 29%, 31% and 29% lower than the reference trees (2013 ISA, Table 9–14; 2020 ISA, Figure 8–17).

[234] As summarized in the ISA, O_3 can mediate changes in plant carbon budgets (affecting carbon allocation to leaves, stems, roots and other biomass pools) contributing to growth impacts, and altering ecosystem properties such as productivity, carbon sequestration and biogeochemical cycling. In this way, O_3 mediated changes in carbon allocation can ''scale up'' to population, community and ecosystem-level effects including changes in soil biogeochemical cycling, increased tree mortality, shifts in community composition, changes in species interactions, declines in ecosystem productivity and carbon sequestration and alteration of ecosystem water cycling (ISA, section 8.1.3).

[235] The prior CASAC 2014 letter on the second draft PA in that review stated the following (Frey, 2014b, p. 9–10):

For example, CASAC concurs that trees are important from a public welfare perspective because they provide valued services to humans, including aesthetic value, food, fiber, timber, other forest products, habitat, recreational opportunities, climate regulation, erosion control, air pollution removal, and hydrologic and fire regime stabilization. Damage effects to trees that are adverse to public welfare occur in such locations as national parks, national refuges, and other protected areas, as well as to timber for commercial use. The CASAC concurs that biomass loss in trees is a relevant surrogate for damage to tree growth that affects ecosystem services such as habitat provision for wildlife, carbon storage, provision of food and fiber, and pollution removal. Biomass loss may also have indirect process-related effects such as on nutrient and hydrologic cycles. Therefore, biomass loss is a scientifically valid surrogate of a variety of adverse effects to public welfare.

[236] The CASAC letter on the draft PA in the current review stated the following (Cox, 2020a, Consensus Responses to Charge Questions p. 18):

The RBL appears to be appropriately considered as a surrogate for an array of adverse welfare effects and based on consideration of ecosystem services and potential for impacts to the public as well as conceptual relationships between vegetation growth effects and ecosystem scale effects. Biomass loss is a scientifically sound surrogate of a variety of adverse effects that could be exerted to public welfare. . . . In the previous review, the Administrator used RBL as a surrogate for consideration of the broader array of vegetation related effects of potential welfare significance that included effects of growth of individual sensitive species and extended to ecosystem level effects such as community composition in natural forests, particularly in protected public lands (80 FR 65406, October 26, 2015). The EPA believes, and the CASAC concurs, that information available in the present review does not call into question this approach, indicating there continues to be support for the use of tree seedling RBL as a proxy for the broader array of vegetation-related effects, most particularly those related to growth.

[237] Further, the EPA lacks sufficient information in the air quality criteria to identify requisite air quality for these effects.

With regard to the two newly identified categories of insect-related effects, the Administrator finds there to be insufficient information to judge the current standard inadequate based on these effects, as discussed in section III.B.3 below. He does not claim that RBL provides a surrogate for these effects. However, he notes that the available information in the air quality criteria does not indicate a greater sensitivity of such effects as compared to O_3 effects on vegetation growth, and that he lacks sufficient information in the air quality criteria to identify requisite air quality for these effects.

(vi) W126 Index in Areas Meeting Current Standard

In objecting to the proposed decision, one group of commenters disagree with EPA's findings regarding the W126 index levels in areas that meet the current standard. In so doing, these commenters claim that the EPA is mistaken to claim that in virtually all design value periods and locations at which the current standard was met across the period covered by the historical dataset the 3-year W126 index was at or below 17 ppm-hrs because they variously assert there are either 25 or 21 such occurrences, and they further assert there to be either 50 occurrences of a single-year W126 index at or above 19 ppm-hrs or 52 occurrences of a single-year W126 index above 19 ppm-hrs. These counts are in disagreement with the air quality analyses documented in Appendix 4D of the PA. For example, out of 8,292 values across nearly 20 years for U.S. ambient air monitoring sites, distributed across all nine climate regions, with air quality that meets the current standard, there are just eight occurrences of a 3-year W126 index value above 17 ppm-hrs (PA, Appendix 4D, Tables 4D–10 and 4D–7). This means that 99.9% of the records (virtually all) were at or below 17 ppm-hrs. While the details of each step of the analyses in the PA are extensively documented, including data handling, rounding conventions and data acceptability criteria (PA, Appendix 4D, section4D.2), the lack of documentation provided by the commenters and their conflicting claims (indicated above) leave the EPA to hypothesize that the reason for the disagreements include differences with regard to these details, such as those regarding rounding conventions. As described in the PA, W126 values ''were rounded to the nearest unit ppm-hr for applications requiring direct comparison to a W126 level,'' a convention intended to provide consistency in the precision of the comparison as the W126 levels for comparison were also in whole numbers (PA, Appendix 4D, section 4D.2.2). With the rounding conventions applied in the PA, there are eight 3-year W126 index values greater than 17 ppm-hrs (*i.e.,* equal to 18 or 19). It may be that the commenters counted unrounded 3-year W126 index values as low as 17.01 as being greater than 17 ppm-hrs, although the reason for them providing two conflicting counts is unclear. Similarly with regard to the counts for single-year W126 index values above 19 ppm-hrs, the commenters may have counted unrounded single-year index values as low as 19.01 ppm-hrs as being greater than 19 ppm-hrs. Thus, we find the commenters criticism of the EPA's characterization of the findings of the air quality analyses, as well as the commenters' counts, to be unfounded.

Some commenters claim EPA pays inadequate attention to the relatively few occurrences of single-year W126 index values at or above 19 ppm-hrs that have occurred at sites meeting the current standard since 2002 and that the standard must be set to avoid such occurrences. The EPA disagrees with these commenters, as described below, after carefully considering the relatively few occurrences of W126 index values at or above 19 ppm-hrs, including single-year values. In so doing, we have given particular focus on Class I areas, recognizing the attention given to such areas by the Administrator in judging the potential for effects adverse to the public welfare, a focus recognized by the CASAC and with which the prior CASAC explicitly concurred (Cox, 2020a; Frey, 2014b, p. 9).

Among the nearly 500 values for monitoring sites in or near Federal Class I areas across the U.S., during periods from 2000 through 2018 when the current standard was met, there are no occurrences of a 3-year average W126 index above 19 ppm-hrs (PA, Table 4–1). Across this same period in the same Class I locations, there are just 15 occurrences of single-year W126 index values above 19 ppm-hrs, all of which date prior to 2013 (PA, Appendix 4D, section 4D.3.2.4). All of these occurrences are below 25 ppm-hrs. Thus, in addition to their being relatively few occurrences of a single-year W126 above 19 ppm-hrs in/near a Class I area in the 19-year dataset, none of them (the most recent of which was in 2012) is higher than 25 ppm-hrs; in fact, the highest is 23 ppm-hrs (PA, Appendix 4D, section 4D.3.2.4).

We have also considered the full 19-year dataset for locations beyond those in or near Class I areas, noting that, at other sites across the U.S., occurrences of single-year W126 index above 19 ppm-hrs (22) were predominantly in urban areas, including Los Angeles, and the highest values were just equal to 25 ppm-hrs, or, in one instance, just equal to 26 ppm-hrs, when rounded (85 FR 49895, 49904, August 14, 2020; PA, sections 4.4 and 4.5, Appendix 4D). In considering the potential risk posed by these scattered occurrences, largely in urban areas, with none since 2012 in or near a Class I areas, we additionally consider the data on peak hourly concentrations also discussed above (Wells, 2020). Together, these data indicate the control provided by the current standard in areas that are of particular focus in protecting the public welfare, on the extent and frequency of occurrence of cumulative exposures in terms of the W126 index (and of peak concentrations) of a magnitude of potential concern. As discussed in section III.B.3 below, the Administrator does not find the air quality patterns allowed by the current standard, as indicated by these analyses, to pose a risk of adverse effects to the public welfare.

In their criticism of the EPA's air quality analyses, one commenter claims that the analyses are difficult to evaluate for California and other West region states and suggest that California sites brought into compliance with the existing standard would still have elevated W126 index values, similar to sites in the Southwest region. We disagree with the commenter's claim that the air quality analyses suggest that compliance with the existing standard would not reduce the W126 index values at California sites. In making their claim, the commenters cite Figures 4D–4 and 4D–5 of the PA. These figures, however, simply document W126 index at sites with various design values at one point in time (2016–2018). They do not describe analyses of trends over time, with changes in air quality. Yet, that very issue was the subject of separate regression analyses in the PA (PA, Appendix 4D, section 4D.3.2.3). These analyses show that the Southwest region, which had highest W126 index values at sites meeting the current standard, also exhibited the greatest improvement in the W126 metric values per unit decrease in their design value (slope of 0.93) over the nearly 20 year period analyzed. The pattern is very similar for the West region (with a slope of 0.80), with the exception of three sites (in downtown LA); however, the design values for these sites are above 100 ppb, making such projections quite uncertain (PA, Appendix 4D, section 4D.3.2.3).

(vii) Climate Effects

In support of their disagreement with the EPA's proposed decision, some commenters claim that EPA needs to establish a standard to protect from radiative forcing and related climate effects. In so doing, they stated that EPA cannot rely on uncertainty by retaining the existing standard and instead, given the uncertainties recognized in the ISA, which they suggest could mean current information underestimates O_3 climate related impacts, the Administrator should strengthen the existing standard or establish an additional standard. Some commenters additionally assert that the EPA has failed to address a recommendation from CASAC regarding a quantitative analysis, while also criticizing EPA conclusions regarding a carbon storage analysis in the last review. The EPA disagrees with the commenters that the available information is sufficient to identify such a standard that could be judged to provide the requisite protection under the Act, and notes that the commenters do not submit or describe such information; nor do the commenters identify a standard that they claim would provide such protection.

With regard to the CASAC recommendation cited by some commenters, we note in its review of the draft PA, the CASAC recommended changes to the PA to ''more thoroughly address effects of ozone on climate change,'' that would include some quantitation, such as estimates of climate change related to a change in O_3 (Cox 2020a, Consensus Responses to Charge Questions p. 22). In consideration of this advice, the final PA included additional discussion on the available information and tools related to such estimates. As discussed below, we conclude that this information, as documented in the ISA, does not provide a foundation with which to derive such estimates as might pertain to O_3 and public health and welfare considerations relevant to decisions on the NAAQS.[238]

As recognized in the proposal and summarized in section III.A.2 above, there are a number of limitations and uncertainties that affect our ability to characterize the extent of any relationships between O_3 concentrations in ambient air in the U.S. and climate-related effects, thus precluding a quantitative characterization of climate responses to changes in O_3 concentrations in ambient air at regional (vs global) scales. While evidence supports a causal relationship between the global abundance of O_3 in the troposphere and radiative forcing, and a likely causal relationship between the global abundance of O_3 in the troposphere and effects on temperature, precipitation, and related climate variables (ISA, section IS.5.2 and Appendix 9; Myhre et al., 2013), the non-uniform distribution of O_3 (spatially and temporally) makes the development of quantitative relationships between the magnitude of such effects and differing O_3 concentrations in the U.S. challenging (ISA, Appendix 9). Additionally, ''the heterogeneous distribution of ozone in the troposphere complicates the direct attribution of spatial patterns of temperature change to ozone induced [radiative forcing]'' and there are ''ozone climate feedbacks that further alter the relationship between ozone [radiative forcing] and temperature (and other climate variables) in complex ways'' (ISA, Appendix 9, section 9.3.1, p. 9–19). Thus, various uncertainties ''render the precise magnitude of the overall effect of tropospheric ozone on climate more uncertain than that of the well-mixed GHGs'' and ''[c]urrent limitations in climate modeling tools, variation across models, and the need for more comprehensive observational data on these effects represent sources of uncertainty in quantifying the precise magnitude of climate responses to ozone changes, particularly at regional scales'' (ISA, section IS.6.2.2, Appendix 9, section 9.3.3, p. 9–22). For example, current limitations in modeling tools include ''uncertainties associated with simulating trends in upper tropospheric ozone concentrations'' (ISA, section 9.3.1, p. 9–19), and uncertainties such as ''the magnitude of [radiative forcing] estimated to be attributed to tropospheric ozone'' (ISA, section 9.3.3, p. 9–22). Further, ''precisely quantifying the change in surface temperature (and other climate variables) due to tropospheric ozone changes requires complex climate simulations that include all relevant feedbacks and interactions'' (ISA, section 9.3.3, p. 9–22). For example, an important limitation in current climate modeling capabilities for O_3 is representation of important urban- or regional-scale physical and chemical processes, such as O_3 enhancement in high-temperature urban situations or O_3 chemistry in city centers where NOx is abundant. Because of such limitations we cannot quantify or judge the impact of incremental changes in O_3 concentrations in the U.S. on radiative forcing and subsequent climate effects.

Thus, as discussed in section III.B.3 below, the significant limitations and uncertainties summarized here together preclude identification of an O_3 standard that could be judged to provide requisite protection of the public welfare from adverse effects linked to O_3 influence on radiative forcing, and related climate effects. Contrary to the commenters' charge that the lack of a quantitative analysis of climate-related effects due to recognition of such limitations and uncertainties is unlawful and arbitrary, the information available in this review is insufficient to judge the existing standard inadequate or to identify an appropriate revision based on O_3-related climate effects. In the face of insufficient evidence for such conclusions, it might, on the contrary, be judged unlawful and arbitrary for the Agency to perform guesswork to assert a particular new standard provided requisite protection for this category of effects. The EPA agrees with the commenters that ''perfect information'' is not required. However, information that provides for assessment of how the current and potential alternative or additional standards would affect O_3-related climate impacts is lacking. As noted in the ISA, few studies have even attempted to estimate ''climate response to changes in tropospheric ozone concentrations alone in the future atmosphere,'' and effects of O_3 on radiative forcing and climate depend on many factors other than tropospheric ozone concentrations, including ''changes in a suite of climate-sensitive

[238] In raising EPA's conclusions on a carbon storage analysis in the last review, some commenters repeat their comments in the last review that claimed that the relatively lesser weight the EPA placed on the 2014 WREA estimates of carbon storage (in terms of CO_2) was inconsistent with the emphasis the EPA placed on CO_2 emissions reductions estimated for another regulatory action. The commenters overlook, however, key distinctions between the two types of estimates in the two different analyses which appropriately led the EPA to recognize much greater uncertainty in the WREA estimates and accordingly give them less weight. While the WREA estimates were for amounts of CO_2 removed from the air and stored in vegetation as a result of plant photosynthesis occurring across the U.S., the estimates for the other action were for reductions in CO_2 produced and emitted from power plants (79 FR 34830, 34931–33). The potentially transient nature of carbon storage in vegetation makes a ton of additional carbon uptake by plants in the former arguably unequal to a ton of reduced emissions from fossil fuels. Further, there are appreciably larger uncertainties involved in attempting to quantify the additional carbon uptake by plants which requires complex modeling of biological and ecological processes and their associated sources of uncertainty, and there is no new information available in the current review that would reduce such uncertainties in quantitative estimates of carbon storage benefits to climate. In recognizing the public welfare value of ecosystem carbon storage, we additionally note, however, that protection provided by the current standard from vegetation effects (and RBL) also provides a degree of protection in terms of carbon storage.

factors, such as the water vapor content of the atmosphere'' (ISA, p. 9–20; Myhre et al., 2013). Thus, as discussed in section III.B.3 below, while the Administrator recognizes that the evidence supports a relationship of tropospheric O_3 with climate effects, he judges the quantitative uncertainties to be too great to support identification of a standard specific to such effects.

4. Administrator's Conclusions

Based on the large body of evidence concerning the welfare effects, and potential for public welfare impacts, of exposure to O_3 in ambient air, and taking into consideration the attendant uncertainties and limitations of the evidence, the Administrator concludes that the current secondary O_3 standard provides the requisite protection against known or anticipated adverse effects to the public welfare, and should therefore be retained, without revision. In reaching these conclusions, the Administrator has carefully considered the assessment of the available welfare effects evidence and conclusions contained in the ISA, with supporting details in the 2013 ISA and past AQCDs; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA (summarized in sections III.A.2 and III.A.3 above); the advice and recommendations from the CASAC (summarized in section III.B.1.b above); and public comments (as discussed in section III.B.2 above and the separate Response to Comments document), as well as the August 2019 decision of the D.C. Circuit remanding the secondary standard established in the last review to the EPA for further justification or reconsideration.

In considering the currently available information in this review of the O_3 secondary standard, the Administrator recognizes the longstanding evidence base for vegetation-related effects, augmented in some aspects since the last review, described in section III.A.2.a above. The currently available evidence describes an array of effects on vegetation and related ecosystem effects causally or likely to be causally related to O_3 in ambient air, as well as the causal relationship of tropospheric O_3 in radiative forcing and subsequent likely causally related effects on temperature, precipitation and related climate variables. The Administrator also takes note of the quantitative analyses and policy evaluations documented in the PA that, with CASAC advice and consideration of public comment, inform the judgments required of him in reaching his decision on a secondary standard that provides the requisite protection under the Act.

As an initial matter, the Administrator recognizes the continued support in the current evidence for O_3 as the indicator for photochemical oxidants (as recognized in section III.B.1.c above). In so doing, he notes that no newly available evidence has been identified in this review regarding the importance of photochemical oxidants other than O_3 with regard to abundance in ambient air, and potential for welfare effects, and that, as stated in the current ISA, ''the primary literature evaluating the health and ecological effects of photochemical oxidants includes ozone almost exclusively as an indicator of photochemical oxidants'' (ISA, section IS.1.1). Thus, the Administrator recognizes that, as was the case for previous reviews, the evidence base for welfare effects of photochemical oxidants does not indicate an importance of any other photochemical oxidants. For these reasons, described with more specificity in the ISA and PA, he proposes to conclude it is appropriate to retain O_3 as the indicator for the secondary NAAQS for photochemical oxidants (85 FR 49896, August 14, 2020).

In his review of the existing secondary O_3 standard, in light of the evidence base and quantitative analyses available today, the Administrator has given particular attention to consideration of the issues raised by the August 2019 court remand, and related issues raised in public comment, as well as analyses that were conducted or updated in this review in consideration of the remand and related public comment. In so doing, he has also given careful consideration of the form and averaging time of the current standard and its ability to control the patterns of O_3 concentrations that contribute to environmental exposures of potential concern to the public welfare. Further, he has considered what is indicated by the information currently available with regard to exposure metrics, supported by the current evidence, for assessing potential risks posed to vegetation, and protection provided from such exposures. Additionally, with regard to visible foliar injury, he has considered the current evidence in the ISA in combination with quantitative information and policy evaluations in the PA, advice from the CASAC and public comment, in making judgments regarding adequacy of the protection provided by the current standard from adverse effects to the public welfare related to this effect. Before turning to these issues, discussed, in turn, below in the context of the EPA's understanding of the information now available in the current review, he addresses two endpoints newly identified in this review, as well as tropospheric O_3 effects related to climate.

With regard to the two insect-related categories of effects with new ISA determinations in this review, the Administrator takes note of the conclusions that the current evidence is sufficient to infer likely causal relationships of O_3 with alterations of plant-insect signaling and insect herbivore growth and reproduction (as summarized in section III.A.2.a above). He additionally recognizes the PA finding that uncertainties in the current evidence, as summarized in section III.A.2 above, preclude a full understanding of such effects, the air quality conditions that might elicit them, the potential for impacts in a natural ecosystem. Accordingly, the Administrator notes a lack of clarity in the characterization of these effects, and a lack of important quantitative information to consider such effects in this context such that it is not feasible to relate different patterns of O_3 concentrations with specific risks of such alterations. As a result, the Administrator concludes there is insufficient information to judge how particular ambient air concentrations of O_3 relate to the degree of impacts on public welfare related to these effects. Thus, he concludes there is insufficient information to judge the current standard inadequate or to identify an appropriate revision based on these effects.

Before focusing further on the key vegetation-related effects identified above, the Administrator first considers the strong evidence documenting tropospheric O_3 as a greenhouse gas causally related to radiative forcing, and likely causally related to subsequent effects on variables such as temperature and precipitation. In so doing, he takes note of the limitations and uncertainties in the evidence base that affect characterization of the extent of any relationships between O_3 concentrations in ambient air in the U.S. and climate-related effects, and preclude quantitative characterization of climate responses to changes in O_3 concentrations in ambient air at regional or national (vs global) scales, as summarized in sections III.A.2 above. As a result, he recognizes the lack of important quantitative tools with which to consider such effects in this context such that it is not feasible to relate different patterns of O_3 concentrations at the regional (or national) scale in the U.S. with specific risks of alterations in temperature, precipitation and other

climate-related variables. The Administrator finds that these significant limitations and uncertainties together preclude his identification of an O_3 standard reasonably judged to provide requisite protection of the public welfare from adverse effects linked to O_3 influence on radiative forcing, and related climate effects. Thus, the Administrator concludes that the information available in this review is insufficient to judge the existing standard inadequate or to identify an appropriate revision based on O_3-related climate effects.

The Administrator turns now to vegetation-related effects, the evidence for which as a whole is extensive, spans several decades, and supports the Agency's conclusions of causal or likely to be causal relationship for O_3 in ambient air with an array of effect categories. These categories include reduced vegetation growth, reproduction, crop yield, productivity and carbon sequestration in terrestrial systems; increased tree mortality; alteration of terrestrial community composition, belowground biogeochemical cycles and ecosystem water cycling; and visible foliar injury (ISA, Appendix 8). As an initial matter, the Administrator notes the new ISA determination that the current evidence is sufficient to infer likely causal relationships of O_3 with increased tree mortality. With regard to the current evidence for this effect, the Administrator notes that the evidence does not indicate a potential for O_3 concentrations that occur in locations that meet the current standard to cause increased tree mortality, as summarized in section III.A.2.a above (PA, section 4.3.1). Accordingly, he finds it appropriate to focus on more sensitive effects, such as tree seedling growth, in his review of the standard. Thus, in considering the adequacy of protection provided by the current standard from adverse effects to the public welfare related to these effects, the Administrator begins by considering vegetation growth and conceptually related effects with a focus on RBL (described in section III.B.2 above), then turns to a specific consideration of crop yield loss and lastly, to consideration of visible foliar injury.

With regard to vegetation growth and related effects, the Administrator has considered discussions in the PA and in response to public comments in section III.B.2 above, and finds it appropriate for identification of the requisite protection to extend beyond consideration of a magnitude of growth effects, *per se,* that he may judge adverse to the public welfare. Rather, the Administrator extends his consideration beyond that, judging it appropriate to consider reduced growth (*i.e.,* RBL) as a proxy for an array of other vegetation-related effects to the public welfare. As discussed in section III.B.2 above, these categories of effects include reduced vegetation growth, reproduction, productivity and carbon sequestration in terrestrial systems, and also alteration of terrestrial community composition, belowground biogeochemical cycles and ecosystem water cycling. In adopting RBL as a proxy for this array of effects, the Administrator notes that such a use is consistent with advice from CASAC, and that RBL was also adopted as a proxy for this array of effects by the prior Administrator, in consideration of advice from the prior CASAC.

In assessments of RBL estimated from O_3 exposure, the Administrator takes note of the PA consideration of the established E–R relationships for RBL in tree seedlings of 11 species with O_3 exposures in terms of W126 index (PA, Appendix 4A). In so doing, he agrees with the PA conclusion regarding 6% RBL, with which the CASAC concurred, as described in sections III.B.1.b and III.B.2 above), and judges that for his use of RBL as a proxy, maintaining O_3 concentrations such that associated estimates of RBL fall below 6%, as a median across the 11 species represented by the established E–R relationships would assure the appropriate protection. In making these judgments, he observes that they were also adopted by the prior Administrator, with consideration of advice from the prior CASAC.

Further, based on considerations discussed in the PA, advice from CASAC and discussion in section III.B.2 above, Administrator has considered the use of RBL in his judgment of the public welfare protection provided by the secondary standard. Based on those considerations, including uncertainties in the E–R relationships and their use in the way described here, the Administrator judges it appropriate for the standard to protect against W126 index values associated with a median RBL at or above 6% (while also controlling peak hourly concentrations, as discussed below). Based on this judgment, in addition to a recognition of uncertainty in these estimates (in light of the discussion in section III.B.2.b(ii) above regarding the appropriate duration or averaging for the W126 index metric) he concludes it appropriate for the standard to generally control exposures in terms of W126 index to a level of 17 ppm-hrs, recognizing that the RBL estimated for such a W126 index value is 5.3%, a value appreciably below 6%.

With regard to the appropriate O_3 exposure metric to employ in assessing adequacy of air quality control in protecting against RBL, the Administrator has considered the discussions in the PA, and in response to public comments in section III.B.2 above regarding the available evidence and air quality analyses. He has also considered this in the context of the court remand with regard to the EPA's use of a 3-year average W126 index to assess protection from RBL and the court's reference to advice from the prior CASAC on protection against ''unusually damaging years'' (described in section III.B.2 above). In so doing, the Administrator considers below the extent of conceptual similarities of the 3-year average W126 index with some aspects of the derivation approach for the established E–R functions, the context of RBL as a proxy (as recognized above), and limitations associated with a reliance solely on W126 index as a metric to control exposures that might be termed ''unusually damaging.''

With regard to the established E–R functions used to describe the relationship of RBL with O_3 in terms of a seasonal W126 index, the Administrator recognizes that the E–R functions were derived mathematically from studies of different exposure durations (varying from shorter than one to multiple growing seasons) by applying adjustments so that they would yield estimates normalized to the same period of time (season), such that the estimates may represent average impact for a season, as summarized in section III.A.1.c(ii) above (PA, section 4.5.1.2, Appendix 4A, Attachment 1). He notes the compatibility of W126 index averaged over multiple growing seasons or years with these adjustments. He also notes the exposure levels represented in the data underlying the E–R functions are somewhat limited with regard to the relatively lower cumulative exposure levels most commonly associated with the current standard (*e.g.,* at or below 17 ppm-hrs), indicating additional uncertainty for application to such levels. Further, he notes the PA observation that some of the underlying studies did not find statistically significant effects of O_3 at the lower exposure levels, indicating some uncertainty in predictions of an O_3-related RBL at those levels, as summarized in section III.A.1.c(ii) above (PA, section 4.5.1.2). He additionally notes the differing patterns of hourly concentrations of the elevated exposure levels in the datasets from which the E–R functions from the patterns in ambient

air meeting the current standard across the U.S. today, as summarized in section III.B.2.b(ii). With these considerations regarding the E–R functions and their underlying datasets in mind, he also takes note of year-to-year variability of factors other than O_3 exposures that affect tree growth in the natural environment (*e.g.,* related to variability in soil moisture, meteorological, plant-related and other factors), that have the potential to affect O_3 E–R relationships (ISA, Appendix 8, section 3.12; 2013 ISA section 9.4.8.3; PA, sections 4.3 and 4.5). Based on these considerations, the Administrator finds there to be a consistency of his use of the W126 index averaged over multiple years with the approach used in deriving the E–R function, and with other factors that may affect growth in the natural environment.

In light of such considerations, the Administrator agrees with the PA finding that several factors contribute uncertainty and some resulting imprecision or inexactitude to RBL estimated from single-year seasonal W126 index values, as discussed in section III.D.1.b(ii) of the proposal (85 FR 49900–01, August 14, 2020; PA sections 4.5.1.2 and 4.5.3). The Administrator additionally recognizes the qualitative and conceptual nature of our understanding, in many cases, of relationships of O_3 effects on plant growth and productivity with larger-scale impacts, such as those on populations, communities and ecosystems. From these considerations, he judges that use of a seasonal RBL averaged over multiple years, such as a 3-year average, is reasonable, and provides a more stable and well-founded RBL estimate for his purposes as a proxy to represent the array of vegetation-related effects identified above. The Administrator additionally takes note of the CASAC advice agreeing with the EPA's focus on a 3-year average W126 for this purpose, concluding such a focus to be reasonable and scientifically sound, as summarized in section III.B.1.b above. In light of these considerations, the Administrator finds there to be support for use of an average seasonal W126 index derived from multiple years (with their representation of variability in environmental factors), concluding the use of such averaging to provide an appropriate representation of the evidence and attention to considerations summarized above. In so doing, he finds that sole reliance on single year W126 estimates for reaching judgments with regard to magnitude of O_3 related RBL and associated judgments of public welfare protection would ascribe a greater specificity and certainty to such estimates than supported by the current evidence. Rather, he finds it appropriate, for purposes of considering public welfare protection from effects for which RBL is used as a proxy, to primarily consider W126 index in terms of a 3-year average metric.

In his consideration of the appropriateness of using a 3-year average W126 metric, the Administrator additionally takes note of the discussion in section III.B.2 above with regard to protection against ''unusually damaging years,'' a caution raised by the prior CASAC in considering a secondary standard in terms of a 3-year average W126 index (and an issue raised in the court remand). With regard to this caution, the Administrator finds informative the discussion in section III.B.2 above regarding the extent to which a standard in terms of a W126 metric might be expected to control exposure circumstances of concern (*e.g.,* for growth effects, among others). This discussion and its focus on air quality analyses in the PA and additional analyses conducted in consideration of public comment investigate the annual occurrence of elevated hourly O_3 concentrations which may contribute to vegetation exposures of concern (PA, Appendix 2A, section 2A.2; Wells, 2020).[239]

These air quality analyses illustrate limitations of the W126 index for purposes of controlling peak concentrations, and also the strengths of the current standard in this regard. As discussed more fully in section III.B.2.b(ii) above, the W126 index cannot, by virtue of its definition, always differentiate between air quality patterns with high peak concentrations and those without such concentrations. This is demonstrated in the air quality analyses which show that the form and averaging time of the existing standard is much more effective than the W126 index in limiting peak concentrations (*e.g.,* hourly O_3 concentrations at or above 100 ppb) and in limiting number of days with any such hours (Wells, 2020, *e.g.,* Figures 4, 5, 8, 9 compared to Figures 6, 7, 10 and 11). A similar finding is evidence in the historical data extending back to 2000. These data show the appreciable reductions in peak concentrations that have been achieved in the U.S. as air quality has improved under O_3 standards of the existing form and averaging time (Wells, 2020, Figures 12 and 13). From these analyses, the Administrator concludes that the form and averaging time of the current standard is effective in controlling peak hourly concentrations and that a W126 index based standard would be much less effective in providing the needed protection against years with such elevated and potentially damaging hourly concentrations. Thus, in light of the current evidence and quantitative air quality analyses, the Administrator notes that the W126 index, by its very definition, does not provide specificity with regard to year-to-year variability in elevated hourly O_3 concentrations with the potential to contribute to the ''unusually damaging years'' that the prior CASAC identified for increased concern. In so doing, he disagrees with the statement of the prior CASAC that a single-year W126 index would necessarily provide protection from such years. Further, he judges that a standard based on either a 3-year or a single-year W126 index would not be expected to provide effective control of the peak concentrations that may contribute to ''unusually damaging years'' for vegetation.

Thus, in considering the extent of protection provided by the current standard, in addition to considering seasonal W126 averaged over a 3-year period to estimate median RBL using the established E–R functions, the Administrator finds it appropriate to also consider other metrics, including peak hourly concentrations. While he recognizes that the evidence does not indicate a particular threshold number of hours at or above 100 ppb (or another reference point for elevated concentrations), he takes particular note of the evidence of greater impacts from higher concentrations (particularly with increased frequency) and of the air quality analyses that document variability in such concentrations for the same W126 index value. In light of these considerations, he judges such a multipronged approach to be needed to ensure appropriate consideration of exposures of concern and the associated protection from them afforded by the secondary standard. Thus, the Administrator concludes that use of a seasonal W126 averaged over a 3-year period, which is the design value period for the current standard, to estimate median RBL using the established E–R functions, in combination with a

[239] The ISA references the longstanding recognition of the risk posed to vegetation of peak hourly O_3 concentrations (*e.g.,* ''[h]igher concentrations appear to be more important than lower concentrations in eliciting a response'' [ISA, p. 8–180]; ''higher hourly concentrations have greater effects on vegetation than lower concentrations'' [2013 ISA, p. 91–4] ''studies published since the 2006 O_3 AQCD do not change earlier conclusions, including the importance of peak concentrations, . . . in altering plant growth and yield'' [2013 ISA, p. 9–117]).

broader consideration of air quality patterns, such as peak hourly concentrations, is appropriate for considering the public welfare protection provided by the standard.

In the discussion above, the Administrator recognizes a number of public welfare policy judgments important to his review of the current standard that include the appropriateness of the W126 index, averaged across a 3-year period, for assessing the extent of protection afforded by the standard from cumulative seasonal O_3 exposures. In reflecting on these judgments, the current evidence presented in the ISA and the associated evaluations in the PA, the Administrator concludes that the currently available information supports such judgments, additionally noting the CASAC concurrence with regard to the scientific support for these judgments (Cox 2020a, Consensus Responses to Charge Questions p. 21). Accordingly, the Administrator concludes that the current evidence base and available information (qualitative and quantitative) continues to support consideration of the potential for O_3-related vegetation impacts in terms of the RBL estimates from established E–R functions as a quantitative tool within a larger framework of considerations pertaining to the public welfare significance of O_3 effects. Such consideration includes effects that are associated with effects on vegetation, and particularly those that conceptually relate to growth, and that are causally or likely causally related to O_3 in ambient air, yet for which there are greater uncertainties affecting estimates of impacts on public welfare. The Administrator additionally notes that this approach to weighing the available information in reaching judgments regarding the secondary standard additionally takes into account uncertainties regarding the magnitude of growth impact that might be expected in mature trees (*e.g.,* compared to seedlings), and of related, broader, ecosystem-level effects for which the available tools for quantitative estimates are more uncertain and those for which the policy foundation for consideration of public welfare impacts is less well established.

In his consideration of the adequacy of protection provided by the current standard, the Administrator does not consider every possible instance of an effect on vegetation growth from O_3 to be adverse to public welfare, although he recognizes that, depending on factors including extent and severity, such vegetation-related effects have the potential to be adverse to public welfare. Comments from the current CASAC, in the context of its review of the draft PA, expressed the view that the strategy described by the prior Administrator for the secondary standard established in 2015 with its focus on limiting 3-year average W126 index values somewhat below those associated with a 6% RBL in the median species and associated W126 index target of 17 ppm-hrs (in terms of a 3-year average), at or below which the 2015 standard was expected to generally restrict cumulative seasonal exposure, is ''still scientifically reasonable'' and ''still effective in particularly protecting the public welfare in light of vegetation impacts from ozone'' (Cox, 2020a, Consensus Responses to Charge Questions p. 21). In light of this advice and based on the current evidence as evaluated in the PA, the Administrator judges that this approach or framework, with its focus on controlling cumulative seasonal exposures associated with an RBL of 6% or greater, by limiting air quality in terms of a 3-year average W126 index, to or below a target of 17 ppm-hrs, in combination with a broader consideration of air quality patterns, such as control of peak hourly concentrations, associated with meeting the current standard, is appropriate for his use in this review. In so doing, he additional notes the isolated, rare occurrences in locations meeting the current standard of such exposures at 19 ppm-hrs. Based on the current information to inform consideration of vegetation effects and their potential adversity to public welfare, he additionally judges that the RBL estimates associated with such marginally higher exposures in isolated, rare instances are not indicative of effects that would be adverse to the public welfare, particularly in light of variability in the array of environmental factors that can influence O_3 effects in different systems and uncertainties associated with estimates of effects associated with this magnitude of cumulative exposure in the natural environment.

With regard to O_3 effects on crop yield, the Administrator, as an initial matter, takes note of the long-standing evidence, qualitative and quantitative, of the reducing effect of O_3 on the yield of many crops, as summarized in the PA and current ISA and characterized in detail in past reviews (*e.g.,* 2013 ISA, 2006 AQCD, 1997 AQCD, 2014 WREA). He additionally notes the established E–R functions for 10 crops and the estimates of RYL derived from them, as presented in the PA (PA, Appendix 4A, section 4A.1, Table 4A–4), and the potential public welfare significance of reductions in crop yield, as summarized in section III.A.2.b above. In so doing, however, he additionally recognizes that not every effect on crop yield will be adverse to public welfare. In the case of crops in particular there are a number of complexities related to the heavy management of many crops to obtain a particular output for commercial purposes, and related to other factors, that the Administrator takes into consideration in evaluating potential O_3-related public welfare impacts, as summarized in section III.B.2.b(iv) above (PA, sections 4.5.1.3 and 4.5.3).

Similarly, the Administrator concludes that the extensive management of agricultural crops that occurs to elicit optimum yields (*e.g.,* through irrigation and usage of soil amendments, such as fertilizer) is relevant in evaluating the extent of RYL estimated from experimental O_3 exposures that should be judged adverse to the public welfare. He considers these opportunities in crop management for market objectives, as well as complications in judging relative adversity that relate to market responses and their effects on producers and consumers in evaluating the potential impact on public welfare of estimated crop yield losses. Further, the Administrator takes note of the conclusion of the CASAC that the available evidence does not call into question the adequacy of the current secondary standard and that it should be retained (Cox 2020a, p.1).

The Administrator also considered the public comments, discussed in section III.B.2.b(iv) above, suggesting that the proposed decision was not giving adequate consideration to crop yield effects and that his decision should consider a statement by the prior CASAC, raised in public comments, that a 5% RYL estimate, as the median based on the 10 E–R functions, ''represents an adverse impact.'' With regard to the prior CASAC statement, he notes the discussion in section III.B.2.b(iv) above regarding the unclear basis for the prior CASAC judgment, both with regard to a connection of an estimated 5% RYL to broader impacts and to judgments on significance of a 5% RYL to the public welfare. In considering the adequacy of protection of the public welfare from effects related to crop yield loss, the Administrator considers the air quality analyses and the W126 index levels commonly occurring in areas that meet the current standard. In so doing, he notes that W126 index values (3-year average) were at or below 17 ppm-hrs in virtually all monitoring sites with air quality meeting the current standard.

Based on the established E–R functions, the median RYL estimate corresponding to 17 ppm-hrs is 5.1%. In considering single-year index values, as discussed in section III.B.2.b(vi), the vast majority are similarly low (with more than 99% less than or equal to 17 ppm-hrs), and the higher values predominantly occur in urban areas. The Administrator additionally takes note of the discussion in section III.B.2.b(ii) above regarding the role of elevated hourly concentrations in effects on vegetation growth and yield. In so doing, in addition to his consideration of W126 index occurring in areas that meet the current standard, he also takes note of the control of elevated hourly O_3 concentrations that is exerted by the current standard.

In light of all of the above, in reaching his judgment regarding public welfare implications of the W126 index values summarized here (and associated estimated RYL), including the isolated and rare occurrence of somewhat higher values, the Administrator notes that the secondary standard is not intended to protect against all known or anticipated O_3-related effects, but rather those that are judged to be adverse to the public welfare. He also takes into consideration the extensive management of agricultural crops, and the complexities associated with identifying adverse public welfare effects for market-traded goods (where producers and consumers may be impacted differently). Based on all of these factors, the Administrator disagrees with the prior CASAC statement that an estimated median RYL of 5% represents an adverse impact and further judges that an estimated median RYL of 5.1%, based on experimental exposures, would not constitute an adverse effect on public welfare. Accordingly, the Administrator notes that the current standard generally maintains air quality at a W126 index below 17 ppm-hrs, with few exceptions, and accordingly would limit the estimated RYL (based on experimental O_3 exposures) to this degree. Therefore, he concludes that the current standard provides adequate protection of public welfare related to crop yield loss and does not need to be revised to provide additional protection against this effect. In so doing, the Administrator notes the conclusions by the current CASAC that the evidence supports retaining the current standard, without revision.

Turning to consideration of visible foliar injury and protection afforded by the secondary standard from associated impacts to the public welfare, the Administrator takes note of the long-standing and well-established evidence base, updated in the ISA for this review, and of policy-relevant analyses presented in the PA to inform his judgments regarding a secondary standard that provides appropriate protection of the public welfare from this effect. In so doing, he has also taken into account issues raised by public comments, both with regard to our understanding of relationships between O_3 exposure circumstances and extent and severity of injury in natural areas across the U.S., and with regard to the extent of our understanding of the relationship of injury extent and severity to public welfare effects anticipated to be adverse, and the *Murray Energy* remand.

In considering public welfare implications of this effect, he notes the potential for this effect, when of a significant extent and severity, to reduce aesthetic and recreational values, such as the aesthetic value of scenic vistas in protected natural areas including national parks and wilderness areas, as well as other areas similarly protected by state and local governments for similar public uses. Based on these considerations, the Administrator recognizes that, depending on its severity and spatial extent, as well as the location(s) and the associated intended use, the impact of visible foliar injury on the physical appearance of plants has the potential to be significant to the public welfare. In this regard, he agrees with the PA statement that cases of widespread and relatively severe injury during the growing season (particularly when sustained across multiple years and accompanied by obvious impacts on the plant canopy) might reasonably be expected to have the potential to adversely impact the public welfare in scenic and/or recreational areas, particularly in areas with special protection, such as Class I areas (PA, sections 4.3.2 and 4.5.1). In so doing, the Administrator notes that the secondary standard is not meant to protect against all known or anticipated O_3-related welfare effects, but rather those that are judged to be adverse to the public welfare, and further notes that there are not established measures for when such welfare effects should be judged adverse to the public welfare. Rather, the level of protection from known or anticipated adverse effects to public welfare that is requisite for the secondary standard is a public welfare policy judgment to be made by the Administrator.

While recognizing there to be a paucity of established approaches for interpreting specific levels of severity and extent of foliar injury in natural areas with regard to impacts on the public welfare (*e.g.,* related to recreational services), the Administrator recognizes that injury to whole stands of trees of a severity apparent to the casual observer (*e.g.,* when viewed as a whole from a distance) would reasonably be expected to affect recreational values and thus pose a risk of adverse effects to the public welfare. He further notes that the available information does not provide for specific characterization of the incidence and severity that would not be expected to be apparent to the casual observer, nor for clear identification of the pattern of O_3 concentrations that would provide for such a situation.

In this context, the Administrator takes note of the system developed by the USFS for its monitoring program [240] to categorize BI scores of visible foliar injury at biosites (sites with O_3-sensitive vegetation assessed for visible foliar injury) in natural vegetated areas by severity levels (described in section III.A.2.c(ii) above). While recognizing that quantitative analyses and evidence are lacking that might support a more precise conclusion with regard to a magnitude of BI score coupled with an extent of occurrence that might be specifically identified as adverse to the public welfare, the Administrator also takes note of the D.C. Circuit's holding that substantial uncertainty about the level at which visible foliar injury may become adverse to public welfare does not necessarily provide a basis for declining to evaluate whether the existing standard provides requisite protection against such effects. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 619–20 (D.C. Cir. 2019). In this context, he considers the discussion in the PA and in sections III.A.2.b, III.A.2.c and III.B.2 above regarding the USFS biosite monitoring program. He finds the scale of this program's objectives, which focus on natural settings in the U.S. and forests as opposed to individual plants, to be suited for his consideration with regard to the public welfare protection afforded by the current standard, and consequently, he finds the data and analyses generated by the program informative in such considerations.

In this context, he takes note of the USFS system, including its descriptors for BI scores of differing magnitude intended for that Agency's consideration in identifying areas of potential impact to forest resources. As described in section III.A.2.b(iii) above, very low BI scores (at or below 5) are

[240] During the period from 1994 (beginning in eastern U.S.) through 2011, the USFS conducted surveys of the occurrence and severity of visible foliar injury on sensitive species at sites across most of the U.S. following a national protocol.

described by the USFS scheme as ''little or no foliar injury'' (Smith et al., 2007; Smith et al., 2012).[241] The Administrator notes that BI scores above 15 are categorized as moderate to severe (and scores above 25 as severe). In so doing, in light of considerations raised in the PA and consideration of public comment, he recognizes the lower categories of BI scores as indicative of injury of generally lesser risk to the natural area or to public enjoyment, which he judges unlikely to be indicative of injury of such a magnitude or extent as to pose risk of adverse effects to the public welfare. Thus, the Administrator reaches the conclusion that occurrence of the lower categories of BI scores does not pose concern for the public welfare, but that findings of BI scores categorized as ''moderate to severe'' injury by the USFS scheme would be an indication of visible foliar injury occurrence that, depending on extent and severity, may raise public welfare concerns. In this framework, the Administrator considers the PA evaluations of the currently available information and what it indicates with regard to patterns of air quality of concern for such an occurrence, and the extent to which they are expected to occur in areas that meet the current standard.

In so doing, the Administrator takes particular note of the USFS biosite monitoring program studies of the occurrence, extent and severity of visible foliar injury in indicator species in defined plots or biosites in natural areas across the U.S. These studies of data for USFS biosites (sites with O_3-sensitive vegetation assessed for visible foliar injury) have often summarized O_3 concentrations in terms of cumulative exposure metrics (*e.g.,* SUM06 or W126 index). Some of these studies, particularly those examining such data across multiple years and multiple regions of the U.S., have reported that variation in cumulative O_3 exposure, in terms of such metrics, does not completely explain the patterns of occurrence and severity of injury observed. Although the availability of detailed analyses that have explored multiple exposure metrics and other influential variables is limited, multiple studies have indicated a potential role for an additional metric, one related to the occurrence of days with relatively high concentrations (*e.g.,* number of days with a 1-hour concentration at or above 100 ppb), as summarized in section III.A.2.c above (PA, section 4.5.1.2). Thus, the Administrator takes note of this evidence indicating an influence of peak concentrations on BI scores (beyond an influence of cumulative exposure). He also finds noteworthy the extensive evidence of trends across the past nearly 20 years that indicate reductions in severity of visible foliar injury that parallel reductions in peak concentrations that have been suggested to be influential in the severity of visible foliar injury.[242]

Further, the Administrator considers the PA analysis of a dataset developed from USFS biosite index scores, combined with W126 estimates and soil moisture categories, summarized in section III.A.2.c above. In so doing, he takes note of the PA observation that important uncertainties remain in the understanding of the O_3 exposure conditions that will elicit visible foliar injury of varying severity and extent in natural areas, and particularly in light of the other environmental variables that influence its occurrence, and of the recognition by the CASAC that ''uncertainties continue to hamper efforts to quantitatively characterize the relationship of [visible foliar injury] occurrence and relative severity with ozone exposures'' (Cox 2020a, Consensus Responses to Charge Questions, p. 20). Notwithstanding, and while being mindful of, such uncertainties with regard to predictive O_3 metric or metrics and a quantitative function relating them to incidence and severity of visible foliar injury in natural areas (as also noted in the USFS studies referenced above), the Administrator takes note of the PA finding that the incidence of nonzero BI scores, and, particularly of relatively higher scores (such as scores above 15 which are indicative of ''moderate to severe'' injury in the USFS scheme) appears to markedly increase only with W126 index values above 25 ppm-hrs, as summarized in section III.B.2.b above (PA, section 4.3.3 and Appendix 4C).

In light of these observations, the Administrator finds the current evidence to be incomplete with regard to information to support a quantitative characterization of air quality that would be anticipated to result in visible foliar injury of an extent and severity to cause adverse effects to the public welfare. The Administrator also considers discussion in the court's remand of the 2015 standard with regard to visible foliar injury (*Murray Energy Corp.* v *EPA*, 936 F.3d at 619–20). The court concluded that the EPA had failed to offer a reasoned explanation for deciding not to specify a level of air quality to protect against adverse effects related to visible foliar injury. In particular, the court stated that the EPA had not explained why it was unable to choose such a level although the prior CASAC had provided advice with regard to a specific level. The EPA's disagreement with the prior CASAC on its identified level is explained in section III.B.2 above, as is the reason why the EPA did not find the analysis on which the prior CASAC based its advice to be appropriate for such a conclusion.[243] This and other associated issues raised by the court have been raised in public comments on the proposal for this action and are addressed in section III.B.2 above.

Based on the evidence and quantitative analyses available in the present review, and advice from the current CASAC, the Administrator considers the question of a level of air quality that would provide protection against visible foliar injury related effects known or anticipated to cause adverse effects to the public welfare. Based on the evidence and associated quantitative analyses in this review, the Administrator's judgment reflects his recognition of less confidence and greater uncertainty in the existence of adverse public welfare effects with lower O_3 exposures. In this context, the Administrator judges that W126 index values at or below 25 ppm-hrs, when in combination with infrequent occurrences of hourly concentrations at or above 100 ppb, would not be anticipated to pose risk of visible foliar injury of an extent and severity so as to be adverse to the public welfare.

With these conclusions in mind, the Administrator considers the air quality analyses presented in the PA and the additional analyses developed in response to public comment. In so doing, he notes that a W126 index above

[241] Studies that consider such data for purposes of identifying areas of potential impact to the forest resource suggest this category corresponds to ''none'' with regard to ''assumption of risk'' (Smith et al., 2007; Smith et al., 2012).

[242] For example, the PA describes findings from USFS studies that have concluded a ''declining risk of probable impact'' over the 16-year period of the program, especially after 2002 (*e.g.,* Smith, 2012), and the parallel national reductions in O_3 concentrations from 2000 through 2018 in terms of cumulative seasonal exposures, as well as in peak O_3 concentrations such as the annual fourth highest daily maximum 8-hour concentration and also the occurrence of 1-hour concentrations above 100 ppb (PA, Figure 2–11, Appendix 2A, Tables 2A–2 to 2A–4, and Appendix 4D, Figure 4D–9).

[243] As discussed in section III.B.2.b, the cumulative frequency graph relied on by the CASAC does not present biosite scores for comparison at different cumulative exposure levels. Accordingly, it does not provide the type of analysis that is needed for the EPA to reach a conclusion about the extent of protection that different patterns of O_3 concentrations would provide against visible foliar injury of an extent and severity as to pose risk of adverse effects to the public welfare.

25 ppm-hrs (either as a 3-year average or in a single year) is not seen to occur at monitoring locations (including in or near Class I areas) where the current standard is met, and that, in fact, values above 17 or 19 ppm-hrs are rare, as summarized in section III.A.3 above (PA, Appendix 4C, section 4C.3; Appendix 4D, section 4D.3.2.3). Further, the Administrator takes note of the PA consideration of the USFS publications that identify an influence of peak concentrations on BI scores (beyond an influence of cumulative exposure) and the PA observation of the appreciable control of peak concentrations exerted by the form and averaging time of the current standard, as evidenced by the air quality analyses which document reductions in 1-hour daily maximum concentrations with declining design values. He also notes, as discussed above, the uncommonness of days with any hours at or above 100 ppb at monitoring sites that meet the current standard, as well as the minimal number of hours on any such days (Wells, 2020). Based on these considerations, the Administrator concludes that the current standard provides control of air quality conditions that contribute to increased BI scores and to scores of a magnitude indicative of ''moderate to severe'' foliar injury.

The Administrator further takes note of the PA finding that the current information, particularly in locations meeting the current standard or with W126 index estimates likely to occur under the current standard, does not indicate a significant extent and degree of injury (*e.g.,* based on analyses of BI scores in the PA, Appendix 4C) or specific impacts on recreational or related services for areas, such as wilderness areas or national parks. Thus, he gives credence to the associated PA conclusion that the evidence indicates that areas that meet the current standard are unlikely to have BI scores reasonably considered to be impacts of public welfare significance. Based on all of the considerations raised here, the Administrator concludes that the current standard provides sufficient protection of natural areas, including particularly protected areas such as Class I areas, from O_3 concentrations in the ambient air that might be expected to elicit visible foliar injury of such an incidence and severity as would reasonably be judged adverse to the public welfare.

With a primary focus on RBL in its role as proxy, the Administrator further considers the analyses available in this review of recent air quality at sites across the U.S., particularly including those sites in or near Class I areas, and also the analyses of historical air quality. In so doing, the Administrator recognizes that these analyses are distributed across all nine NOAA climate regions and 50 states, although some geographic areas within specific regions and states may be more densely covered and represented by monitors than others, as summarized in section III.C of the proposal (PA, Appendix 4D). The Administrator notes that the findings from both the analysis of the air quality data from the most recent period and from the larger analysis of historical air quality data extending back to 2000, as presented in the PA and summarized in section III.A.3 above, are consistent with the air quality analyses available in the last review. That is, in virtually all design value periods and all locations at which the current standard was met across the 19 years and 17 design value periods (in more than 99.9% of such observations), the 3-year average W126 metric was at or below 17 ppm-hrs. Further, in all such design value periods and locations the 3-year average W126 index was at or below 19 ppm-hrs. The Administrator additionally considers the protection provided by the current standard from the occurrence of O_3 exposures within a single year with potentially damaging consequences, such as a significantly increased incidence of areas with visible foliar injury that might be judged moderate to severe, as discussed in section III.B.2 above. In so doing, he takes notes of the PA analyses, summarized in section III.A.2.c above, of USFS BI scores, giving particular focus to scores above 15, termed ''moderate to severe injury'' by the USFS categorization scheme, as described in section III.A.2.b above (PA, sections 4.3.3.2, 4.5.1.2 and Appendix 4C). He notes the PA finding that incidence of sites with BI scores above 15 markedly increases with W126 index estimates above 25 ppm-hrs. In this context, he additionally takes note of the air quality analysis finding of a scarcity of single-year W126 index values above 25 ppm-hrs at sites that meet the current standard, with just a single occurrence across all U.S. sites with design values meeting the current standard in the 19-year historical dataset dating back to 2000 (PA, section 4.4 and Appendix 4D). Further, in light of the evidence indicating that peak short-term concentrations (*e.g.,* of durations as short as one hour) may also play a role in the occurrence of visible foliar injury, the Administrator additionally takes note of the air quality analyses in the PA and in the additional analysis documented in Wells (2020). These analyses of data from the past 20 years show a declining trend in 1-hour daily maximum concentrations mirroring the declining trend in design values, supporting the PA conclusion that the form and averaging time of the current standard provides appreciable control of peak 1-hour concentrations. Furthermore, these analyses indicate there to be only a few days among sites meeting the current standard, with hourly concentrations at or above 100 ppb (just seven in the period from 2000 through 2018) (Wells, 2020). In light of these findings from the air quality analyses and considerations in the PA, both with regard to 3-year average W126 index values at sites meeting the current standard and the rarity of such values at or above 19 ppm-hrs, and with regard to single-year W126 index values at sites meeting the current standard, and the rarity of such values above 25 ppm-hrs, as well as with regard to the appreciable control of 1-hour daily maximum concentrations, the Administrator judges that the current standard provides adequate protection from air quality conditions with the potential to be adverse to the public welfare.

In reaching his conclusion on the current secondary O_3 standard, the Administrator recognizes, as is the case in NAAQS reviews in general, his decision depends on a variety of factors, including science policy judgments and public welfare policy judgments, as well as the currently available information. With regard to the current review, the Administrator gives primary attention to the principal effects of O_3 as recognized in the current ISA, the 2013 ISA and past AQCDs, and for which the evidence is strongest (*e.g.,* growth, reproduction, and related larger-scale effects, as well as, visible foliar injury). With regard to growth and the categories of effects identified above for which RBL has been identified for use as a proxy, based on all of the considerations above, including the discussion of air quality immediately above, the Administrator judges the current standard to provide adequate protection for air quality conditions with the potential to be adverse to the public welfare. Further, with regard to visible foliar injury, the Administrator concludes that the currently available information on visible foliar injury and with regard to air quality analyses that may be informative with regard to air quality conditions associated with appreciably increased incidence and severity of BI scores at USFS biomonitoring sites, and with particular attention to Class I and other areas afforded special protection,

indicates the current standard to provide adequate protection from visible foliar injury of an extent or severity that might be anticipated to be adverse to the public welfare.

In summary, the Administrator has based his decision on the public welfare protection afforded by the secondary O_3 standard from identified O_3-related welfare effects, and from their potential to present adverse effects to the public welfare, on judgments regarding what the available evidence, quantitative information, and associated uncertainties and limitations (such as those identified above) indicate with regard to the protection provided from the array of O_3 welfare effects. He finds that, as a whole, this information, as summarized above, and presented in detail in the ISA and PA, does not indicate the current standard to allow air quality conditions with implications of concern for the public welfare. He has additionally considered the advice from the CASAC in this review, including its finding ''that the available evidence does not reasonably call into question the adequacy of the current secondary ozone standard and concurs that it should be retained'' (Cox, 2020a, p. 1), and well as public comment on the proposed decision. Based on all of the above considerations, including his consideration of the currently available evidence and quantitative exposure/risk information, the Administrator concludes that the current secondary standard is requisite to protect the public welfare from known or anticipated adverse effects of O_3 and related photochemical oxidants in ambient air, and thus that the current standard should be retained, without revision.

C. Decision on the Secondary Standard

For the reasons discussed above and taking into account information and assessments presented in the ISA and PA, the advice from the CASAC, and consideration of public comments, the Administrator concludes that the current secondary O_3 standard is requisite to protect the public welfare from known or anticipated adverse effects, and is retaining the current standard without revision.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

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

The Office of Management and Budget (OMB) has determined that this action is a significant regulatory action and it was submitted to OMB for review. Any changes made in response to OMB recommendations have been documented in the docket. Because this action does not change the existing O_3 NAAQS, it does not impose costs or benefits relative to the baseline of continuing with the current NAAQS in effect. EPA has thus not prepared a Regulatory Impact Analysis for this action.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action. There are no quantified cost estimates for this action because EPA is retaining the current standards.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. There are no information collection requirements directly associated with a decision to retain a NAAQS without any revision under section 109 of the CAA, and this action retains the existing O_3 NAAQS without any revisions.

D. 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. Rather, this action retains, without revision, existing national standards for allowable concentrations of O_3 in ambient air as required by section 109 of the CAA. See also *American Trucking Associations* v. *EPA,* 175 F.3d 1027, 1044–45 (D.C. Cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities), rev'd in part on other grounds, *Whitman* v. *American Trucking Associations,* 531 U.S. 457 (2001).

E. Unfunded Mandates Reform Act (UMRA)

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

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes. This action does not change existing regulations; it retains the existing O_3 NAAQS, without revision. Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. The health effects evidence and risk assessment information for this action, which focuses on children and people (of all ages) with asthma as key at-risk populations, is summarized in section II.A.2 and II.A.3 above and described in the ISA and PA, copies of which are in the public docket for this action.

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

This action is not a ''significant energy action'' for purposes of Executive Order 13211. The action is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action retains the current O_3 NAAQS. This decision does not change existing requirements. The Administrator of the Office of Information and Regulatory Affairs has not otherwise designated this action as a significant energy action. Thus, this decision does not constitute a significant energy action as defined in Executive Order 13211.

J. National Technology Transfer and Advancement Act

This action does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and

adverse human health or environmental effects on minority, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The action described in this document is to retain without revision the existing O_3 NAAQS based on the Administrator's conclusions that the existing primary standard protects public health, including the health of sensitive groups, with an adequate margin of safety, and that the existing secondary standard protects public welfare from known or anticipated adverse effects. As discussed in section II above, the EPA expressly considered the available information regarding health effects among at-risk populations in reaching the decision that the existing standard is requisite.

L. Determination Under Section 307(d)

Section 307(d)(1)(V) of the CAA provides that the provisions of section 307(d) apply to ''such other actions as the Administrator may determine.'' Pursuant to section 307(d)(1)(V), the Administrator determines that this action is subject to the provisions of section 307(d).

M. Congressional Review Act

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).

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Andrew Wheeler,

Administrator.

[FR Doc. 2020–28871 Filed 12–30–20; 8:45 am]

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