FEDERAL REGISTER

Vol. 84 Thursday,
No. 100 May 23, 2019

Pages 23703–23990

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 84 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Contents

Federal Register

Vol. 84, No. 100

Thursday, May 23, 2019

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Proclamations:

9704 (Amended by Proc. 9893) 23983
9705 (Amended by Proc. 9894) 23987
9893.....23983
9894.....23987

8 CFR

103.....23930
214.....23930

14 CFR

39.....23703
97 (2 documents) 23710, 23712

Proposed Rules:

39 (2 documents) 23740, 23742

15 CFR

774.....23886

18 CFR

35.....23902

26 CFR

1.....23716

33 CFR

165 (4 documents) 23719, 23720, 23721

Proposed Rules:

165.....23748

40 CFR

52 (2 documents) 23723, 23725
63.....23727

Proposed Rules:

52.....23750

42 CFR

422.....23832
423.....23832

49 CFR

10.....23728
209.....23730
213.....23730
214.....23730
215.....23730
217.....23730
218.....23730
219.....23730
220.....23730
221.....23730
222.....23730
223.....23730
224.....23730
225.....23730
227.....23730
228.....23730
229.....23730
230.....23730
231.....23730
232.....23730
233.....23730
234.....23730
235.....23730
236.....23730
237.....23730
238.....23730
239.....23730
240.....23730
241.....23730
242.....23730
243.....23730
270.....23730
272.....23730

50 CFR

660.....23737

Rules and Regulations

Federal Register
Vol. 84, No. 100
Thursday, May 23, 2019

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0790; Product Identifier 2018–NM–078–AD; Amendment 39–19629; AD 2019–08–08]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2010–14–05, which applied to certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. AD 2010–14–05 required inspection for the part numbers of the system and brake accumulators, and repetitive replacement of affected accumulators. This AD adds requirements for relocating the accumulators and revising the existing maintenance or inspection program to incorporate new or more restrictive airworthiness limitations. This AD also adds optional terminating action for certain airplanes. This AD was prompted by reports of on-ground hydraulic accumulator screw cap or end cap failure that resulted in the loss of the associated hydraulic system and high-energy impact damage to adjacent systems and structure. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 27, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 27, 2019.

ADDRESSES: For service information identified in this final rule, contact Bombardier, Inc., 200 Côte-Vertu Road West, Dorval, Québec H4S 2A3, Canada; North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; email *ac.yul@aero.bombardier.com;* internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0790.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0790; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Darren Gassetto, Aerospace Engineer, Mechanical Systems & Administrative Services, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7323; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2010–14–05, Amendment 39–16350 (75 FR 37994, July 1, 2010) (''AD 2010–14–05''). AD 2010–14–05 applied to certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. The NPRM published in the **Federal Register** on September 14, 2018 (83 FR 46670). The NPRM was prompted by reports of on-ground hydraulic accumulator screw cap or end cap failure that resulted in the loss of the associated hydraulic system and high-energy impact damage to adjacent systems and structure. The NPRM proposed to continue to require inspection for the part numbers of the system and brake accumulators, and repetitive replacement of affected accumulators. The NPRM also proposed to require relocating the accumulators and revising the existing maintenance or inspection program to incorporate new or more restrictive airworthiness limitations. The NPRM also proposed to add optional terminating action for certain airplanes. We are issuing this AD to address failure of one of the brake accumulator screw caps/end caps, which could result in impact damage causing loss of both hydraulic systems No. 2 and No. 3, and the consequent loss of both braking and nose wheel steering, the potential for a runway excursion, and damage to the airplane.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2009–39R1, dated October 13, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. The MCAI states:

> Seven cases of on-ground hydraulic accumulator screw cap or end cap failure have been experienced on CL–600–2B19 (CRJ) aircraft, resulting in loss of the associated hydraulic system and high-energy impact damage to adjacent systems and structure. The lowest number of flight cycles accumulated at the time of failure, to date, has been 6991 flight cycles.
>
> Although there have been no failures to date on any CL–600–1A11, CL–600–2A12 or CL–600–2B16 aircraft, the same accumulators as those installed on the CL–600–2B19, Part Numbers (P/N) 08–60163–002 and 08–60164–002 are installed on some of the aircraft listed in the Applicability section of this directive.
>
> Notes:
>
> 1. Earlier accumulators, P/Ns 2770571–102, 2770571–103, 2770571–104 and 2770571–105, were installed in production on the following aircraft: CL–600–1A11 [all Serial Numbers (S/Ns)], CL–600–2A12 (all S/Ns) and CL–600–2B16 (S/Ns 5001 through 5194 and 5301 through 5524 only). These accumulators do not require inspection or replacement. However, if any of the accumulators with the above P/Ns have been replaced in-service by P/Ns 08–60163–002 and 08–60164–002, these latter accumulators require replacement.

2. Prior to issuance of [Canadian] AD CF–2009–39, the only accumulators ever installed in production on CL–600–2B16 aircraft, S/Ns 5525 through 5665 and 5701 through 5908, are P/Ns 08–60163–002 and 08–60164–002; these accumulators require replacement.

3. After issuance of [Canadian] AD CF–2009–39 [which corresponds to FAA AD 2010–14–05], accumulators with P/Ns specified in Note 2, above, began to feature various S/N suffixes. Only accumulators with S/N suffix ''TNAE'' do not require replacement, but they are subject to other mandatory actions detailed in this AD.

4. Stainless steel accumulators P/Ns 601R75139–3 (11094–4) and 601R75139–1 (11093–4) were installed in production on CL–600–2B16 aircraft, S/Ns 5909 and subsequent. These accumulators do not require replacement, but they are subjected to other mandatory actions detailed in this AD.

A detailed analysis of the systems and structure in the potential line of trajectory of a failed screw cap/end cap for each accumulator, P/Ns 08–60163–002 and 08–60164–002, has been conducted. On the Challengers, it has been identified that the worst case scenario would be a failure of system No. 1, 2 or 3 accumulator screw caps/end caps (depending on the model), resulting in a potential uncontrolled fire in a non-designated fire zone.

The original version of this [Canadian] AD gave instructions to perform identification and records checks, where applicable, and replace accumulators, P/Ns 08–60163–002 and 08–60164–002 within the time compliance specified.

* * * * *

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0790.

Comments

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

Request To Refer to Latest Service Information

Bombardier requested that we refer to the latest version of the service information: Bombardier Challenger CL–605 Time Limits/Maintenance Checks (TLMC), Revision 19, dated May 29, 2018.

We agree to refer to the latest service information. The specific tasks required by paragraph (j) of this AD have not changed in the latest available service information. The current version of the Bombardier Challenger CL–605 Time Limits/Maintenance Checks, Part 2, Airworthiness Limitations, is Revision 20, dated November 19, 2018. We have changed all references accordingly in this final rule, with credit provided in paragraph (l)(6) of this AD for the prior accomplishment of Revision 18, dated December 4, 2017, and Revision 19, dated May 29, 2018.

The current version of the Bombardier Challenger CL–604 Time Limits/Maintenance Checks, Part 2, Airworthiness Limitations, is Revision 31, dated November 19, 2018. We have changed all references accordingly in this final rule, with credit provided in paragraph (l)(5) of this AD for the prior accomplishment of Revision 30, dated December 4, 2017.

Request for Minor Editorial Changes

Bombardier requested several minor changes to the NPRM, including correcting a typographical error in an email address, updating the address for Bombardier, updating the airplane identity to match the models and variants as listed on the current type certificate data sheet (TCDS), and clarifying part numbers and service bulletin numbers. We agree and have revised this AD accordingly.

Request To Revise Model Callout

Bombardier asked us to change ''604 Variants'' to ''604 Variant'' in the SUMMARY and ''Actions Since AD 2010–14–05 Was Issued'' section of the NPRM.

We disagree with this request because there are multiple variants for the CL–600–2B16 airplanes. We have not changed this final rule regarding this issue.

Comment Regarding TLMC Revision Status

Bombardier noted that the TLMC revisions listed in figure 2 to paragraph (j) of this AD are the latest versions published on the customer website and not when the tasks were introduced. No change was requested or made.

Request To Clarify Applicability

Bombardier requested that we revise the applicability for Model CL–600–2B16 airplanes in paragraph (c)(5) of the proposed AD by changing serial numbers ''5701 and subsequent'' to ''5701 through 5988.''

We agree to make this change. We have determined that production for this model ended with serial number 5988; therefore, there is no change to the affected airplanes in this AD.

Request To Revise Certain Airplanes Subject to Accumulator Relocation

Bombardier requested that we revise the affected airplanes identified in paragraph (i)(4) of the proposed AD, from ''S/Ns 5701 and subsequent'' to ''S/Ns 5701 to 5982.''

We agree with the request. We have determined that accumulators on airplanes with serial numbers after 5982 have been relocated. We have revised paragraph (i)(4) of this AD accordingly.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously, and minor editorial changes. We have determined that these minor changes:

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

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

The following Bombardier service information describes procedures for replacing hydraulic system accumulators with new, overhauled, or refurbished accumulators. These documents are distinct since they apply to different airplane models.

- Service Bulletin 600–0742, Revision 04, dated June 11, 2015.
- Service Bulletin 601–0597, Revision 04, dated June 11, 2015.
- Service Bulletin 604–29–008, Revision 04, dated June 11, 2015.
- Service Bulletin 605–29–001, Revision 04, dated June 10, 2015.

The following Bombardier service information describes procedures for relocating hydraulic system accumulators. These documents are distinct since they apply to different airplane models in different configurations.

- Service Bulletin 600–0764, dated October 8, 2015.
- Service Bulletin 600–0767, dated August 25, 2016.
- Service Bulletin 601–0633, dated October 8, 2015.
- Service Bulletin 601–0637, dated August 25, 2016.
- Service Bulletin 604–29–013, Revision 02, dated April 18, 2016.
- Service Bulletin 605–29–006, Revision 02, dated April 19, 2016.

The following Bombardier Time Limits/Maintenance Checks describe certain systems life limits of the safe life items. These documents are distinct since they apply to different airplane models in different configurations.

- Section 5–10–20, Time Limits (Systems), of the Bombardier Challenger 600 Time Limits/Maintenance Checks, PSP 605, Revision 39, dated January 8, 2018.

• Section 5–10–20, Time Limits (Systems), of the Bombardier Challenger 601 Time Limits/Maintenance Checks, PSP 601–5, Revision 46, dated January 8, 2018.

• Section 5–10–20, Time Limits (Systems), of the Bombardier Challenger 601 Time Limits/Maintenance Checks, PSP 601A–5, Revision 42, dated January 8, 2018.

• Section 5–10–11, Life Limits (Systems), of the Bombardier Challenger CL–604 Time Limits/Maintenance Checks, Part 2, Airworthiness Limitations, Revision 31, dated November 19, 2018.

• Section 5–10–11, Life Limits (Systems), of the Bombardier Challenger CL–605 Time Limits/Maintenance Checks, Part 2, Airworthiness Limitations, Revision 20, dated November 19, 2018.

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

Costs of Compliance

We estimate that this AD affects 130 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions: 20 work-hours × $85 per hour = $1,700	$7,717	$9,417	$1,224,210.
New actions: Up to 170 work-hours × $85 per hour = Up to $14,450	Up to $41,635	Up to $56,085	Up to $7,291,050.

For the new maintenance/inspection program revision, we have determined that this action takes an average of 90 work-hours per operator, although we recognize that this number may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet, we have determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, we estimate the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all known costs in our cost estimate.

Authority for This Rulemaking

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

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

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2010–14–05, Amendment 39–16350 (75 FR 37994, July 1, 2010), and adding the following new AD:

2019–08–08 Bombardier, Inc.: Amendment 39–19629; Docket No. FAA–2018–0790; Product Identifier 2018–NM–078–AD.

(a) Effective Date

This AD is effective June 27, 2019.

(b) Affected ADs

This AD replaces AD 2010–14–05, Amendment 39–16350 (75 FR 37994, July 1, 2010) (''AD 2010–14–05'').

(c) Applicability

This AD applies to the Bombardier, Inc., airplanes, certificated in any category, identified in paragraphs (c)(1) through (c)(5) of this AD.

(1) Model CL–600–1A11 (600) airplanes, serial numbers 1004 through 1085 inclusive.

(2) Model CL–600–2A12 (601) airplanes, serial numbers 3001 through 3066 inclusive.

(3) Model CL–600–2B16 airplanes (601–3A Variant), serial numbers 5001 through 5134 inclusive.

(4) Model CL–600–2B16 airplanes (601–3R Variant), serial numbers 5135 through 5194 inclusive.

(5) Model CL–600–2B16 airplanes (604 Variant), serial numbers 5301 through 5665 inclusive and 5701 through 5988 inclusive.

Note 1 to paragraph (c) of this AD: Certain Model CL–600–2B16 (604 Variant) airplanes

might be referred to by the marketing designation CL–605.

(d) Subject

Air Transport Association (ATA) of America Code 29, Hydraulic power.

(e) Reason

This AD was prompted by reports of on-ground hydraulic accumulator screw cap or end cap failure that resulted in the loss of the associated hydraulic system and high-energy impact damage to adjacent systems and structure. We are issuing this AD to address failure of one of the brake accumulator screw caps/end caps, which could result in impact damage causing loss of both hydraulic systems No. 2 and No. 3, and the consequent loss of both braking and nose wheel steering, the potential for a runway excursion, and damage to the airplane.

(f) Compliance

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

(g) Retained Part Number Inspection and Accumulator Replacement, With Revised Formatting, Service Information, and Affected Part Numbers

This paragraph restates the requirements of paragraph (g) of AD 2010–14–05, with revised formatting, service information, and affected part numbers. Do the following actions as applicable.

(1) Within 50 flight hours after August 5, 2010 (the effective date of AD 2010–14–05), inspect to determine the part numbers of the system accumulators numbers 1, 2, and 3, and brake accumulators numbers 2 and 3 that are installed on the airplane. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number of each accumulator can be conclusively determined from that review. If all of the installed accumulators have part number (P/N) 2770571–102, 2770571–103, 2770571–104, 2770571–105, 601R75139–3 (11094–4), or 601R75139–1 (11093–4), no further action is required by paragraph (g) of this AD.

(2) *Except as provided in paragraph (g)(1) of this AD:* At the applicable time in paragraph (g)(2)(i), (g)(2)(ii), or (g)(2)(iii) of this AD, replace the accumulator with a new, overhauled, or refurbished accumulator with the same part number, in accordance with the Accomplishment Instructions of the applicable service bulletin listed in figure 1 to paragraphs (g)(2) and (g)(3) of this AD.

(i) For each accumulator having P/Ns 08–60163–002 (601R75138–1), and 08–60164–002 (601R75138–3), as applicable, that has accumulated more than 3,650 total flight cycles as of August 5, 2010 (the effective date of AD 2010–14–05): Replace the accumulator within 100 flight cycles after August 5, 2010.

(ii) For each accumulator having P/N 08–60163–002 (601R75138–1), and 08–60164–002 (601R75138–3), as applicable, that has accumulated 3,650 total flight cycles or fewer as of August 5, 2010: Replace the accumulator before the accumulation of 3,750 total flight cycles on the accumulator.

(iii) For each accumulator having P/N 08–60163–002 (601R75138–1), and 08–60164–002 (601R75138–3), as applicable, for which it is not possible to determine the number of flight cycles accumulated: Replace the accumulator within 100 flight cycles after August 5, 2010.

Figure 1 to paragraphs (g)(2) and (g)(3) of this AD –
Service bulletins for accumulator replacement

Airplane Model –	Bombardier Service Bulletin –	Revision –	Dated –
CL-600-1A11 (600)	600-0742	04	June 11, 2015
CL-600-2A12 (601) CL-600-2B16 (601-3A and 601-3R Variants)	601-0597	04	June 11, 2015
CL-600-2B16 (604 Variant)	604-29-008	04	June 11, 2015
CL-600-2B16 (605*)	605-29-001	04	June 10, 2015

*Model CL-600-2B16 (604 Variant), referred to by the marketing designation CL-605.

(3) Thereafter, before the accumulation of 3,750 total flight cycles on any accumulator having P/Ns 08–60163–002 (601R75138–1), and 08–60164–002 (601R75138–3), as applicable, replace the accumulator with a new, overhauled, or refurbished accumulator having the same part number, in accordance with the Accomplishment Instructions of the applicable service bulletin listed in figure 1 to paragraphs (g)(2) and (g)(3) of this AD.

(h) New Provision of This AD: Terminating Action for Certain Accumulators

For each accumulator with one of the part number and serial number (S/N) suffixes listed in paragraphs (h)(1) through (h)(4) of this AD, the repetitive replacement specified in paragraphs (g)(2) and (g)(3) of this AD is not required.

(1) P/N 08–60163–002 with S/N suffix TNAE.

(2) P/N 08–60164–002 with S/N suffix TNAE.

(3) P/N 601R75139–3 (11094–4).

(4) P/N 601R75139–1 (11093–4).

(i) New Requirement of This AD: Relocation of Accumulators

Within 60 months or 2,400 flight cycles, whichever occurs first after the effective date of this AD, relocate the hydraulic system accumulators as specified in paragraphs (i)(1) through (i)(4) of this AD, as applicable. Relocation of the hydraulic system accumulators as required by this paragraph does not terminate any repetitive replacement required by paragraph (g)(2) or (g)(3) of this AD.

(1) For Model CL–600–1A11 (600) airplanes, S/Ns 1004 through 1085 inclusive: Relocate accumulators as specified in paragraphs (i)(1)(i) and (i)(1)(ii) of this AD.

(i) Relocate hydraulic system Nos. 1 and 2 accumulators, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 600–0764, dated October 8, 2015.

(ii) Relocate hydraulic system No. 3 accumulator, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 600–0767, dated August 25, 2016.

(2) For Model CL–600–2A12 (601) airplanes, S/Ns 3001 through 3066 inclusive, and Model CL–600–2B16 (601–3A and 601–3R Variants) airplanes, S/Ns 5001 through 5194 inclusive: Relocate accumulators as specified in paragraphs (i)(2)(i) and (i)(2)(ii) of this AD.

(i) Relocate hydraulic system Nos. 1 and 2 accumulators, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 601–0633, dated October 8, 2015.

(ii) Relocate hydraulic system No. 3 accumulator, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 601–0637, dated August 25, 2016.

(3) For Model CL–600–2B16 (604 Variant) airplanes, S/Ns 5301 through 5665 inclusive: Relocate hydraulic system No. 3 accumulator, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 604–29–013, Revision 02, dated April 18, 2016.

(4) For Model CL–600–2B16 (605) airplanes, S/Ns 5701 through 5982 inclusive and subsequent (*i.e.,* Model CL–600–2B16 (604 Variant), referred to by the marketing designation CL–605): Relocate hydraulic system No. 3 accumulator, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 605–29–006, Revision 02, dated April 19, 2016.

(j) New Requirement of This AD: Revision of Maintenance/Inspection Program

Within 50 flight hours after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate the tasks specified in figure 2 to paragraph (j) of this AD.

BILLING CODE 4910–13–P

Figure 2 to paragraph (j) of this AD: *Time Limits/Maintenance Checks (TLMC) tasks*

Airplane model	TLMC manual number	Section	Part number/task number
CL-600-1A11 (600)	Bombardier Challenger 600 Time Limits/Maintenance Checks, PSP 605, Revision 39, dated January 8, 2018	5-10-20, Time Limits (Systems)	601R75138-1 (08-60163-002) with "TNAE" after the S/N
			601R75138-3 (08-60164-002) with "TNAE" after the S/N
CL-600-2A12 (601)	Bombardier Challenger 601 Time Limits/Maintenance Checks, PSP 601-5, Revision 46, dated January 8, 2018	5-10-20, Time Limits (Systems)	601R75138-1 (08-60163-002) with "TNAE" after the S/N
			601R75138-3 (08-60164-002) with "TNAE" after the S/N

Airplane model	TLMC manual number	Section	Part number/task number
CL-600-2B16 (601-3A and 601-3R Variants)	Bombardier Challenger 601 Time Limits/Maintenance Checks, PSP 601A-5, Revision 42, dated January 8, 2018	5-10-20, Time Limits (Systems)	601R75138-1 (08-60163-002) with "TNAE" after the S/N
			601R75138-3 (08-60164-002) with "TNAE" after the S/N
CL-600-2B16 (604 Variant)	Bombardier Challenger CL−604 Time Limits/Maintenance Checks, Part 2, Airworthiness Limitations, Revision 31, dated November 19, 2018	5-10-11, Life Limits (Systems)	29-10-00-101
			29-10-00-102
CL-600-2B16 (605*)	Bombardier Challenger CL-605 Time Limits/Maintenance Checks, Part 2, Airworthiness Limitations, Revision 20, dated November 19, 2018	5-10-11, Life Limits (Systems)	29-10-00-101
			29-10-00-102

*Model CL-600-2B16 (604 Variant), referred to by the marketing designation CL-605.

BILLING CODE 4910–13–C

(k) No Alternative Actions or Intervals

After the maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (n)(1) of this AD.

(l) Credit for Previous Actions

(1) Replacement of an accumulator with a new accumulator having the same part number is also acceptable for compliance with the requirements of paragraphs (g)(2) and (g)(3) of this AD, if done before August 5, 2010 (the effective date of AD 2010–14–05), in accordance with the applicable service bulletin listed in figure 3 to paragraph (l)(1) of this AD. This service information is not incorporated by reference in this AD.

BILLING CODE 4910–13–P

Figure 3 to paragraph (l)(1) of this AD – *Previous service bulletins for AD 2010-14-05*

Airplane Model –	Bombardier Service Bulletin –	Revision –	Dated –
CL-600-1A11 (600)	600-0742	Basic	November 10, 2008
		01	July 6, 2009
CL-600-2A12 (601) CL-600-2B16 (601-3A and 601-3R Variants)	601-0597	Basic	November 10, 2008
		01	July 6, 2009
CL-600-2B16 (604 Variant)	604-29-008	Basic	November 10, 2008
		01	July 6, 2009
CL-600-2B16 (605*)	605-29-001	Basic	November 10, 2008
		01	July 6, 2009

*Model CL-600-2B16 (604 Variant), referred to by the marketing designation CL-605.

(2) Replacement of an accumulator with a new accumulator having the same part number is also acceptable for compliance with the requirements of paragraphs (g)(2) and (g)(3) of this AD, if done before the effective date of this AD in accordance with the applicable service bulletin listed in figure 4 to paragraph (l)(2) of this AD.

Figure 4 to paragraph (l)(2) of this AD – *Previous service bulletins for this AD*

Airplane Model –	Bombardier Service Bulletin –	Revision –	Dated –
CL-600-1A11 (600)	600-0742	02**	May 10, 2010
		03*	April 10, 2012
CL-600-2A12 (601) CL-600-2B16 (601-3A and 601-3R Variants)	601-0597	02**	May 10, 2010
		03*	April 10, 2012
CL-600-2B16 (604 Variant)	604-29-008	02**	May 10, 2010
		03*	April 10, 2012
CL-600-2B16 (605***)	605-29-001	02**	May 10, 2010
		03*	April 10, 2012

*This service information is not incorporated by reference in this AD.

**This service information was incorporated by reference in AD 2010-14-05.

***Model CL-600-2B16 (604 Variant), referred to by the marketing designation CL-605.

BILLING CODE 4910–13–C

(3) This paragraph provides credit for actions required by paragraph (i)(3) of this AD, if those actions were performed before the effective date of this AD, in accordance with Bombardier Service Bulletin 604–29–013, dated April 30, 2015; or Bombardier Service Bulletin 604–29–013, Revision 01, dated October 19, 2015. This service information is not incorporated by reference in this AD.

(4) This paragraph provides credit for actions required by paragraph (i)(4) of this AD, if those actions were performed before the effective date of this AD, in accordance with Bombardier Service Bulletin 605–29–006, dated April 30, 2015; or Bombardier Service Bulletin 605–29–006, Revision 01, dated October 19, 2015. This service information is not incorporated by reference in this AD.

(5) *For Model CL–600–2B16 (604 Variant) airplanes:* This paragraph provides credit for the actions required by paragraph (j) of this AD, if those actions were performed before the effective date of this AD using Section 5–10–11, Life Limits (Systems), of the Bombardier Challenger CL–604 Time Limits/Maintenance Checks, Part 2, Airworthiness Limitations, Revision 30, dated December 4, 2017. This service information is not incorporated by reference in this AD.

(6) *For Model CL–600–2B16 (605) airplanes:* This paragraph provides credit for the actions required by paragraph (j) of this AD for, if those actions were performed before the effective date of this AD using Section 5–10–11, Life Limits (Systems), of the Bombardier Challenger CL–605 Time Limits/Maintenance Checks, Part 2, Airworthiness Limitations, Revision 18, dated December 4, 2017; or Revision 19, dated May 29, 2018. This service information is not incorporated by reference in this AD.

(m) Special Flight Permit

Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the airplane can be modified, provided the following conditions are met:

(1) An engineering recommendation must be obtained via the Bombardier process Service Request for Product Support Action (SRPSA) at *SRPSA@aero.bombardier.com.*

(2) Approval of the special flight permit must be obtained from the Flight Standards District Office.

(n) Other FAA AD Provisions

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch.

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

(ii) AMOC 15–76R1 and AMOC 15–53, approved previously for AD 2010–14–05, are approved as AMOCs for the corresponding provisions of paragraph (g)(2) of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2009–39R1, dated October 13, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0790.

(2) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, Mechanical Systems & Administrative Services, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7323; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (p)(5) and (p)(6) of this AD.

(p) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on June 27, 2019.

(i) Bombardier Service Bulletin 600–0742, Revision 04, dated June 11, 2015.

(ii) Bombardier Service Bulletin 600–0764, dated October 8, 2015.

(iii) Bombardier Service Bulletin 600–0767, dated August 25, 2016.

(iv) Bombardier Service Bulletin 601–0597, Revision 04, dated June 11, 2015.

(v) Bombardier Service Bulletin 601–0633, dated October 8, 2015.

(vi) Bombardier Service Bulletin 601–0637, dated August 25, 2016.

(vii) Bombardier Service Bulletin 604–29–008, Revision 04, dated June 11, 2015.

(viii) Bombardier Service Bulletin 604–29–013, Revision 02, dated April 18, 2016.

(ix) Bombardier Service Bulletin 605–29–001, Revision 04, dated June 10, 2015.

(x) Bombardier Service Bulletin 605–29–006, Revision 02, dated April 19, 2016.

(xi) Section 5–10–11, Life Limits (Systems), of the Bombardier Challenger CL–604 Time Limits/Maintenance Checks, Part 2, Airworthiness Limitations, Revision 31, dated November 19, 2018.

(xii) Section 5–10–11, Life Limits (Systems), of the Bombardier Challenger CL–605 Time Limits/Maintenance Checks, Part 2, Airworthiness Limitations, Revision 20, dated November 19, 2018.

(xiii) Section 5–10–20, Time Limits (Systems), of the Bombardier Challenger 600 Time Limits/Maintenance Checks, PSP 605, Revision 39, dated January 8, 2018.

(xiv) Section 5–10–20, Time Limits (Systems), of the Bombardier Challenger 601 Time Limits/Maintenance Checks, PSP 601–5, Revision 46, dated January 8, 2018.

(xv) Section 5–10–20, Time Limits (Systems), of the Bombardier Challenger 601 Time Limits/Maintenance Checks, PSP 601A–5, Revision 42, dated January 8, 2018.

(4) For service information identified in this AD, contact Bombardier, Inc., 200 Côte-Vertu Road West, Dorval, Québec H4S 2A3, Canada; North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; email *ac.yul@aero.bombardier.com;* internet *http://www.bombardier.com.*

(5) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on April 25, 2019.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–10748 Filed 5–22–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31251; Amdt. No. 3851]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) foroperations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the

commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective May 23, 2019. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 23, 2019.

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

For Examination

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

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

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

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

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

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

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

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

Availability and Summary of Material Incorporated by Reference

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

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

The Rule

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

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

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

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

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on May 3, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

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

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

Effective 20 June 2019

Akiak, AK, Akiak, RNAV (GPS) RWY 3, Orig-C
Akiak, AK, Akiak, RNAV (GPS) RWY 21, Orig-C
Kodiak, AK, Kodiak, ILS Y OR LOC Y RWY 26, Amdt 3B
Kodiak, AK, Kodiak, VOR RWY 26, Amdt 3A
Prescott, AZ, Prescott Rgnl—Ernest A. Love Fld, Prescott Three Graphic DP
Prescott, AZ, Prescott Rgnl—Ernest A. Love Fld, Takeoff Minimums and Obstacle DP, Amdt 5A
Tucson, AZ, Ryan Field, NDB RWY 6R, Amdt 2
Tucson, AZ, Ryan Field, RNAV (GPS) RWY 6R, Orig
Hawthorne, CA, Jack Northrop Field/Hawthorne Muni, Takeoff Minimums and Obstacle DP, Amdt 5
Stockton, CA, Stockton Metropolitan, ILS OR LOC RWY 29R, ILS RWY 29R SA CAT II, Amdt 22
Stockton, CA, Stockton Metropolitan, Takeoff Minimums and Obstacle DP, Amdt 1
New Smyrna Beach, FL, New Smyrna Beach Muni, RNAV (GPS) RWY 2, Orig-B
New Smyrna Beach, FL, New Smyrna Beach Muni, RNAV (GPS) RWY 7, Orig-B
New Smyrna Beach, FL, New Smyrna Beach Muni, RNAV (GPS) RWY 25, Orig-B
New Smyrna Beach, FL, New Smyrna Beach Muni, RNAV (GPS) RWY 29, Orig-B
Burlington, IA, Southeast Iowa Rgnl, RNAV (GPS) RWY 30, Amdt 1B
Washington, IA, Washington Muni, VOR RWY 36, Amdt 1C
Chicago, IL, Chicago O'Hare Intl, ILS OR LOC RWY 4R, ILS RWY 4R SA CAT I, ILS RWY 4R SA CAT II, Amdt 8
Morris, MN, Morris Muni—Charlie Schmidt Fld, RNAV (GPS) RWY 14, Amdt 1C
Morris, MN, Morris Muni—Charlie Schmidt Fld, RNAV (GPS) RWY 32, Amdt 1C
St Joseph, MO, Rosecrans Memorial, ILS OR LOC RWY 35, Amdt 31C
St Joseph, MO, Rosecrans Memorial, LOC BC RWY 17, Amdt 9B
St Joseph, MO, Rosecrans Memorial, VOR OR TACAN RWY 17, Amdt 14B
St Joseph, MO, Rosecrans Memorial, VOR OR TACAN RWY 35, Orig-B
Oshkosh, NE, Garden County/King Rhiley Field, Takeoff Minimums and Obstacle DP, Orig-A
Bend, OR, Bend Muni, RNAV (GPS) RWY 34, Orig-A
Bend, OR, Bend Muni, RNAV (GPS) Z RWY 16, Orig-A
Darlington, SC, Darlington County, RNAV (GPS) RWY 5, Orig-D
Cleveland, TX, Cleveland Muni, RNAV (GPS) RWY 16, Orig-C
College Station, TX, Easterwood Field, RNAV (GPS) RWY 29, Amdt 1B
Spokane, WA, Spokane Intl, RNAV (RNP) Z RWY 3, Amdt 1B

RESCINDED: On April 22, 2019 (84 FR 16606), the FAA published an Amendment in Docket No. 31247, Amdt No. 3847, to Part 97 of the Federal Aviation Regulations under sections 97.33. The following entry for Plainville, CT, effective June 20, 2019, is hereby rescinded in its entirety:

Plainville, CT, Robertson Field, RNAV (GPS) RWY 2, Orig-A

[FR Doc. 2019–10736 Filed 5–22–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31252; Amdt. No. 3852]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

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

DATES: This rule is effective May 23, 2019. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 23, 2019.

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

For Examination

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

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

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

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

For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

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

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

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

This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

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

The material incorporated by reference describes SIAPs, Takeoff

Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

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

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

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

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

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

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on May 3, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

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

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

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

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
20–Jun–19 ...	CA	San Francisco	San Francisco Intl	8/1355	4/17/19	ILS OR LOC RWY 19L, Amdt 22.
20–Jun–19 ...	RI	Providence	Theodore Francis Green State.	8/3750	4/16/19	ILS OR LOC RWY 34, Amdt 12A.
20–Jun–19 ...	RI	Providence	Theodore Francis Green State.	8/3752	4/16/19	RNAV (GPS) RWY 34, Amdt 2.
20–Jun–19 ...	RI	Providence	Theodore Francis Green State.	8/3757	4/16/19	RNAV (GPS) Y RWY 23, Amdt 2A.
20–Jun–19 ...	RI	Providence	Theodore Francis Green State.	8/3758	4/16/19	VOR/DME RWY 16, Amdt 4E.
20–Jun–19 ...	RI	Providence	Theodore Francis Green State.	8/3759	4/16/19	VOR/DME RWY 23, Amdt 6G.
20–Jun–19 ...	AK	Holy Cross	Holy Cross	8/7339	4/17/19	RNAV (GPS) RWY 1, Orig-C.
20–Jun–19 ...	NC	Roxboro	Person County	8/7445	4/16/19	RNAV (GPS) RWY 6, Orig.
20–Jun–19 ...	NC	Roxboro	Person County	8/7447	4/16/19	RNAV (GPS) RWY 24, Orig-A.
20–Jun–19 ...	MS	Bay St Louis	Stennis Intl	9/0465	4/3/19	NDB RWY 18, Amdt 2A.
20–Jun–19 ...	MN	Bigfork	Bigfork Muni	9/0660	4/3/19	RNAV (GPS) RWY 33, Orig-C.
20–Jun–19 ...	CQ	Tinian Island	Tinian Intl	9/0965	4/17/19	NDB–A, Amdt 3.
20–Jun–19 ...	IA	Spencer	Spencer Muni	9/0996	4/3/19	ILS OR LOC RWY 12, Amdt 2A.
20–Jun–19 ...	IN	Marion	Marion Muni	9/1367	4/3/19	VOR RWY 15, Amdt 10D
20–Jun–19 ...	KS	Oakley	Oakley Muni	9/1396	4/18/19	RNAV (GPS) RWY 34, Orig.
20–Jun–19 ...	KS	Oakley	Oakley Muni	9/1397	4/18/19	NDB RWY 34, Amdt 3.
20–Jun–19 ...	IA	Boone	Boone Muni	9/1600	4/3/19	RNAV (GPS) RWY 15, Amdt 1B.
20–Jun–19 ...	KY	Frankfort	Capital City	9/1683	4/3/19	VOR RWY 25, Amdt 3C.
20–Jun–19 ...	KY	Frankfort	Capital City	9/1684	4/3/19	LOC RWY 25, Amdt 3B.
20–Jun–19 ...	MI	Alpena	Alpena County Rgnl	9/1687	4/3/19	RNAV (GPS) RWY 1, Orig-B.
20–Jun–19 ...	IN	Muncie	Delaware County Rgnl	9/1865	4/3/19	RNAV (GPS) RWY 14, Orig-A.
20–Jun–19 ...	IA	Oskaloosa	Oskaloosa Muni	9/1870	4/3/19	RNAV (GPS) RWY 13, Amdt 1.
20–Jun–19 ...	IA	Oskaloosa	Oskaloosa Muni	9/1871	4/3/19	RNAV (GPS) RWY 31, Amdt 1.
20–Jun–19 ...	MT	Havre	Havre City–County	9/2097	4/17/19	RNAV (GPS) RWY 8, Orig-A.
20–Jun–19 ...	MT	Havre	Havre City–County	9/2098	4/17/19	RNAV (GPS) RWY 26, Orig-A.
20–Jun–19 ...	MT	Havre	Havre City–County	9/2100	4/17/19	VOR RWY 26, Amdt 9A.
20–Jun–19 ...	FL	Tallahassee	Tallahassee Intl	9/2214	4/3/19	RADAR–1, Amdt 6A.
20–Jun–19 ...	FL	Tallahassee	Tallahassee Intl	9/2241	4/3/19	ILS OR LOC RWY 27, ILS RWY 27 (CAT II), Amdt 10B.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
20–Jun–19 ...	FL	Tallahassee	Tallahassee Intl	9/2242	4/3/19	ILS OR LOC RWY 36, Amdt 25D.
20–Jun–19 ...	FL	Melbourne	Melbourne Intl	9/2327	4/3/19	RNAV (GPS) RWY 9R, Amdt 1B.
20–Jun–19 ...	FL	Melbourne	Melbourne Intl	9/2328	4/3/19	ILS OR LOC RWY 9R, Amdt 12A.
20–Jun–19 ...	OH	Carrollton	Carroll County–Tolson	9/2428	4/3/19	RNAV (GPS) RWY 7, Orig–B.
20–Jun–19 ...	OH	Carrollton	Carroll County–Tolson	9/2429	4/3/19	VOR–A, Amdt 1A.
20–Jun–19 ...	OK	Poteau	Robert S Kerr	9/2495	4/3/19	Takeoff Minimums and Obstacle DP, Amdt 4.
20–Jun–19 ...	TX	Stephenville	Stephenville Clark Rgnl ...	9/2497	4/3/19	Takeoff Minimums and Obstacle DP, Orig.
20–Jun–19 ...	IA	Algona	Algona Muni	9/2585	4/18/19	RNAV (GPS) RWY 12, Orig-C.
20–Jun–19 ...	SD	Martin	Martin Muni	9/2619	4/18/19	RNAV (GPS) RWY 32, Amdt 1.
20–Jun–19 ...	AR	Fort Smith	Fort Smith Rgnl	9/2675	4/3/19	RADAR–1, Amdt 8C.
20–Jun–19 ...	AZ	Tucson	Tucson Intl	9/3101	4/17/19	LOC BC RWY 29R, Amdt 8A.
20–Jun–19 ...	AZ	Tucson	Tucson Intl	9/3114	4/17/19	RNAV (RNP) Y RWY 11L, Orig-A.
20–Jun–19 ...	AZ	Tucson	Tucson Intl	9/3117	4/17/19	VOR/DME OR TACAN RWY 29R, Amdt 2D.
20–Jun–19 ...	NH	Nashua	Boire Field	9/3122	4/18/19	ILS OR LOC RWY 14, Amdt 1B.
20–Jun–19 ...	TX	Stamford	Arledge Field	9/3169	4/3/19	RNAV (GPS) RWY 17, Orig.
20–Jun–19 ...	CO	Delta	Blake Field	9/3176	4/30/19	Takeoff Minimums and Obstacle DP, Orig.
20–Jun–19 ...	MN	Grand Rapids	Grand Rapids/Itasca Co–Gordon Newstrom Fld.	9/3284	4/3/19	VOR RWY 34, Amdt 11A.
20–Jun–19 ...	MN	Grand Rapids	Grand Rapids/Itasca Co–Gordon Newstrom Fld.	9/3285	4/3/19	RNAV (GPS) RWY 16, Orig-A.
20–Jun–19 ...	MN	Grand Rapids	Grand Rapids/Itasca Co–Gordon Newstrom Fld.	9/3289	4/3/19	ILS OR LOC RWY 34, Amdt 2A.
20–Jun–19 ...	RI	Providence	Theodore Francis Green State.	9/3325	4/16/19	RNAV (GPS) RWY 16, Orig-D.
20–Jun–19 ...	CA	Big Bear City	Big Bear City	9/3434	4/17/19	RNAV (GPS) RWY 26, Amdt 2A.
20–Jun–19 ...	OH	Wapakoneta	Neil Armstrong	9/3519	4/3/19	RNAV (GPS) RWY 8, Orig-A.
20–Jun–19 ...	TX	Stamford	Arledge Field	9/3932	4/3/19	RNAV (GPS) RWY 35, Orig.
20–Jun–19 ...	CA	San Diego/El Cajon	Gillespie Field	9/4128	4/23/19	RNAV (GPS) RWY 9L, Orig.
20–Jun–19 ...	CA	San Diego/El Cajon	Gillespie Field	9/4130	4/23/19	RNAV (GPS) RWY 17, Amdt 2E.
20–Jun–19 ...	AK	Bethel	Bethel	9/4380	4/23/19	RNAV (GPS)–A, Amdt 1B.
20–Jun–19 ...	TX	Wichita Falls	Kickapoo Downtown	9/4534	4/3/19	NDB RWY 35, Amdt 4A.
20–Jun–19 ...	NC	Washington	Washington–Warren	9/5107	4/3/19	Takeoff Minimums and Obstacle DP, Amdt 1A.
20–Jun–19 ...	IL	Chicago/Prospect Heights/Wheeling.	Chicago Executive	9/5198	4/3/19	VOR RWY 16, Orig-E.
20–Jun–19 ...	IL	Chicago/Prospect Heights/Wheeling.	Chicago Executive	9/5199	4/3/19	ILS OR LOC RWY 16, Amdt 2D.
20–Jun–19 ...	GA	Waynesboro	Burke County	9/5241	4/3/19	RNAV (GPS) RWY 8, Orig–A.
20–Jun–19 ...	GA	Waynesboro	Burke County	9/5242	4/3/19	RNAV (GPS) RWY 26, Orig-A.
20–Jun–19 ...	OH	Columbus	Rickenbacker Intl	9/5454	4/18/19	RNAV (GPS) RWY 5R, Amdt 1B.
20–Jun–19 ...	OH	Columbus	Rickenbacker Intl	9/5456	4/18/19	RNAV (GPS) RWY 23R, Orig-B.
20–Jun–19 ...	OH	Columbus	Rickenbacker Intl	9/5457	4/18/19	RNAV (GPS) RWY 5L, Orig-A.
20–Jun–19 ...	OH	Middletown	Middletown Regional/Hook Field.	9/5569	4/3/19	LOC RWY 23, Amdt 7I.
20–Jun–19 ...	OH	Middletown	Middletown Regional/Hook Field.	9/5570	4/3/19	NDB RWY 23, Amdt 9B.
20–Jun–19 ...	FL	Fort Lauderdale	Fort Lauderdale/Hollywood Intl.	9/5822	4/30/19	RNAV (RNP) Y RWY 10L, Amdt 1C
20–Jun–19 ...	OH	Piqua	Piqua Airport—Hartzell Field.	9/5877	4/18/19	VOR–A, Amdt 13C.
20–Jun–19 ...	OH	Piqua	Piqua Airport—Hartzell Field.	9/5879	4/18/19	RNAV (GPS) RWY 8, Orig-D.
20–Jun–19 ...	OH	Piqua	Piqua Airport—Hartzell Field.	9/5880	4/18/19	RNAV (GPS) RWY 26, Orig-C.
20–Jun–19 ...	OH	Piqua	Piqua Airport—Hartzell Field.	9/5887	4/18/19	VOR RWY 26, Amdt 6D.
20–Jun–19 ...	CA	Van Nuys	Van Nuys	9/5997	4/17/19	LDA–C, Amdt 3A.
20–Jun–19 ...	CA	Van Nuys	Van Nuys	9/5998	4/17/19	VOR–A, Amdt 4C.
20–Jun–19 ...	CA	Van Nuys	Van Nuys	9/5999	4/17/19	VOR–B, Amdt 4A.
20–Jun–19 ...	OH	Toledo	Toledo Express	9/6083	4/3/19	RADAR–1, Amdt 19B.
20–Jun–19 ...	OH	Toledo	Toledo Express	9/6084	4/3/19	VOR RWY 34, Amdt 7C.
20–Jun–19 ...	LA	Patterson	Harry P Williams Memorial	9/6124	4/3/19	Takeoff Minimums and Obstacle DP, Amdt 1A.
20–Jun–19 ...	WV	Moundsville	Marshall County	9/6197	4/16/19	RNAV (GPS) RWY 6, Orig-C.
20–Jun–19 ...	WV	Moundsville	Marshall County	9/6198	4/16/19	RNAV (GPS) RWY 24, Orig-A.
20–Jun–19 ...	WV	Moundsville	Marshall County	9/6199	4/16/19	VOR/DME–A, Amdt 2B.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
20–Jun–19 ...	WV	Huntington	Tri–State/Milton J Ferguson Field.	9/6428	4/16/19	ILS OR LOC RWY 30, Amdt 7A.
20–Jun–19 ...	WV	Huntington	Tri–State/Milton J Ferguson Field.	9/6429	4/16/19	RNAV (GPS) RWY 30, Amdt 1A.
20–Jun–19 ...	WV	Huntington	Tri–State/Milton J Ferguson Field.	9/6430	4/16/19	RNAV (GPS) RWY 12, Amdt 3A.
20–Jun–19 ...	NJ	Teterboro	Teterboro	9/6874	4/16/19	VOR RWY 24, Orig-E.
20–Jun–19 ...	NJ	Teterboro	Teterboro	9/6875	4/16/19	ILS OR LOC RWY 6, Amdt 29H.
20–Jun–19 ...	NJ	Teterboro	Teterboro	9/6877	4/16/19	RNAV (GPS) Y RWY 6, Amdt 2C.
20–Jun–19 ...	NJ	Teterboro	Teterboro	9/6878	4/16/19	VOR/DME RWY 6, Orig-E.
20–Jun–19 ...	NJ	Teterboro	Teterboro	9/6879	4/16/19	VOR/DME–B, Amdt 2E.
20–Jun–19 ...	NJ	Teterboro	Teterboro	9/6880	4/16/19	ILS OR LOC RWY 19, Orig-B.
20–Jun–19 ...	WA	Spokane	Spokane Intl	9/7205	4/30/19	RNAV (GPS) Y RWY 8, Amdt 2C.
20–Jun–19 ...	AR	North Little Rock	North Little Rock Muni	9/7332	4/3/19	LOC/DME RWY 5, Orig-A.
20–Jun–19 ...	AR	North Little Rock	North Little Rock Muni	9/7333	4/3/19	VOR RWY 35, Amdt 1.
20–Jun–19 ...	AR	North Little Rock	North Little Rock Muni	9/7334	4/3/19	RNAV (GPS) RWY 35, Orig.
20–Jun–19 ...	SC	Florence	Florence Rgnl	9/7337	4/16/19	RNAV (GPS) RWY 1, Orig-A.
20–Jun–19 ...	NC	Edenton	Northeastern Rgnl	9/7339	4/16/19	ILS OR LOC RWY 19, Orig-B.
20–Jun–19 ...	MA	Northampton	Northampton	9/7342	4/3/19	RNAV (GPS) RWY 14, Orig.
20–Jun–19 ...	NJ	Teterboro	Teterboro	9/7370	4/16/19	RNAV (GPS) X RWY 6, Amdt 2A.
20–Jun–19 ...	CA	San Andreas	Calaveras Co–Maury Rasmussen Field.	9/7375	4/17/19	RNAV (GPS) RWY 31, Amdt 1.
20–Jun–19 ...	CO	Delta	Blake Field	9/7792	4/30/19	RNAV (GPS) RWY 3, Orig.
20–Jun–19 ...	VA	Dublin	New River Valley	9/7889	4/16/19	RNAV (GPS) RWY 24, Amdt 1.
20–Jun–19 ...	VA	Dublin	New River Valley	9/7890	4/16/19	ILS OR LOC Z RWY 6, Amdt 5.
20–Jun–19 ...	VA	Dublin	New River Valley	9/7891	4/16/19	ILS OR LOC Y RWY 6, Orig.
20–Jun–19 ...	VA	Dublin	New River Valley	9/7892	4/16/19	RNAV (GPS) RWY 6, Orig.
20–Jun–19 ...	MO	Monticello	Lewis County Rgnl	9/7993	4/3/19	RNAV (GPS) RWY 36, Orig-A.
20–Jun–19 ...	MO	Monticello	Lewis County Rgnl	9/7997	4/3/19	RNAV (GPS) RWY 18, Orig–A.
20–Jun–19 ...	MS	Jackson	Hawkins Field	9/8000	4/16/19	Takeoff Minimums and Obstacle DP, Amdt 1.
20–Jun–19 ...	TX	Lubbock	Lubbock Preston Smith Intl.	9/8133	4/3/19	RNAV (RNP) Z RWY 17R, Orig–B.
20–Jun–19 ...	TX	Lubbock	Lubbock Preston Smith Intl.	9/8134	4/3/19	RNAV (RNP) Z RWY 35L, Orig-B.
20–Jun–19 ...	TX	Lubbock	Lubbock Preston Smith Intl.	9/8135	4/3/19	RNAV (GPS) RWY 26, Amdt 3.
20–Jun–19 ...	TX	Lubbock	Lubbock Preston Smith Intl.	9/8136	4/3/19	RNAV (GPS) Y RWY 17R, Amdt 2B.
20–Jun–19 ...	TX	Lubbock	Lubbock Preston Smith Intl.	9/8137	4/3/19	RNAV (GPS) Y RWY 35L, Amdt 2A.
20–Jun–19 ...	LA	Patterson	Harry P Williams Memorial	9/8208	4/3/19	RNAV (GPS) RWY 24, Amdt 1C.
20–Jun–19 ...	LA	Patterson	Harry P Williams Memorial	9/8218	4/3/19	RNAV (GPS) RWY 6, Orig-B.
20–Jun–19 ...	KS	Oakley	Oakley Muni	9/8268	4/3/19	Takeoff Minimums and Obstacle DP, Orig.
20–Jun–19 ...	WI	Watertown	Watertown Muni	9/8741	4/3/19	RNAV (GPS) RWY 5, Orig.
20–Jun–19 ...	NC	Roxboro	Person County	9/8949	4/30/19	ILS OR LOC RWY 6, Amdt 1A.
20–Jun–19 ...	GU	Guam	Guam Intl	9/9122	4/17/19	ILS OR LOC RWY 6L, Amdt 4A.
20–Jun–19 ...	GU	Guam	Guam Intl	9/9123	4/17/19	ILS OR LOC RWY 6R, Orig-C.
20–Jun–19 ...	CA	Hayward	Hayward Executive	9/9129	4/17/19	VOR/DME–A, Amdt 3A.
20–Jun–19 ...	CA	Hayward	Hayward Executive	9/9130	4/17/19	LOC/DME RWY 28L, Amdt 3B.
20–Jun–19 ...	CA	Hayward	Hayward Executive	9/9131	4/17/19	RNAV (GPS) RWY 28L, Amdt 1B.
20–Jun–19 ...	IA	Washington	Washington Muni	9/9241	4/3/19	RNAV (GPS) RWY 13, Orig.
20–Jun–19 ...	IA	Washington	Washington Muni	9/9243	4/3/19	RNAV (GPS) RWY 18, Amdt 1.
20–Jun–19 ...	IA	Washington	Washington Muni	9/9244	4/3/19	RNAV (GPS) RWY 31, Orig.
20–Jun–19 ...	IA	Washington	Washington Muni	9/9245	4/3/19	RNAV (GPS) RWY 36, Amdt 1.
20–Jun–19 ...	TX	Abilene	Abilene Rgnl	9/9466	4/3/19	RNAV (GPS) RWY 17L, Amdt 1A.
20–Jun–19 ...	GA	Jekyll Island	Jekyll Island	9/9510	4/16/19	Takeoff Minimums and Obstacle DP, Orig.
20–Jun–19 ...	OK	Seminole	Seminole Muni	9/9812	4/3/19	RNAV (GPS) RWY 16, Amdt 1.
20–Jun–19 ...	OK	Seminole	Seminole Muni	9/9813	4/3/19	NDB RWY 16, Amdt 4.
20–Jun–19 ...	CA	Bishop	Bishop	9/9882	4/17/19	RNAV (RNP) RWY 30, Orig-C.
20–Jun–19 ...	WA	Shelton	Sanderson Field	9/9903	4/17/19	RNAV (GPS) RWY 23, Amdt 1.

[FR Doc. 2019–10737 Filed 5–22–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9859]

RIN 1545–BO88

Amount Determined Under Section 956 for Corporate United States Shareholders

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that reduce the amount determined under section 956 of the Internal Revenue Code with respect to certain domestic corporations. This document finalizes the proposed regulations published on November 5, 2018. The final regulations affect certain domestic corporations that own (or are treated as owning) stock in foreign corporations.

DATES:

Effective Date: These regulations are effective on July 22, 2019.

Applicability Date: For the date of applicability, see § 1.956–1(g)(4).

FOR FURTHER INFORMATION CONTACT: Rose E. Jenkins, (202) 317–6934.

SUPPLEMENTARY INFORMATION:

Background

On November 5, 2018, the Department of the Treasury (''Treasury Department'') and the IRS published proposed regulations (REG–114540–18) under section 956 in the **Federal Register** (83 FR 55324) (the ''proposed regulations''). No public hearing was requested or held, and no substantive comments were received with respect to the proposed regulations. All written comments received in response to the proposed regulations are available at *www.regulations.gov* or upon request. This Treasury decision adopts the proposed regulations, with the changes described in the Summary of Comments and Explanation of Revisions section of this preamble, as final regulations.

Summary of Comments and Explanation of Revisions

The final regulations, like the proposed regulations, exclude corporations that are United States shareholders (as defined in section 951(b)) (''U.S. shareholders'') from the application of section 956 to maintain symmetry between the taxation of actual repatriations and the taxation of effective repatriations. To achieve this result, the final regulations provide that the amount otherwise determined under section 956 (the ''tentative section 956 amount'') with respect to a U.S. shareholder for a taxable year of a controlled foreign corporation (as defined in section 957) (''CFC'') is reduced to the extent that the U.S. shareholder would be allowed a deduction under section 245A if the U.S. shareholder had received a distribution from the CFC in an amount equal to the tentative section 956 amount (the ''hypothetical distribution'').

In general, under section 245A and the final regulations, respectively, neither an actual dividend to a corporate U.S. shareholder, nor such a shareholder's tentative section 956 amount, will result in additional U.S. tax.

I. Allocation of Hypothetical Distribution

While not raised in any written comments, published commentary on the proposed regulations raised concerns regarding how the proposed rules apply in the case of a CFC that has prior year earnings and profits (''E&P'') described in section 959(c)(1) and current-year E&P described in section 959(c)(3) that do not result in an inclusion under section 951 or section 951A. Even though a dividend of the current-year E&P would potentially be eligible for a deduction under section 245A, a distribution by the CFC would not qualify for a section 245A deduction, because under section 959(c), the distribution would be allocated to the prior-year E&P described in section 959(c)(1) first. Therefore, any tentative section 956 amount for the year might not be reduced by the proposed rule. To address this issue, the final regulations include an ordering rule treating a hypothetical distribution as attributable first to E&P described in section 959(c)(2), then to E&P described in section 959(c)(3), consistent with the allocation of an amount determined under section 956 pursuant to section 959(f)(1). This rule, which differs from the general rule for allocation of distributions in section 959(c) by not treating any amount as attributable to E&P described in section 959(c)(1), is necessary to reflect the fact that the amount to which the hypothetical distribution applies is in fact a tentative section 956 amount. This rule is illustrated in a new example in § 1.956–1(a)(3)(iii).

II. Domestic Partnerships and Their Partners

Section 245A(g) grants the Secretary authority to prescribe regulations for the treatment of U.S. shareholders owning stock of specified 10-percent owned foreign corporations through a partnership. As noted in the Comments and Request for Public Hearing section of the preamble to the proposed regulations, the Treasury Department and the IRS have studied the appropriate application of the regulations to U.S. shareholders that are domestic partnerships, which may have partners that are a combination of domestic corporations, U.S. individuals, or other persons. As noted in the Background section of this preamble, no substantive comments were received with respect to the proposed regulations, including with respect to the two methods of applying the rules in the case of domestic partnerships that were described in the preamble to the proposed regulations. Accordingly, consistent with the first method described in that preamble, the final regulations provide that the tentative section 956 amount with respect to a domestic partnership is reduced to the extent that one or more domestic corporate partners would be entitled to a section 245A deduction if the partnership received such amount as a distribution, and any remaining amount of the domestic partnership's inclusion under sections 951(a)(1)(B) and 956 is allocated to the partners in the same proportion as net income would result to the partners upon a hypothetical distribution (that is, a distribution from the CFC to the domestic partnership). *See* § 1.956–1(a)(2)(i) and (iii). The rules concerning domestic partnerships are illustrated in a new example in § 1.956–1(a)(3)(iv).

III. Revisions to Existing Examples

The final regulations also update certain examples in the regulations under section 956 to reflect that section 956 may no longer apply in the case of corporate U.S. shareholders. *See* § 1.956–1(b)(4) (amended facts common to several examples, to refer to a United States citizen, rather than domestic corporation).

IV. Applicability Date

The final regulations apply to taxable years of a CFC beginning on or after July 22, 2019, and to taxable years of a U.S. shareholder in which or with which such taxable years of the CFC end. However, consistent with the reliance

allowed for the proposed regulations, taxpayers may apply the final regulations for taxable years of a CFC beginning after December 31, 2017, and for taxable years of a U.S. shareholder in which or with which such taxable years of the CFC end, provided that the taxpayer and United States persons that are related (within the meaning of section 267 or 707) to the taxpayer consistently apply the regulations with respect to all CFCs in which they are U.S. shareholders for taxable years of the CFCs beginning after December 31, 2017. *See* section 7805(b)(7).

Special Analyses

OIRA has determined that this final rule is a significant regulatory action pursuant to section 3(f) of Executive Order (E.O.) 12866 and the April 11, 2018, Memorandum of Agreement between the Department of Treasury and the Office of Management and Budget (OMB). However, OIRA has waived review of this final rule in accordance with section 6(a)(3)(A) of E.O. 12866.

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities, although some small entities that are domestic corporations could be affected by the regulations. However, even if a substantial number of small entities were to be affected by this regulation, the Treasury Department and the IRS estimate that the economic impact on such small entities would not be significant as the regulation is expected to marginally reduce compliance costs for smaller entities. This is because the Treasury Department and the IRS believe that the cost-saving benefits of the regulations with respect to complex third-party borrowing arrangements, internal financial management structures, and restructurings of worldwide operations will generally be available only to large U.S. multinational corporations with 20 or more CFCs. The Treasury Department and the IRS believe that U.S. multinational corporations with fewer than 20 CFCs generally will not have the types of arrangements in place that would otherwise need to be structured and monitored to avoid section 956. The regulations generally will not affect small entities that are not domestic corporations.

Pursuant to section 7805(f), the notice of proposed rulemaking preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses. No comments were received.

There are no information collection requirements associated with these final regulations.

The Administrator of OIRA has determined that this is a major rule for purposes of the Congressional Review Act (CRA) (5 U.S.C. 801 *et seq.*). Under section 801(3) of the CRA, a major rule takes effect 60 days after the rule is published in the **Federal Register**.

Drafting Information

The principal author of the final regulations is Rose E. Jenkins of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **PARAGRAPH 1.** The authority citation for part 1 is amended by revising the entry for § 1.956–1 to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.956–1 also issued under 26 U.S.C. 245A(g), 956(d), and 956(e).

* * * * *

■ **PAR. 2.** Section 1.956–1 is amended by:

■ 1. Revising paragraph (a).

■ 2. In the paragraph (b)(4) introductory text, removing the language ''following examples'' and adding in its place ''examples in this paragraph (b)(4)'' and removing the language ''domestic corporation'' and adding in its place ''United States citizen.''

■ 3. In paragraph (b)(4), designating *Examples 1* through *8* as paragraphs (b)(4)(i) through (viii), respectively.

■ 4. In newly designated paragraphs (b)(4)(i) through (viii), redesignating the paragraphs in the first column as the paragraphs in the second column:

Old paragraphs	New paragraphs
(b)(4)(i)(i) and (ii)	(b)(4)(i)(A) and (B)
(b)(4)(ii)(i) and (ii)	(b)(4)(ii)(A) and (B)
(b)(4)(iii)(i) and (ii)	(b)(4)(iii)(i) and (ii)
(b)(4)(iv)(i) and (ii)	(b)(4)(iv)(A) and (B)
(b)(4)(v)(i) and (ii)	(b)(4)(v)(A) and (B)
(b)(4)(vi)(i) and (ii)	(b)(4)(vi)(A) and (B)
(b)(4)(vii)(i) and (ii)	(b)(4)(vii)(A) and (B)
(b)(4)(viii)(i) and (ii)	(b)(4)(viii)(A) and (B)

■ 5. In newly redesignated paragraph (b)(4)(ii)(A), removing the language ''*Example 1* of this paragraph (b)(4)'' and adding in its place ''paragraph (b)(4)(i)(A) of this section (the facts in *Example 1*).''

■ 6. Revising the heading for paragraph (g).

■ 7. In the first sentence of paragraph (g)(1), removing the language ''Paragraph (a)'' and adding in its place ''Paragraph (a)(1)''.

■ 8. Adding paragraphs (g)(4) and (5).

■ 9. Removing the parenthetical authority citation at the end of the section.

The revisions and additions read as follows:

§ 1.956–1 Shareholder's pro rata share of the average of the amounts of United States property held by a controlled foreign corporation.

(a) *Overview and scope*—(1) *In general.* Subject to the provisions of section 951(a) and the regulations in this part, a United States shareholder of a controlled foreign corporation is required to include in gross income the amount determined under section 956 with respect to the shareholder for the taxable year but only to the extent not excluded from gross income under section 959(a)(2) and the regulations in this part.

(2) *Reduction for certain United States shareholders*—(i) *In general.* For a taxable year of a controlled foreign corporation, the amount determined under section 956 with respect to each share of stock of the controlled foreign corporation owned (within the meaning of section 958(a)) by a United States shareholder is the amount that would be determined under section 956 with respect to such share for the taxable year, absent the application of this paragraph (a)(2) for the taxable year (such amount, the *tentative section 956 amount,* and in the aggregate with respect to all shares owned (within the meaning of section 958(a)) by the United States shareholder, the *aggregate tentative section 956 amount*), reduced by the amount of the deduction under section 245A, if any, that the shareholder would be allowed if the shareholder received as a distribution from the controlled foreign corporation an amount equal to the tentative section 956 amount with respect to such share on the last day during the taxable year on which the foreign corporation is a controlled foreign corporation (*hypothetical distribution*). For purposes of the preceding sentence, in the case of a United States shareholder that is a domestic partnership, the aggregate amount of the deductions under section 245A, if any, that domestic corporations that are partners of the domestic

partnership (including indirect partners through other partnerships) would be allowed with respect to a hypothetical distribution is treated as the amount of the deduction under section 245A that the domestic partnership would be allowed.

(ii) *Determination of the amount of the deduction that would be allowed under section 245A with respect to a hypothetical distribution.* For purposes of determining the amount of the deduction under section 245A that a United States shareholder would be allowed with respect to a share of stock of a controlled foreign corporation by reason of a hypothetical distribution, the rules in paragraphs (a)(2)(ii)(A) through (C) of this section apply—

(A) If a United States shareholder owns a share of stock of a controlled foreign corporation indirectly (within the meaning of section 958(a)(2)), then—

(*1*) Sections 245A(a) through (d), 246(a), and 959 apply to the hypothetical distribution as if the United States shareholder directly owned (within the meaning of section 958(a)(1)(A)) the share;

(*2*) Section 245A(e) applies to the hypothetical distribution as if the distribution were made to the United States shareholder through each entity by reason of which the United States shareholder indirectly owns such share and pro rata with respect to the equity that gives rise to such indirect ownership;

(*3*) To the extent that a distribution treated as made to a controlled foreign corporation pursuant to the hypothetical distribution by reason of paragraph (a)(2)(ii)(A)(*2*) of this section would be subject to section 245A(e)(2), the United States shareholder is treated as not being allowed a deduction under section 245A by reason of the hypothetical distribution; and

(*4*) Section 246(c) applies to the hypothetical distribution by substituting the phrase ''owned (within the meaning of section 958(a))'' for the term ''held'' each place it appears in section 246(c);

(B) Section 246(c) applies to the hypothetical distribution by substituting ''the last day during the taxable year on which the foreign corporation is a controlled foreign corporation'' for the phrase ''the date on which such share becomes ex-dividend with respect to such dividend'' in section 246(c)(1)(A); and

(C) The hypothetical distribution is treated as attributable first to earnings and profits of the controlled foreign corporation described in section 959(c)(2), then to earnings and profits of the controlled foreign corporation described in section 959(c)(3).

(iii) *Special rule in the case of domestic partnerships*—(A) *In general.* In the case of a domestic partnership whose tentative section 956 amount with respect to a share of stock of a controlled foreign corporation is reduced pursuant to paragraph (a)(2)(i) of this section for a taxable year, the portion of any inclusion under section 951(a)(1)(B) of the domestic partnership with respect to such share for the taxable year allocated to a partner of the domestic partnership (including an indirect partner through one or more other partnerships) must equal the product of the inclusion and the ratio determined by dividing—

(*1*) The net hypothetical distribution income with respect to the partner; by

(*2*) The aggregate of the net hypothetical distribution income with respect to all of the partners of the domestic partnership.

(B) *Definition of net hypothetical distribution income.* The term *net hypothetical distribution income* means, with respect to a hypothetical distribution to a domestic partnership and a partner of the domestic partnership (including an indirect partner through one or more other partnerships), the amount of the hypothetical distribution that would be allocable to the partner reduced by the amount of the deduction under section 245A with respect to the hypothetical distribution that would be allowable to the partner.

(3) *Examples.* The examples in this paragraph (a)(3) illustrate the application of paragraph (a)(2) of this section.

(i) *Example 1*—(A) *Facts.* (*1*) USP, a domestic corporation, owns all of the single class of stock of FC, a foreign corporation. The stock of FC consists of 100 shares, and USP satisfies the holding period requirement of section 246(c) (as modified by paragraph (a)(2)(ii)(B) of this section) with respect to each share of FC stock. Any dividend from FC to USP would not constitute a hybrid dividend for purposes of section 245A(e). FC owns all of the stock of USS, a domestic corporation. FC's adjusted basis in the stock of USS is $0.

(*2*) The functional currency of FC is the U.S. dollar. FC has $100x of undistributed earnings as defined in section 245A(c)(2) at the end of the taxable year, $90x of which constitute undistributed foreign earnings as defined in section 245A(c)(3), and $10x of which are described in section 245(a)(5)(B) (that is, earnings attributable to a dividend that FC received from USS). None of the earnings and profits of FC are described in section 959(c)(1) or (2) or are earnings and profits attributable to income excluded from subpart F income under section 952(b). FC's applicable earnings (as defined in section 956(b)(1)) are $100x. FC also has held an obligation of USP with an adjusted basis of $120x on every day during the taxable year of FC, and such obligation was acquired while all of its stock was owned by USP.

(B) *Analysis.* Because USP directly owns all of the stock of FC at the end of FC's taxable year, USP's aggregate tentative section 956 amount with respect to FC is $100x, the lesser of USP's pro rata share of the average amounts of United States property held by FC ($120x) and its pro rata share of FC's applicable earnings ($100x). Under paragraph (a)(2)(i) of this section, USP's section 956 amount with respect to FC is its aggregate tentative section 956 amount with respect to FC reduced by the deduction under section 245A that USP would be allowed if USP received an amount equal to its aggregate tentative section 956 amount as a distribution with respect to the FC stock. USP would be allowed a $90x deduction under section 245A with respect to the foreign-source portion of the $100x hypothetical distribution (that is, an amount of the dividend that bears the same ratio to the dividend as the $90x of undistributed foreign earnings bears to the $100x of undistributed earnings). Accordingly, USP's section 956 amount with respect to FC is $10x, its aggregate tentative section 956 amount ($100x) with respect to FC reduced by the amount of the deduction that USP would have been allowed under section 245A with respect to the hypothetical distribution ($90x).

(ii) *Example 2*—(A) *Facts.* The facts are the same as in paragraph (a)(3)(i)(A) of this section (the facts in *Example 1*), except that all $100x of FC's undistributed earnings are described in section 959(c)(2).

(B) *Analysis.* As in paragraph (a)(3)(i)(B) of this section (the analysis in *Example 1*), USP's aggregate tentative section 956 amount with respect to FC is $100x, the lesser of USP's pro rata share of the average amounts of United States property held by FC ($120x) and its pro rata share of FC's applicable earnings ($100x). However, paragraph (a)(2) of this section does not reduce USP's section 956 amount because USP would not be allowed any deduction under section 245A with respect to the $100x hypothetical distribution by reason of section 959(a) and (d). Accordingly, USP's section 956 amount is $100x. However, under sections 959(a)(2) and 959(f)(1), USP's inclusion under section 951(a)(1)(B) with respect to FC is $0, because USP's section 956 amount with respect to FC does not exceed the earnings and profits of FC described in section 959(c)(2) with respect to USP. The $100x of earnings and profits of FC described in section 959(c)(2) are reclassified as earnings and profits described in section 959(c)(1).

(iii) *Example 3*—(A) *Facts.* The facts are the same as in paragraph (a)(3)(i)(A) of this section (the facts in *Example 1*), except that FC has $200x of undistributed earnings, which constitute undistributed foreign earnings as defined in section 245A(c)(3), of which $100x are described in section 959(c)(1)(A) and $100x are described in section 959(c)(3).

(B) *Analysis.* USP's aggregate tentative section 956 amount with respect to FC is $20x, the lesser of $20x, the excess of USP's pro rata share of the average amounts of

United States property held by FC ($120x) over the earnings and profits described in section 959(c)(1)(A) with respect to USP ($100x), and its pro rata share of FC's applicable earnings ($100x). Under paragraph (a)(2)(i) of this section, USP's section 956 amount with respect to FC is its aggregate tentative section 956 amount with respect to FC reduced by the deduction under section 245A that USP would be allowed if USP received an amount equal to its aggregate tentative section 956 amount as a distribution with respect to the FC stock. USP would be allowed a $20x deduction under section 245A with respect to the foreign-source portion of the $20x hypothetical distribution, which, under paragraph (a)(2)(ii)(C) of this section, is treated as attributable to the earnings and profits of FC described in section 959(c)(3) despite the fact that FC has $100x of earnings and profits described in section 959(c)(1)(A) that would otherwise be distributed before earnings and profits described in section 959(c)(3). Accordingly, USP's section 956 amount with respect to FC is $0, its aggregate tentative section 956 amount ($20x) with respect to FC reduced by the amount of the deduction that USP would have been allowed under section 245A with respect to the hypothetical distribution after applying the rule in paragraph (a)(2)(ii)(C) of this section ($20x).

(iv) *Example 4*—(A) *Facts.* The facts are the same as in paragraph (a)(3)(i)(A) of this section (the facts in *Example 1*), except that USP is a domestic partnership in which USC1 and USC2, each a domestic corporation, and USI, a United States citizen, have owned 50%, 30%, and 20%, respectively, of the capital and profits interests for five years.

(B) *Analysis.* As in paragraph (a)(3)(i)(B) of this section (the analysis in *Example 1*), USP's aggregate tentative section 956 amount with respect to FC is $100x. Under paragraph (a)(2)(i) of this section, USP's section 956 amount with respect to FC is its aggregate tentative section 956 amount with respect to FC reduced by the aggregate amount of deductions under section 245A that USC1, USC2, and USI would be allowed if USP received an amount equal to its aggregate tentative section 956 amount as a distribution with respect to the FC stock. Assuming that, under section 245A, USC1 and USC2 would be allowed a $45x deduction and a $27x deduction, respectively, with respect to the foreign-source portion of their $50x and $30x distributive shares of the $100x hypothetical distribution (that is, an amount of the dividend that bears the same ratio to the dividend as the $90x of undistributed foreign earnings bears to the $100x of undistributed earnings), USP's section 956 amount with respect to FC is $28x, its aggregate tentative section 956 amount ($100x) with respect to FC reduced by the aggregate amount of the deductions that its partners would have been allowed under section 245A with respect to the hypothetical distribution ($72x ($45x + $27x)). Under paragraph (a)(2)(iii) of this section, the portion of its $28x inclusion under section 951(a)(1)(B) with respect to FC that is allocated to USC1 is $5x ($28x x (($50x − $45x)/($50x − $45x + $30x − $27x + $20x))); the portion that is allocated to USC2 is $3x ($28x x (($30x − $27x) / ($50x − $45x + $30x − $27x + $20x))); and the portion that is allocated to USI is $20x ($28x x ($20x / ($50x − $45x + $30x − $27x + $20x))).

(v) *Example 5*—(A) *Facts.* (*1*) USP, a domestic corporation, owns all of the single class of stock of FC1, a foreign corporation, and has held such stock for five years. FC1 has held 70% of the single class of stock of FC2, a foreign corporation, for three years. The other 30% of the FC2 stock has been held since FC2's formation by a foreign individual unrelated to USP or FC1. Any dividend from FC2 or FC1 to FC1 or USP, respectively, would not constitute a hybrid dividend for purposes of section 245A(e). FC2 has a calendar taxable year. On December 1, Year 1, FC1 acquires the remaining 30% of the stock of FC2 for cash. On June 30, Year 2, FC1 sells to a third party the 30% of FC2 stock acquired in Year 1 at no gain. FC2 made no distributions during Year 1.

(*2*) The functional currency of FC1 and FC2 is the U.S. dollar. For Year 1, FC2 has $120x of undistributed earnings as defined in section 245A(c)(2), all of which constitute undistributed foreign earnings. None of the earnings and profits of FC2 are described in section 959(c)(1) or (2) or are earnings and profits attributable to income excluded from subpart F income under section 952(b). FC2's applicable earnings (as defined in section 956(b)(1)) for Year 1 are $120x. FC2 has held an obligation of USP with an adjusted basis of $100x on every day of Year 1 that was acquired while USP owned all of the stock of FC1 and FC1 held 70% of the single class of stock of FC2.

(B) *Analysis.* Because USP indirectly owns (within the meaning of section 958(a)) all of the stock of FC2 at the end of Year 1, USP's aggregate tentative section 956 amount with respect to FC2 for Year 1 is $100x, the lesser of USP's pro rata share of the average amounts of United States property held by FC2 ($100x) and its pro rata share of FC2's applicable earnings ($120x). Under paragraph (a)(2)(i) of this section, USP's section 956 amount with respect to FC2 for Year 1 is its aggregate tentative section 956 amount with respect to FC2 reduced by the deduction under section 245A that USP would be allowed if USP received an amount equal to its aggregate tentative section 956 amount as a distribution with respect to the FC2 stock that USP owns indirectly within the meaning of section 958(a)(2). For purposes of determining the consequences of this hypothetical distribution, under paragraph (a)(2)(ii)(A)(*1*) of this section, USP is treated as owning the FC2 stock directly. In addition, under paragraph (a)(2)(ii)(A)(*4*) of this section, the holding period requirement of section 246(c) is applied by reference to the period during which USP owned (within the meaning of section 958(a)) the stock of FC2. Therefore, with respect to the hypothetical distribution from FC2 to USP, USP would satisfy the holding period requirement under section 246(c) with respect to the 70% of the FC2 stock that USP indirectly owned for three years through FC1, but not with respect to the 30% of the FC2 stock that USP indirectly owned through FC1 for a period of less than 365 days. Accordingly, USP's section 956 amount with respect to FC2 for Year 1 is $30x, its aggregate tentative section 956 amount ($100x) reduced by the amount of the deduction that USP would have been allowed under section 245A with respect to the hypothetical distribution ($70x).

* * * * *

(g) *Applicability dates.** * *

(4) Paragraphs (a)(2) and (3) of this section apply to taxable years of controlled foreign corporations beginning on or after July 22, 2019, and to taxable years of a United States shareholder in which or with which such taxable years of the controlled foreign corporations end. Notwithstanding the preceding sentence, a United States shareholder may apply paragraphs (a)(2) and (3) of this section to taxable years of controlled foreign corporations beginning after December 31, 2017, and to taxable years of the United States shareholder in which or with which such taxable years of the controlled foreign corporations end, provided that the United States shareholder and United States persons that are related (within the meaning of section 267 or 707) to the United States shareholder consistently apply those paragraphs with respect to all controlled foreign corporations in which they are United States shareholders for taxable years of the controlled foreign corporations beginning after December 31, 2017.

(5) Paragraph (e)(6) of this section applies to property acquired in exchanges occurring on or after June 24, 2011.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: May 9, 2019.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2019–10749 Filed 5–22–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0240]

Recurring Safety Zone; Chester Fireworks, Chester, WV

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the temporary safety zone for the

Chester Volunteer Fire Department Fireworks, to provide for the safety of persons, vessels, and the marine environment on the navigable waters of the Ohio River during this event. Our regulation for marine events within the Eighth Coast Guard District identifies the regulated area for this event in Chester, WV. During the enforcement period, entry into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative.

DATES: The regulations in 33 CFR 165.801, Table 1, Line 38, will be enforced from 9:30 p.m. through 11 p.m. on July 4, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Petty Officer Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a temporary safety zone for the Chester Volunteer Fire Department Fireworks, in 33 CFR 165.801, Table 1, Line 38 from 9:30 p.m. through 11:00 p.m. on July 4, 2019. This action is being taken to provide for the safety of persons, vessels, and the marine environment on the navigable waters of the Ohio River during this event. Our regulation for marine events within the Eighth Coast Guard District, § 165.801, specifies the location of the safety zone for the Chester Volunteer Fire Department Fireworks, which covers a one mile stretch of the Ohio River. Entry into the safety zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. Persons or vessels desiring to enter into or pass through the area must request permission from the COTP or a designated representative. They can be reached on VHF FM channel 16. If permission is granted, all persons and vessel shall comply with the instructions of the COTP or designated representative.

In addition to this notice of enforcement in the **Federal Register**, the COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), Marine Safety Information Bulletins (MSIBs), and/or through other means of public notice as appropriate at least 24 hours in advance of enforcement.

Dated: May 13, 2019.

A.W. Demo,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2019–10763 Filed 5–22–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0239]

Recurring Safety Zone; PUSH Beaver County, Beaver, PA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the annual safety zone for the PUSH Beaver County Fireworks, to provide for the safety of persons, vessels, and the marine environment on the navigable waters of Ohio River during this event. Our regulation for marine events within the Eighth Coast Guard District identifies the regulated area for this event in Beaver, PA. During the enforcement period, entry into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative.

DATES: The regulations in 33 CFR 165.801, Table 1, Line 20 will be enforced from 8 p.m. through 10:30 p.m. on June 22, 2019, unless the firework display is postponed because of adverse weather, in which case, this rule will be enforced on June 23, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Petty Officer Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the annual safety zone on the Ohio River for the PUSH Beaver County, in 33 CFR 165.801, Table 1, Line 20 from 8:00 p.m. through 10:30 p.m. on June 22, 2019, unless the firework display is postponed because of adverse weather, in which case, this rule will be enforced on June 23, 2019. This action is being taken to provide for the safety of persons, vessels, and the marine environment on the navigable waters of the Ohio River during this event. Our regulation for marine events within the Eighth Coast Guard District, § 165.801, Table 1, Line 20, specifies the location of the safety zone for the PUSH Beaver County, which covers a one half mile stretch of the Ohio River. Entry into the safety zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. Persons or vessels desiring to enter into or pass through the area must request permission from the COTP or a designated representative. They can be reached on VHF FM channel 16. If permission is granted, all persons and vessel shall comply with the instructions of the COTP or designated representative.

In addition to this notice of enforcement in the **Federal Register**, the COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), Marine Safety Information Bulletins (MSIBs), and/or through other means of public notice as appropriate at least 24 hours in advance of enforcement.

Dated: May 20, 2019.

A.W. Demo,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2019–10771 Filed 5–22–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0229]

Recurring Safety Zone; Wheeling Annual Dragon Boat Race, Wheeling, WV

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Wheeling Annual Dragon Boat Race to provide for the safety of persons, vessels, and the marine environment on the navigable waters of the Ohio River during this event. Our regulation for marine events within the Eighth Coast Guard District identifies the regulated area for this event in Wheeling, WV. During the enforcement periods, entry into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative.

DATES: The regulations in 33 CFR 165.801, Table 1, Line 70, will be

enforced from 8 a.m. through 2 p.m. August 24, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Petty Officer Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone for the Wheeling Annual Dragon Boat Race in 33 CFR 165.801, Table 1, Line 70, from 8 a.m. through 2 p.m. on August 24, 2019. This action is being taken to provide for the safety of persons, vessels, and the marine environment on the navigable waters of the Ohio River during this event. Our regulation for marine events within the Eighth Coast Guard District, § 165.801 specifies the location of the regulated area for the Wheeling Annual Dragon Boat Race. Entry into the regulated area is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. Persons or vessels desiring to enter into or pass through the regulated area must request permission from the COTP or a designated representative. They can be reached on VHF FM channel 16. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

In addition to this notice of enforcement in the **Federal Register**, the COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), Marine Safety Information Bulletins (MSIBs), and/or through other means of public notice as appropriate at least 24 hours in advance of each enforcement.

Dated: May 13, 2019.

A.W. Demo,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2019–10765 Filed 5–22–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0230]

RIN 1625–AA00

Safety Zone; Ohio River Mile 0.0 to Mile 0.6, Pittsburgh, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Ohio River from mile 0.0 to mile 0.6. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a barge based fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by Captain of the Port Marine Safety Unit Pittsburgh.

DATES: This rule is effective from 8:30 p.m. through 10:30 p.m. on June 8, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2019–0230 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST1 Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard, at telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard received a notice of the event on March 28, 2019. After receiving and fully reviewing the event information, circumstances and exact location, the Coast Guard determined that a safety zone was necessary to protect personnel, vessels, and the marine environment from potential hazards created from a barge based firework display. It would be impracticable to complete the full NPRM process for this safety zone because we need to establish it by June 8, 2019 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Marine Safety Unit Pittsburgh (COTP) has determined that a safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created from a barge based firework display.

IV. Discussion of the Rule

This rule establishes a safety zone on June 8, 2019, from 8:30 p.m. through 10:30 p.m. The safety zone will cover all navigable waters on the Ohio River from mile 0.0 to mile 0.6. The duration of the safety zone is intended to protect personnel, vessels, and the marine environment from potential hazards created by a barge based firework display.

No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of the COTP. To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through Marine Safety Unit Pittsburgh at 412–221–0807. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the safety zone. This safety zone impacts a one-mile stretch of the Ohio River for a limited duration of two hours. Vessel traffic will be informed about the safety zone through local notices to mariners. Moreover, the Coast Guard will issue Broadcast Notices to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission to transit the zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting two hours that will prohibit entry on the Ohio River from mile 0.0 to mile 0.6, during the barge based firework event. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES** F.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0230 to read as follows:

§ 165.T08–0230 Safety Zone; Ohio River, miles 0.0–0.6, Pittsburgh, PA.

(a) *Location.* The following area is a safety zone: All waters of the Ohio River from mile 0.0 to mile 0.6.

(b) *Effective period.* This section is effective from 8:30 p.m. through 10:30 p.m. on June 8, 2019.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry of persons and vessels into this zone is

prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative.

(2) Persons or vessels requiring entry into or passage through the zone must request permission from the COTP or a designated representative. The COTP's representative may be contacted at 412–221–0807.

(3) All persons and vessels shall comply with the instructions of the COTP or a designated representative. Designated COTP representatives include United States Coast Guard commissioned, warrant, and petty officer.

(d) *Information broadcasts.* The Captain COTP or a designated representative will inform the public through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

Dated: May 13, 2019.

A.W. Demo,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2019–10764 Filed 5–22–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2018–0625; FRL–9994–10–Region 5]

Air Plan Approval; Indiana; Volatile Organic Liquid Storage Tank Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving revisions to the Indiana Administrative Code (IAC) rule entitled ''Volatile Organic Liquid Storage Vessels'' as part of Indiana's State Implementation Plan (SIP). This rule has been revised to: Allow sources to use an alternative inspection method to demonstrate compliance, address an inconsistency in the language regarding the calculation of maximum true vapor pressure, exempt sources complying with the National Emission Standards for Hazardous Air Pollutants requirements for storage tanks equipped with floating roofs, clarify language, update references, correct certain errors, and address standard language and style changes that have occurred over time since the rule was last revised. EPA proposed to approve this rule on March 8, 2019 and received no comments.

DATES: This final rule is effective June 24, 2019.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2018–0625. All documents in the docket are listed in the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through *http://www.regulations.gov* or at the EPA Region 5 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for availability information).

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Environmental Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–1767, *dagostino.kathleen@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. What is being addressed in this document?

In this action, EPA is approving amended rule IAC 8–9 Volatile Organic Liquid Storage Vessels as a revision to the Indiana SIP. As discussed more fully in the March 8, 2019 proposed approval (84 FR 8491), the Indiana Department of Environmental Management (IDEM) submitted this amended rule on August 20, 2018 and supplemented the submittal on September 28, 2018 with an email clarifying the interpretation of 326 IAC 8–9–6(i)(3). Specifically, the phrase ''For other liquids,'' at the beginning of 326 IAC 8–9–6(i)(3), was inadvertently retained. This phrase refers to former section 326 IAC 8–9–6(i)(2) which has been deleted. IDEM clarified that this phrase will be ignored when interpreting and/or implementing 326 IAC 8–9–6(i).

II. What comments did we receive on the proposed rule?

EPA provided a 30-day review and comment period for the March 8, 2019, proposed rule. The comment period ended on April 8, 2019. We received no comments on EPA's proposed action.

III. What action is EPA taking?

EPA is approving revisions to Indiana's SIP pursuant to section 110 and part D of the Clean Air Act (CAA) because Indiana's August 20, 2018 submission of rule 326 IAC 8–9, as supplemented on September 28, 2018, is consistent with the requirements of the CAA.

IV. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Indiana Regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov,* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

[1] 62 FR 27968 (May 22, 1997).

• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 22, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Oxides of nitrogen, Ozone, Volatile organic compounds.

Dated: May 14, 2019.

Cathy Stepp,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. In § 52.770, the table in paragraph (c) is amended under ''Article 8. Volatile Organic Compound Rules'', under ''Rule 9. Volatile Organic Liquid Storage Vessels:'' by revising the entries for ''8–9–1,'' ''8–9–2,'' ''8–9–3,'' ''8–9–4,'' ''8–9–5'' and ''8–9–6,'' to read as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED INDIANA REGULATIONS

Indiana citation	Subject	Indiana effective date	EPA approval date	Notes
*	*	*	*	*
Article 8. Volatile Organic Compounds				
*	*	*	*	*
Rule 9. Volatile Organic Liquid Storage Vessels:				
*	*	*	*	*
8–9–1	Applicability	7/16/2018	5/23/2019, [insert **Federal Register** citation].	
8–9–2	Exemptions	7/16/2018	5/23/2019, [insert **Federal Register** citation].	
8–9–3	Definitions	7/16/2018	5/23/2019, [insert **Federal Register** citation].	
8–9–4	Standards	7/16/2018	5/23/2019, [insert **Federal Register** citation].	
8–9–5	Testing and procedures	7/16/2018	5/23/2019, [insert **Federal Register** citation].	
8–9–6	Record keeping and reporting requirements	7/16/2018	5/23/2019, [insert **Federal Register** citation]	Includes supplemental information provided on 9/28/2018.
*	*	*	*	*

* * * * *

[FR Doc. 2019–10725 Filed 5–22–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2017–0454; FRL–9993–97–Region 4]

Air Plan Approval; NC; Permitting Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a portion of a revision to the North Carolina State Implementation Plan (SIP) submitted by the State of North Carolina through the North Carolina Department of Environmental Quality (formerly the North Carolina Department of Environment and Natural Resources (NCDENR)), Division of Air Quality, through a letter dated March 24, 2006. The revision includes changes to permitting regulations. The revision is part of North Carolina's strategy to meet and maintain the national ambient air quality standards (NAAQS). This action is being taken pursuant to the Clean Air Act (CAA or Act) and its implementing regulations.

DATES: This rule is effective June 24, 2019.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2017–0454. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division (formerly the Air, Pesticides and Toxics Management Division), U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Andres Febres, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8966. Mr. Febres can also be reached via electronic mail at *febres-martinez.andres@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Through a letter dated March 24, 2006, the State of North Carolina, through NCDENR, submitted several changes to the North Carolina SIP for EPA approval. EPA is taking final action to approve changes to the following regulations: 15A North Carolina Administrative Code (NCAC) 02Q Sections .0101, *Required Air Quality Permits,* and .0301, *Applicability.*[1] [2] EPA has taken, will take, or will not take separate action on all other changes submitted on March 24, 2006.[3]

Specifically, 2Q Sections .0101, *Required Air Quality Permits,* and .0301, *Applicability,* have been amended to reflect the changes to the North Carolina General Statutes regarding construction to allow additional preconstruction activities for minor sources, and an exception has been added in both sections to allow certain preconstruction activities prior to obtaining a final minor construction permit. 2Q Section .0101 has also been revised to remove a prohibition on entering into irrevocable contracts for the construction, operation, or modification of air cleaning devices. EPA has determined that allowing the foregoing changes are consistent with the requirements of CAA sections 110(a)(2)(C) and 110(l) and federal regulations at 40 CFR 51.160–51.164.

In a notice of proposed rulemaking (NPRM) published on February 14, 2019 (84 FR 4019), EPA proposed to approve the aforementioned revisions to the North Carolina SIP. The NPRM provides additional detail regarding the background and rationale for EPA's action. Comments on the NPRM were due on or before March 18, 2019. EPA received no relevant comments on the proposed action.

II. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of regulations under Subchapter 2Q, *Air Quality Permits.* Specifically, EPA is incorporating Section .0101, *Required Air Quality Permits,* under .0100, *General Provisions,* and Section .0301, *Applicability,* under .0300, *Construction and Operating Permits,* which both have a state effective date of December 1, 2005. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[4]

III. Final Action

EPA is taking final action to approve revisions to 15A NCAC 02Q Section .0101, *Required Air Quality Permits,* and Section .0301, *Applicability,* in the North Carolina SIP submitted by the State of North Carolina on March 24, 2006, pursuant to section 110 because these changes are not inconsistent with the CAA and EPA's regulations. Changes to the other sections in this submission have been or will be processed in a separate action, as appropriate, for approval into the North Carolina SIP.

[1] EPA received this SIP submittal on April 4, 2006.

[2] In the table of North Carolina regulations federally approved into the SIP at 40 CFR 52.1770(c), 15A NCAC 02Q is referred to as ''Subchapter 2Q Air Quality Permits.''

[3] On July 18, 2017, EPA took direct final action on changes to 15A NCAC 02D Sections .0101, .0103, .0810, .1902, .1903, and 15A NCAC 2Q Sections .0103, .0105, .0304, .0305, .0808 and .0810. *See* 82 FR 32767. EPA will be taking separate action on changes to 15A NCAC 02D Sections .1904 and .2001. EPA will not be taking action on changes to 15A NCAC 2D Section .1201 because this rule pertains to incinerators and addresses emission guidelines under CAA sections 111(d), 129, and 40 CFR part 60 and is not a part of the federally-approved SIP. EPA will also not be taking action on changes to Regulation 15A NCAC 02D Section .1401, because these were withdrawn by NCDEQ on June 5, 2017. Finally, changes to two regulations, 15A NCAC 02Q Sections .0508 and .0523, will not be acted on because these rules are part of North Carolina's title V permitting program and are not a part of the SIP.

[4] *See* 62 FR 27968 (May 22, 1997).

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 22, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: May 10, 2019.

Mary S. Walker,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart II—North Carolina

■ 2. In § 52.1770, paragraph (c)(1) is amended by revising the entries ''Section .0101'' and ''Section .0301'' to read as follows:

§ 52.1770 Identification of plan.

* * * * *

(c) * * *

(1) EPA Approved North Carolina Regulations

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
Subchapter 2Q Air Quality Permits				
Section .0100 General Provisions				
Section .0101	Required Air Quality Permits	12/1/2005	5/23/2019, [insert **Federal Register** citation].	
*	*	*	*	*
Section .0300 Construction and Operating Permits				
Section .0301	Applicability	12/1/2005	5/23/2019, [insert **Federal Register** citation].	

(1) EPA APPROVED NORTH CAROLINA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*	*	*

* * * * *

[FR Doc. 2019–10724 Filed 5–22–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants for Source Categories

CFR Correction

In Title 40 of the Code of Federal Regulations, Part 63, 63.8980 to end of part 63, revised as of July 1, 2018, make the following corrections in Subpart UUUUU:

■ 1. On page 188, in § 63.10021, paragraph (e)(9) is revised to read as follows:

§ 63.10021 How do I demonstrate continuous compliance with the emission limitations, operating limits, and work practice standards?

* * * * *

(e) * * *

(9) Report the dates of the initial and subsequent tune-ups in hard copy, as specified in § 63.10031(f)(5), through June 30, 2020. On or after July 1, 2020, report the date of all tune-ups electronically, in accordance with § 63.10031(f). The tune-up report date is the date when tune-up requirements in paragraphs (e)(6) and (7) of this section are completed.

* * * * *

■ 2. On page 195, in § 63.10031, paragraphs (f) introductory text, (f)(1), (2), (4), and (f)(6) introductory text are revised to read as follows:

§ 63.10031 What reports must I submit and when?

* * * * *

(f) On or after July 1, 2020, within 60 days after the date of completing each performance test, you must submit the performance test reports required by this subpart to the EPA's WebFIRE database by using the Compliance and Emissions Data Reporting Interface (CEDRI) that is accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov*). Performance test data must be submitted in the file format generated through use of EPA's Electronic Reporting Tool (ERT) (see *https://www.epa.gov/ttn/chief/ert/index.html*). Only data collected using those test methods on the ERT website are subject to this requirement for submitting reports electronically to WebFIRE. Owners or operators who claim that some of the information being submitted for performance tests is confidential business information (CBI) must submit a complete ERT file including information claimed to be CBI on a compact disk or other commonly used electronic storage media (including, but not limited to, flash drives) to EPA. The electronic media must be clearly marked as CBI and mailed to U.S. EPA/OAPQS/CORE CBI Office, Attention: WebFIRE Administrator, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT file with the CBI omitted must be submitted to EPA via CDX as described earlier in this paragraph. At the discretion of the delegated authority, you must also submit these reports, including the confidential business information, to the delegated authority in the format specified by the delegated authority.

(1) On or after July 1, 2020, within 60 days after the date of completing each CEMS (SO_2, PM, HCl, HF, and Hg) performance evaluation test, as defined in § 63.2 and required by this subpart, you must submit the relative accuracy test audit (RATA) data (or, for PM CEMS, RCA and RRA data) required by this subpart to EPA's WebFIRE database by using CEDRI that is accessed through EPA's CDX (*https://cdx.epa.gov*). The RATA data shall be submitted in the file format generated through use of EPA's Electronic Reporting Tool (ERT) (*https://www.epa.gov/ttn/chief/ert/index.html*). Only RATA data compounds listed on the ERT website are subject to this requirement. Owners or operators who claim that some of the information being submitted for RATAs is confidential business information (CBI) shall submit a complete ERT file including information claimed to be CBI on a compact disk or other commonly used electronic storage media (including, but not limited to, flash drives) by registered letter to EPA and the same ERT file with the CBI omitted to EPA via CDX as described earlier in this paragraph. The compact disk or other commonly used electronic storage media shall be clearly marked as CBI and mailed to U.S. EPA/OAPQS/CORE CBI Office, Attention: WebFIRE Administrator, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. At the discretion of the delegated authority, owners or operators shall also submit these RATAs to the delegated authority in the format specified by the delegated authority. Owners or operators shall submit calibration error testing, drift checks, and other information required in the performance evaluation as described in § 63.2 and as required in this chapter.

(2) On or after July 1, 2020, for a PM CEMS, PM CPMS, or approved alternative monitoring using a HAP metals CEMS, within 60 days after the reporting periods ending on March 31st, June 30th, September 30th, and December 31st, you must submit quarterly reports to the EPA's WebFIRE database by using the CEDRI that is accessed through the EPA's CDX (*https://cdx.epa.gov*). You must use the appropriate electronic reporting form in CEDRI or provide an alternate electronic file consistent with EPA's reporting form output format. For each reporting period, the quarterly reports must include all of the calculated 30-boiler operating day rolling average values derived from the CEMS and PM CPMS.

* * * * *

(4) On or after July 1, 2020, submit the compliance reports required under paragraphs (c) and (d) of this section and the notification of compliance status required under § 63.10030(e) to the EPA's WebFIRE database by using the CEDRI that is accessed through the EPA's CDX (*https://cdx.epa.gov*). You must use the appropriate electronic reporting form in CEDRI or provide an alternate electronic file consistent with EPA's reporting form output format.

* * * * *

(6) Prior to July 1, 2020, all reports subject to electronic submittal in paragraphs (f) introductory text, (f)(1), (2), and (4) of this section shall be submitted to the EPA at the frequency specified in those paragraphs in electronic portable document format (PDF) using the ECMPS Client Tool. Each PDF version of a submitted report must include sufficient information to

assess compliance and to demonstrate that the testing was done properly. The following data elements must be entered into the ECMPS Client Tool at the time of submission of each PDF file:

* * * * *

[FR Doc. 2019–10766 Filed 5–22–19; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 10

[Docket No. OST–2016–0028]

RIN 2105–AE46

Maintenance of and Access to Records Pertaining to Individuals

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: On October 4, 2018, the Department of Transportation issued a notice of proposed rulemaking requesting comment on proposed exemptions from certain requirements of the Privacy Act for the Department's insider threat program system of records. The exemptions are necessary to protect properly classified information from disclosure, preserve the integrity of insider threat inquiries, and protect the identities of sources in such inquiries and any related investigations. The Department received no comments on this proposed rule. As a result, this final rule will finalize the proposed rule without change.

DATES: This final rule is effective May 23, 2019.

ADDRESSES: You may access docket number DOT–OST–2016–0028 by any of the following methods:

- *Federal Rulemaking Portal:* Go to *http://www.regulations.gov.*
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, between 9:00 a.m. and 5:00 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

FOR FURTHER INFORMATION CONTACT: Claire Barrett, Departmental Chief Privacy Officer, Office of the Chief Information Officer, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590 or *privacy@dot.gov* or (202) 366–8135.

SUPPLEMENTARY INFORMATION: DOT identifies a system of records that is exempt from one or more provisions off the Privacy Act (pursuant to 5 U.S.C. 552a(j) or (k)) both in the system of records notice published in the **Federal Register** for public comment and in an appendix to DOT's regulations implementing the Privacy Act (49 CFR part 10, appendix). This rule exempts records in the Insider Threat Program system of records from subsections (c)(3) (Accounting of Disclosures), (d) (Access to Records), (e)(1) and (e)(4)(G) through (I) (Agency Requirements) and (f) (Agency Rules) of the Privacy Act to the extent that records are properly classified, in accordance with 5 U.S.C.552a(k)(1), or consist of investigatory material compiled for law enforcement purposes in accordance with 5 U.S.C. 552a(k)(2).

As DOT received no comments on the notice of proposed rulemaking published on October 4, 2018 (83 FR 50053), we are finalizing the proposed rule without change.

Regulatory Analysis and Notices

A. Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

DOT considered the impact of this rulemaking action under Executive Orders 12866 and 13563 (January 18, 2011, ''Improving Regulation and Regulatory Review''), and DOT Order 2100.6, ''Policies and Procedures for Rulemakings.'' DOT has determined that this action will not constitute a significant regulatory action within the meaning of Executive Order 12866 and within the meaning of DOT regulatory policies and procedures. This rulemaking has not been reviewed by the Office of Management and Budget. This rulemaking will not result in any costs. Since these records would be exempt from certain provisions of the Privacy Act, DOT would not have to expend any funds in order to administer those aspects of the Act.

B. Regulatory Flexibility Act

DOT has evaluated the effect these changes will have on small entities and does not believe that this rulemaking will impose any costs on small entities because the reporting requirements themselves are not changed and because the rule applies only to information on individuals that is maintained by the Federal Government or that is already publicly available. Therefore, I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities.

C. National Environmental Policy Act

DOT has analyzed the environmental impacts of this final action pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. *Id.* Paragraph 3.c.5 of DOT Order 5610.1C incorporates by reference the categorical exclusions for all DOT Operating Administrations. This action is covered by the categorical exclusion listed in the Federal Highway Administration's implementing procedures, ''[p]romulgation of rules, regulations, and directives.'' 23 CFR 771.117(c)(20). The purpose of this rulemaking is to amend the Appendix to DOT's Privacy Act regulations. The Department does not anticipate any environmental impacts and there are no extraordinary circumstances present in connection with this rulemaking.

E. Executive Order 13132 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, Federalism, dated August 4, 1999, and it has been determined that it will not have a substantial direct effect on, or sufficient Federalism implications for, the States, nor would it limit the policymaking discretion of the States. Therefore, the preparation of a Federalism Assessment is not necessary.

F. Executive Order 13084 (Consultation and Coordination With Indian Tribal Governments)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Because it would not effect on Indian Tribal Governments, the funding and consultation requirements of Executive Order 13084 do not apply.

G. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*),

Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. The DOT has determined that this action does not contain a collection of information requirement for the purposes of the PRA.

H. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4, 109 Stat. 48, March 22, 1995) requires Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments; and the private sector. The UMRA requires a written statement of economic and regulatory alternatives for proposed and final rules that contain Federal mandates. A ''Federal mandate'' is a new or additional enforceable duty, imposed on any State, local, or tribal Government; or the private sector. If any Federal mandate causes those entities to spend, in aggregate, $143.1 million or more in any one year (adjusted for inflation), an UMRA analysis is required. This final rule does not impose Federal mandates on any State, local, or tribal governments; or the private sector.

List of Subjects in 49 CFR Part 10

Penalties, Privacy.

In consideration of the foregoing, DOT amends part 10 of title 49, Code of Federal Regulations, as follows:

PART 10—MAINTENANCE OF AND ACCESS TO RECORDS PERTAINING TO INDIVIDUALS

■ 1. The authority citation for part 10 continues to read as follows:

Authority: 5 U.S.C. 552a; 49 U.S.C. 322.

Appendix to Part 10 [Designated as Appendix A to Part 10 and Amended]

■ 2. Designate the appendix to part 10 as appendix A to part 10 and amend newly designated appendix A, in Part II, by revising sections A., B., F., and G. to read as follows:

Appendix A to Part 10—Exemptions

* * * * *

Part II. Specific Exemptions

A. The following systems of records are exempt from subsection (c)(3) (Accounting of Certain Disclosures), (d) (Access to Records), (e)(4)(G), (H), and (I) (Agency Requirements), and (f) (Agency Rules) of 5 U.S.C. 552a, to the extent that they contain investigatory material compiled for law enforcement purposes, in accordance 5 U.S.C. 552a(k)(2):

1. Investigative Record System (DOT/FAA 815) maintained by the Federal Aviation Administration at the Office of Civil Aviation Security in Washington, DC; the FAA regional Civil Aviation Security Divisions; the Civil Aviation Security Division at the Mike Monroney Aeronautical Center in Oklahoma City, Oklahoma; the FAA Civil Aviation Security Staff at the FAA Technical Center in Atlantic City, New Jersey; and the various Federal Records Centers located throughout the country.

2. FHWA Investigations Case File System, maintained by the Office of Program Review and Investigations, Federal Highway Administration (DOT/FHWA 214).

3. Federal Motor Carrier Safety Administration (FMCSA) Enforcement Management Information System, maintained by the Chief Counsel, FMCSA (DOT/FMCSA 002).

4. DOT/NHTSA Investigations of Alleged Misconduct or Conflict of Interest, maintained by the Associate Administrator for Administration, National Highway Traffic Safety Administration (DOT/NHTSA 458).

5. Civil Aviation Security System (DOT/FAA 813), maintained by the Office of Civil Aviation Security Policy and Planning, Federal Aviation Administration.

6. Suspected Unapproved Parts (SUP) Program, maintained by the Federal Aviation Administration (DOT/FAA 852).

7. Motor Carrier Management Information System (MCMIS), maintained by the Federal Motor Carrier Safety Administration (DOT/FMCSA 001).

8. Suspicious Activity Reporting (SAR) database, maintained by the Office of Intelligence, Security, and Emergency Response, Office of the Secretary.

9. Departmental Office of Civil Rights System (DOCRS).

10. Insider Threat Program (DOT/ALL 26).

These exemptions are justified for the following reasons:

1. From subsection (c)(3), because making available to a record subject the accounting of disclosures from records concerning him/her would reveal investigative interest by not only DOT but also the recipient agency, thereby permitting the record subject to take appropriate measures to impede the investigation, as by destroying evidence, intimidating potential witnesses, fleeing the area to avoid the thrust of the investigation, etc.

2. From subsections (d), (e)(4)(G), (H), and (I), and (f), because granting an individual access to investigative records, and granting him/her access to investigative records with that information, could interfere with the overall law enforcement process by revealing a pending sensitive investigation, possibly identify a confidential source, disclose information that would constitute an unwarranted invasion of another individual's personal privacy, reveal a sensitive investigative technique, or constitute a potential danger to the health or safety of law enforcement personnel.

B. The following systems of records are exempt from subsections (c)(3) (Accounting of Certain Disclosures) and (d) (Access to Records) of 5 U.S.C. 552a, in accordance with 5 U.S.C. 552a(k)(2):

1. General Air Transportation Records on Individuals, maintained by various offices in the Federal Aviation Administration (DOT/FAA 847).

2. Investigative Records System, maintained by the Assistant Inspector General for Investigations in the Office of the Inspector General (DOT/OST 100).

3. General Investigations Record System, maintained by the Office of Investigations and Security, Office of the Secretary (DOT/OST 016).

4. Insider Threat Program (DOT/ALL 26).

These exemptions are justified for the following reasons:

1. From subsection (c)(3), because making available to a record subject the accounting of disclosures from records concerning him/her would reveal investigative interest by not only DOT but also the recipient agency, thereby permitting the record subject to take appropriate measures to impede the investigation, as by destroying evidence, intimidating potential witnesses, fleeing the area to avoid the thrust of the investigation, etc.

2. From subsection (d), because granting an individual access to investigative records could interfere with the overall law enforcement process by revealing a pending sensitive investigation, possibly identify a confidential source, disclose information that would constitute an unwarranted invasion of another individual's personal privacy, reveal a sensitive investigative technique, or constitute a potential danger to the health or safety of law enforcement personnel.

* * * * *

F. Those portions of the following systems of records which consist of information properly classified in the interest of national defense or foreign policy in accordance with 5 U.S.C. 552(b)(1) are exempt from sections (c)(3) (Accounting of Certain Disclosures), (d) (Access to Records), (e)(4) (G), (H) and (I) (Agency Requirements), and (f) (Agency Rules) of 5 U.S.C. 552a:

1. Investigative Record System maintained by the Assistant Inspector General for Investigations in the Office of the Inspector General (DOT/OST 100).

2. Personnel Security Records System, maintained by the Office of Investigations and Security, Office of the Secretary (DOT/OST 035).

3. Civil Aviation Security System (DOT/FAA 813), maintained by the Office of Civil Aviation Security, Federal Aviation Administration.

4. General Investigations Record System, maintained by the Office of Investigations and Security, Office of the Secretary (DOT/OST 016).

5. Insider Threat Program (DOT/ALL 26).

The purpose of these exemptions is to prevent the disclosure of material authorized to be kept secret in the interest of national defense or foreign policy, in accordance with 5 U.S.C. 552(b)(1) and 552a(k)(1).

G. Those portions of the following systems of records which consist of information properly classified in the interest of national defense or foreign policy in accordance with 5 U.S.C. 552a(b)(1) are exempt from subsections (c)(3) (Accounting of Certain Disclosures) and (d) (Access to Records) of 5 U.S.C. 552a:

1. Investigative Record System (DOT/FAA 815) maintained by the Federal Aviation

Administration at the Office of Civil Aviation Security in Washington, DC; the FAA regional Civil Aviation Security Divisions; the Civil Aviation Security Division at the Mike Monroney Aeronautical Center in Oklahoma City, Oklahoma; the FAA Civil Aviation Security Staff at the FAA Technical Center in Atlantic City, New Jersey; and the various Federal Records Centers located throughout the country.

2. Insider Threat Program (DOT/ALL 26).

The purpose of these exemptions is to prevent the disclosure of material authorized to be kept secret in the interest of national defense or foreign policy, in accordance with 5 U.S.C. 552(b)(1) and 552a(k)(1).

Issued in Washington, DC, on May 8, 2019.

Elaine L. Chao,

Secretary.

[FR Doc. 2019–10730 Filed 5–22–19; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Parts 209, 213, 214, 215, 217, 218, 219, 220, 221, 222, 223, 224, 225, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 270, and 272

[Docket No. FRA–2016–0090; Notice No. 1]

RIN 2130–AC63

Moving the Federal Railroad Administration (FRA) Civil Penalties Schedules and Guidelines From the Code of Federal Regulations (CFR) to the FRA Website

AGENCY: FRA, U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: To eliminate unnecessary costs and improve public access, FRA is removing its civil penalties schedules and guidelines from the CFR and publishing them on the FRA website.

DATES: This final rule is effective May 23, 2019.

FOR FURTHER INFORMATION CONTACT: Veronica Chittim, Attorney, Safety Law Division, Office of Chief Counsel, FRA, 1200 New Jersey Avenue SE, Washington, DC 20590 (telephone 202–493–0273), *veronica.chittim@dot.gov.*

SUPPLEMENTARY INFORMATION: FRA is authorized as the delegate of the Secretary of Transportation (Secretary) to enforce the Federal railroad safety statutes, regulations, and orders, including the civil penalty provisions codified primarily at 49 U.S.C. ch. 213. *See* 49 U.S.C. 103 and 49 CFR 1.89; 49 U.S.C. chs. 201–213. The Secretary also authorized FRA to enforce certain hazardous materials transportation statutes, regulations, and orders, including the civil penalty provisions, relating to railroad transportation. *See* 49 CFR 1.89; 49 U.S.C. ch. 51.[1] FRA currently has safety regulations in 34 parts of the CFR that contain provisions establishing the agency's authority to impose civil penalties if a person violates any requirement in the pertinent portion of a statute or the CFR, and 32 CFR parts containing FRA regulations include an appendix with a civil penalty schedule or guidelines.

Since 1988, FRA has included the civil penalties schedules or guidelines as an appendix in the corresponding CFR part. Civil penalties schedules and guidelines are not regulations nor are they subject to notice-and-comment requirements. They are merely policy statements that do not bind FRA. Instead, FRA retains full discretion to assess civil penalties for violations that are between the minimum and maximum amounts authorized by statute and adjusted for inflation.[2] Yet, their place in the CFR has necessitated that any changes to them, including adjustments for inflation required by federal law, be published in the **Federal Register**.

Like other federal agencies, FRA is charged by the page for each page in its segment of the CFR, namely title 49, parts 200–299. Currently, the annual rate is $85 per page.[3] FRA, like other agencies, is also charged for each column it prints in the **Federal Register**, currently at a rate of $151 per column.[4]

In this final rule, FRA is removing the civil penalties schedules and guidelines from 49 CFR parts 200–299 and updating references to the schedules and guidelines to reflect their new location on the FRA website, without substantive change.[5] This move will end the unnecessary costs of amending the schedules and guidelines through the **Federal Register** and printing them in the CFR. At the same time, locating the schedules and guidelines on the FRA website will improve public access to those statements of agency policy and simplify enforcement by grouping all schedules and guidelines into one location. Changes for inflation to the minimum, maximum, and aggravated maximum penalty amounts will still be published in the **Federal Register**, as required by federal law.

Public Participation

FRA is proceeding to a final rule without a notice of proposed rulemaking or an opportunity for public comment. The civil penalties schedules and guidelines, and therefore this rule to move those schedules and guidelines to FRA's website without substantive change, are general statements of policy. As such, the notice and comment procedures under the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(A), do not apply.

Regulatory Impact

A. Executive Orders 12866, 13771, and DOT Regulatory Policies and Procedures

FRA evaluated this final rule consistent with Executive Order 12866 (Regulatory Planning and Review), Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs), and DOT policies and procedures. *See* 44 FR 11034, Feb. 26, 1979; 76 FR 3821, Jan. 21, 2011; and 82 FR 9339, Jan. 30, 2017. In this final rule, FRA solely replaces statements of agency policy with references to the statements' new location on the FRA website, and is not a significant regulatory action under section 3(f) of Executive Order 12866.

FRA will realize cost savings from not printing the civil penalties schedules and guidelines in the yearly CFR revision, and therefore this rulemaking is a deregulatory action under Executive Order 13771. Counting the number of pages in the current CFR (as revised Oct. 1, 2018) used by the civil penalties schedules and guidelines, FRA estimates 80.5 fewer pages would be printed in each CFR revision. The migration of the civil penalties schedules and guidelines is a one-time occurrence; however, the cost savings accrue annually, and therefore FRA

[1] Civil penalties related to hazardous materials transportation statutes, regulations, or orders administered by other agencies, such as the Pipeline and Hazardous Materials Safety Administration, are not affected by this rule.

[2] For railroad safety violations, the current statutory minimum civil penalty is $870, the ordinary maximum civil penalty is $28,474, and the aggravated maximum civil penalty is $113,894. *See* 83 FR 60732 (Nov. 27, 2018). For hazardous materials violations, the current statutory minimum civil penalty (for violations relating to training) is $481, the ordinary maximum civil penalty is $79,976, and the aggravated maximum civil penalty is $186,610. *Id.*

[3] *See* GPO Circular Letter No. 1007 (June 4, 2018), available at *https://www.gpo.gov/how-to-work-with-us/agency/circular-letters/open-requisitions-sf1-for-federal-register-and-code-of-federal-regulations.*

[4] *Id.*

[5] This final rule redirects any references to an appendix in the CFR that formerly contained civil penalties schedules and guidelines to FRA's website at *www.fra.dot.gov.* FRA's main website (*www.fra.dot.gov*) will contain a link to FRA's civil penalties guidance website (*www.fra.dot.gov/Page/P1155*) linking to a tabbed workbook containing each respective CFR part's civil penalties table. Language referring to either a ''statement of agency civil penalty policy'' or ''schedule of civil penalty amounts'' is maintained from the existing CFR. *See, e.g.,* 49 CFR 214.5; 49 CFR 222.11.

accounts for them as a yearly cost savings. Also, FRA will realize cost savings from not publishing civil penalty schedules in the **Federal Register** associated with new regulations and amendments to existing regulations. As mentioned, the annual updates for inflation only affect the minimum, maximum, and aggravated maximum penalties, which will continue to be published, resulting in no cost savings. To account for publishing fewer civil penalty schedules associated with new regulations, FRA estimates it published 5 new regulations in the **Federal Register** in the last 10 years, or one-half regulation per year. Each regulation had a corresponding civil penalty schedule occupying approximately 3 columns in the **Federal Register**, or 1.5 columns per one-half regulation per year. In addition, FRA estimates allocating 3 columns per year will sufficiently cover changes to civil penalty schedules published for amendments to existing regulations, for a total **Federal Register** savings of 4.5 columns per year. The cost savings are monetized using the publication costs noted earlier, and illustrated in the table below. FRA uses a 10-year period of analysis in estimating future cost savings to reflect a reasonable regulatory cycle for new regulations and review of existing regulations.

TABLE A–1—COST SAVINGS FROM NOT PUBLISHING CIVIL MONETARY PENALTY SCHEDULES IN THE CFR AND THE **Federal Register**

Year	CFR (80.5 pages @$85 per page)	**Federal Register** (4.5 columns @$151 per column)	Total cost savings
2019	$6,842.50	$679.50	$7,522.00
2020	6,842.50	679.50	7,522.00
2021	6,842.50	679.50	7,522.00
2022	6,842.50	679.50	7,522.00
2023	6,842.50	679.50	7,522.00
2024	6,842.50	679.50	7,522.00
2025	6,842.50	679.50	7,522.00
2026	6,842.50	679.50	7,522.00
2027	6,842.50	679.50	7,522.00
2028	6,842.50	679.50	7,522.00
Total Undiscounted Cost Savings, Nominal			75,220
Present Value (PV) of Total Cost Savings Discounted at 7%			52,831
Present Value (PV) of Total Cost Savings Discounted at 3%			64,164
Total Annualized Cost Savings Using 7% Discount Rate			7,522
Total Annualized Cost Savings Using 3% Discount Rate			7,522

B. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act of 1980 (RFA), Public Law 96–354, as amended, and codified as amended at 5 U.S.C. 601–612, and Executive Order 13272 (Proper Consideration of Small Entities in Agency Rulemaking), require agency review of proposed and final rules to assess their impact on ''small entities'' for purposes of the RFA. An agency must prepare a regulatory flexibility analysis unless it determines and certifies that a rule is not expected to have a significant economic impact on a substantial number of small entities. FRA does not expect this final rule will have a significant economic impact on a substantial number of small entities. Although this final rule will apply to railroads, hazardous materials shippers, and others that are considered small entities, there is no economic impact on any person who complies or is required to comply with the Federal railroad safety laws and the regulations and orders issued under those laws, and the Federal hazardous materials laws and the regulations, special permits, approvals, and orders issued under those laws, because the rule does not change any penalty to which an entity could be subject.

In addition, FRA has determined the RFA does not apply to this rulemaking. FRA is not required to publish its civil penalty schedules and guidelines in the CFR, and the civil penalties schedules and guidelines are general statements of policy, thus the APA notice and comment procedures do not apply to the either penalty schedules themselves or the policy decision to change their location. The Small Business Administration's A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act (2003), provides that:

> If, under the APA or any rule of general applicability governing federal grants to state and local governments, the agency is required to publish a general notice of proposed rulemaking (NPRM), the RFA must be considered [citing 5 U.S.C. 604(a)]. . . .If an NPRM is not required, the RFA does not apply.

Therefore, because FRA is not required to publish the schedules and guidelines in the CFR, the RFA does not apply.

C. Federalism

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), requires FRA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule will not have a substantial effect on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Thus, consistent with Executive Order 13132, FRA is not required to prepare a Federalism assessment.

D. Paperwork Reduction Act

There are no new information collection requirements in this final rule

to submit for OMB review under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

E. Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure, in the aggregate, of $100,000,000 or more, adjusted for inflation, in any one year by State, local, or Indian Tribal governments, or the private sector. Thus, consistent with Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1532), FRA is not required to prepare a written statement detailing the effect of such an expenditure.

F. Environmental Impact

FRA has evaluated this final rule under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), other environmental statutes, related regulatory requirements, and its ''Procedures for Considering Environmental Impacts'' (FRA's NEPA Procedures) (64 FR 28545, May 26, 1999). FRA has determined that this final rule is categorically excluded from detailed environmental review pursuant to section 4(c)(20) of FRA's NEPA Procedures, ''Promulgation of railroad safety rules and policy statements that do not result in significantly increased emissions of air or water pollutants or noise or increased traffic congestion in any mode of transportation.'' *See* 64 FR 28547, May 26, 1999. Categorical exclusions (CEs) are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). *See* 40 CFR 1508.4.

In analyzing the applicability of a CE, the agency must also consider whether extraordinary circumstances warrant a more detailed environmental review through the preparation of an EA or EIS. *See id.* The purpose of this rulemaking is to make FRA-maintained civil penalty schedules and guidelines more easily available. Specifically, FRA is removing civil penalty schedules and guidelines under its authority from the CFR and replacing references to them with references to their new location on FRA's website. Under section 4(c) and (e) of FRA's NEPA Procedures, FRA has concluded no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review.

FRA does not anticipate any environmental impacts from this final rule and finds there are no extraordinary circumstances present in connection with this final rule.

G. Executive Order 12898 (Environmental Justice)

Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, and DOT Order 5610.2(a) (91 FR 27534, May 10, 2012) require DOT agencies to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects, of their programs, policies, and activities on minority populations and low-income populations. The DOT Order instructs DOT agencies to address compliance with Executive Order 12898 and requirements within the DOT Order in rulemaking activities, as appropriate. FRA has evaluated this final rule under Executive Order 12898 and the DOT Order and has determined that it would not cause disproportionately high and adverse human health and environmental effects on minority populations or low-income populations.

H. Executive Order 13175 (Tribal Consultation)

FRA has evaluated this final rule under the principles and criteria contained in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, dated November 6, 2000. The final rule would not have a substantial direct effect on one or more Indian tribes, would not impose substantial direct compliance costs on Indian tribal governments, and would not preempt tribal laws. Therefore, the funding and consultation requirements of Executive Order 13175 do not apply, and FRA is not required to prepare a tribal summary impact statement.

List of Subjects

49 CFR Part 209

Administrative practice and procedure, Hazardous materials transportation, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 213

Bridges, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 214

Bridges, Occupational safety and health, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 215

Freight, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Parts 217, 221, 224, 229, 230, 232, 233, and 239

Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 218

Occupational safety and health, Penalties, Railroad employees, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 219

Alcohol abuse, Drug abuse, Drug testing, Penalties, Railroad safety, Reporting and recordkeeping requirements, Safety, Transportation.

49 CFR Part 220

Penalties, Radio, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 222

Administrative practice and procedure, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 223

Glazing standards, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 225

Investigations, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 227

Noise control, Occupational safety and health, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 228

Penalties, Railroad employees, Reporting and recordkeeping requirements.

49 CFR Part 231

Penalties, Railroad safety.

49 CFR Part 234

Highway safety, Penalties, Railroad safety, Reporting and recordkeeping requirements, State and local governments.

49 CFR Part 235

Administrative practice and procedure, Penalties, Railroad safety, Railroad signals, Reporting and recordkeeping requirements.

49 CFR Part 236

Penalties, Positive Train Control, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 237

Bridges, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 238

Fire prevention, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 240

Administrative practice and procedure, Penalties, Railroad employees, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 241

Communications, Penalties, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 242

Administrative practice and procedure, Penalties, Railroad employees, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 243

Administrative practice and procedure, Penalties, Railroad employees, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 270

Penalties, Railroad safety, Reporting and recordkeeping requirements, System safety.

49 CFR Part 272

Penalties, Railroad employees, Railroad safety, Railroads, Safety, Transportation.

The Final Rule

In consideration of the foregoing, parts 209, 213, 214, 215, 217, 218, 219, 220, 221, 222, 223, 224, 225, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 270, and 272 of subtitle B, chapter II of title 49 of the Code of Federal Regulations are amended as follows:

PART 209—[AMENDED]

■ 1. The authority citation for part 209 continues to read as follows:

Authority: 49 U.S.C. 5123, 5124, 20103, 20107, 20111, 20112, 20114; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 2. Revise the last sentence of § 209.105(a) to read as follows:

§ 209.105 Notice of probable violation.

(a) * * * FRA's website at *www.fra.dot.gov* contains guidelines used by the chief counsel in making initial penalty assessments.

* * * * *

■ 3. In appendix A to part 209, revise the section entitled ''Penalty Schedules; Assessment of Maximum Penalties'' to read as follows:

Appendix A to Part 209—Statement of Agency Policy Concerning Enforcement of the Federal Railroad Safety Laws

* * * * *

Penalty Schedules; Assessment of Maximum Penalties

As recommended by the Department of Transportation in its initial proposal for rail safety legislative revisions in 1987, the RSIA raised the maximum civil penalties for violations of the Federal rail safety laws, regulations, or orders. *Id.,* secs. 3, 13–15, 17. Pursuant to sec. 16 of RSIA, the penalty for a violation of the Hours of Service Act was changed from a flat $500 to a penalty of up to $1,000, as the Secretary of Transportation deems reasonable. Under all the other statutes, and regulations and orders under those statutes, the maximum penalty was raised from $2,500 to $10,000 per violation, except that where a grossly negligent violation or a pattern of repeated violations has created an imminent hazard of death or injury to persons, or has caused death or injury, the penalty was raised to a maximum of $20,000 per violation (''the aggravated maximum penalty'').

The Rail Safety Enforcement and Review Act (RSERA), Pub. L. 102–365, 106 Stat. 972, enacted in 1992, increased the maximum penalty from $1,000 to $10,000, and provided for an aggravated maximum penalty of $20,000 for a violation of the Hours of Service Act, making these penalty amounts uniform with those of FRA's other safety laws, regulations, and orders. RSERA also increased the minimum civil monetary penalty from $250 to $500 for all of FRA's safety regulatory provisions and orders. *Id.,* sec. 4(a).

The Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101–410, 104 Stat. 890, note, as amended by Section 31001(s)(1) of the Debt Collection Improvement Act of 1996 (Pub. L. 104–134, 110 Stat. 1321–373, April 26, 1996) (Inflation Act) required that agencies adjust by regulation each minimum and maximum civil monetary penalty within the agency's jurisdiction for inflation and make subsequent adjustments once every four years after the initial adjustment. Accordingly, FRA's minimum and maximum civil monetary penalties have been periodically adjusted, pursuant to the Inflation Act, through rulemaking.

The Rail Safety Improvement Act of 2008 (''RSIA of 2008''), enacted October 16, 2008, raised FRA's civil monetary ordinary and aggravated maximum penalties to $25,000 and $100,000 respectively. FRA amended the civil penalty provisions in its regulations so as to make $25,000 the ordinary maximum penalty per violation and $100,000 the aggravated maximum penalty per violation, as authorized by the RSIA of 2008, in a final rule published on December 30, 2008 in the **Federal Register**. The December 30, 2008 final rule also adjusted the minimum civil penalty from $550 to $650 pursuant to Inflation Act requirements. A correcting amendment to the civil penalty provisions in 49 CFR part 232 was published on April 6, 2009.

Effective June 25, 2012, the aggravated maximum penalty was raised from $100,000 to $105,000 pursuant to the Inflation Act.

On November 2, 2015, President Barack Obama signed the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Inflation Act). Pub. L. 114–74, Sec. 701. Under the 2015 Inflation Act, agencies must make a catch-up adjustment for civil monetary penalties with the new penalty levels published by July 1, 2016, to take effect no later than August 1, 2016. Moving forward, agencies must make annual inflationary adjustments, starting January 15, 2017, based on Office of Management and Budget guidance. Under the 2015 Inflation Act, effective April 3, 2017, the minimum civil monetary penalty was raised from $839 to $853, the ordinary maximum civil monetary penalty was raised from $27,455 to $27,904, and the aggravated maximum civil monetary penalty was raised from $109,819 to $111,616. Effective November 27, 2018, the minimum civil monetary penalty was raised from $853 to $870, the ordinary maximum civil monetary penalty was raised from $27,904 to $28,474, and the aggravated maximum civil monetary penalty was raised from $111,616 to $113,894.

FRA's traditional practice has been to issue penalty schedules assigning to each particular regulation or order specific dollar amounts for initial penalty assessments. The schedule (except where issued after notice and an opportunity for comment) constitutes a statement of agency policy and was historically issued as an appendix to the relevant part of the Code of Federal Regulations. Schedules are now published on FRA's website at *www.fra.dot.gov*. For each regulation or order, the schedule shows two amounts within the $870 to $28,474 range in separate columns, the first for ordinary violations, the second for willful violations (whether committed by railroads or individuals). In one instance—49 CFR part 231—the schedule refers to sections of the relevant FRA defect code rather than to sections of the CFR text. Of course, the defect code, which is simply a reorganized version of the CFR text used by FRA to facilitate computerization of inspection data, is substantively identical to the CFR text.

The schedule amounts are meant to provide guidance as to FRA's policy in predictable situations, not to bind FRA from using the full range of penalty authority where extraordinary circumstances warrant. The Senate report on the bill that became the RSIA stated:

It is expected that the Secretary would act expeditiously to set penalty levels commensurate with the severity of the violations, with imposition of the maximum

penalty reserved for violation of any regulation where warranted by exceptional circumstances. S. Rep. No. 100–153, 10th Cong., 2d Sess. 8 (1987).

Accordingly, under each of the schedules (ordinarily in a footnote), and regardless of the fact that a lesser amount might be shown in both columns of the schedule, FRA reserves the right to assess the statutory maximum penalty of up to $113,894 per violation where a pattern of repeated violations or a grossly negligent violation has created an imminent hazard of death or injury or has caused death or injury. FRA indicates in the penalty demand letter when it uses the higher penalty amount instead of the penalty amount listed in the schedule.

* * * * *

Appendix B to Part 209—[Amended]

■ 4. Amend appendix B to part 209 by:

■ a. Removing ''49 CFR 172.200–.203'' and adding in its place ''49 CFR 172.200 through 172.203''; and

■ b. Removing the heading ''Civil Penalty Assessment Guidelines'' and the two tables following the heading.

PART 213—[AMENDED]

■ 5. The authority citation for part 213 continues to read as follows:

Authority: 49 U.S.C. 20102–20114 and 20142; Sec. 403, Div. A, Pub. L. 110–432, 122 Stat. 4885; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 6. Revise the last sentence of § 213.15(a) to read as follows:

§ 213.15 Penalties.

(a) * * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

Appendix B to Part 213—[Removed and Reserved]

■ 7. Remove and reserve appendix B to part 213.

PART 214—[AMENDED]

■ 8. The authority citation for part 214 continues to read as follows:

Authority: 49 U.S.C. 20102–20103, 20107, 21301–21302, 31304, 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 9. Revise the last sentence of § 214.5 to read as follows:

§ 214.5 Responsibility for compliance.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

Appendix A to Part 214—[Removed]

■ 10. Remove appendix A to part 214.

PART 215—[AMENDED]

■ 11. The authority citation for part 215 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 12. Revise the last sentence of § 215.7 to read as follows:

§ 215.7 Prohibited acts.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

Appendix B to Part 215—[Removed and Reserved]

■ 13. Remove and reserve appendix B to part 215.

PART 217—[AMENDED]

■ 14. The authority citation for part 217 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 15. Revise the last sentence of § 217.5 to read as follows:

§ 217.5 Penalty.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

Appendix A to Part 217—[Removed]

■ 16. Remove appendix A to part 217.

PART 218—[AMENDED]

■ 17. The authority citation for part 218 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 18. Revise the last sentence of § 218.9 to read as follows:

§ 218.9 Civil penalty.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

■ 19. Revise § 218.41 to read as follows:

§ 218.41 Noncompliance with hump operations rule.

A person (including a railroad and any manager, supervisor, official, or other employee or agent of a railroad) who fails to comply with a railroad's operating rule issued pursuant to § 218.39 is subject to a penalty. See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

■ 20. Revise § 218.55 to read as follows:

§ 218.55 Tampering prohibited.

Any individual who willfully disables a safety device is subject to a civil penalty and to disqualification from performing safety-sensitive functions on a railroad if found unfit for such duties under the procedures provided for in 49 CFR part 209. See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

■ 21. Revise § 218.57 to read as follows:

§ 218.57 Responsibilities of individuals.

Any individual who knowingly operates a train, or permits it to be operated, when the controlling locomotive of that train is equipped with a disabled safety device, is subject to a civil penalty and to disqualification from performing safety-sensitive functions on a railroad if found to be unfit for such duties. See appendix B to this part for a statement of agency enforcement policy concerning violations of this section. See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

■ 22. Revise § 218.59 to read as follows:

§ 218.59 Responsibilities of railroads.

Any railroad that operates a train when the controlling locomotive of a train is equipped with a disabled safety device is subject to a civil penalty. See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

Appendix A to Part 218—[Removed and Reserved]

■ 23. Remove and reserve appendix A to part 218.

PART 219—[AMENDED]

■ 24. The authority citation for part 219 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20140, 21301, 21304, 21311; 28 U.S.C. 2461, note; Sec. 412, Div. A, Pub. L. 110–432, 122 Stat. 4889 (49 U.S.C. 20140, note); and 49 CFR 1.89.

■ 25. Revise the last sentence of § 219.10 to read as follows:

§ 219.10 Penalties.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

Appendix A to Part 219—[Removed and Reserved]

■ 26. Remove and reserve appendix A to part 219.

PART 220—[AMENDED]

■ 27. The authority citation for part 220 continues to read as follows:

Authority: 49 U.S.C. 20102–20103, 20103, note, 20107, 21301–21302, 20701–20703, 21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 28. Revise the last sentence of § 220.7 to read as follows:

§ 220.7 Penalty.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

Appendix C to Part 220—[Removed]

■ 29. Remove appendix C to part 220.

PART 221—[AMENDED]

■ 30. The authority citation for part 221 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 31. Revise the last sentence of § 221.7 to read as follows:

§ 221.7 Civil penalty.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

Appendix C to Part 221—[Removed]

■ 32. Remove appendix C to part 221.

PART 222—[AMENDED]

■ 33. The authority citation for part 222 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20153, 21301, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 34. Revise the section heading and last sentence of § 222.11 to read as follows:

§ 222.11 What are the penalties for failure to comply with this part?

* * * FRA's website at *www.fra.dot.gov* contains a schedule of civil penalty amounts used in connection with this part.

Appendix H to Part 222—[Removed]

■ 35. Remove appendix H to part 222.

PART 223—[AMENDED]

■ 36. The authority citation for part 223 continues to read as follows:

Authority: 49 U.S.C. 20102–20103, 20133, 20701–20702, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 37. Revise the last sentence of § 223.7 to read as follows:

§ 223.7 Responsibility.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

Appendix B to Part 223—[Removed]

■ 38. Remove appendix B to part 223.

PART 224—[AMENDED]

■ 39. The authority citation for part 224 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20148 and 21301; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 40. Revise the last sentence of § 224.11(a) to read as follows:

§ 224.11 Penalties.

(a) * * * FRA's website at *www.fra.dot.gov* contains a schedule of civil penalty amounts used in connection with this part.

* * * * *

Appendix A to Part 224—[Removed and Reserved]

■ 41. Remove and reserve appendix A to part 224.

PART 225—[AMENDED]

■ 42. The authority citation for part 225 is revised to read as follows:

Authority: 49 U.S.C. 103, 322(a), 20103, 20107, 20901–20902, 21301, 21302, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 43. Revise the last sentence of § 225.12(h)(1) to read as follows:

§ 225.12 Rail Equipment Accident/Incident Reports alleging employee human factor as cause; Employee Human Factor Attachment; notice to employee; employee supplement.

* * * * *

(h) * * *

(1) * * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

■ 44. Revise the third sentence of § 225.29 to read as follows:

§ 225.29 Penalties.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

Appendix A to Part 225—[Removed and Reserved]

■ 45. Remove and reserve appendix A to part 225.

PART 227—[AMENDED]

■ 46. The authority citation for part 227 continues to read as follows:

Authority: 49 U.S.C. 20103, 20103, note, 20701–20702; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 47. Revise the last sentence of § 227.9(a) to read as follows:

§ 227.9 Penalties.

(a) * * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

Appendix G to Part 227—[Removed]

■ 48. Remove appendix G to part 227.

PART 228—[AMENDED]

■ 49. The authority citation for part 228 is revised to read as follows:

Authority: 49 U.S.C. 103, 20103, 20107, 21101–21109; Sec. 108, Div. A, Pub. L. 110–432, 122 Stat. 4860–4866, 4893–4894; 49 U.S.C. 21301, 21303, 21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 50. Revise the third sentence of § 228.6(a) to read as follows:

§ 228.6 Penalties.

(a) * * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy. * * *

* * * * *

Appendix B to Part 228—[Removed and Reserved]

■ 51. Remove and reserve appendix B to part 228.

PART 229—[AMENDED]

■ 52. The authority citation for part 229 continues to read as follows:

Authority: 49 U.S.C. 103, 322(a), 20103, 20107, 20901–02, 21301, 21301, 21302, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 53. Revise the last sentence of § 229.7(b) to read as follows:

§ 229.7 Prohibited acts and penalties.

* * * * *

(b) * * * FRA's website at *www.fra.dot.gov* contains a statement of agency civil penalty policy.

* * * * *

Appendix B to Part 229—[Removed and Reserved]

■ 54. Remove and reserve appendix B to part 229.

PART 230—[AMENDED]

■ 55. The authority citation for part 230 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20702; 28 U.S.C. 2461, note; and 49 CFR 1.89.

Appendix D to Part 230—[Removed]

■ 56. Remove appendix D to part 230.

PART 231—[AMENDED]

■ 57. The authority citation for part 231 continues to read as follows:

Authority: 49 U.S.C. 20102–20103, 20107, 20131, 20301–20303, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 58. Revise the last sentence of § 231.0(f) to read as follows:

§ 231.0 Applicability and penalties.

* * * * *

(f) * * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

■ 59. Revise the last sentence of § 231.33(g) to read as follows:

§ 231.33 Procedure for special approval of existing industry safety appliance standards.

* * * * *

(g) * * * Civil penalties will be assessed under this part by using the applicable defect code in the statement of agency civil penalty policy on FRA's website at *www.fra.dot.gov.*

■ 60. Revise the last sentence of § 231.35(g) to read as follows:

§ 231.35 Procedure for modification of an approved industry safety appliance standard for new railcar construction.

* * * * *

(g) * * * Civil penalties will be assessed under this part by using the applicable defect code in the statement of agency civil penalty policy on FRA's website at *www.fra.dot.gov.*

Appendix A to Part 231—[Removed]

■ 61. Remove appendix A to part 231.

PART 232—[AMENDED]

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

Authority: 49 U.S.C. 20102–20103, 20107, 20133, 20141, 20301–20303, 20306, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 63. Revise the last sentence of § 232.11(a) to read as follows:

§ 232.11 Penalties.

(a) * * * FRA's website at *www.fra.dot.gov* contains a schedule of civil penalty amounts used in connection with this part.

* * * * *

■ 64. Revise the first sentence of § 232.213(b) to read as follows:

§ 232.213 Extended haul trains.

* * * * *

(b) Failure to comply with any of the requirements contained in paragraph (a) of this section will be considered an improper movement of a designated priority train for which appropriate civil penalties may be assessed as outlined in the statement of civil penalty policy on FRA's website at *www.fra.dot.gov.*

* * * * *

Appendix A to Part 232—[Removed and Reserved]

■ 65. Remove and reserve appendix A to part 232.

PART 233—[AMENDED]

■ 66. The authority citation for part 233 continues to read as follows:

Authority: 49 U.S.C. 504, 522, 20103, 20107, 20501–20505, 21301, 21302, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 67. Revise the last sentence of § 233.11 to read as follows:

§ 233.11 Civil penalties.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

Appendix A to Part 233—[Removed]

■ 68. Remove appendix A to part 233.

PART 234—[AMENDED]

■ 69. The authority citation for part 234 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20152, 20160, 21301, 21304, 21311, 22501 note; Pub. L. 110–432, Div. A., Sec. 202, 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 70. Amend § 234.6 by removing ''§ 234.11 of this part'' everywhere it appears and adding ''§ 234.11'' in its place and revising the third sentence of paragraph (a) to read as follows:

§ 234.6 Penalties.

(a) * * * FRA's website at *www.fra.dot.gov* contains a schedule of civil penalty amounts used in connection with this part. * * *

* * * * *

Appendix A to Part 234—[Removed and Reserved]

■ 71. Remove and reserve appendix A to part 234.

PART 235—[AMENDED]

■ 72. The authority citation for part 235 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 73. Revise the last sentence of § 235.9 to read as follows:

§ 235.9 Civil penalty.

* * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

Appendix A to Part 235—[Removed]

■ 74. Remove appendix A to part 235.

PART 236—[AMENDED]

■ 75. The authority citation for part 236 is revised to read as follows:

Authority: 49 U.S.C. 20102–20103, 20107, 20133, 20141, 20157, 20301–20303, 20306, 20501–20505, 20701–20703, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 76. Revise the last sentence of § 236.0(f) to read as follows:

§ 236.0 Applicability, minimum requirements, and penalties.

* * * * *

(f) * * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

Appendix A to Part 236—[Removed and Reserved]

■ 77. Remove and reserve appendix A to part 236.

PART 237—[AMENDED]

■ 78. The authority citation for part 237 continues to read as follows:

Authority: 49 U.S.C. 20102–20114; Pub. L. 110–432, Div. A, Sec. 417; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 79. Revise the last sentence of § 237.7(a) to read as follows:

§ 237.7 Penalties.

(a) * * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

Appendix B to Part 237—[Removed]

■ 80. Remove appendix B to part 237.

PART 238—[AMENDED]

■ 81. The authority citation for part 238 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20133, 20141, 20302–20303, 20306, 20701–20702, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 82. Revise the last sentence of § 238.11(a) to read as follows:

§ 238.11 Penalties.

(a) * * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

■ 83. Revise the last sentence of § 238.229(d) to read as follows:

§ 238.229 Safety appliances—general.

* * * * *

(d) * * * When appropriate, civil penalties for improperly using or hauling a piece of equipment with a defective welded safety appliance or safety appliance bracket or support addressed in this section will be assessed as an improperly applied safety appliance pursuant to the penalty schedule on FRA's website at *www.fra.dot.gov* under the appropriate defect code contained therein.

* * * * *

■ 84. In § 238.230, revise the last sentence of paragraph (c) introductory

text, add a heading for paragraph (e), and revise the last sentence of paragraph (e) to read as follows:

§ 238.230 Safety appliances—new equipment.

* * * * *

(c) * * * When appropriate, civil penalties for improperly using or hauling a piece of equipment with a defective welded safety appliance or safety appliance bracket or support addressed in this section will be assessed pursuant to the penalty schedule on FRA's website at *www.fra.dot.gov* under the appropriate defect code contained therein.

* * * * *

(e) *Civil penalties.* * * * Civil penalties will be assessed under part 231 of this chapter by using the applicable defect code contained on FRA's website at *www.fra.dot.gov.*

Appendix A to Part 238—[Removed and Reserved]

■ 85. Remove and reserve appendix A to part 238.

PART 239—[AMENDED]

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

Authority: 49 U.S.C. 20102–20103, 20105–20114, 20133, 21301, 21304, and 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 87. Revise the last sentence of § 239.11 to read as follows:

§ 239.11 Penalties.

* * * FRA's website at *www.fra.dot.gov* contains a schedule of civil penalty amounts used in connection with this part.

Appendix A to Part 239—[Removed]

■ 88. Remove appendix A to part 239.

PART 240—[AMENDED]

■ 89. The authority citation for part 240 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20135, 21301, 21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 90. Revise the last sentence of § 240.11(a) to read as follows:

§ 240.11 Penalties and consequences for noncompliance.

(a) * * * See FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

Appendix A to Part 240—[Removed and Reserved]

■ 91. Remove and reserve appendix A to part 240.

PART 241—[AMENDED]

■ 92. The authority citation for part 241 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 21301, 21304, 21311; 28 U.S.C. 2461, note; 49 CFR 1.89.

Appendix B to Part 241—[Removed and Reserved]

■ 93. Remove and reserve appendix B to part 241.

PART 242—[AMENDED]

■ 94. The authority citation for part 242 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20135, 20138, 20162, 20163, 21301, 21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 95. Revise the last sentence of § 242.11(a) to read as follows:

§ 242.11 Penalties and consequences for noncompliance.

(a) * * * *See* FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

Appendix A to Part 242—[Removed and Reserved]

■ 96. Remove and reserve appendix A to part 242.

PART 243—[AMENDED]

■ 97. The authority citation for part 243 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20131–20155, 20162, 20301–20306, 20701–20702, 21301–21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 98. Revise the last sentence of § 243.7(a) to read as follows:

§ 243.7 Penalties and consequences for noncompliance.

(a) * * * *See* FRA's website at *www.fra.dot.gov* for a statement of agency civil penalty policy.

* * * * *

Appendix to Part 243—[Removed]

■ 99. Remove the appendix to part 243.

PART 270—[AMENDED]

■ 100. The authority citation for part 270 continues to read as follows:

Authority: 49 U.S.C. 20103, 20106–20107, 20118–20119, 20156, 21301, 21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 101. The stay of 49 CFR part 270 is lifted.

■ 102. Revise the last sentence of § 270.7(a) to read as follows:

§ 270.7 Penalties and responsibility for compliance.

(a) * * * FRA's website at *www.fra.dot.gov* contains a schedule of civil penalty amounts used in connection with this part.

* * * * *

Appendix A to Part 270—[Removed and Reserved]

■ 103. Remove and reserve appendix A to part 270.

■ 104. Title 49 CFR part 270 is stayed until September 4, 2019.

PART 272—[AMENDED]

■ 105. The authority citation for part 272 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20109, note; 28 U.S.C. 2461, note; 49 CFR 1.89; and sec. 410, Div. A, Pub. L. 110–432, 122 Stat. 4888.

Appendix A to Part 272—[Removed]

■ 106. Remove appendix A to part 272.

Issued in Washington, DC.

Ronald L. Batory,

Administrator.

[FR Doc. 2019–09979 Filed 5–22–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 170831849–8404–01]

RIN 0648–XG904

Fisheries Off West Coast States; Modifications of the West Coast Recreational and Commercial Salmon Fisheries; Inseason Actions #1 Through #5

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

ACTION: Modification of fishing seasons.

SUMMARY: NMFS announces five inseason actions in the ocean salmon fisheries. These inseason actions modified the commercial and recreational salmon fisheries in the area from Cape Falcon, OR, to Pigeon Point, CA.

DATES: The effective dates for the inseason actions are set out in this document under the heading Inseason Actions.

FOR FURTHER INFORMATION CONTACT: Peggy Mundy at 206–526–4323.

SUPPLEMENTARY INFORMATION:

Background

In the 2018 annual management measures for ocean salmon fisheries (83

FR 19005, May 1, 2018), NMFS announced management measures for the commercial and recreational fisheries in the area from Cape Falcon, OR, to the U.S./Mexico border, effective from 0001 hours Pacific Daylight Time (PDT), May 1, 2018, until the effective date of the 2019 management measures, as published in the **Federal Register** (84 FR 19729, May 6, 2019). NMFS is authorized to implement inseason management actions to modify fishing seasons and quotas as necessary to provide fishing opportunity while meeting management objectives for the affected species (50 CFR 660.409). Inseason actions in the salmon fishery may be taken directly by NMFS (50 CFR 660.409(a)—Fixed inseason management provisions) or upon consultation with the Pacific Fishery Management Council (Council) and the appropriate State Directors (50 CFR 660.409(b)—Flexible inseason management provisions). The state management agencies that participated in the consultations described in this document were: California Department of Fish and Wildlife (CDFW) and Oregon Department of Fish and Wildlife (ODFW).

The annual salmon management cycle begins May 1 and continues through April 30 of the following year. As described in the final rule for 2019 ocean salmon management measures (84 FR 19729, May 6, 2019), the April Council meeting in 2019 occurred too late to allow enough time for NMFS to review, approve, and implement the Council's recommended management measures by May 1. Therefore, the rule implementing the salmon fishery management measures in 2018 (84 FR 19005, May 1, 2018) remained in effect from May 1, 2018, until the effective date of this 2019 rule, May 6, 2019. Fisheries scheduled to begin before May 6, 2019, were conducted under the 2018 management measures for the May 1 to May 6 time period. All five inseason actions in this document apply to management measures implemented through the 2018 rule (83 FR 19005, May 1, 2018).

Inseason Actions

Inseason Action #1

Description of the action: Inseason action #1 postponed the starting date for commercial salmon fisheries in the area from Cape Falcon, OR, to Humbug Mountain, OR, and in the area from Humbug Mountain, OR, to the Oregon/California border, previously scheduled to open on March 15, 2019, to April 20, 2019.

Effective dates: Inseason action #1 took effect on March 15, 2019, and remained in effect until May 6, 2019.

Reason and authorization for the action: The purpose of inseason action #1 was to limit fishery impacts on age-4 Klamath River fall-run Chinook salmon (KRFC) in order to meet Endangered Species Act (ESA) requirements for threatened California Coastal Chinook salmon (CCC). NMFS' ESA biological opinion on Council-managed salmon fisheries limits fishery impacts to no more than 16 percent ocean harvest rate on age-4 KRFC as a surrogate for CCC. The NMFS West Coast Regional Administrator (RA) considered Chinook salmon forecasts and anticipated fishery impacts for 2019 and determined that this inseason action was necessary to meet management and conservation objectives. Inseason modification of fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #1 occurred on March 11, 2019. Representatives from NMFS, ODFW, CDFW, and the Council participated in this consultation.

Inseason Action #2

Description of the action: Inseason action #2 cancelled the commercial salmon fishery from Horse Mountain, CA, to Point Arena, CA, that was previously scheduled to open April 16 through 30, 2019.

Effective dates: Inseason action #2 took effect April 16, 2019, and remained in effect until May 6, 2019.

Reason and authorization for the action: The purpose of inseason action #2 was to limit fishery impacts on age-4 KRFC, as described above in inseason action #1. The RA considered Chinook salmon forecasts and anticipated fishery impacts for 2019 and determined that this inseason action was necessary to meet management and conservation objectives. Inseason modification of fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #2 occurred on March 11, 2019. Representatives from NMFS, ODFW, CDFW, and the Council participated in this consultation.

Inseason Action #3

Description of the action: Inseason action #3 postponed the starting date for recreational salmon fisheries in the area from Horse Mountain, CA, to Point Arena, CA, and in the area from Point Arena, CA, to Pigeon Point, CA, previously scheduled to open on April 6, 2019, to April 13, 2019.

Effective dates: Inseason action #3 took effect on April 6, 2019, and remained in effect until May 1, 2019.

Reason and authorization for the action: The purpose of inseason action #3 was to limit fishery impacts on age-4 KRFC, as described above in inseason action #1, endangered Sacramento River winter-run Chinook salmon and overfished Sacramento River fall-run Chinook salmon (SRFC). The RA considered Chinook salmon forecasts and anticipated fishery impacts for 2019 and determined that this inseason action was necessary to meet management and conservation objectives. Inseason modification of fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #3 occurred on March 11, 2019. Representatives from NMFS, ODFW, CDFW, and the Council participated in this consultation.

Inseason Action #4

Description of the action: Inseason action #4 postponed the starting date for commercial salmon fisheries in the area from Cape Falcon, OR, to Humbug Mountain, OR, and in the area from Humbug Mountain, OR, to the Oregon/California border, previously scheduled to open May 4, under the 2018 rule, to May 6 in 2019.

Effective dates: Inseason action #4 took effect on May 4, 2019, and remained in effect until May 6, 2019.

Reason and authorization for the action: The purpose of inseason action #4 was to limit fishery impacts on overfished KRFC, overfished SRFC, and ESA-listed CCC. The RA considered Chinook salmon forecasts and anticipated fishery impacts for 2019 and determined that this inseason action was necessary to meet management and conservation objectives. Inseason modification of fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #4 occurred on April 15, 2019. Representatives from NMFS, ODFW, CDFW, and the Council participated in this consultation.

Inseason Action #5

Description of the action: Inseason action #5 postponed the starting date for the commercial salmon fishery in the area from the Oregon/California border to Humboldt South Jetty, CA, previously scheduled to open May 1, under the 2018 rule, to June 1 in 2019.

Effective dates: Inseason action #5 took effect on May 1, 2019, and remained in effect until May 6, 2019.

Reason and authorization for the action: The purpose of inseason action #3 was to limit fishery impacts on overfished KRFC, overfished SRFC, and ESA-listed CCC. The RA considered Chinook salmon forecasts and anticipated fishery impacts for 2019 and determined that this inseason action was necessary to meet management and conservation objectives. Inseason modification of fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #5 occurred on April 15, 2019. Representatives from NMFS, ODFW, CDFW, and the Council participated in this consultation.

All other restrictions and regulations remain in effect as announced for the 2018 ocean salmon fisheries and 2019 salmon fisheries opening prior to May 6, 2019 (83 FR 19005, May 1, 2018), and as modified by prior inseason actions.

The RA determined that the best available information indicated that Chinook salmon abundance forecasts and expected fishery effort in 2019 supported the above inseason actions recommended by the states of Oregon and California. The states manage the fisheries in state waters adjacent to the areas of the U.S. exclusive economic zone consistent with these federal actions. As provided by the inseason notice procedures of 50 CFR 660.411, actual notice of the described regulatory action was given, prior to the time the action was effective, by telephone hotline numbers 206–526–6667 and 800–662–9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF–FM and 2182 kHz.

Classification

NOAA's Assistant Administrator (AA) for NMFS finds that good cause exists for this notification to be issued without affording prior notice and opportunity for public comment under 5 U.S.C. 553(b)(B) because such notification would be impracticable. As previously noted, actual notice of the regulatory action was provided to fishers through telephone hotline and radio notification. This action complies with the requirements of the annual management measures for ocean salmon fisheries (83 FR 19005, May 1, 2018), the Pacific Coast Salmon Fishery Management Plan (FMP), and regulations implementing the FMP under 50 CFR 660.409 and 660.411. Prior notice and opportunity for public comment was impracticable because NMFS and the state agencies had insufficient time to provide for prior notice and the opportunity for public comment between the time Chinook salmon catch and effort projections and abundance forecasts were developed and fisheries impacts were calculated, and the time the fishery modifications had to be implemented in order to ensure that fisheries are managed based on the best available scientific information, ensuring that conservation objectives and limits for impacts to salmon species listed under the ESA are not exceeded. The AA also finds good cause to waive the 30-day delay in effectiveness required under 5 U.S.C. 553(d)(3), as a delay in effectiveness of this action would allow fishing at levels inconsistent with the goals of the FMP and the current management measures.

This action is authorized by 50 CFR 660.409 and 660.411 and is exempt from review under Executive Order 12866.

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

Dated: May 20, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–10808 Filed 5–22–19; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 100
Thursday, May 23, 2019

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0389; Product Identifier 2018–SW–035–AD]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2018–10–07, which applies to Sikorsky Aircraft Corporation (Sikorsky) Model S–76C helicopters. AD 2018–10–07 requires inspecting the engine collective position transducer (CPT). Since we issued AD 2018–10–07, we determined that an additional part-numbered engine CPT is affected by the same unsafe condition. This proposed AD would retain the requirements of AD 2018–10–07 and expand the applicability to include the additional engine CPT. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by July 8, 2019.

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

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

For service information identified in this NPRM, contact your local Sikorsky Field Representative or Sikorsky's Service Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800-Winged-S or 203–416–4299; email *wcs_cust_service_eng.gr-sik@lmco.com.* Operators may also log on to the Sikorsky 360 website at *https://www.sikorsky360.com.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0389; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Nick Rediess, Aerospace Engineer, Boston ACO Branch, Compliance & Airworthiness Division, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7159; email: *nicholas.rediess@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0389; Product Identifier 2018–SW–035–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued AD 2018–10–07, Amendment 39–19282 (83 FR 23355, May 21, 2018), (''AD 2018–10–07''), for Sikorsky Model S–76C helicopters with a Turbomeca, S.A., Arriel 2S1 or Arriel 2S2 engine with an engine CPT part number (P/N) 76900–01821–104 installed. AD 2018–10–07 requires initial and recurring inspections of each CPT by measuring resistance, linearity resistance movement, and differential voltage, and depending on the outcome of the inspections, replacing the CPT. AD 2018–10–07 resulted from 20 reports of One Engine Inoperative (OEI) incidents resulting from wear of an engine CPT. We issued AD 2018–10–07 to detect wear of a CPT prior to it causing an OEI condition and possible emergency landing.

Actions Since AD 2018–10–07 Was Issued

Since AD 2018–10–07 was issued, Sikorsky has introduced CPT P/N 76900–01821–105. While this part is expected to be an improvement over CPN P/N 76900–01821–104 in regard to the frequency of the potential unsafe condition, there is not enough service history on this new part to indicate that it will eliminate the unsafe condition.

This NPRM would retain the requirements of AD 2018–10–07 and would expand the applicability to include engine CPT P/N 76900–01821–105. Inspections of engine CPT P/N 76900–01821–105 are necessary since it is subject to the same unsafe condition as P/N 76900–01821–104 due to design similarity.

Related Service Information Under 1 CFR Part 51

We reviewed Sikorsky S–76 Helicopter Alert Service Bulletin (ASB) 76–73–8, Revision A, dated December 4, 2015 (ASB 76–73–8A), which specifies a one-time inspection of total resistance, linearity resistant movement, excitation voltage, and differential voltage of the CPTs using CPT Test Box P/N 76700–40009–042.

We reviewed Sikorsky Maintenance Manual, SA 4047–76C–2, Temporary Revision No. 73–07, dated August 17, 2016 (TR 73–07), which specifies removing, installing, and adjusting the CPTs, and inspecting total resistance,

linearity resistant movement, excitation voltage, and differential voltage of the CPTs. TR 73–07 also divides the procedures by CPT Test Box P/N by providing separate procedures for test boxes modified by Sikorsky Special Service Instructions (SSI) No. 76–96, dated August 19, 2016, which is not incorporated by reference in this AD.

We also reviewed Sikorsky Maintenance Manual, SA 4047–76C–2, Temporary Revision No. 73–08, dated September 20, 2017 (TR 73–08), which updates the procedures in TR 73–07. TR 73–08 does not divide the procedures by CPT Test Box P/N as it eliminates the procedures for CPT Test Box P/N 76700–40009–042. TR 73–08 omits obsolete figures and it provides inspection results as pass or fail.

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

Other Related Service Information

We reviewed Sikorsky S–76 Helicopter ASB 76–73–8, Basic Issue, dated August 21, 2015 (ASB 76–73–8). ASB 76–73–8 contains the same procedures as ASB 76–73–8A; however, ASB 76–73–8A updates Sikorsky's contact information for submitting a purchase order.

We also reviewed Sikorsky SA 4047–76C–2–1, Temporary Revision No. 5–181, dated August 21, 2015 (TR 5–181); Task 5–20–00 of Sikorsky Airworthiness Limitations and Inspection Requirements, Publication No. SA 4047–76C–2–1, Revision 24, dated December 15, 2015 (Task 5–20–00); and Section 73–22–04 of Chapter 73 Engine Fuel and Control, of Sikorsky Maintenance Manual, SA 4047–76C–2, Revision 31, dated December 15, 2015 (Section 73–22–04). TR 5–181 specifies adding CPT inspections referenced in Section 73–22–04 to the 300-hour inspection checklist contained in Task 5–20–00.

We reviewed Sikorksy Safety Advisory No. SSA–S76–11–0002, dated May 17, 2011. This service information provides precautionary instructions to minimize hazardous situations that might result from an unreliable CPT.

We also reviewed Sikorsky SSI No. 76–96, dated August 19, 2016, which contains procedures to modify CPT Test Box P/N 76700–40009–042 and re-identify it as P/N 76700–40009–043. This one-time modification reduces the instructions to inspect the CPT and improves the inspection accuracy.

We reviewed Sikorsky SSI No. 76–87, dated July 24, 2015, and SSI No. 76–87A, Revision A, dated August 21, 2015. These SSIs specify a one-time inspection of total resistance, linearity resistant movement, excitation voltage, and differential voltage of the CPTs using CPT Test Box P/N 76700–40009–042.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would retain all of the requirements of AD 2018–10–07, but would add engine CPT P/N 76900–01821–105 to the applicability.

Differences Between This Proposed AD and the Service Information

Sikorsky ASB 76–73–8A, TR 73–07, and TR 73–08 specify using and returning Sikorsky's CPT data sheet and any failed CPT to Sikorsky. This proposed AD would not.

Interim Action

We consider this proposed AD to be an interim action. The design approval holder is currently developing a modification that will address the unsafe condition identified in this proposed AD. Once this modification is developed, approved, and available, we might consider additional rulemaking.

Costs of Compliance

We estimate that this proposed AD affects 115 helicopters of U.S. registry. We estimate the following costs to comply with this proposed AD. Labor costs are estimated at $85 per work-hour.

The inspections would take about 3.75 work-hours for an estimated cost of $319 per helicopter and $36,685 for the U.S. fleet per inspection cycle. Replacing a CPT would take about 6 work-hours and parts would cost $3,072 for an estimated replacement cost of $3,582.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2018–10–07, Amendment 39–19282 (83 FR 23355, May 21, 2018), and adding the following new AD:

Sikorsky Aircraft Corporation: Docket No. FAA–2019–0389; Product Identifier 2018–SW–035–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by July 8, 2019.

(b) Affected ADs

This AD replaces AD 2018–10–07, Amendment 39–19282 (83 FR 23355, May 21, 2018).

(c) Applicability

This AD applies to Sikorsky Aircraft Corporation Model S–76C helicopters, certificated in any category, with a Turbomeca, S.A., Arriel 2S1 or Arriel 2S2 engine with an engine collective position transducer (CPT) part number (P/N) 76900–01821–104 or 76900–01821–105 installed.

(d) Subject

Joint Aircraft System Component (JASC): 7300, Engine Fuel and Control.

(e) Unsafe Condition

This AD was prompted by reports of wear of the CPT that has resulted in several One Engine Inoperative (OEI) incidents. We are issuing this AD to prevent failure of a CPT. The unsafe condition, if not addressed, could result in a reduction in power to one engine resulting in an annunciated momentary OEI condition and subsequent emergency landing.

(f) Compliance

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

(g) Required Actions

(1) Within 130 hours time-in-service (TIS):

(i) Measure resistance of each engine CPT and replace the CPT if the measured resistance is not within tolerance by following the Accomplishment Instructions, paragraphs 3.C.(1) through 3.C.(8)(b), of Sikorsky S–76 Helicopter Alert Service Bulletin ASB 76–73–8, Revision A, dated December 4, 2015 (ASB 76–73–8A), if using Test Box P/N 76700–40009–042 or by following paragraph 3.B.(11) of Sikorsky Maintenance Manual, SA 4047–76C–2, Temporary Revision No. 73–08, dated September 20, 2017 (TR 73–08), if using Test Box P/N 76700–40009–043. You are not required to use Sikorsky's CPT data sheet or submit a data sheet to Sikorsky.

(ii) Measure the linearity resistance movement of each engine CPT and replace the CPT if there is a linear abnormality or change in resistance that is not within tolerance by following the Accomplishment Instructions, paragraphs 3.D.(1) through 3.D.(14)(b), of ASB 76–73–8A, if using Test Box P/N 76700–40009–042 or by following paragraph 3.B.(12) of TR 73–08, if using Test Box P/N 76700–40009–043. You are not required to use Sikorsky's CPT data sheet or submit a data sheet to Sikorsky.

(iii) Measure the differential voltage of each engine CPT and replace the CPT if the measured voltage is not within tolerance by following the Accomplishment Instructions, paragraphs 3.E. through 3.G.(1) of ASB 76–73–8A, if using Test Box P/N 76700–40009–042 or by following paragraph 3.B.(13) of TR 73–08, if using Test Box P/N 76700–40009–043. You are not required to use Sikorsky's CPT data sheet or submit a data sheet to Sikorsky.

(2) Thereafter, at intervals not to exceed 300 hours TIS:

(i) If using Test Box P/N 76700–40009–042:

(A) Measure resistance of each engine CPT and replace the CPT if the resistance is not within tolerance by following paragraph 4.B.(11) of Sikorsky Maintenance Manual, SA 4047–76C–2, Temporary Revision No. 73–07, dated August 17, 2016 (TR 73–07), except you are not required to use Sikorsky's CPT data sheet or return a failed CPT to Sikorsky.

(B) Measure the linearity resistance movement of each engine CPT and replace the CPT if the movement exceeds tolerance by following paragraphs 4.B.(12)(a) through 4.B.(13)(f) of TR 73–07, except you are not required to use Sikorsky's CPT data sheet or return a failed CPT to Sikorsky.

(C) Measure the differential voltage of each CPT by following paragraphs 4.B.(14) through 4.B.(15)(h) of TR 73–07, except you are not required to use Sikorsky's CPT data sheet. If the maximum voltage is greater than 100 millivolts or the minimum voltage is less than −100 millivolts, replace the CPT.

(ii) For helicopters using Test Box P/N 76700–40009–043:

(A) Measure resistance of each engine CPT and replace the CPT if the resistance is not within tolerance by following paragraph 5.B.(11) of TR 73–07 or paragraph 3.B.(11) of TR 73–08, except you are not required to use Sikorsky's CPT data sheet or return a failed CPT to Sikorsky.

(B) Measure the resistance linearity of each engine CPT and replace the CPT if the resistance is not within tolerance by following paragraph 5.B.(12) of TR 73–07 or paragraph 3.B.(12) of TR 73–08, except you are not required to use Sikorsky's CPT data sheet or return a failed CPT to Sikorsky.

(C) Measure the differential voltage of each engine CPT and replace the CPT if the resistance is not within tolerance by following paragraphs 5.B.(13)(a) through 5.B.(13)(k) of TR 73–07 or paragraph 3.B.(13) of TR 73–08, except you are not required to use Sikorsky's CPT data sheet or return a failed CPT to Sikorsky.

(h) Credit for Previous Actions

Actions accomplished before the effective date of this AD in accordance with the procedures specified in Sikorsky S–76 Helicopter Alert Service Bulletin ASB 76–73–8, Basic Issue, dated August 21, 2015; Sikorsky Special Service Instruction SSI No. 76–87, dated July 24, 2015; or Sikorsky Special Service Instruction SSI No. 76–87, Revision A, dated August 21, 2015, are considered acceptable for compliance with the corresponding actions specified in paragraph (g)(1) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD.

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

(j) Related Information

(1) For more information about this AD, contact Nick Rediess, Aerospace Engineer, Boston ACO Branch, Compliance & Airworthiness Division, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7159; email: *nicholas.rediess@faa.gov.*

(2) For service information identified in this AD, contact your local Sikorsky Field Representative or Sikorsky's Service Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800-Winged-S or 203–416–4299; email *wcs_cust_service_eng.gr-sik@lmco.com.* Operators may also log on to the Sikorsky 360 website at *https://www.sikorsky360.com.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Issued in Fort Worth, Texas, on May 15, 2019.

Helene Gandy,

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

[FR Doc. 2019–10772 Filed 5–22–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0113; Product Identifier 2017–NM–060–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposal to supersede Airworthiness Directive (AD) 2016–12–09, which applies to certain Airbus Model A330–200, –200 Freighter, and –300 series airplanes; and Model A340–200 and –300 series airplanes. This action revises the notice of proposed rulemaking (NPRM) by revising the compliance time for the modification of the inside center wing box (CWB). We are proposing this AD to address the unsafe condition on these products. Since these actions would impose an additional burden over those in the NPRM, we are reopening the comment

period to allow the public the chance to comment on these changes.

DATES: The comment period for the NPRM published in the **Federal Register** on February 26, 2018 (83 FR 8201), is reopened.

We must receive comments on this SNPRM by July 8, 2019.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, 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.

For the material identified in this SNPRM that will be incorporated by reference (IBR), contact the European Aviation Safety Agency (EASA), at Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *http://www.regulations.gov.*

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0113; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this SNPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206–231–3229.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0113; Product Identifier 2017–NM–060–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this SNPRM. We will consider all comments received by the closing date and may amend this SNPRM based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this SNPRM.

Discussion

We issued AD 2016–12–09, Amendment 39–18558 (81 FR 38573, June 14, 2016) (''AD 2016–12–09''). AD 2016–12–09 requires actions to address an unsafe condition on certain Airbus Model A330–200, –200 Freighter, and –300 series airplanes, and Model A340–200 and –300 series airplanes. AD 2016–12–09 requires removing fasteners, doing a rototest inspection of fastener holes, installing new fasteners, oversizing the holes and doing rototest inspections for cracks if necessary, and repairing any cracking that was found.

We issued an NPRM to amend 14 CFR part 39 by adding an AD to supersede AD 2016–12–09 that would apply to certain Airbus Model A330–200, –200 Freighter, and –300 series airplanes; and Model A340–200 and –300 series airplanes. The NPRM published in the **Federal Register** on February 26, 2018 (83 FR 8201) (''the NPRM''). The NPRM was prompted by reports that cracks were found on an adjacent hole of certain frames of the CWB. The NPRM proposed to require repetitive inspections of the fastener holes at frame (FR) 40, and, for certain airplanes, proposed to require a modification. The NPRM also proposed to provide an optional terminating action, for certain airplanes, which terminates the inspections.

Actions Since the NPRM was Issued

Since we issued the NPRM, we have determined that the compliance time for the modification of the inside CWB must be revised.

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0249, dated November 16, 2018 (''EASA AD 2018–0249'') (also referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Model A330–200, –200 Freighter, and –300 series airplanes; and Model A340–200 and –300 series airplanes. The MCAI states:

> During accomplishment of A330 Airworthiness Limitation Item (ALI) task 57–11–04 on the rear fitting of the Frame (FR) 40 between stringers (STR) 38 and STR39 on both left-hand (LH) and right-hand (RH) sides of the fuselage, cracks were found on an adjacent hole. After reaming at second oversize of the subject hole, the crack was still present. As a result of a sampling inspection program, additional crack findings were reported on this adjacent hole on other A330 and A340 aeroplanes.
>
> This condition, if not detected and corrected, could affect the structural integrity of the centre fuselage of the aeroplane.
>
> Prompted by these findings, Airbus issued the applicable Inspection [service bulletin] SB (at the time, all at original issue) to provide inspection instructions and, consequently, EASA issued AD 2014–0149 [which corresponds to FAA AD 2016–12–09] to require removal of the fasteners and repetitive special detailed inspections (SDI), including rototests, of fastener holes at FR40 vertical web above or below CWB lower panel reference on both LH and RH sides of the fuselage, and, depending on findings, accomplishment of the applicable corrective actions. That [EASA] AD did not apply to aeroplanes on which Airbus modification (mod) 55792 or mod 55306 had been embodied in production.
>
> After that [EASA] AD was issued, Airbus published SB A330–57–3115 Revision 01 and SB A340–57–4124 Revision 02, which introduced revised thresholds and intervals for the repetitive inspections of the inside CWB (above bottom skin). In addition, for certain aeroplanes, Airbus developed mod 206051, introducing reinforcement of the structural integrity of the inside CWB (above bottom skin) area, and published the applicable Modification SB (both original issue), which avoided the need for repetitive inspections for the inside of the CWB for those aeroplane. Airbus also published SB A330–57–3116 Revision 01 and SB A340–57–4125 Revision 01, to include aeroplanes in post-mod 44360 and post-mod 49202 configuration for inspections of the outside CWB (below bottom skin), and introduced revised thresholds and intervals for the repetitive inspections of the outside CWB, and to provide an alleviation of the number of holes to be inspected. The repetitive inspection program for aeroplanes in pre-mod 44360 configuration remained unchanged.
>
> Consequently, EASA issued AD 2017–0069 [which corresponds to the FAA NPRM], partially retaining the requirements of EASA AD 2014–0149, which was superseded, to require new repetitive SDI (which include rototests) of the fastener holes at FR40 of the inside and the outside CWB (above and

below bottom skin), and the implementation of the modification of the inside CWB.

Since that [EASA] AD was issued, Airbus finalised an inspection program for A330–200F aeroplanes and published SB A330–57–3116 Revision 02, SB A330–57–3132 Revision 01 and SB A330–57–3129 Revision 01 accordingly. Airbus also published the applicable Modification SB, introducing a lower threshold for the modification, which allows operation to the Extended Service Goal (ESG) objective without any additional inspections. For the same reason, Airbus issued SB A330–57–3115 Revision 02, SB A330–57–4124 Revision 03, SB A330–57–3130 Revision 01 and SB A340–57–4137 Revision 01, for aeroplanes in post-mod 206050 configuration. Finally, it was determined that the lower threshold for embodiment of the applicable Modification SB must be counted from aeroplane first flight, not since Airbus mod 206049 implementation, as previously indicated.

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2017–0069, which is superseded, extends the compliance time for A330–200F aeroplanes as no accomplishment instructions existed before, adds references to the latest Airbus SB revisions, introduces a window of embodiment for modification of the inside CWB, as well as a correction of the window of embodiment for the applicable Optional Modification SB.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0113.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2016–12–09, this proposed AD would retain certain of the requirements of AD 2016–12–09. Those requirements are referenced in EASA 2018–0249, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related IBR Material Under 1 CFR Part 51

EASA AD 2018–0249 describes procedures for repetitive inspections of the fastener holes at FR40 vertical web of the affected CWB lower panel area for any cracking, and on-condition actions; modification of the inside CWB and an optional terminating action (modification of fastener holes by cold-working), which terminates the repetitive inspections. On-condition actions include installing new fasteners, additional inspections, repair, and modification. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Comments

We gave the public the opportunity to participate in developing this proposed AD. We considered the comments received.

Request To Use the Latest Service Information

American Airlines (AAL) and Delta Airlines (DAL) requested that we use the latest service information in the NPRM. AAL also requested that we provide credit for earlier revisions of certain service information.

We agree with the commenters request. We have revised this proposed AD to refer to EASA AD 2018–0249, dated November 16, 2018, which specifies the latest service information required to complete the actions specified in this proposed AD. EASA AD 2018–0249 also provides credit for earlier revisions of the applicable service information.

Request To Remove Certain Language From the NPRM

DAL requested that we remove the ''pre-mod'' and ''post-mod'' language from the NPRM. DAL stated that paragraph (g) of the proposed AD (in the NPRM) defines accomplishment of repetitive inspections using Airbus Service Bulletin A330–57–3114, Airbus Service Bulletin A330–57–3115, Airbus Service Bulletin A330–57–3116, Airbus Service Bulletin A340–57–4123, Airbus Service Bulletin A330–57–4124, and Airbus Service Bulletin A340–57–4125. DAL stated that each subparagraph in paragraph (g) of the proposed AD (in the NPRM) tries to address the affected airplanes using language such as ''pre-mod 56306 and pre-mod 55792.''

DAL commented that it finds the pre-mod and post-mod language confusing and finds the effectivity in the service information more clear. DAL stated that in order to clarify the NPRM, it recommended that the NPRM state something such as, ''for A330–200 and -300 series airplanes as listed in the effectivity of the SB.'' DAL stated that it believes this clarification would also apply to paragraphs (m), (o), and (p) of the proposed AD (in the NPRM).

We agree to clarify. The intent of paragraph (g) of the proposed AD (in the NPRM) was to provide additional details about which service information was applicable for the specified actions in the proposed AD, including which service information applied to specific airplane configurations. Paragraphs (m), (o) and (p) of the proposed AD (in the NPRM) also specified the airplane configuration for which the specified actions are applicable, which was intended to help operators determine which actions were applicable to a given airplane.

As we stated previously, we have revised this proposed AD to refer to EASA AD 2018–0249, dated November 16, 2018, which specifies which actions are applicable for which airplane configurations. EASA AD 2018–0249 has redefined configurations and clarified the ''pre-mod'' and ''post-mod'' language.

Request To Remove the Word ''and'' From a Certain Paragraph in the Proposed AD

DAL requested that we remove the word ''and'' from paragraph (g)(1)(iii) of the proposed AD (in the NPRM) where it discusses accomplishment of Airbus Service Bulletin A330–57–3115 for airplanes ''in pre-mod 56306 and pre-mod 55792 configuration.'' DAL stated that normally the interpretation of the word ''and'' would mean those airplanes which are both pre-mod 56306 and pre-mod 55792. DAL commented that it has many airplanes in one group or the other, but no airplanes which are both pre-mod 56306 and pre-mod 55792.

DAL stated that its airplanes are specified in the effectivity paragraph of the service information, and it was able to determine that the ''and'' was intended to mean those airplanes which are either pre-mod 56306 or pre-mod 55792. DAL commented that EASA AD 2017–0069 refers to the modification numbers in the reason section of the service information, but thereafter refers to the service information effectivity, which avoids the confusion of the interpretation of ''and'' in the text.

We agree with the commenter's request. As we stated previously, we have revised this proposed AD to refer to EASA AD 2018–0249, dated November 16, 2018, which clarifies airplane configurations. EASA AD 2018–0249 does not include the language DAL commented on.

Request To Revise the Grace Period From 18 Months to 24 Months

DAL requested that we revise the grace period for the modification specified in paragraph (m) of the proposed AD (in the NPRM) from 18 months to 24 months. DAL stated that paragraph (m) of the proposed AD (in the NPRM) specifies to do the modification using Airbus Service Bulletin A330–57–3129, which calls for modification within the limits of the service information, or within a grace period of 18 months after the effective date of the AD. DAL commented that its hangar check visit interval is 24 months.

DAL stated that it believes that the hangar aviation maintenance technicians have more structural repair experience and that the quality of the work would be greater if the experienced hangar crew could do the work. DAL also stated that the grace period in table 1 to paragraph (h) of the proposed AD (in the NPRM) would also need to be revised.

We disagree with the commenter's request. The grace period, as part of the compliance time, is established by EASA to mitigate the unsafe condition. In developing the compliance time for this proposed AD action, we considered not only the safety implications of the identified unsafe condition, but the average utilization rate of the affected fleet, the practical aspects of an orderly modification of the fleet during regular maintenance periods, the availability of required parts, and the time necessary for the rulemaking process. The proposed compliance time following the effective date of the final rule was determined to be appropriate. We have not changed this proposed AD in this regard.

Request To Remove Paragraph (o)(1) of the Proposed AD (in the NPRM)

DAL requested paragraph (o)(1) of the proposed AD (in the NPRM) be removed. DAL stated that paragraph (o)(1) of the proposed AD (in the NPRM) addressed the modification of post-mod 44360 airplanes, which are those affected by the inspection in Airbus Service Bulletin A330–57–3116 and terminated by Airbus Service Bulletin A330–57–3132.

DAL also stated that paragraph (o)(1) of the proposed AD (in the NPRM) includes a provision that requires that the modification be accomplished within the applicable compliance times specified in paragraph (g)(1) of the proposed AD (in the NPRM), which is the repetitive inspection specified in Airbus Service Bulletin A330–57–3116. DAL commented that this means that the option to terminate exists only up to the limit specified in Airbus Service Bulletin A330–57–3116. DAL also commented that after the initial accomplishment of inspections specified in Airbus Service Bulletin A330–57–3116 and while doing the repetitive inspections specified in Airbus Service Bulletin A330–57–3116, the optional terminating action specified in Airbus Service Bulletin A330–57–3132 no longer exists. DAL stated that it does not find a similar requirement in EASA AD 2017–0069, and it is not clear about why such a requirement would be technically required.

We agree to clarify. Paragraph (o)(1) of the proposed AD (in the NPRM) describes an optional terminating action for a certain airplane configuration subject to repetitive inspections in accordance with paragraph (h) of the proposed AD (in the NPRM). This is the same action specified in paragraph (8) of EASA AD 2017–0069 (and paragraph (13) of EASA AD 2018–0249), which is part of the proposed requirements in paragraph (g) of this SNPRM. To address the unsafe condition, the modification specified in Airbus Service Bulletin A330–57–3132 must be accomplished at the time specified in Airbus Service Bulletin A330–57–3116, which describes a lower bound (limit) of flight cycles or flight hours since first flight of the airplane. Airbus Service Bulletin A330–57–3116 does not remove the option for the modification once an operator has begun doing the repetitive inspections on an airplane, but instead allows the option of doing the modification before further flight after an inspection is accomplished. We have not changed this proposed AD in this regard.

Request To Add Manufacturer Serial Numbers to the NPRM

DAL requested that we add manufacturer serial numbers to paragraph (q)(3) of the proposed AD (in the NPRM). DAL stated that the paragraph lists several Airbus Technical Dispositions, but it was unable to find those Airbus Technical Dispositions on the Airbus website. DAL also commented that its local Airbus representatives were unable to find those Airbus Technical Dispositions.

DAL stated that it submitted a request to Airbus and was told that these are individual repairs to individual airplanes per a telex. DAL stated that since the Airbus Technical Dispositions are not readily available, the inclusion of that Airbus Technical Dispositions specified in the NPRM would require each operator to submit a telex requesting clarification. DAL commented that if the NPRM is updated with a list of affected manufacturer serial numbers, each operator could review the list of manufacturer serial numbers, and if the operator does not have any manufacturer serial numbers on the list, the rest of the paragraph would not apply to the operator.

We agree with the commenter's request. We have revised paragraph (i) of this proposed AD to specify the affected manufacturer serial numbers for each Airbus Technical Disposition.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Certain changes described above expand the scope of the NPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Proposed Requirements of This SNPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2018–0249 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. As a result, EASA AD 2018–0249 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with the provisions specified in EASA AD 2018–0249, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information specified in EASA AD 2018–0249 that is required for compliance with EASA AD 2018–0249 will be available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0113 after the FAA final rule is published.

Costs of Compliance

We estimate that this proposed AD affects 103 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2016–12–09 ..	Up to 155 work-hours × $85 per hour = $13,175.	$0	Up to $13,175 ..	Up to $1,357,025.
New proposed actions	Up to 145 work-hours × $85 per hour = $12,325.	Up to $650	Up to $12,975 ...	Up to $1,336,425.

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
Up to 145 work-hours × $85 per hour = $12,325	Up to $621	Up to $12,946.

We estimate the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. We have no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 105 work-hours × $85 per hour = $8,925	Up to $22,488 ..	Up to $31,413.

Authority for This Rulemaking

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

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

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2016–12–09, Amendment 39–18558 (81 FR 38573, June 14, 2016), and adding the following new AD:

Airbus SAS: Docket No. FAA–2018–0113; Product Identifier 2017–NM–060–AD.

(a) Comments Due Date

We must receive comments by July 8, 2019.

(b) Affected ADs

This AD replaces AD 2016–12–09, Amendment 39–18558 (81 FR 38573, June 14, 2016) (''AD 2016–12–09'').

(c) Applicability

This AD applies to Airbus SAS Model airplanes identified in paragraphs (c)(1) through (c)(5) of this AD, certificated in any category, as identified in European Aviation Safety Agency (EASA) AD 2018–0249, dated November 16, 2018 (''EASA AD 2018–0249'').

(1) Model A330–201, –202, –203, –223, and –243 airplanes.

(2) Model A330–223F and –243F airplanes.

(3) Model A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes.

(4) Model A340–211, –212, and –213 airplanes.

(5) Model A340–311, –312, and –313 airplanes.

(d) Subject

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

(e) Reason

This AD was prompted by reports that cracks were found on an adjacent hole of certain frames of the center wing box (CWB) and a determination that the compliance time specified in AD 2016–12–09 for the modification of the inside CWB must be revised. We are issuing this AD to address cracking of certain holes of certain frames of the CWB, which could affect the structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2018–0249.

(h) Exceptions to EASA AD 2018–0249

(1) For purposes of determining compliance with the requirements of this AD: Where EASA AD 2018–0249 refers to its effective date or the effective date of EASA AD 2017–0069, this AD requires using the effective date of this AD.

(2) For purposes of determining compliance with the requirements of this AD: Where EASA AD 2018–0249 refers to the effective date of EASA AD 2014–0149, this AD requires using June 29, 2016 (the effective date of AD 2016–12–09).

(3) The ''Remarks'' section of EASA AD 2018–0249 does not apply to this AD.

(i) Reference to Manufacturer Serial Numbers for Airbus Technical Dispositions

Figure 1 to paragraph (i) of this AD identifies the Airbus Technical Dispositions specified in paragraph (9) of EASA AD 2018–0249 and their associated manufacturer serial numbers.

Figure 1 to paragraph (i) of this AD – *Airbus Technical Dispositions*

Airbus Technical Disposition	Manufacturer Serial Numbers (MSN)
Airbus Technical Disposition LR57D11023270	MSN 0176 through 0512 inclusive, 0522
Airbus Technical Disposition LR57D11023714	MSN 0176 through 0512 inclusive, 0522
Airbus Technical Disposition LR57D11029170	MSN 0001 through 0175 inclusive
Airbus Technical Disposition LR57D11029171	MSN 0001 through 0175 inclusive
Airbus Technical Disposition LR57D11029172	MSN 0176 through 0512 inclusive, 0522
Airbus Technical Disposition LR57D11029173	MSN 0176 through 0512 inclusive, 0522
Airbus Technical Disposition LR57D11030740	MSN 0001 through 0175 inclusive
Airbus Technical Disposition LR57D11030741	MSN 0001 through 0175 inclusive

(j) Terminating Action for AD 2016–12–09

Accomplishing the actions required by this AD terminates all requirements of AD 2016–12–09.

(k) No Reporting Requirement

Although the service information referenced in EASA AD 2018–0249 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (m)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC*): For any service information referenced in EASA AD 2018–0249 that contains RC procedures and tests: Except as required by paragraph (l)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(m) Related Information

(1) For information about EASA AD 2018–0249, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email *ADs@easa.europa.eu;* Internet

www.easa.europa.eu. You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this EASA AD at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. EASA AD 2018–0249 may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0113.

(2) For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206–231–3229.

Issued in Des Moines, Washington, on May 6, 2019.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–10654 Filed 5–22–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0335]

RIN 1625–AA00

Safety Zone; Fireworks Display, Delaware Bay, Lewes, DE

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on the waters of Delaware Bay off Lewes, DE, from 9 p.m. to 10 p.m. on July 4, 2019, during the Lewes, DE, Fireworks Display. The safety zone is necessary to ensure the safety of participant vessels, spectators, and the boating public during the event. This regulation prohibits persons and non-participant vessels from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port (COTP) Delaware Bay or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 24, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2019–0335 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email: If you have questions on this rule, call or email Petty Officer Thomas Welker, U.S. Coast Guard, Sector Delaware Bay, Waterways Management Division, Coast Guard; telephone (215) 271–4814, email *Thomas.j.welker@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On April 11, 2019, Schaefer Fireworks notified the Coast Guard that it will be conducting a fireworks display off Lewes, DE, from 9 p.m. to 10 p.m. on July 4, 2019. The display will be launched from a barge in Delaware Bay. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Delaware Bay (COTP) has determined that this temporary safety zone is necessary to provide safety during the fireworks display, and to ensure protection of participants, spectators and other boaters.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters. The Coast Guard proposes this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The COTP proposes to establish a temporary safety zone on the waters of Delaware Bay off Lewes, DE, during a fireworks display from a barge. The event is scheduled to take place between 9 p.m. and 10 p.m. on July 4, 2019. The safety zone will extend 350 yards around the barge, which will be anchored at approximate position latitude 38°47′12.07″ N, longitude 075°07′48.89″ W. No person or vessel will be permitted to enter, transit through, anchor in, or remain within the safety zone without obtaining permission from the COTP Delaware Bay or a designated representative. If authorization to enter, transit through, anchor in, or remain within the safety zone is granted by the COTP Delaware Bay or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP Delaware Bay or a designated representative. The Coast Guard will provide public notice of the safety zone by Local Notice to Mariners, Broadcast Notice to Mariners, and by on-scene actual notice from designated representatives. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

The impact of this rule is not significant for the following reasons: (1) The safety zone will not impact a navigational channel; (2) although persons and vessels may not enter, transit through, anchor in, or remain within the safety zone without authorization from the COTP Delaware Bay or a designated representative, they may operate in the surrounding area during the enforcement period; (3) persons and vessels will still be able to enter, transit through, anchor in, or remain within the regulated area if authorized by the COTP Delaware Bay or a designated representative; and (4) the Coast Guard will provide advance notification of the safety zone to the local maritime community by Local Notice to Mariners, Broadcast Notice to Mariners, or by on-scene actual notice from designated representatives.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations

that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule proposes a safety zone that will prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within a limited area on the navigable water in the Delaware Bay, during a fireworks display lasting approximately one hour. This rule is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A preliminary Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *http://www.regulations.gov/privacyNotice.*

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0335 to read as follows:

§ 165.T05–0335 Safety Zone; Fireworks, Delaware Bay, Lewes DE.

(a) *Location.* The following area is a safety zone: All waters of Delaware Bay off Lewes, DE within 350 yards of the fireworks barge anchored in approximate position latitude 38°47′12.07″ N, longitude 075°07′48.89″ W.

(b) *Definitions* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard petty officer, warrant or commissioned officer on board a Coast Guard vessel or on board a federal, state, or local law enforcement vessel assisting the Captain of the Port (COTP), Delaware Bay in the enforcement of the safety zone.

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

(2) To seek permission to enter or remain in the zone, contact the COTP or the COTP's representative via VHF–FM channel 16 or 215–271–4807. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(3) No vessel may take on bunkers or conduct lightering operations within the safety zone during its enforcement period.

(4) This section applies to all vessels except those engaged in law enforcement, aids to navigation servicing, and emergency response operations.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement period.* This zone will be enforced from approximately 9 p.m. to 10 p.m. on July 4, 2019.

Dated: May 10, 2019.

S.E. Anderson,

Captain, U.S. Coast Guard, Captain of the Port Delaware Bay.

[FR Doc. 2019–10791 Filed 5–22–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2018–0257; FRL–9993–98–Region 4]

Air Plan Approval; North Carolina: PSD Requirements for GHGs

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions dated July 30, 2012, and January 12, 2018, submitted by the State of North Carolina through the North Carolina Department of Environmental Quality (NCDEQ). These SIP revisions are related to the State's Prevention of Significant Deterioration (PSD) permitting program requirements for greenhouse gases (GHGs). This action is being proposed pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before June 24, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2018–0257 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Andres Febres, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Mr. Febres can be reached by telephone at (404) 562–8966 or via electronic mail at *febres-martinez.andres@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What action is the agency taking?

EPA received two SIP revisions from NCDEQ, dated July 30, 2012, and January 12, 2018, that include changes to North Carolina's SIP-approved air quality rule at 15 North Carolina Administrative Code (NCAC) 02D .0544—*Prevention of Significant Deterioration Requirements for Greenhouse Gases.*[1] [2] [3] The 2012 and 2018 revisions include several administrative and typographical changes to the rule, as well as a modification to the date associated with the incorporation by reference (IBR) of 40 CFR 51.166 that was initially meant to capture EPA's final action entitled ''Deferral for CO_2 Emissions From Bioenergy and Other Biogenic Sources Under the Prevention of Significant Deterioration (PSD) and Title V Programs'' (hereinafter referred to as the ''Biomass Deferral Rule'' and discussed in Section II.B, below). In a March 4, 2019, letter, North Carolina asked EPA to approve changes to the IBR-related paragraph in Section 0544, including the date modification, but to exclude the adoption of the Biomass Deferral Rule from the IBR.[4]

The 2018 submittal also seeks to remove the PSD requirements for major stationary sources based solely on their GHG emissions; add a new paragraph—paragraph (d)—regarding the global warming potential for GHGs; and re-letter several paragraphs in the rule due to the addition of the new paragraph (*e.g.,* changing paragraph (d) in the SIP-approved rule to paragraph (e)).[5] The revisions removing PSD requirements based solely on GHG emissions are in response to court decisions invalidating and vacating the Federal regulations that applied PSD permitting requirements to major sources based solely on their GHG emissions.[6] More

[1] EPA notes that the agency received the SIP revisions on August 3, 2012, and February 2, 2018, respectively.

[2] In the table of North Carolina regulations approved into the SIP at 40 CFR 52.1770(c), 15A NCAC 02D is referred to as ''Subchapter 2D Air Pollution Control Requirements.''

[3] The PSD permitting program is established in part C of title I of the CAA and applies in areas that meet the National Ambient Air Quality Standards (NAAQS)—''attainment areas''—as well as areas where there is insufficient information to determine if the area meets the NAAQS—''unclassifiable areas.'' EPA's regulations governing PSD implementation are located at 40 CFR 51.166 and 52.21.

[4] The March 4, 2019, supplemental letter is located in the docket for this proposed rulemaking.

[5] In North Carolina's January 12, 2018, SIP revision cover letter, the State also mentions changes to rule 15 NCAC 02D Section .0502—*Applicability,* which relates to title V permitting requirements for GHGs. This rule is mentioned because it was approved, together with Section .0544, by the North Carolina Rules Review Commission, but the redline strikeout changes were not include as part of the January12, 2018 SIP package. Additionally, North Carolina explains in its letter that they do not wish for EPA to review these changes because they are not part of the SIP but rather part of the State's title V operating permit program.

[6] *See Utility Air Regulatory Group (UARG)* v. *EPA,* 134 S. Ct. 2427 (2014); *Coalition for Responsible Regulation, Inc.* v. *EPA,* 606 Fed. Appx. 6, 7 (D.C. Cir. 2015).

detail on the court decisions is included in Section II, below.

EPA is proposing to approve the July 30, 2012, and January 12, 2018, SIP revisions as supplemented by the State's March 4, 2019, letter.[7] EPA's analysis of North Carolina's submittal and the reasoning for proposing approval is included in Section III, below.

II. Background

A. GHG Tailoring Rule

On January 2, 2011, GHG emissions were, for the first time, covered by the PSD and title V operating permit programs.[8] To establish a process for phasing in the permitting requirements for stationary sources of GHGs under the CAA's PSD and title V programs, on June 3, 2010, EPA published a final rule entitled ''Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule'' (hereinafter referred to as the ''GHG Tailoring Rule''). *See* 75 FR 31514. In Step 1 of the GHG Tailoring Rule, which began on January 2, 2011, EPA limited application of PSD and title V requirements to sources and modifications of GHG emissions, but only if they were subject to PSD or title V ''anyway'' due to their emissions of pollutants other than GHGs. These sources and modifications covered under Step 1 are commonly referred to as ''anyway sources'' and ''anyway modifications,'' respectively.

In Step 2 of the GHG Tailoring Rule, which applied as of July 1, 2011, the PSD and title V permitting requirements extended beyond the sources and modifications covered under Step 1 to apply to sources that were classified as major sources based solely on their GHG emissions or potential to emit GHGs. Step 2 also applied PSD permitting requirements to modifications of otherwise major sources that would increase only GHG emissions above the level in the Federal PSD regulations. EPA generally described the sources and modifications covered by PSD under Step 2 of the Tailoring Rule as ''Step 2 sources and modifications'' or ''GHG-only sources and modifications.''

Subsequently, EPA published Step 3 of the GHG Tailoring Rule on July 12, 2012. *See* 77 FR 41051. In this rule, EPA decided against further phase-in of the PSD and title V requirements for sources emitting lower levels of GHG emissions. Thus, the thresholds for determining PSD and title V applicability based on emissions of GHGs remained the same as established in Steps 1 and 2 of the Tailoring Rule.

On June 23, 2014, the U.S. Supreme Court addressed the application of stationary source permitting requirements to GHG emissions in *Utility Air Regulatory Group (UARG)* v. *EPA,* 134 S. Ct. 2427 (2014). The Supreme Court upheld EPA's regulation of GHG Step 1—or ''anyway'' sources—but held that EPA may not treat GHGs as air pollutants for the purpose of determining whether a source is a major source (or is undergoing a major modification) and thus require the source to obtain a PSD or title V permit. Therefore, the Court invalidated the PSD and title V permitting requirements for GHG Step 2 sources and modifications.

In accordance with the Supreme Court's decision, on April 10, 2015, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) issued an Amended Judgment vacating the regulations that implemented Step 2 of the GHG Tailoring Rule, but not the regulations that implement Step 1 of the GHG Tailoring Rule. *See Coalition for Responsible Regulation, Inc.* v. *EPA,* 606 Fed. Appx. 6, 7 (D.C. Cir. 2015). The Amended Judgment specifically vacated the EPA regulations under review (including 40 CFR 51.166(b)(48)(v) and 40 CFR 52.21(b)(49)(v)) ''to the extent they require a stationary source to obtain a PSD permit if greenhouse gases are the only pollutant (i) that the source emits or has the potential to emit above the applicable major source thresholds, or (ii) for which there is a significant emissions increase from a modification.'' *Id.* at 7–8.

EPA promulgated a good cause final rule on August 19, 2015, entitled ''Prevention of Significant Deterioration and Title V Permitting for Greenhouse Gases: Removal of Certain Vacated Elements.'' *See* 80 FR 50199 (August 19, 2015) (hereinafter referred to as the ''Good Cause GHG Rule''). The rule removed from the Federal regulations the portions of the PSD permitting provisions for Step 2 sources that were vacated by the D.C. Circuit (*i.e.,* 40 CFR 51.166(b)(48)(v) and 52.21(b)(49)(v)). EPA therefore no longer has the authority to conduct PSD permitting for Step 2 sources, nor can the Agency approve provisions submitted by a state for inclusion in its SIP providing this authority. On October 3, 2016, EPA proposed to revise provisions in the PSD permitting regulations applicable to GHGs to address the GHG applicability threshold for PSD in order to fully conform with *UARG* and the Amended Judgment, but those revisions have not been finalized. *See* 81 FR 68110.

B. Biomass Deferral Rule

On July 20, 2011, EPA finalized the Biomass Deferral Rule, which deferred for a period of three years, the application of PSD and Title V permitting requirements to carbon dioxide (CO_2) emissions from bioenergy and other biogenic stationary sources (also known as biogenic CO_2 emissions). *See* 76 FR 43490. During this three-year period, stationary sources that combust biomass and constructed or modified a facility would have avoided the application of PSD to biogenic CO_2 emissions resulting from construction or modification. The deferral applied only to biogenic CO_2 emissions and did not affect other GHGs emitted from the combustion of biomass fuel and decomposition of biogenic material or non-GHG pollutants. Additionally, the deferral only applied to biogenic CO_2 emissions in the PSD and Title V programs; it did not apply to any other EPA programs, such as the GHG Reporting Program.[9]

On July 12, 2013, the D.C. Circuit vacated the Biomass Deferral Rule, but on November 14, 2013, issued an order delaying the vacatur of the Biomass Deferral Rule until the United States Supreme Court made a final decision in the *UARG* case related to the GHG Tailoring Rule. *See Center for Biological Diversity* v. *EPA,* 722 F.3d 401. After a final decision was made by the Supreme Court on June 23, 2014, in *UARG,* EPA did not take formal action to remove the Biomass Deferral Rule from the CFR. Although the language of the Biomass Deferral Rule remains in place at 40 CFR 51.166(b)(48)(ii)(*a*), 52.21(b)(49)(ii)(a), 70.2(2), and 71.2(2), the deferral is no longer operative.

III. Analysis of State's Submittal

The proposed changes to the SIP-approved version of 15 NCAC 02D .0544 in the July 30, 2012, SIP revision include administrative edits to the rule and an update to the IBR date for 40 CFR 51.166 at Section .0544(n) (subsequently re-lettered to paragraph (o) in the January 12, 2018, SIP revision). The administrative changes include the correction of acronyms for New Source Review (NSR) found under paragraphs (a) and (b) of the rule, as well as the clarification of a reference to the ''owner or operator'' of a facility made in the last subparagraph of paragraph (m) (subsequently re-lettered

[7] Pursuant to the State's March 4, 2019, letter, EPA's proposed approval of the IBR date does not include the Biomass Deferral Rule. As discussed in Section III, below, EPA's proposed approval is also based on the State's interpretation of Section .0544(b)(1) included in a December 7, 2018, letter from NCDEQ.

[8] *See* 75 FR 17004 (April 2, 2010).

[9] See *https://www.epa.gov/ghgreporting* for information on the GHG Reporting Program.

to paragraph (n) in the January 12, 2018, SIP revision).

The change to the IBR date included in the July 30, 2012, SIP revision seeks to revise the date from August 2, 2010, to July 20, 2011. The State originally included this change to capture the promulgation of the Biomass Deferral Rule. However, because the Biomass Deferral Rule was subsequently vacated but no formal action was taken to remove the language from the Federal PSD regulations after the *UARG* decision, North Carolina decided to withdraw the change to the IBR date paragraph from the July 30, 2012, SIP revision through a letter dated January 16, 2015.[10] [11]

In its January 12, 2018, SIP revision, as supplemented by its March 4, 2019, letter, North Carolina seeks to make additional changes to Section .0544. Specifically, North Carolina seeks to: (1) Modify the language of .0544(a) in order to capture the effects of the *UARG* decision on PSD and title V permitting requirements for GHG-only, or Step 2, sources; (2) add a new paragraph to Section .0544—paragraph (d)—to automatically incorporate any changes to the Federal GHG global warming potentials; (3) re-letter certain paragraphs in Section .0544 due to the addition of paragraph (d); (4) make administrative edits to the section; and (5) modify the IBR paragraph to, among other things, change the IBR date of 40 CFR 51.166 to July 20, 2011. As discussed above, North Carolina's March 4, 2019, letter asks EPA to approve changes to the IBR-related paragraph in Section 0544, including the date modification, but to exclude the Biomass Deferral Rule from the IBR.

As previously mentioned, the *UARG* decision invalidated and vacated the PSD and title V permitting requirements for GHG-only, or Step 2, sources and modifications. North Carolina had previously adopted the GHG Tailoring Rule through the August 2, 2010, IBR date of 40 CFR 51.166 found in the current SIP-approved version of Section .0544(n). North Carolina's January 12, 2018, SIP revision seeks to add language to Section .0544 to capture the effects of the *UARG* decision. Specifically, North Carolina proposes to add the following language to paragraph (a) of Section .0544—''A major stationary source or major modification shall not be required to obtain a prevention of significant deterioration (PSD) permit on the sole basis of its greenhouse gases emissions.'' Given the *UARG* decision and the fact that the State is still being as stringent as the current Federal PSD requirements for GHGs, EPA is proposing to approve these changes.

Additionally, in the January 12, 2018, SIP revision, North Carolina adds paragraph (d) to Section .0544 in order to automatically incorporate any changes to the Federal GHG global warming potentials into the definition of ''subject to regulation'' incorporated by reference from 40 CFR 51.166(b)(48) that may occur after the IBR date. In order to determine if a source is subject to regulation for GHGs, a source's total GHG emissions are calculated using the global warming potentials published in Table A–1 of Subpart A of 40 CFR part 98.[12] North Carolina's revision ensures that any future changes EPA makes to Table A–1 are concurrently incorporated into the State's SIP-approved PSD program for greenhouse gases without the need for further SIP revisions. For this reason, EPA is proposing to incorporate paragraph (d) into the SIP. Furthermore, due to the addition of paragraph (d), the State seeks to re-letter the remaining paragraphs in the rule (*e.g.,* changing paragraph (e) in the SIP-approved rule to paragraph (f)). EPA is proposing to approve this organizational change.

Originally, the January 12, 2018, SIP revision also sought to re-letter the IBR paragraph at Section .0544(n) to paragraph (o) and revise the IBR date of 40 CFR 51.166 from August 2, 2010, to July 20, 2011, without exception. Because North Carolina had previously asked EPA not to approve the updates to the IBR paragraph submitted in the July 30, 2012, SIP revision, EPA requested clarification from the State on whether they want EPA to incorporate the changes to the IBR-related paragraph into the SIP. Subsequently, on December 7, 2018, North Carolina submitted a letter to EPA stating that it was not requesting that EPA approve paragraph (o) into the SIP because the Biomass Deferral Rule had expired and EPA had not taken action to remove the rule language from 40 CFR 51.166.

However, due to the re-lettering, approving the revisions to Section .0544 into the SIP without paragraph (o) could cause confusion for the general public and would create an inconsistency between the SIP-approved version and the state version of the rule. Therefore, North Carolina submitted the March 4, 2019, letter asking EPA to approve all changes to Section .0544 from its July 30, 2012, and January 12, 2018, SIP revisions, including the adoption of paragraph (o) with the IBR date update, but to exclude the adoption of the Biomass Deferral Rule language from the July 20, 2011, IBR of 40 CFR 51.166. Therefore, EPA is proposing to incorporate paragraph (o) into the SIP with this exclusion.[13]

Finally, the January 12, 2018 SIP revision also seeks to remove the term ''immediately'' from the following subparagraph (Section .0544(b)(1)) in the definition of ''baseline actual emissions'':

> For an existing emissions unit, baseline actual emissions means the average rate, in tons per year, at which the emissions unit actually emitted the pollutant during any consecutive 24-month period selected by the owner or operator within the 5-year period immediately preceding the date that a complete permit application is received by the Division for a permit required under this Rule. The Director shall allow a different time period, not to exceed 10 years immediately preceding the date that a complete permit application is received by the Division, if the owner or operator demonstrates that it is more representative of normal source operation. . . .

In the December 7, 2018, supplemental letter, the State explained that the term was eliminated as the result of a technical correction from the North Carolina Rules Review Commission to remove extraneous text throughout North Carolina's rules. North Carolina also stated that it intends to enforce subparagraph (b)(1) as if the term ''immediately'' were present in the rule. EPA's proposed action to incorporate the change is based on the State's interpretation of this subparagraph as explained in its December 7, 2018 letter.

All other changes to Section .0544 consist of administrative and typographical corrections that have no effect on how the PSD provisions for

[10] The January 16, 2015 letter is located in the docket for this proposed rulemaking.

[11] In a notice of proposed rulemaking (NPRM) published on April 19, 2013, EPA proposed to approve the IBR-related changes to Section .0544 in North Carolina's July 30, 2012, SIP revision to capture the Biomass Deferral Rule. EPA never took final action to approve those changes because of the July 12, 2013 vacatur of the Rule. Today's proposal supersedes the April 19, 2013, NPRM.

[12] GHGs, as defined in the definition of ''subject to regulation'' at 40 CFR 51.166(b)(48), is the aggregate of six different gases: Carbon dioxide, nitrous oxide, methane, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride. To calculate the total GHG emissions for a source: (1) The mass amount of emissions, in tons per year (tpy), of each individual GHG is multiplied by its global warming potential found in Table A–1 of Subpart A of 40 CFR 98, and (2) the resulting values for each individual GHG are added. This results in the total GHG emissions for the source expressed in tpy of CO_2 equivalent (tpy CO_2e).

[13] If EPA takes final action to approve the July 30, 2012, and the January 12, 2018, SIP revisions, it will place a note in the entry for Section .0544 in the table of North Carolina SIP-approved rules, at 40 CFR 52.1770(c), explaining that the Biomass Deferral Rule is excluded from the July 20, 2011 IBR of 40 CFR 51.166.

GHG would operate in the State. For all of the reasons discussed above, EPA proposes to incorporate the changes to Section .0544 into the North Carolina SIP from the July 30, 2012 and January 12, 2018, SIP revisions but exclude the Biomass Deferral Rule language from the IBR of 40 CFR 51.166.

IV. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference, under Subchapter 2D, *Air Pollution Control Requirements* of the North Carolina SIP, Section .0544—''Prevention of Significant Deterioration Requirements for Greenhouse Gases,'' state-effective September 1, 2015.[14] EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Proposed Action

EPA is proposing to approve North Carolina's July 30, 2012, and January 12, 2018, SIP revisions that revise the PSD requirements for GHGs under 15 NCAC 02D .0544—*Prevention of Significant Deterioration Requirements for Greenhouse Gases* as described above. Specifically, EPA is proposing to approve language under paragraph (a) that will prevent the regulation of GHG-only, or Step 2 sources; the adoption of new paragraph (d), regarding the definition of global warming potential for GHGs, and the re-lettering of Section .0544 following the new paragraph (d); the deletion of the term ''immediately'' from paragraph (b)(1); the adoption of paragraph (o), excluding incorporation of the Biomass Deferral Rule into the July 20, 2011 IBR of 40 CFR 51.166; and adoption of various administrative edits such as the addition of acronyms and typographical corrections throughout the rule. EPA believes that these changes are consistent with the requirements of the CAA.

VI. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: May 10, 2019.

Mary S. Walker,

Acting Regional Administrator, Region 4.

[FR Doc. 2019–10723 Filed 5–22–19; 8:45 am]

BILLING CODE 6560–50–P

[14] As discussed above, EPA is proposing to exclude the Biomass Deferral Rule from the July 20, 2011 IBR of 40 CFR 51.166, found in Section .0544(o).

Notices

Federal Register
Vol. 84, No. 100
Thursday, May 23, 2019

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Submission for Review

AGENCY: U.S. Agency for International Development (USAID).

ACTION: 30-Day notice and request for comments.

SUMMARY: The U.S. Agency for International Development (USAID) offers the general public and other federal agencies the opportunity to comment on an existing information collection request (ICR) Document 2019–04772, Research Technical Assistance Center (RTAC) Partner Pool Application. As required by the Paperwork Reduction Act of 1995, as amended by the Clinger-Cohen Act, USAID is soliciting comments for this collection. The information collection was published in the **Federal Register** on March 15, 2019, allowing for a 60-day public comment period.

No comments were received regarding the **Federal Register** Notice. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until June 24, 2019. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to: Desk Officer for USAID, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), 725 17th Street NW, Washington, DC 20503 or email address: OIRA *Submission@OMB.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Tara Hill, Acting Division Chief, HESN 2.0 Awards Management Division (USAID/Global Development Lab), *thill@usaid.gov* or 202–712–0589.

SUPPLEMENTARY INFORMATION: This agency information collection previously published at 84 FR 9476.

Analysis

Agency: USAID.
Title: Certification of Identity.
OMB Number: OMB 0412–0589.
Form Number: AID Form 507–1.
Affected Public: Individuals.
Number of Respondents: 600.
Estimated Total Annual Burden Hours: 50.

Note: The 60 Day Notice references incorrect information in III. Data for the *Title, OMB Number, Expiration Date,* and *Type of Request* section.

Coy A. Lindsay,

Records and Information Management Specialist, Bureau for Management Office of Management Services, Information and Records Division.

[FR Doc. 2019–10776 Filed 5–22–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Document No. AMS–SC–19–0044]

Notice of Request for Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Marketing Service's (AMS) intention to request for an extension and revision of a currently approved information collection for Specialty Crops Market News Division.

DATES: Comments must be received by July 22, 2019.

ADDRESSES: Interested persons are invited to submit written comments on the internet at *http://www.regulations.gov* or to Specialty Crops Market News Division, AMS, USDA, 1400 Independence Avenue SW, Room 1529 South, Stop 0238, Washington, DC 20250–0238. Comments should make reference to the dates and page number of this issue of the **Federal Register** and will be made available for public inspection in the above office during regular business hours or at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Terry C. Long, Director; Specialty Crops Market News Division, (202) 720–2175, Fax: (202) 720–0011.

SUPPLEMENTARY INFORMATION:

Title: Specialty Crops Market News Division.

OMB Number: 0581–0006.

Expiration Date of Approval: November 30, 2019.

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

Abstract: Collection and dissemination of information for specialty crops production and to facilitate trading by providing a price base used by producers, wholesalers, and retailers to market product.

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), section 203(g) directs and authorizes the collection and dissemination of marketing information including adequate outlook information, on a market area basis, for the purpose of anticipating and meeting consumer requirements, aiding in the maintenance of farm income and to bring about a balance between production and utilization.

The specialty crops industry provides information on a voluntary basis that is gathered through confidential telephone and face-to-face interviews by market reporters. Reporters request supply, demand, and price information of over 330 fresh fruit, vegetable, nut, ornamental, and other specialty crops, such as honey. The information is collected, compiled, and disseminated by Specialty Crops Market News Division in its critical role as an impartial third party. It is collected and reported in a manner which protects the confidentiality of the respondent and their operations.

The Specialty Crops Market News Division reports are used by academia and various government agencies for regulatory and other purposes, but are primarily used by the specialty crops trade, which includes packers, processors, brokers, retailers, producers, and associated industries. Members of the specialty crops industry regularly make it clear that they need and expect the Department of Agriculture to issue price and supply market reports for commodities of regional, national and

international significance in order to assist in making immediate production and marketing decisions and as a guide to the amount of product in the supply channel. In addition, the Agricultural Marketing Service buys hundreds of millions of dollars of specialty crops products each year for domestic feeding programs, and Specialty Crops Market News Division data is a critical component of the decision making process.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .101 hours per response.

Respondents: Specialty crops industry, or other for-profit businesses, individuals or households, farms.

Estimated Number of Respondents: 2,776.

Estimated Number of Responses per Respondent: 202.

Estimated Total Annual Burden on Respondents: 56,636 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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

Dated: May 20, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–10813 Filed 5–22–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FTPP–19–0043]

Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Marketing Service's (AMS) intention to request approval from the Office of Management and Budget (OMB) for an extension of a currently approved information collection for the Reporting and Recordkeeping Requirements Under Regulations Under the Perishable Agricultural Commodities Act, 1930, as amended.

DATES: Comments received by July 22, 2019 will be considered.

Additional Information or Comments: You may submit written or electronic comments to: Natalie Worku, PACA Recordkeeping and Reporting Comments, AMS, Fair Trade Practices Program, PACA Division, 1400 Independence Avenue SW, Room 1510–S, Stop 0242, Washington DC 20250–0242; fax: 202–690–4413; or internet: *http://www.regulations.gov.*

SUPPLEMENTARY INFORMATION:

Title: Reporting and Recordkeeping Requirements Under Regulations (Other than Rules of Practice) Under the Perishable Agricultural Commodities Act, 1930.

OMB Number: 0581–0031.

Expiration Date of Approval: November 30, 2019.

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

Abstract: The PACA was enacted by Congress in 1930 to establish a code of fair trading practices covering the marketing of fresh and frozen fruits and vegetables in interstate or foreign commerce. It protects growers, shippers, and distributors dealing in those commodities by prohibiting unfair and fraudulent trade practices.

The law provides a forum for resolving contract disputes, and a mechanism for the collection of damages from anyone who fails to meet contractual obligations. In addition, the PACA provides for prompt payment to fruit and vegetable sellers and for revocation of licenses and sanctions against firms or principals found to have violated the law's standards for fair business practices. The PACA also imposes a statutory trust that attaches to perishable agricultural commodities received by regulated entities, products derived from the commodities, and any receivables or proceeds from the sale of the commodities. The trust exists for the benefit of produce suppliers, sellers, or agents that have not been paid, and continues until they have been paid in full.

The PACA is enforced through a licensing system. All commission merchants, dealers, and brokers engaged in business subject to the PACA must be licensed. Retailers and grocery wholesalers must renew their licenses every three years. All other licensees renew yearly. Those who engage in practices prohibited by the PACA may have their licenses suspended or revoked.

The information collected pursuant to OMB Number 0581–0031 is used to administer licensing provisions under the PACA, to adjudicate contract disputes, and to enforce the PACA and the regulations. The purpose of this notice is to solicit comments from the public concerning our information collection.

We estimate the paperwork and time burden of the above referenced information collection to be as follows:

Form FTPP–211, Application for License: average of .25 hours per application per response.

Form FTPP–231–1 (or 231–1A, or 231–2, or 231–2A), Application for Renewal or Reinstatement of License: Average of .05 hours per application per response.

Regulations Section 46.13—Letters to Notify USDA of Changes in Business Operations: Average of .05 hours per notice per response.

Regulations Section 46.4—Limited Liability Company Articles of Organization and Operating Agreement: Average of .083 hours with approximately 2,968 annual responses.

Regulations Section 46.18—Record of Produce Received: Average of 5 hours with approximately 6,725 recordkeepers.

Regulations Section 46.20—Records Reflecting Lot Numbers: Average of 8.25 hours with approximately 683 recordkeepers.

Regulations Section 46.46(c)(2)—Waiver of Rights to Trust Protection: Average of .25 hours per notice with approximately 100 principals.

Regulations Sections 46.2(aa)(11) and 46.46(e)(1)—Copy of Written Agreement Reflecting Times for Payment: Average of 20 hours with approximately 2,343 recordkeepers.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 3 hours per response annually.

Respondents: Commission merchants, dealers, and brokers engaged in the business of buying, selling, or negotiating the purchase or sale of commercial quantities of fresh and/or frozen fruits and vegetables in interstate or foreign commerce are required to be licensed under the PACA (7 U.S.C. 499(c)(a)).

Estimated Number of Respondents: 13,600.

Estimated Total Annual Responses: 28,547.

Estimated Number of Responses per Respondent: 2.10 (rounded).

Estimated Total Annual Burden on Respondents: 87,409 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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

Dated: May 20, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–10812 Filed 5–22–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

May 20, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by June 24, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: 7 CFR 764, Direct Loan Making.

OMB Control Number: 0560–0237.

Summary of Collection: The Farm Loan Program (FLP) in the Farm Service Agency (FSA) provides loans to family farmers to purchase real estate and equipment and finance agricultural production. The regulation as specified in 7 CFR 764 covered by this collection describes the policies and procedures the agency uses to provide supervised credit to FLP applicants requesting direct loan assistance in accordance with the provisions of the Consolidated Farm and Rural Development Act (CONTACT) (Pub. L. 87–128), as amended. Direct loan making information collection requirements include financial and production records of the operation, as well as information necessary to obtain liens on collateral, provide evidence of the indebtedness, and ensure repayment of the loan.

Need and Use of the Information: Information is submitted by the applicants to the local agency office serving the county in which their business is headquartered. The information is necessary to thoroughly evaluate the applicant's request for a direct loan and is used by agency officials to: (1) Ensure that cash flow projections used in determining loan repayment are based on the actual production history of the operation, (2) Ensure that a loan is adequately secured; (3) Ensure the applicant meets the statutorily established program eligibility requirements; and (4) Obtain assignment on income or sales proceeds, when appropriate, to ensure timely repayment of the loans. Since the agency is mandated to provide supervised credit, failure to collect the information, or collecting it less frequently, could result in the failure of the farm operation or loss of agency security property.

Description of Respondents: Business or other for-profit; Farms.

Number of Respondents: 184,871.

Frequency of Responses: Reporting: On occasion; Annually.

Total Burden Hours: 280,094.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–10769 Filed 5–22–19; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Forest Service

Siskiyou (OR) Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meetings.

SUMMARY: The Siskiyou (OR) Resource Advisory Committee (RAC) will meet in Brookings, Oregon. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following website: *https://cloudapps-usda-gov.secure.force.com/FSSRS/RAC_Page?id=001t0000002Jcv6AAC.*

DATES: The meetings will be held on the following dates:

- Tuesday, June 11, 2019, from 1:00 p.m.–5:00 p.m.,
- Wednesday, June 12, 2019, from 8:00 a.m.–3:00 p.m., and
- Thursday, June 13, 2019, from 8:00 a.m.–3:00 p.m.

All RAC meetings are subject to cancellation. For updated status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meetings will be held at the Curry Campus of Southwestern Oregon Community College, in the Community Room #137, 96082 Lone Ranch Parkway, Brookings, Oregon.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses, when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Medford Interagency Office, 3040 Biddle Road, Medford, Oregon. Please call ahead at 541–618–2113 or email at *vgibbons@fs.fed.us* to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Virginia Gibbons RAC Coordinator, by phone at 541–618–2113 or by email at *vgibbons@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of these meetings are to:

1. Approve minutes from April 25, 2017 meeting;

2. Review projects previously authorized under Title II of the Secure Rural Schools (SRS) Act; and

3. Review, discuss, and recommend proposed Title II projects under the current SRS Act reauthorization.

The meetings are open to the public. The agendas will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by June 7, 2019, to be scheduled on the agendas for the June 11, 2019, June 12, 2019, and June 13, 2019 meetings. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meetings. Written comments and requests for time to make oral comments must be sent to Virginia Gibbons, RAC Coordinator, 3040 Biddle Road, Medford, Oregon 97504; by email to *vgibbons@fs.fed.us,* or by facsimile at 541–618–2144.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: May 16, 2019.

Frank Beum,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2019–10814 Filed 5–22–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Idaho Panhandle Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Idaho Panhandle Resource Advisory Committee (RAC) will meet in Coeur d'Alene, Idaho. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following website: *http://www.fs.usda.gov/main/ipnf/workingtogether/advisorycommittees.*

DATES: The meeting will be held on Friday, June 21, 2019, at 9:00 a.m.

All RAC meetings are subject to cancellation. For updated status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at the Idaho Panhandle National Forests Supervisor's Office, 3815 Schreiber Way, Coeur d'Alene, Idaho.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses, when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Idaho Panhandle National Forests Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Phillip Blundell, RAC Coordinator, by phone at 208–783–2101 or by email at *phillipblundell@usda.gov.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to:

1. Review project propsals;

2. Recommend projects to the Designated Federal Officer (DFO); and

3. Conduct any necessary administrative business.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by June 14, 2019. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Phillip Blundell, RAC Coordinator, Post Office Box 159, Smelterville, Idaho; by email to *phillipblundell@usda.gov,* or by facsimile at 208–783–2154.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: May 16, 2019.

Frank Beum,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2019–10816 Filed 5–22–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest Advisory Board

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Black Hills National Forest Advisory Board (Board) will meet in Rapid City, South Dakota. The Board is established consistent with the Federal Advisory Committee Act of 1972, the Forest and Rangeland Renewable Resources Planning Act of 1974, the National Forest Management Act of 1976, and the Federal Public Lands Recreation Enhancement Act. Additional information concerning the Board, including the meeting summary/minutes, can be found by visiting the Board's website at: *http://www.fs.usda.gov/main/blackhills/workingtogether/advisorycommittees.*

DATES: The meeting will be held on Wednesday, June 19, 2019, at 1:00 p.m.

All meetings are subject to cancellation. For updated status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at the Forest Service Center, 8221 Mount Rushmore Road, Rapid City, South Dakota.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the Black Hills National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Scott Jacobson, Committee Coordinator, by phone at 605–440–1409 or by email at *sjjacobson@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide:

(1) Orientation Topic: Timber Sale Program;

(2) District Updates;

(3) Mineral Withdrawal Botanical Area and Research Natural Area Working Group update;

(4) Motorized Trail Strategy Working Group update;

(5) Recreation Site Analysis (RSA) Working Group update; and

(6) August Field Trip.

The meeting is open to the public. If time allows, the public may make oral statements of three minutes or less. Individuals wishing to make an oral statement should submit a request in writing by June 10, 2019, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Board may file written statements with the Board's staff before or after the meeting. Written comments and time requests for oral comments must be sent to Scott Jacobson, Black Hills National Forest Supervisor's Office, 1019 North Fifth Street, Custer, South Dakota 57730; by email to *sjjacobson@fs.fed.us,* or via facsimile to 605–673–9208.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: May 16, 2019.

Frank Beum,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2019–10815 Filed 5–22–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the Fruits, Nuts, and Specialty Crops Surveys. Revision to burden hours will be needed due to changes in the size of the target population, sample design, minor changes in questionnaire design, the addition of several reimbursable surveys and discontinuation of several specialty commodity surveys due to revisions warranted by the 2017 Census of Agriculture.

DATES: Comments on this notice must be received by July 22, 2019 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0039, by any of the following methods:

- *Email: omboffICer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E-fax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–2707. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at *omboffICer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Fruits, Nuts, and Specialty Crops Surveys.

OMB Control Number: 0535–0039.

Expiration Date of Approval: October 31, 2019.

Type of Request: To revise and extend a currently approved information collection for a period of three years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare and issue State and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture and also to conduct the Census of Agriculture.

The Fruits, Nuts, and Specialty Crops survey program collects information on acreage, yield, production, price, and value of citrus and non-citrus fruits and nuts and other specialty crops in States with significant commercial production. The program provides data needed by the U.S. Department of Agriculture and other government agencies to administer programs and to set trade quotas and tariffs. Producers, processors, other industry representatives, State Departments of Agriculture, and universities also use forecasts and estimates provided by these surveys. All questionnaires included in this information collection will be voluntary.

The changes that were made to the fruit and nut commodity surveys at NASS can be found on the NASS website *https://www.nass.usda.gov/Surveys/Program_Review/2019/Noncitrus-Fruit-and-Tree-Nut-Program.pdf.*

The changes that were made to other programs can be found at *https://www.nass.usda.gov/Surveys/Program_Review/index.php.*

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork

Reduction Act of 1995 (Pub. L. 104–113) and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

Estimate of Burden: Public reporting burden for this information collection is based on approximately 55 individual surveys with expected response times of 5–60 minutes. The frequency of data collection for the different surveys will include annual, seasonal, quarterly, monthly, and one weekly survey. Estimated number of responses per respondent is 1.1. Publicity materials and instruction sheets will account for approximately 5 minutes of additional burden per respondent. Respondents who refuse to complete a survey will be allotted 2 minutes of burden per attempt to collect the data. Several new surveys have been added to this information collection to account for some specialty commodities conducted under cooperative agreements with several States.

Respondents: Producers, processors, and handlers.

Estimated Number of Respondents: 75,000.

Estimated Total Annual Burden on Respondents: 26,000 hours.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

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

Signed at Washington, DC, May 2, 2019.

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2019–10782 Filed 5–22–19; 8:45 am]

BILLING CODE 3410–20–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Nevada Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Nevada Advisory Committee (Committee) to the Commission will be held at 2:00 p.m. (Pacific Time) Thursday, May 30, 2019, the purpose of meeting is for the Committee to debrief the May 3, 2019 Community Forum.

DATES: The meeting will be held on Thursday, May 30, 2019 at 2:00 p.m. PT.

Public Call Information: Dial: 877–260–1479, Conference ID: 6760059.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 877–260–1479, conference ID number: 6760059. Any interested member of the public may call this number and listen to the meeting. 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. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlJAAQ.*

Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Approval of Minutes for May 3, 2019 Community Forum
III. Debrief May 3 Community Forum
IV. Discuss Report Writing Schedule
V. Public Comment
VI. Next Steps
VII. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstances of the federal government shutdown.

Dated: May 18, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–10758 Filed 5–22–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–36–2019]

Foreign-Trade Zone (FTZ) 7—Mayaguez, Puerto Rico, Notification of Proposed Production Activity, Bristol-Myers Squibb Holdings Pharma, Ltd. (Pharmaceuticals), Manati, Puerto Rico

Bristol-Myers Squibb Holdings Pharma, Ltd. (BMS) submitted a notification of proposed production activity to the FTZ Board for its facility in Manati, Puerto Rico. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on May 13, 2019.

BMS already has authority to produce certain pharmaceutical products within Subzone 7J. The current request would add finished products and a foreign status material/component to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status material/component and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt BMS from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, for the foreign-status material/component noted below and in the existing scope of authority, BMS would be able to choose the duty rates during customs entry procedures that apply to pegbelfermin in measured and finished dosages (duty-free). BMS would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The material/component sourced from abroad is pegbelfermin—active pharmaceutical ingredient (duty-free).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is July 2, 2019.

A copy of the notification will be available for public inspection in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Christopher Wedderburn at *Chris.Wedderburn@trade.gov* or (202) 482–1963.

Dated: May 17, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–10805 Filed 5–22–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–77–2018]

Foreign-Trade Zone (FTZ) 168—Dallas/Fort Worth, Texas, Authorization of Production Activity, Gulfstream Aerospace Corporation (Disassembly of Aircraft), Dallas, Texas

On December 7, 2018, the Metroplex International Trade Development Corporation, grantee of FTZ 168, submitted a notification of proposed production activity to the FTZ Board on behalf of Gulfstream Aerospace Corporation, within Subzone168E, in Dallas, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (83 FR 64517–64518, December 17, 2018). On May 16, 2019, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: May 16, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–10806 Filed 5–22–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–832]

Carbon and Alloy Steel Wire Rod From Turkey: Correction to Notice of Opportunity To Request Administrative Review

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

FOR FURTHER INFORMATION CONTACT: Brenda E. Waters, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

On May 1, 2019, Commerce published its notification to parties of the opportunity to request an administrative review of countervailing duty orders and inadvertently omitted Carbon and Alloy Steel Wire Rod from Turkey (C–489–832), POR 9/5/2017–12/31/2018. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 84 FR 18479 (May 1, 2019).

This notice serves as a correction to include the countervailing duty order Carbon and Alloy Steel Wire Rod from Turkey (C–489–832) administrative review in the referenced notice.

Dated: May 16, 2019.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–10804 Filed 5–22–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–085]

Certain Quartz Surface Products From the People's Republic of China: Final Affirmative Countervailing Duty Determination, and Final Affirmative Determination of Critical Circumstances

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

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of certain quartz surface products (quartz surface products) from the People's Republic of China (China).

DATES: Applicable May 23, 2019.

FOR FURTHER INFORMATION CONTACT: Darla Brown or Joshua Tucker, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1791 or (202) 482–2044, respectively.

SUPPLEMENTARY INFORMATION:

Background

The petitioner in this investigation is Cambria Company, LLC. In addition to the Government of China (GOC), the mandatory respondents in this investigation are Fasa Industrial Corporation Limited (Fasa Industrial), Foshan Hero Stone Co., Ltd. (Hero Stone), and Foshan Yixin Stone Co., Ltd. (Foshan Yixin).

The events that occurred since Commerce published the *Preliminary Determination* [1] on September 21, 2018; the post-preliminary analysis [2] on November 6, 2018; and the *Preliminary Critical Circumstances Determination* [3] on November 15, 2018, are discussed in the Issues and Decision Memorandum,

[1] *See Certain Quartz Surface Products from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with Final Antidumping Duty Determination,* 83 FR 47881 (September 21, 2018) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Post-Preliminary Analysis of Countervailing Duty Investigation: Certain Quartz Surface Products from the People's Republic of China,'' dated November 6, 2018.

[3] *See Certain Quartz Surface Products from the People's Republic of China: Preliminary Affirmative Determination of Critical Circumstances, in Part, in the Countervailing Duty Investigation,* 83 FR 57419 (November 15, 2018) (*Preliminary Critical Circumstances Determination*).

which is hereby adopted by this notice.[4] The Issues and Decision Memorandum also details the changes we made since the *Preliminary Determination* to the subsidy rates calculated for the mandatory respondents and all other producers/exporters. 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,* and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Commerce exercised its discretion to toll all deadlines affected by the partial Federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[5] The revised deadline for the final determination of this investigation is now May 14, 2019.

Period of Investigation

The period of investigation is January 1, 2017, through December 31, 2017.

Scope of the Investigation

The products covered by this investigation are quartz surface products from China. For a complete description of the scope of the investigation, *see* Appendix I.

Scope Comments

During the course of this investigation and the concurrent less-than-fair-value (LTFV) investigation of quartz surface products from China, Commerce received scope comments from interested parties. Commerce issued a Preliminary Scope Decision Memorandum to address these comments and set aside a period of time for parties to address scope issues in scope case and rebuttal briefs.[6] We received comments from interested parties on the Preliminary Scope Decision Memorandum, which we addressed in the Final Scope Decision Memorandum.[7] In addition, on February 14, 2019, the petitioner submitted a proposed clarification to the scope of this and the concurrent LTFV investigation.[8] In response to the petitioner's proposed scope clarification, Commerce established a separate scope briefing schedule and received case and rebuttal briefs regarding the proposed clarification, which we addressed in the Proposed Scope Clarification Decision Memorandum.[9] As a result, for this final determination, we made certain changes to the scope of these investigations from that published in the *Preliminary Determination.*[10] *See* Appendix I.

Final Affirmative Determination of Critical Circumstances

In the *Preliminary Critical Circumstances Determination,* Commerce preliminarily determined, pursuant to section 703(e)(1) of the Tariff Act of 1930, as amended (the Act), that critical circumstances exist for Fasa Industrial and Hero Stone, but not for Foshan Yixin or the companies covered by the all-others rate. For this final determination, we continue to find that critical circumstances exist for Fasa Industrial and Hero Stone pursuant to section 705(a)(2) of the Act. Moreover, we now find that Foshan Yixin and its unaffiliated suppliers, Foshan Nanhai Julang Quartz Co. (Foshan Nanhai) and Qinguan Yuefeng Decoration Material Co. (Qinguan Yuefeng), as well as the companies covered by the all-others rate received export-contingent countervailable subsidies during the POI through the Export Buyer's Credit program that are inconsistent with the Subsidies and Countervailing Measures Agreement and had massive imports of the subject merchandise over a relatively short period. Therefore, in accordance with section 705(a)(2) of the Act, we also find that critical circumstances exist with respect to Foshan Yixin, Foshan Nanhai, Qinguan Yuefeng, and the companies covered by the all-others rate. For the analysis of critical circumstances for this final determination, *see* the Issues and Decision Memorandum at Comment 10.

Analysis of Subsidy Programs and Comments Received

In the Issues and Decision Memorandum, we address the subsidy programs under investigation and all issues raised in parties' case and rebuttal briefs, other than those issues related to scope. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice as Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[11] For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

Verification

As provided in section 782(i) of the Act, Commerce verified the subsidy information reported by Foshan Yixin. We used standard verification procedures, including an examination of relevant accounting records and original source documents provided by the respondent.[12]

Changes Since the Preliminary Determination

In addition to now finding critical circumstances for Foshan Yixin and companies covered by the all-others rate, based on our review and analysis of the comments received from parties and corrections presented at verification, we made certain changes to the subsidy rate calculations for Foshan Yixin. We also assigned individual

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Certain Quartz Surface Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[5] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[6] *See* Memorandum, ''Certain Quartz Surface Products from the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determination,'' dated September 14, 2018 (Preliminary Scope Decision Memorandum).

[7] *See* Memorandum, ''Certain Quartz Surface Products from the People's Republic of China: Final Scope Comments Decision Memorandum,'' dated May 10, 2019 (Final Scope Decision Memorandum).

[8] *See* Petitioner's Letter, ''Certain Quartz Surface Products from the People's Republic of China: Request to Extend Deadline to Submit Factual Information,'' dated February 14, 2019.

[9] *See* Memorandum, ''Certain Quartz Surface Products from the People's Republic of China: Proposed Scope Clarification Decision Memorandum,'' dated concurrently with this notice (Proposed Scope Clarification Memorandum).

[10] This scope modification will not apply to merchandise entered prior to the publication of this notice in the **Federal Register**.

[11] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[12] *See* Memorandum, ''Verification of the Questionnaire Responses of Foshan Yixin Stone Co., Ltd.,'' dated December 14, 2018.

estimated subsidy rates based on adverse facts available to Foshan Yixin's unaffiliated suppliers that failed to cooperate in this investigation: Foshan Nanhai and Qinguan Yuefeng. As a result of the changes to Foshan Yixin's calculated rate, Commerce has also revised the all-others rate. For a discussion of these changes, *see* the Issues and Decision Memorandum.[13]

Final Determination

In accordance with section 705(c)(1)(B)(i)(I) of the Act, we calculated an individual estimated subsidy rate for Foshan Yixin (for entries produced and exported by Foshan Yixin), and established individual estimated subsidy rates for Fasa Industrial, Foshan Nanhai, Hero Stone, and Qinguan Yuefeng. Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, we will determine an ''all others'' rate equal to the weighted-average countervailable subsidy rates established for exporters and producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act. In the final determination of this investigation, Commerce calculated rates for Fasa Industrial and Hero Stone in accordance with section 776 of the Act.[14] Therefore, the only rate that is not zero, *de minimis,* or based entirely on facts otherwise available is the rate calculated for Foshan Yixin. Consequently, the rate calculated for Foshan Yixin is also assigned as the rate for ''all other'' producers and exporters.

Commerce determines the total estimated net countervailable subsidy rates to be the following:

Company	Subsidy rate (%)
Foshan Hero Stone Co., Ltd.[15]	190.99
Fasa Industrial Corporation Limited	190.99
Foshan Yixin Stone Co., Ltd	45.32
Foshan Nanhai Julang Quartz Co	190.99
Qinguan Yuefeng Decoration Material Co	190.99
All Others	45.32

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination of Critical Circumstances* and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, Commerce instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise for Fasa Industrial and Hero Stone, as described in the scope of the investigation section, entered, or withdrawn from warehouse, for consumption on or after June 23, 2018, which is 90 days prior to the date of publication of the *Preliminary Determination* in the **Federal Register**. Additionally, as a result of our *Preliminary Determination,* for Foshan Yixin and the companies covered by the all-others rate, Commerce instructed CBP to suspend liquidation of entries of subject merchandise, as described in the scope of the investigation section, entered, or withdrawn from warehouse, for consumption on or after the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we issued instructions to CBP to discontinue the suspension of liquidation for countervailing duty (CVD) purposes for subject merchandise entered, or withdrawn from warehouse, on or after January 19, 2019, but to continue the suspension of liquidation of all entries from September 21, 2018 (or, in the case of Fasa Industrial and Hero Stone, June 23, 2018), through January 18, 2019.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for such entries of subject merchandise in the amounts indicated above. If the ITC also issues a final affirmative determination of critical circumstances, on the basis of our final affirmative critical circumstances determination, we will additionally instruct CBP to suspend liquidation and require a cash deposit on all entries of quartz surface products from China effective June 23, 2018. If the ITC issues a final affirmative injury determination but a final negative determination of critical circumstances, we will instruct CBP to liquidate entries prior to the date of publication of the *Preliminary Determination* without regard to duties, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

International Trade Commission Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. Because Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of quartz surface products from China, or sales (or the likelihood of sales) for importation, of quartz surface products from China. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a CVD order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Notification Regarding Administrative Protective Orders

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act.

[13] *See* Issues and Decision Memorandum.

[14] We also assigned rates to Foshan Yixin's unaffiliated suppliers Foshan Nanhai and Qinguan Yuefeng in accordance with section 776 of the Act.

[15] Commerce has found the following companies to be cross-owned with Foshan Hero Stone Co., Ltd.: Mingwei Quartz New Environmental Protection Materials Co., Ltd.; and Foshan Quartz Stone Imp & Exp Co., Ltd.

Dated: May 14, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the investigation is certain quartz surface products.[16] Quartz surface products consist of slabs and other surfaces created from a mixture of materials that includes predominately silica (*e.g.,* quartz, quartz powder, cristobalite) as well as a resin binder (*e.g.,* an unsaturated polyester). The incorporation of other materials, including, but not limited to, pigments, cement, or other additives does not remove the merchandise from the scope of the investigation. However, the scope of the investigation only includes products where the silica content is greater than any other single material, by actual weight. Quartz surface products are typically sold as rectangular slabs with a total surface area of approximately 45 to 60 square feet and a nominal thickness of one, two, or three centimeters. However, the scope of this investigation includes surface products of all other sizes, thicknesses, and shapes. In addition to slabs, the scope of this investigation includes, but is not limited to, other surfaces such as countertops, backsplashes, vanity tops, bar tops, work tops, tabletops, flooring, wall facing, shower surrounds, fire place surrounds, mantels, and tiles. Certain quartz surface products are covered by the investigation whether polished or unpolished, cut or uncut, fabricated or not fabricated, cured or uncured, edged or not edged, finished or unfinished, thermoformed or not thermoformed, packaged or unpackaged, and regardless of the type of surface finish.

In addition, quartz surface products are covered by the investigation whether or not they are imported attached to, or in conjunction with, non-subject merchandise such as sinks, sink bowls, vanities, cabinets, and furniture. If quartz surface products are imported attached to, or in conjunction with, such non-subject merchandise, only the quartz surface product is covered by the scope.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise fabricated in a third country, including by cutting, polishing, curing, edging, thermoforming, attaching to, or packaging with another product, or any other finishing, packaging, or fabrication that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the quartz surface products.

The scope of the investigation does not cover quarried stone surface products, such as granite, marble, soapstone, or quartzite. Specifically excluded from the scope of the investigation are crushed glass surface products. Crushed glass surface products must meet each of the following criteria to qualify for this exclusion: (1) The crushed glass content is greater than any other single material, by actual weight; (2) there are pieces of crushed glass visible across the surface of the product; (3) at least some of the individual pieces of crushed glass that are visible across the surface are larger than one centimeter wide as measured at their widest cross-section (glass pieces); and (4) the distance between any single glass piece and the closest separate glass piece does not exceed three inches.

The products subject to the scope are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under the following subheading: 6810.99.0010. Subject merchandise may also enter under subheadings 6810.11.0010, 6810.11.0070, 6810.19.1200, 6810.19.1400, 6810.19.5000, 6810.91.0000, 6810.99.0080, 6815.99.4070, 2506.10.0010, 2506.10.0050, 2506.20.0010, 2506.20.0080, and 7016.90.10. The HTSUS subheadings set forth above are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

[16] Quartz surface products may also generally be referred to as engineered stone or quartz, artificial stone or quartz, agglomerated stone or quartz, synthetic stone or quartz, processed stone or quartz, manufactured stone or quartz, and Bretonstone®.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2019–10799 Filed 5–22–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–900]

Diamond Sawblades and Parts Thereof From the People's Republic of China: Notice of Court Decision Not in Harmony With the Final Results of Review, Rescission of Administrative Review in Part, and Amended Final Results of the Antidumping Duty Administrative Review; 2013–2014

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

SUMMARY: On May 7, 2019, the United States Court of International Trade (CIT) sustained the final remand redetermination pertaining to the administrative review of the antidumping duty order on diamond sawblades and parts thereof from the People's Republic of China covering the period November 1, 2013, through October 31, 2014. The Department of Commerce (Commerce) is notifying the public that the CIT's final judgment in this case is not in harmony with the final results of the administrative review, that Commerce is rescinding the administrative review in part, and that Commerce is amending the final results with respect to the respondents eligible for separate rates.

DATES: Applicable May 17, 2019.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun or Minoo Hatten, 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) 482–5760 or (202) 482–1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 14, 2016, Commerce published the *Final Results,* in which we valued cores produced by Weihai Xiangguang Mechanical Industrial Co., Ltd. (Weihai) using a build-up methodology, and calculated surrogate truck freight distance using the average of the distances between industrial estates in Bangkok and the Port of Bangkok.[1] On March 22, 2018, the CIT remanded the *Final Results* to Commerce to re-examine: (1) The withdrawals of review requests with

[1] *See Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2013–2014,* 81 FR 38673 (June 14, 2016) (*Final Results*) and accompanying Issues and Decision Memorandum at Comments 11 and 19.

respect to Weihai in light of *Glycine & More, Inc.* v. *United States,* 880 F.3d 1335 (Fed. Cir. 2018) (*Glycine & More*); and (2) the surrogate truck freight distance used in the valuation of the truck freight expense. In addition, the CIT granted Commerce's request for a voluntary remand to address the issues concerning the valuation of Weihai's purchased cores and the rate for non-selected separate rate respondents.[2]

In the first final remand redetermination, we stated our intent to accept all withdrawals of review requests with respect to Weihai, rescind the administrative review with respect to Weihai, and revise the surrogate truck freight distance. Because we intended to rescind the administrative review in part with respect to Weihai, we treated the issue of the valuation of Weihai's cores as moot. We assigned the revised rate for the Jiangsu Fengtai Single Entity [3] as the separate rate to eligible non-selected respondents.[4]

On February 1, 2019, the CIT remanded the *Final Results* to Commerce to reconsider Commerce's methodology in determining the separate rate for the non-selected respondents in this litigation. In addition, the CIT ordered that, if Commerce decides on remand to reinstate Weihai in the administrative review, Commerce must make appropriate adjustments in line with the CIT's previous remand order regarding the cores valuation and the revision to the surrogate truck freight distance with respect to Weihai.[5]

In the second final remand redetermination, we continued to accept all withdrawals of review requests with respect to Weihai and stated our intent to rescind the administrative review, in part, with respect to Weihai. In response to the CIT's remand order, we relied on data for Weihai and the Jiangsu Fengtai Single Entity to recalculate the separate rate for the eligible non-selected respondents, with the adjustments to the cores valuation and the surrogate truck freight distance for Weihai.[6] On May 7, 2019, the CIT sustained our second final remand redetermination in its entirety.[7]

Timken Notice

In its decision in *Timken Co.* v. *United States,* 893 F.2d 337, 341 (Fed. Cir. 1990) (*Timken*), as clarified by *Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010), the United States Court of Appeals for the Federal Circuit held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's May 7, 2019, final judgment sustaining the second final remand redetermination constitutes the CIT's final decision which is not ''in harmony'' with the *Final Results.* This notice is published in fulfillment of the publication requirements of *Timken.* Accordingly, Commerce will continue the suspension of liquidation of the subject merchandise pending expiration of the period to appeal or, if appealed, pending a final and conclusive court decision.

Rescission of Administrative Review in Part

In accordance with 19 CFR 351.213(d), Commerce will rescind an administrative review in part ''if a party that requested a review withdraws the request within 90 days of the date of the publication of notice of initiation of the requested review. The Secretary may extend this time limit if the Secretary decides that it is reasonable to do so.'' [8] Subsequent to the initiation of the review, the petitioner and Weihai timely withdrew their requests for review of Weihai.[9] Robert Bosch Tools Corporation (Bosch) withdrew its request for review of Weihai after the regulatory 90-day period [10] but we extended this time limit and accepted Bosch's withdrawal of its review request because we find it reasonable to do so under 19 CFR 351.213(d).[11] Because no other party requested a review of Weihai, we are rescinding the review in part with respect to Weihai in accordance with 19 CFR 351.213(d)(1).

Amended Final Results of Review

Because there is now a final court decision, Commerce is amending the *Final Results* with respect to the separate rate respondents as follows:

Exporter	Weighted-average dumping margin (percent)
Bosun Tools Co., Ltd	39.66
Chengdu Huifeng Diamond Tools Co., Ltd[12]	39.66
Danyang Huachang Diamond Tools Manufacturing Co., Ltd	39.66
Danyang NYCL Tools Manufacturing Co., Ltd	39.66
Danyang Weiwang Tools Manufacturing Co., Ltd	39.66
Guilin Tebon Superhard Material Co., Ltd	39.66
Hangzhou Deer King Industrial and Trading Co., Ltd	39.66
Hong Kong Hao Xin International Group Limited	39.66
Huzhou Gu's Import & Export Co., Ltd	39.66

[2] *See Diamond Sawblades Manufacturers' Coalition* v. *United States,* 301 F. Supp. 3d 1326 (CIT 2018).

[3] The Jiangsu Fengtai Single Entity is comprised of Jiangsu Fengtai Diamond Tool Manufacture Co., Ltd., Jiangsu Fengtai Tools Co., Ltd., and Jiangsu Fengtai Sawing Industry Co., Ltd. *See* the Memorandum, ''Diamond Sawblades and Parts Thereof from the People's Republic of China—Collapsing of Jiangsu Fengtai Diamond Tool Manufacture Co., Ltd. and Affiliated Producers,'' dated November 30, 2015.

[4] *See* Final Remand Redetermination dated August 6, 2018, pursuant to *Diamond Sawblades Manufacturers' Coalition* v. *United States,* 301 F. Supp. 3d 1326 (CIT 2018), and available at *https://enforcement.trade.gov/remands/18-28.pdf, aff'd in part, remanded in part, Diamond Sawblades Manufacturers' Coalition* v. *United States,* 359 F. Supp. 3d 1374 (CIT 2019).

[5] *See Diamond Sawblades Manufacturers' Coalition* v. *United States,* 359 F. Supp. 3d 1374 (CIT 2019).

[6] *See* Final Second Remand Redetermination dated March 29, 2019, pursuant to *Diamond Sawblades Manufacturers' Coalition* v. *United States,* 359 F. Supp. 3d 1374 (CIT 2019), and available at *https://enforcement.trade.gov/remands/19-17.pdf.*

[7] *See Diamond Sawblades Manufacturers' Coalition* v. *United States,* Court No. 16–00124, Slip Op. 19–54 (CIT May 7, 2019).

[8] *See* 19 CFR 351.213(d).

[9] *See* the petitioner's and Weihai's withdrawals of review request dated March 23, 2015.

[10] *See* Bosch's withdrawal of review request dated April 8, 2015.

[11] *See* Final Remand Redetermination dated August 6, 2018, pursuant to *Diamond Sawblades Manufacturers' Coalition* v. *United States,* 301 F. Supp. 3d 1326 (CIT 2018), and available at *https://enforcement.trade.gov/remands/18-28.pdf, aff'd, remanded on other grounds, Diamond Sawblades Manufacturers' Coalition* v. *United States,* 359 F. Supp. 3d 1374 (CIT 2019).

[12] Commerce determined that Chengdu Huifeng New Material Technology Co., Ltd., is the successor-in-interest to Chengdu Huifeng Diamond Tools Co., Ltd. *See Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review,* 82 FR 60177 (December 19, 2017).

Exporter	Weighted-average dumping margin (percent)
Jiangsu Fengtai Single Entity	56.67
Jiangsu Huachang Tools Manufacturing Co., Ltd	39.66
Jiangsu Inter-China Group Corporation[13]	39.66
Jiangsu Youhe Tool Manufacturer Co., Ltd	39.66
Orient Gain International Limited	39.66
Pantos Logistics (HK) Company Limited	39.66
Qingyuan Shangtai Diamond Tools Co., Ltd	39.66
Quanzhou Zhongzhi Diamond Tool Co., Ltd	39.66
Rizhao Hein Saw Co., Ltd	39.66
Saint-Gobain Abrasives (Shanghai) Co., Ltd	39.66
Shanghai Jingquan Industrial Trade Co., Ltd	39.66
Wuhan Wanbang Laser Diamond Tools Co[14]	39.66
Xiamen ZL Diamond Technology Co., Ltd	39.66
Zhejiang Wanli Tools Group Co., Ltd	39.66

In the event the CIT's ruling is not appealed or, if appealed, upheld by a final and conclusive court decision, Commerce will instruct the U.S. Customs and Border Protection (CBP) to assess antidumping duties on unliquidated entries of subject merchandise based on the revised rates Commerce determined and listed above and, for Weihai, at the rate equal to the cash deposit of the estimated antidumping duty required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(2).

Cash Deposit Requirements

As the cash deposit rate for Jiangsu Huachang Tools Manufacturing Co., Ltd., has not been subject to subsequent administrative reviews, Commerce will issue revised cash deposit instructions to CBP adjusting the rate from 29.76 percent to 39.66 percent, effective May 17, 2019. For all other respondents listed above, because the cash deposit rates have been updated in subsequent administrative reviews,[15] we will not update their cash deposit rates as a result of these amended final results.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: May 16, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–10803 Filed 5–22–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–844]

Certain Lined Paper Products From India: Final Results of Countervailing Duty Administrative Review; 2016

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

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to Goldenpalm Manufacturers Pvt. Limited (Goldenpalm), a producer/exporter of certain lined paper products (lined paper) from India for the period of review January 1, 2016, through December 31, 2016.

DATES: Applicable May 23, 2019.

FOR FURTHER INFORMATION CONTACT: John Conniff, 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) 482–1009.

Background

Commerce published the *Preliminary Results* of this administrative review on October 10, 2018.[1] Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[2] On March 5, 2019, we postponed the final results of review by 57 days, until May 15, 2019.[3] Based on an analysis of the comments received, Commerce has made certain changes to the subsidy rate listed in the *Preliminary Results.* The final subsidy rate is listed in the ''Final Results of Administrative Review'' section below.

Scope of the Order

The products covered by the order are certain lined paper products from India. For a full description of the scope, *see* the Issues and Decision Memorandum.[4]

Analysis of Comments Received

The issues raised by the Government of India, Goldenpalm, and the

[13] *See Diamond Sawblades and Parts Thereof from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2013–2014,* 80 FR 75854, 75855, n.15 (December 4, 2015), for the name variation of this company.

[14] Commerce determined that Wuhan Wanbang Laser Diamond Tools Co., Ltd., is the successor-in-interest to Wuhan Wanbang Laser Diamond Tools Co. *See Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review,* 81 FR 20618 (April 8, 2016).

[15] *See Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2015–2016,* 83 FR 17527, 17528 (April 20, 2018), for Bosun Tools Co., Ltd., Danyang NYCL Tools Manufacturing Co., Ltd., and Wuhan Wanbang Laser Diamond Tools Co., and *Diamond Sawblades and Parts Thereof from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 39673, 39674, n.10 (August 10, 2018), unchanged in *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), for all other respondents listed above for which the cash deposit rates will not be updated as a result of these amended final results.

[1] *See Certain Lined Paper Products from India: Preliminary Results of Countervailing Duty Administrative Review; Calendar Year 2016,* 83 FR 50896 (October 10, 2018) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[3] *See* Memorandum, ''Extension of Deadline for Final Results of Countervailing Duty Review,'' dated March 5, 2019.

[4] *See* Memorandum, ''Decision Memorandum for the Final Results of Administrative Review; 2016: Certain Lined Paper Products from India,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

petitioner [5] in their case and rebuttal briefs are addressed in the Issues and Decision Memorandum. The issues are identified in the Appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://trade.gov/enforcement/frn/.* The signed Issues and Decision Memorandum and electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on comments received from interested parties, we have continued to apply adverse facts available (AFA) pursuant to sections 776(a) and (b) of the Tariff Act of 1930, as amended (the Act) to Goldenpalm, and to the GOI in various respects, but we have revised the AFA program rate assigned to Goldenpalm under the Government of Tamil Nadu's Capital Subsidies and Electricity Tax Exemption program. For a discussion of this and other issues, *see* the Issues and Decision Memorandum.

Methodology

We conducted this review in accordance with section 751(a)(1)(A) of the Act. For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[6] For a full description of the methodology underlying our conclusions, including any determination that relied upon the use of AFA pursuant to sections 776(a) and (b) of the Act, *see* the Issues and Decision Memorandum.

Final Results of Administrative Review

In accordance with section 777A(e) of the Act and 19 CFR 351.221(b)(5), we find that the following net countervailable subsidy rate exists for the mandatory respondent, Goldenpalm, for the period January 1, 2016, through December 31, 2016:

Manufacturer/exporter	Subsidy rate (percent *ad valorem*)
Goldenpalm Manufacturers Pvt. Limited	197.33

Assessment and Cash Deposit Requirements

In accordance with 19 CFR 351.212(b)(2), we intend to issue appropriate assessment instructions to Customs and Border Protection (CBP) 15 days after publication of the final results of this review. We will instruct CBP to liquidate shipments of subject merchandise produced and/or exported by the company listed above, entered or withdrawn from warehouse, for consumption from January 1, 2016, through December 31, 2016, at the *ad valorem* rate listed above.

Cash Deposit Requirements

We intend also to instruct CBP to collect cash deposits of estimated countervailing duties, in the amounts shown above for Goldenpalm, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most-recent company-specific or all-others rate applicable to the company, as appropriate.[7] Accordingly, the cash deposit requirements that will be applied to companies covered by this order, but not examined in this administrative review, are those established in the most recently completed segment of the proceeding for each company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibilities concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: May 15, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

APPENDIX

[FR Doc. 2019–10802 Filed 5–22–19; 8:45 am]

BILLING CODE 3510–DS–P

[5] The petitioner is the American Association of School Paper Suppliers.

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and, section 771(5A) of the Act regarding specificity.

[7] *See Notice of Amended Final Determination of Sales at Less Than Fair Value: Certain Lined Paper Products from the People's Republic of China; Notice of Antidumping Duty Orders: Certain Lined Paper Products from India, Indonesia and the People's Republic of China; and Notice of Countervailing Duty Orders: Certain Lined Paper Products from India and Indonesia,* 71 FR 56949, 56953 (September 28, 2006).

DEPARTMENT OF COMMERCE

International Trade Administration

Subsidy Programs Provided by Countries Exporting Softwood Lumber and Softwood Lumber Products to the United States; Request for Comment

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

SUMMARY: The Department of Commerce (Commerce) seeks public comment on any subsidies, including stumpage subsidies, provided by certain countries exporting softwood lumber or softwood lumber products to the United States during the period July 1, 2018, through December 31, 2018.

DATES: Comments must be submitted by June 10, 2019.

ADDRESSES: See the Submission of Comments section below.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4793.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to section 805 of Title VIII of the Tariff Act of 1930 (the Softwood Lumber Act of 2008), the Secretary of Commerce is mandated to submit to the appropriate Congressional committees a report every 180 days on any subsidy provided by countries exporting softwood lumber or softwood lumber products to the United States, including stumpage subsidies. Commerce submitted its last subsidy report on December 20, 2018. As part of its newest report, Commerce intends to include a list of subsidy programs identified with sufficient clarity by the public in response to this notice.

Request for Comments

Given the large number of countries that export softwood lumber and softwood lumber products to the United States, we are soliciting public comment only on subsidies provided by countries which had exports accounting for at least one percent of total U.S. imports of softwood lumber by quantity, as classified under Harmonized Tariff Schedule of the United States (HTSUS) codes 4407.1001, 4407.1100, 4407.1200, 4407.1905, 4407.1906, 4407.1910,[1] during the period July 1, 2018, through December 31, 2018. Official U.S. import data published by the United States International Trade Commission's DataWeb indicate that four countries (Brazil, Canada, Germany, and Sweden) exported softwood lumber to the United States during that time period in amounts sufficient to account for at least one percent of U.S. imports of softwood lumber products. We intend to rely on similar previous six-month periods to identify the countries subject to future reports on softwood lumber subsidies. For example, we will rely on U.S. imports of softwood lumber and softwood lumber products during the period January 1, 2019, through June 30, 2019, to select the countries subject to the next report.

Under U.S. trade law, a subsidy exists where an authority: (i) Provides a financial contribution; (ii) provides any form of income or price support within the meaning of Article XVI of the GATT 1994; or (iii) makes a payment to a funding mechanism to provide a financial contribution to a person, or entrusts or directs a private entity to make a financial contribution, if providing the contribution would normally be vested in the government and the practice does not differ in substance from practices normally followed by governments, and a benefit is thereby conferred.[2]

Parties should include in their comments: (1) The country which provided the subsidy; (2) the name of the subsidy program; (3) a brief description (no more than 3–4 sentences) of the subsidy program; and (4) the government body or authority that provided the subsidy.

Submission of Comments

As specified above, to be assured of consideration, comments must be received no later than 5:00 p.m., Eastern Standard Time, on Monday, June 10, 2019. All comments must be submitted through the Federal eRulemaking Portal at *http://www.regulations.gov,* Docket No. ITA–2019–0001, unless the commenter does not have access to the internet. The materials in the docket will not be edited to remove identifying or contact information, and Commerce cautions against including any information in an electronic submission that the submitter does not want publicly disclosed. Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF formats only.

Commenters who do not have access to the internet may submit the original and one electronic copy of each set of comments by mail or hand delivery/courier.

All comments should be addressed to James Maeder, Associate Deputy Assistant Secretary for Antidumping and Countervailing Duties, at U.S. Department of Commerce, Room 18022, 1401 Constitution Avenue NW, Washington, DC 20230.

Dated: May 16, 2019.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Investigations.

[FR Doc. 2019–10801 Filed 5–22–19; 8:45 am]

BILLING CODE 3510–DS–P

[1] For previous lumber subsidies reports, Commerce relied solely on HTSUS code 4407.1001 (coniferous wood sawn or chipped lengthwise, sliced or peeled, of a thickness exceeding 6 mm), which accounted for the vast majority of subject imports. In October 2018, HTSUS code 4407.1001 became obsolete and was replaced by HTSUS codes 4407.1100 (pine wood sawn or chipped lengthwise, sliced or peeled, over 6 mm thick), 4407.1200 (fir and spruce wood sawn or chipped lengthwise, sliced or peeled, over 6 mm thick), 4407.1905 (mixtures of spruce, pine and fir (SPF) wood sawn or chipped lengthwise, sliced or peeled, over 6 mm thick, not treated with preservatives), 4407.1906 (mixtures of hemlock and fir (hem-fir) wood sawn or chipped lengthwise, sliced or peeled, over 6 mm thick, not treated with preservatives), and 4407.1910 (other coniferous wood, nesoi, sawn or chipped lengthwise, sliced or peeled, over 6 mm thick, whether or not treated with preservatives).

[2] *See* section 771(5)(B) of the Tariff Act of 1930, as amended.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–084]

Certain Quartz Surface Products From the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value, and Final Affirmative Determination of Critical Circumstances

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

SUMMARY: The Department of Commerce (Commerce) determines that certain quartz surface products (quartz surface products) from the People's Republic of China (China) are being, or are likely to be, sold in the United States at less than fair value (LTFV).

DATES: Applicable May 23, 2019.

FOR FURTHER INFORMATION CONTACT: Andrew Medley or Whitley Herndon, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4987 or (202) 482–6274, respectively.

SUPPLEMENTARY INFORMATION:

Background

The petitioner in this investigation is Cambria Company, LLC. The mandatory respondents in this investigation are CQ International,[1] Guangzhou Hercules Quartz Stone Co., Ltd. (Hercules Quartz), Foshan Hero Stone Co., Ltd. (Hero Stone), and Foshan Yixin Stone Co., Ltd. (Yixin Stone).

On November 20, 2018, Commerce published the *Preliminary Determination* of sales at LTFV of quartz surface products from China.[2] A summary of the events that occurred since Commerce published the *Preliminary Determination,* as well as a full discussion of the issues raised by the parties for this final determination, may be found in the Issues and Decision Memorandum, which is hereby adopted by this notice.[3] 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,* and ACCESS is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Commerce exercised its discretion to toll all deadlines affected by the partial Federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[4] The revised deadline for the final determination of this investigation is now May 14, 2019.

Period of Investigation

The period of investigation is October 1, 2017, through March 31, 2018.

Scope of the Investigation

The products covered by this investigation are quartz surface products from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

During the course of this investigation, and the concurrent countervailing duty (CVD) investigation of quartz surface products from China, Commerce received scope comments from interested parties. Commerce issued a Preliminary Scope Decision Memorandum to address these comments and set aside a period of time for parties to address scope issues in scope case and rebuttal briefs.[5] We received comments from interested parties on the Preliminary Scope Decision Memorandum, which we addressed in the Final Scope Decision Memorandum.[6] In addition, on February 14, 2019, the petitioner submitted a proposed clarification to the scope of this and the concurrent CVD investigation.[7] In response to the petitioner's proposed scope clarification, Commerce established a separate scope briefing schedule and received case and rebuttal briefs regarding the proposed clarification, which we addressed in the Proposed Scope Clarification Decision Memorandum.[8] As a result, for this final determination, we made certain changes to the scope of these investigations from that published in the *Preliminary Determination*.[9] *See* Appendix I.

Final Affirmative Determination of Critical Circumstances

In accordance with 735(a)(3) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.206, Commerce determines that critical circumstances exist with respect to imports of quartz surface products from CQ International,[10] Foshan Yixin Stone Co., Ltd. (Yixin Stone), all non-individually examined companies receiving a separate rate, and the China-wide entity. For a full description of the methodology and results of Commerce's final affirmative critical circumstances analysis, *see* the Issues and Decision Memorandum at Comment 2.

Analysis of Comments Received

In the Issues and Decision Memorandum, we address all issues raised in parties' case and rebuttal briefs, other than those issues related to scope. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice as Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 731 of the Act. Export price was calculated in accordance with section 772(a) of the Act. Constructed export price was calculated in accordance with section 772(b) of the Act. Because China is a non-market economy within the meaning of section 771(18) of the Act, normal value (NV) was calculated in accordance with section 773(c) of the Act. For a full description of the methodology underlying Commerce's determination, *see* the Preliminary Decision Memorandum; *see also* the Issues and Decision Memorandum.

Verification

As provided in section 782(i) of the Act, Commerce verified the sales and factors of production data reported by CQ International and Yixin Stone. We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by the respondents.

Changes Since the Preliminary Determination

Based on our review and analysis of the comments received from interested parties, and our findings at verification, we made certain changes to the

[1] We have ''collapsed'' CQ International Limited with two affiliated companies, Suzhou Colorquartzstone New Material Co., Ltd. and Shanghai Meiyang Stone Co., Ltd., and, as a result, we are treating them as a single-entity (collectively, CQ International).

[2] *See Certain Quartz Surface Products from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 83 FR 58540 (November 20, 2018) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Certain Quartz Surface Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[5] *See* Memorandum, ''Certain Quartz Surface Products from the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determination,'' dated September 14, 2018 (Preliminary Scope Decision Memorandum).

[6] *See* Memorandum, ''Certain Quartz Surface Products from the People's Republic of China: Final Scope Comments Decision Memorandum,'' dated May 10, 2019 (Final Scope Decision Memorandum).

[7] *See* Petitioner's Letter, ''Certain Quartz Surface Products from the People's Republic of China: Request to Extend Deadline to Submit Factual Information,'' dated February 14, 2019.

[8] *See* Memorandum, Certain Quartz Surface Products from the People's Republic of China: Proposed Scope Clarification Decision Memorandum,'' dated concurrently with this notice (Proposed Scope Clarification Memorandum).

[9] This scope modification will not apply to merchandise entered prior to the publication of this notice in the **Federal Register**.

[10] We have ''collapsed'' CQ International Limited with two affiliated companies, Suzhou Colorquartzstone New Material Co., Ltd. and Shanghai Meiyang Stone Co., Ltd., and, as a result, we are treating them as a single-entity (collectively, CQ International).

calculation of the antidumping duty margins applicable to CQ International, Yixin Stone, those companies entitled to a separate rate, and the China-wide entity. Further, we now find Hercules Quartz to be part of the China-wide entity. For a discussion of these changes, *see* the Issues and Decision Memorandum.

China-Wide Entity and Use of Adverse Facts Available

For the reasons explained in the *Preliminary Determination,* we continue to find that the use of adverse facts available (AFA), pursuant to sections 776(a) and (b) of the Act, is warranted in determining the rate for the China-wide entity.[11] In selecting the AFA rate for the China-wide entity, Commerce's practice is to select a rate that is sufficiently adverse to ensure that the uncooperative party does not obtain a more favorable result by failing to cooperate than if it had fully cooperated.[12] Specifically, it is Commerce's practice to select, as an AFA rate, the higher of: (a) The highest dumping margin alleged in the petition; or, (b) the highest calculated dumping margin of any respondent in the investigation.[13] For the final determination, we are assigning the China-wide entity, as AFA, the highest petition margin of 336.69 percent. We are able to corroborate the highest petition dumping margin, to the extent practicable within the meaning of section 776(c) of the Act, using transaction-specific dumping margins calculated for CQ International and Yixin Stone and, thus, we assigned this dumping margin to the China-wide entity as AFA. For further discussion, *see* the Issues and Decision Memorandum at ''Use of Adverse Facts Available.''

Separate Rates

For the final determination, we continue to find that CQ International and Yixin Stone are eligible for separate rates. Section 735(c)(5)(A) of the Act provides that the estimated ''all others'' rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding zero or *de minimis* margins, and any margins determined entirely under section 776 of Act.[14] In this proceeding, Commerce calculated an above *de minimis* rate that is not based entirely on facts available for two mandatory respondents under individual examination, *i.e.,* CQ International and Yixin Stone. Thus, looking to section 735(c)(5)(A) of the Act for guidance, and consistent with our practice, we are assigning the weighted-average, based on publicly ranged sales data, of these mandatory respondents' rates as the rate for non-individually examined companies that have qualified for a separate rate.[15]

Combination Rates

In the *Initiation Notice,*[16] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. For a list of the respondents that established eligibility for their own separate rates and the exporter/producer combination rates applicable to these respondents, *see* Appendix III.

Final Determination

Commerce determines that quartz surface products from China are being, or are likely to be, sold in the United States at LTFV, and that the following dumping margins exist:

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset) (percent)
Foshan Yixin Stone Co., Ltd	Foshan Yixin Stone Co., Ltd	333.09	295.02
Foshan Yixin Stone Co., Ltd	QingYuan Yue Feng Decoration Material Co., Ltd	333.09	295.02
Suzhou Colorquartzstone New Material Co., Ltd., Shanghai Meiyang Stone Co., Ltd., CQ International Limited.	Suzhou Colorquartzstone New Material Co., Ltd. and Shanghai Meiyang Stone Co., Ltd.	265.81	255.27
Non-Individually Examined Exporters Receiving Separate Rates (*see* Appendix III).	Producers Supplying the Non-Individually-Examined Exporters Receiving Separate Rates (*see* Appendix III).	297.40	259.33
China-Wide Entity[17]	China-Wide Entity	336.69	326.15

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will

[11] The China-wide entity includes Foshan Hero Stone Co., Ltd.; Foshan Quartz Stone Imp & Exp Co., Ltd.; Guangzhou Hercules Quartz Stone Co., Ltd.; Hero Stone Co., Ltd.; and Vemy Quartz Surface Co., Ltd.

[12] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Purified Carboxymethyl Cellulose from Finland,* 69 FR 77216 (December 27, 2004), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Purified Carboxymethyl Cellulose from Finland,* 70 FR 28279 (May 17, 2005).

[13] *See, e.g., Certain Stilbenic Optical Brightening Agents from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 77 FR 17436, 17438 (March 26, 2012); *Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Flat-Rolled Carbon Quality Steel Products from the People's Republic of China,* 65 FR 34660 (May 31, 2000), and accompanying Issues and Decision Memorandum.

[14] *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Rescission of Reviews in Part,* 73 FR 52823, 52824 (September 11, 2008), and accompanying Issues and Decision Memorandum at Comment 16.

[15] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 71 FR 77373, 77377 (December 26, 2006), unchanged in *Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 19690 (April 19, 2007).

[16] *See Certain Quartz Surface Products from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 83 FR 22613, 22617 (May 16, 2018) (*Initiation Notice*).

[17] The following companies failed to establish their eligibility for a separate rate and, therefore, are part of the China-wide entity: Foshan Hero Stone Co., Ltd.; Foshan Quartz Stone Imp & Exp Co., Ltd.; Guangzhou Hercules Quartz Stone Co., Ltd.; Hero Stone Co., Ltd.; and Vemy Quartz Surface Co., Ltd. *See* Preliminary Decision Memorandum; *see also* Issues and Decision Memorandum.

instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of quartz surface products from CQ International, Yixin Stone, the separate rates companies, and the China-wide entity, and, in accordance with section 735(c)(4)(B) of the Act, because we continue to find that critical circumstances exist, we will instruct CBP to continue to suspend liquidation of all appropriate entries of quartz surface products which were entered, or withdrawn from warehouse, for consumption on or after August 22, 2018, which is 90 days prior to the date of publication of the *Preliminary Determination* of this investigation in the **Federal Register**.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion CVD proceeding when CVD provisional measures are in effect. Accordingly, where Commerce makes an affirmative determination for domestic subsidy pass-through or export subsidies, Commerce offsets the calculated estimated weighted-average dumping margin by the appropriate rate(s). In this case, we have made an affirmative determination for domestic subsidy pass-through and export subsidies for certain respondents. However, suspension of liquidation for provisional measures in the companion CVD case has been discontinued; therefore, we are not instructing CBP to collect cash deposits based upon the adjusted estimated weighted-average dumping margin for those subsidies at this time.

In addition, pursuant to section 735(c)(1)(B)(ii) of the Act, Commerce will instruct CBP to require a cash deposit equal to the weighted-average amount by which NV exceeds U.S. price as follows: (1) The cash deposit rate for the exporter/producer combination listed in the table above or in Appendix III will be the rate identified for that combination in that table or Appendix III; (2) for all combinations of exporters/producers of merchandise under consideration that have not received their own separate rate above or in Appendix III, the cash deposit rate will be the cash deposit rate established for the China-wide entity; and (3) for all non-Chinese exporters of the merchandise under consideration which have not received their own separate rate above, the cash deposit rate will be the cash deposit rate applicable to the Chinese exporter/producer combination that supplied that non-Chinese exporter. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of quartz surface products from China, or sales (or the likelihood of sales) for importation, of quartz surface products from China. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated, and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Orders

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: May 14, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the investigation is certain quartz surface products.[18] Quartz surface products consist of slabs and other surfaces created from a mixture of materials that includes predominately silica (*e.g.,* quartz, quartz powder, cristobalite) as well as a resin binder (*e.g.,* an unsaturated polyester). The incorporation of other materials, including, but not limited to, pigments, cement, or other additives does not remove the merchandise from the scope of the investigation. However, the scope of the investigation only includes products where the silica content is greater than any other single material, by actual weight. Quartz surface products are typically sold as rectangular slabs with a total surface area of approximately 45 to 60 square feet and a nominal thickness of one, two, or three centimeters. However, the scope of this investigation includes surface products of all other sizes, thicknesses, and shapes. In addition to slabs, the scope of this investigation includes, but is not limited to, other surfaces such as countertops, backsplashes, vanity tops, bar tops, work tops, tabletops, flooring, wall facing, shower surrounds, fire place surrounds, mantels, and tiles. Certain quartz surface products are covered by the investigation whether polished or unpolished, cut or uncut, fabricated or not fabricated, cured or uncured, edged or not edged, finished or unfinished, thermoformed or not thermoformed, packaged or unpackaged, and regardless of the type of surface finish.

In addition, quartz surface products are covered by the investigation whether or not they are imported attached to, or in conjunction with, non-subject merchandise such as sinks, sink bowls, vanities, cabinets, and furniture. If quartz surface products are imported attached to, or in conjunction with, such non-subject merchandise, only the quartz surface product is covered by the scope.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise fabricated in a third country, including by cutting, polishing, curing, edging, thermoforming, attaching to, or packaging with another product, or any other finishing, packaging, or fabrication that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the quartz surface products.

The scope of the investigation does not cover quarried stone surface products, such as granite, marble, soapstone, or quartzite. Specifically excluded from the scope of the investigation are crushed glass surface products. Crushed glass surface products must meet each of the following criteria to qualify for this exclusion: (1) The crushed glass content is greater than any other single material, by actual weight; (2) there are pieces of crushed glass visible across the surface of the product; (3) at least some of the individual pieces of crushed glass that are visible across the surface are larger than one centimeter wide as measured at their widest cross-section (glass pieces); and (4) the

[18] Quartz surface products may also generally be referred to as engineered stone or quartz, artificial stone or quartz, agglomerated stone or quartz, synthetic stone or quartz, processed stone or quartz, manufactured stone or quartz, and Bretonstone®.

distance between any single glass piece and the closest separate glass piece does not exceed three inches.

The products subject to the scope are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under the following subheading: 6810.99.0010. Subject merchandise may also enter under subheadings 6810.11.0010, 6810.11.0070, 6810.19.1200, 6810.19.1400, 6810.19.5000, 6810.91.0000, 6810.99.0080, 6815.99.4070, 2506.10.0010, 2506.10.0050, 2506.20.0010, 2506.20.0080, and 7016.90.10. The HTSUS subheadings set forth above are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

Appendix III

SEPARATE RATES COMPANIES

Exporter	Producer
Non-individually examined exporters receiving separate rates	Producers supplying the non-individually-examined exporters receiving separate rates
Anhui Youlisi Quartz Building Materials Co., Ltd d.b.a Anhui Uviistone Quartz Building Material Co., Ltd.	Anhui Youlisi Quartz Building Materials Co., Ltd d.b.a Anhui Uviistone Quartz Building Material Co., Ltd.
Ansen Investment And Development Co., Limited	Yunfu Honghai Stone Co., Ltd.
Ansen Investment And Development Co., Limited	Foshan Adamant Science & Technology Co., Ltd.
Ansen Investment And Development Co., Limited	Heshan City Nande Stone Co., Ltd.
Ansen Investment And Development Co., Limited	Dongguan Lafite Quartz-Stone Co., Ltd.
Ansen Investment And Development Co., Limited	Foshan Shunde O'Riordan Building Materials Manufacture Co., Ltd.
Aurea Stone Solutions Inc	Jiangxi Fasa Industrial Corporation Limited.
Best Bath & Kitchen Co., Limited	Fujian Province Kaisida Quartz Co., Ltd.
Best Cheer (Xiamen) Stone Works Co., Ltd	Best Cheer (Xiamen) Stone Works Co., Ltd.
Best Cheer (Xiamen) Stone Works Co., Ltd	Quanzhou Best Cheer Industry Co., Ltd.
Bestone High Tech Materials Co., Limited	Bestone High Tech Materials Co., Limited.
Bestone High Tech Materials Co., Limited	GuangDong Bosun Quartz Stone Co., Ltd.
Bestone High Tech Materials Co., Limited	Heshan Biyu Stone Co., Ltd.
Bestview (Fuzhou) Import & Export Co. Ltd	Dongguan Lafite Quartz Stone Co., Ltd.
Bestview (Fuzhou) Import & Export Co. Ltd	Nanan Fute Stone Co., Ltd.
Bestview (Fuzhou) Import & Export Co. Ltd	Foshan City Lewistone New Material Co., Limited.
Bestview (Fuzhou) Import & Export Co. Ltd	Yifeng Industries Corporation Co., Ltd.
Deyuan Panmin International Limited	Fujian Panmin Co., Ltd.
DH Group Co., Limited d.b.a. Xiamen DH Stone Co., Limited	DH Group Co., Limited.
DH Group Co., Limited d.b.a. Xiamen DH Stone Co., Limited	Nan An Zheng Shun Building Material Co., Ltd.
DH Group Co., Limited d.b.a. Xiamen DH Stone Co., Limited	Nan An Ju Jiu Building Materials Co., Ltd.
DH Group Co., Limited d.b.a. Xiamen DH Stone Co., Limited	Whitley New Material Co., Ltd.
East Asia Limited	Heshan City Nande Co., Ltd.
East Asia Limited	Vemy Quartz Surface Co., Ltd.
East Asia Limited	Lanling Jinzhao New Material Co., Ltd.
East Asia Limited	Rong Hua Fu Quartz Co., Ltd.
East Asia Limited	Runtai Stone Co., Ltd.
Elite Industry International Group Limited	Heshan Biyu Stone Industry Co., Ltd.
Enming Art Stone Co., Ltd	Thinking Industries Corporation Limited.
Ersten Surfaces Limited	Huizhou Zhongbo Engineering Stone Co., Ltd.
Ersten Surfaces Limited	Guangdong Xiongjie Building Materials Co., LTD.
Farfield Trade Co., Ltd	Ronghuafu Yunfu Stone Co., Ltd.
Farfield Trade Co., Ltd	Yunfu Meiao Stone Co., Ltd.
Foshan Adamant Science & Technology Co., Ltd	Foshan Adamant Science & Technology Co., Ltd.
Foshan Biyu Stone Co., Limited	Foshan City Gaoming Biyustone Co., Ltd.
Foshan Biyu Stone Co., Limited	Foshan City Gaoming Biyu New Materials Co., Ltd.
Foshan Bluesea Quartz Stone Co., Ltd	Foshan Bluesea Quartz Stone Co., Ltd.
Heshan Nande Stone Industry Co., Ltd	Heshan Nande Stone Industry Co., Ltd.
Foshan Evergreen Import and Export Co., Ltd	Foshan Yixin Stone Co., Ltd.
Foshan Leda Building Materials Co., Ltd	Foshan Leda Building Materials Co., Ltd.
Foshan Leda Building Materials Co., Ltd	Hengyang Athena Quartz Stone Co., Ltd.
Foshan Monica Quartz Stone Co., Ltd	Foshan Monica Quartz Stone Co., Ltd.
Foshan Nanhai Cuipo Artificial Quartz Co., Ltd	Yunfu Stone Solutions Co., Ltd.
Foshan Nanhai Cuipo Artificial Quartz Co., Ltd	Qingyuan Yuefeng Decoration Materials Co., Ltd.
Foshan Nanhai Cuipo Artificial Quartz Co., Ltd	Yunfu Xiangyun Stone Co., Ltd.

SEPARATE RATES COMPANIES—Continued

Exporter	Producer
Non-individually examined exporters receiving separate rates	Producers supplying the non-individually-examined exporters receiving separate rates
Foshan Nanhai Cuipo Artificial Quartz Co., Ltd	Yunfu Ronghuafu Stone Co., Ltd.
Foshan Nanhai Cuipo Artificial Quartz Co., Ltd	Heshan City Nande Stone Co., Ltd.
Foshan Nanhai Cuipo Artificial Quartz Co., Ltd	Yunfu Wayon Stone Co., Ltd.
Foshan Opalus Stone Co., Ltd	Foshan Oubo Stone Co., Ltd.
Foshan Opaly Composite Materials Co., Ltd	Foshan Opaly Composite Materials Co., Ltd.
Foshan Rongguan Glass Material For Building Co., Ltd	Foshan Rongguan Glass Material For Building Co., Ltd.
Foshan Sanshui Queen Ceramic Inc	Foshan Sanshui Queen Ceramic Inc.
Foshan Shunde O'Riordan Building Materials Manufacture Co., Ltd	Foshan Shunde O'Riordan Building Materials Manufacture Co., Ltd.
Free Trans International Trading Limited	Foshan Xianghai Quartz Stone Co., Ltd.
Free Trans International Trading Limited	Foshan Tianci Quartz Stone Co., Ltd.
Fujian Nan'an Zuci Building Material Co., Ltd	Fujian Nan'an Zuci Building Material Co., Ltd.
Fujian Nan'an Zuci Building Material Co., Ltd	Shanghai Yijin Decorating Materials Co., Ltd.
Fujian Pengxiang Industrial Co., Ltd	Fujian Pengxiang Industrial Co., Ltd.
Fujian Putian Wangzhong New Type Building Materials Co., Ltd	Fujian Putian Wangzhong New Type Building Materials Co., Ltd.
Fujian Quanzhou Risheng Stone Co., Ltd	Fujian Quanzhou Risheng Stone Co., Ltd.
Fuzhou CBM Imp. And Exp. Co., Ltd	Fujian Nan'an Zuci Building Material Co., Ltd.
Fuzhou CBM Imp. And Exp. Co., Ltd	Dongguan Lafite Quartz-Stone Co., Ltd.
Golden Dragon Stone Co., Limited	Foshan Rongguan Glass Material For Building Co., Ltd.
Golden Dragon Stone Co., Limited	One Stone Quartz Co., Ltd.
Guangdong Bitto New Material Technologies Co., Ltd	Guangdong Bitto New Material Technologies Co., Ltd.
Guangdong Bosun Quartz Stone Co., Ltd	Guangdong Bosun Quartz Stone Co., Ltd.
Guangdong Overland Ceramics Co., Ltd	Guangdong Overland Ceramics Co., Ltd.
Guangdong Zhongxun New Material Co., Ltd	Guangdong Zhongxun New Material Co., Ltd.
Guangzhou Gelandy New Material Co., Ltd	Guangzhou Gelandy New Material Co., Ltd.
Guangzhou Wei Sheng Stone Building Materials Co., Ltd	Huizhou Zhongbo Engineering Stone Co., Ltd.
HCH Industrial Co., Ltd d.b.a., Shenzhen Hengchang hao Industrial Co., Ltd.	J W Quartz Co., Ltd.
HCH Industrial Co., Ltd d.b.a., Shenzhen Hengchang hao Industrial Co., Ltd.	He Shan Biyu Stone Co., LTD.
HCH Industrial Co., Ltd d.b.a., Shenzhen Hengchang hao Industrial Co., Ltd.	Dongguan kaisa stone Co., Ltd.
HCH Industrial Co., Ltd d.b.a., Shenzhen Hengchang hao Industrial Co., Ltd.	Vemy Quartz Surfaces Co., Ltd.
HCH Industrial Co., Ltd d.b.a., Shenzhen Hengchang hao Industrial Co., Ltd.	Heng Jia Stone.
HCH Industrial Co., Ltd d.b.a., Shenzhen Hengchang hao Industrial Co., Ltd.	Hubei Guantai Building Materials Co., Ltd.
HCH Industrial Co., Ltd d.b.a., Shenzhen Hengchang hao Industrial Co., Ltd.	Dongguan Huaxiang Stone Co., Ltd.
HCH Industrial Co., Ltd d.b.a., Shenzhen Hengchang hao Industrial Co., Ltd.	Guangzhou Hercules Quartz Stone Co., Ltd.
Heshan Biyu Stone Company	Heshan Biyu Stone Company.
Hirsch Glass (Dalian) Co., Ltd	Hirsch Glass (Dalian) Co., Ltd.
Hirsch Glass (Dalian) Co., Ltd	Foshan Yixin Stone Co., Ltd.
HongKong FS Development Limited	Yunfu Chuangyun New Meterail Co., Ltd.
HongKong FS Development Limited	RONGHUAFU Yunfu Stone Co., Ltd.
Huahe Stone (Yunfu) Co., Ltd	Huahe Stone (Yunfu) Co., Ltd.
Huidong Hexingtai Industry Co., Ltd	Huidong Hexingtai Industry Co., Ltd.
Intec Stone (Xiamen) Ltd	Intec Stone (Xiamen) Ltd.
Jiangxi Jingwei Stone Co., Ltd, d.b.a. Jiangxi Jingwei Stone Material Ltd.	Jiangxi Jingwei Stone Co., Ltd, d.b.a. Jiangxi Jingwei Stone Material Ltd.
Kaistar (Xiamen) Co., Ltd	Fujian Best Matrix Quartz Co., Ltd.
Kaistar (Xiamen) Co., Ltd	Kinstone (Jieyang) Stone Co., Ltd.
Kaistar (Xiamen) Co., Ltd	Jieyang Bai Sheng Stone Limited.
KBI Construction Materials Ltd	YUNFU HongHai Stone Co., Ltd.
KBI Construction Materials Ltd	Guangdong Si Hui YuLong Stone Co., Ltd.
KBI Construction Materials Ltd	Foshan Vemy Building Material Co., Ltd.
KBI Construction Materials Ltd	Foshan Adamant Science & Technology Co., Ltd.
KBI Construction Materials Ltd	Yun Fu Xiang Yun Stone Co., Ltd.
Landmark Surface Company Limited	Guangdong Lai Ma Ke Environmental Building Materials Company Limited.
Landmark Surface Company Limited	Foshan Gaoming Dexing Quartz Stone Co., Ltd.
Lanling Jinzhao New Material Co., Ltd	Lanling Jinzhao New Material Co., Ltd.
Lindberg Stone Co., Limited	Dongguan City Lafite Quartz-Stone Co., Ltd.
Lixin Stone Co., Limited	Heshan City Nande Stone Co., Ltd.
Lixin Stone Co., Limited	Guangdong Dexing Quartz Stone Co., Ltd.
Lixin Stone Co., Limited	Guangzhou Hercules Quartz Stone Co., Ltd.
Lixin Stone Co., Limited	Foshan Adamant Science & Technology Co., Ltd.
Lixin Stone Co., Limited	Vemy Building Materials Co., Ltd.

SEPARATE RATES COMPANIES—Continued

Exporter	Producer
Non-individually examined exporters receiving separate rates	Producers supplying the non-individually-examined exporters receiving separate rates
Lixin Stone Co., Limited	Yunfu Honghai Stone Co., Ltd.
Lixin Stone Co., Limited	Dongguan Lefei New Stone Materials Co., Ltd.
Lixin Stone Co., Limited	Dongguan Lafite Quartz-stone Co., Ltd.
Lixin Stone Co., Limited	Huahe Stone (Yunfu) Co., Ltd.
Lixin Stone Co., Limited	Guangdong BOSUN Quartz Stone Co., Ltd.
Lixin Stone Co., Limited	Foshan Nanhai Yachang Building Materials Products Co., Ltd.
Loyalty Enterprise Development (Xinyang) Co., Ltd	Loyalty Enterprise Development (Xinyang) Co., Ltd.
Lulong Ruitong Trading Co., Ltd	Lulong Ruitong Trading Co., Ltd.
Macostone International Industry Co., Limited	Qingyuan Yuefeng Decoration Materials Co., Ltd.
Macostone International Industry Co., Limited	Lanling Modern Materials Co., Ltd.
Monica Surfaces Company Limited	Foshan Monica Quartz Stone Co., Ltd.
Nan'an Guangtaixiang Stone Co., Ltd	Nan'an Guangtaixiang Stone Co., Ltd.
Nanchang Montary Industrial Co., Ltd	Yunfu Kimria Quarts Stone Co., Ltd.
Nanchang Montary Industrial Co., Ltd	Yunfu Montary Stone Co., Ltd.
New Powerstone Industry Co., Limited	Qing Yuan Yuefeng Quartz Stone Co., Ltd.
New Powerstone Industry Co., Limited	Shandong Whitley New Materials Co., Ltd.
New Powerstone Industry Co., Limited	Foshan Devialef New Materials Co., Ltd.
New Powerstone Industry Co., Limited	Yunan Guanglai Stone Co., Ltd.
New Powerstone Industry Co., Limited	Nanan Guangtaixiang Stone Co., Ltd.
Newstar (Quanzhou) Industrial Co., Ltd	Quanzhou Yifeng Industries Corporation.
One Stone Quartz Co., Ltd	Wuzhou Yuanhong Building Materials Product Co., Ltd.
Penglai Huasheng Electronic Co., Ltd	Shandong Sunfull Industrial Co., Ltd.
Po Nice International Trading Limited	Xinyun Stone (Yunfu) Co., Ltd.
Po Nice International Trading Limited	Guangzhou Hercules Quartz Stone Co., Ltd.
Po Nice International Trading Limited	Ronghuafu Yunfu Stone Co., Ltd.
Po Nice International Trading Limited	Henan Namei Quartz Stone Technology Co., Ltd.
Po Nice International Trading Limited	Lanling Jinzhao New Material Co., Ltd.
Po Nice International Trading Limited	Foshan Opalus Quartz Stone Co., Ltd.
Po Nice International Trading Limited	Zhejiang Tiancheng Stone Enterprise Co., Ltd.
Po Nice International Trading Limited	Zhejiang Sanxing Cheng Yuan Energy Science and Technology Co., Ltd.
Po Nice International Trading Limited	LESSO Technology Industry (Chengdu) Co., Ltd.
Qinhuangdao Jingwei Stone Co., Ltd	Qinhuangdao Jingwei Stone Co., Ltd.
Quanzhou Franco Trade Co., Ltd	Fujian Pengxiang Industrial Co., Ltd.
Quanzhou Xinxing Stone Technics Co., Ltd	Quanzhou Xinxing Stone Technics Co., Ltd.
Quanzhou Yifeng Co., Ltd. (AKA Quanzhou Yifeng Industries Corporation).	Quanzhou Yifeng Co., Ltd. (AKA Quanzhou Yifeng Industries Corporation).
Ronghuafu Yunfu Stone Co., Ltd	Ronghuafu Yunfu Stone Co., Ltd.
Shanghai Rightime International Trading Co., Ltd	Fujian Quanzhou Risheng Stone Co., Ltd.
Shunsen Industries Corporation	Shunsen Industries Corporation.
Shunsen Industries Corporation	Thinking Industries Corporation.
Sinostone (Guangdong) Co., Ltd	Sinostone (Guangdong) Co., Ltd.
Stone Solutions Co., Ltd	Stone Solutions Co., Ltd.
Sunjoin Imp. & Exp. (Xiamen) Co., Limited	Henan Namei Quartz Stone Technology Co., Ltd.
Sunjoin Imp. & Exp. (Xiamen) Co., Limited	Thinking Industries Cooperation Limited.
Sunjoin Imp. & Exp. (Xiamen) Co., Limited	Nan'an Hanwa New Building Material Co., Ltd.
Sunjoin Imp. & Exp. (Xiamen) Co., Limited	Quanzhou Yifeng Industries Corporation.
Teltos Quartz Stone Co., Ltd	Teltos Quartz Stone Co., Ltd.
Vquartz Stone Limited	Vquartz Stone Limited.
Wanfeng Compound Stone Technology Co., Ltd	Wanfeng Compound Stone Technology Co., Ltd.
Wanfu Building Materials Products Co., Ltd. Nanan Fujian	Wanfu Building Materials Products Co., Ltd. Nanan Fujian.
Wuxi Yushea Furniture Co., Ltd	Yunfu Zhengfang Stone Company.
Xiamen Ally Group Co., Ltd	Thinking Industries Corporation Limited.
Xiamen Ally Group Co., Ltd	Nanan Fute Stone Co., Ltd.
Xiamen Avanti Stone Industrial Co., Ltd	Foshan Xinyixin Stone Industry Co., Ltd.
Xiamen Best Cheer Industry Co., Ltd	Xiamen Best Cheer Industry Co., Ltd.
Xiamen Best Cheer Industry Co., Ltd	Quanzhou Best Cheer Industry Co., Ltd.
Xiamen City Yadilong Imp & Exp. Co., Ltd	Quanzhou Yifeng Co., Ltd.
Xiamen City Yadilong Imp & Exp. Co., Ltd	Xiamen Orienti New Building Materials Ltd.
Xiamen Deyuan Panmin Trading Co., Ltd	Fujian Panmin Co., Ltd.
Xiamen Duojia Stone Material Co., Ltd. d.b.a. Xiamen Multi-Family Stone Co., Ltd.	Foshan Yixin Stone Co., Ltd.
Xiamen Duojia Stone Material Co., Ltd. d.b.a. Xiamen Multi-Family Stone Co., Ltd.	Foshan Blue Sea Quartz Stone Co., Ltd.
Xiamen Duojia Stone Material Co., Ltd. d.b.a. Xiamen Multi-Family Stone Co., Ltd.	Foshan Ronguan Glass Material For Building Co., Ltd.
Xiamen Duojia Stone Material Co., Ltd. d.b.a. Xiamen Multi-Family Stone Co., Ltd.	One Stone Quartz Co., Ltd.
Xiamen Duojia Stone Material Co., Ltd. d.b.a. Xiamen Multi-Family Stone Co., Ltd.	Quanzhou Yifeng Co., Ltd.

SEPARATE RATES COMPANIES—Continued

Exporter	Producer
Non-individually examined exporters receiving separate rates	Producers supplying the non-individually-examined exporters receiving separate rates
Xiamen Duojia Stone Material Co., Ltd. d.b.a. Xiamen Multi-Family Stone Co., Ltd.	Xiamen Orienti New Building Materials Ltd.
Xiamen Duojia Stone Material Co., Ltd. d.b.a. Xiamen Multi-Family Stone Co., Ltd.	Fujian Panmin Xincai Ltd. Co.
Xiamen Duojia Stone Material Co., Ltd. d.b.a. Xiamen Multi-Family Stone Co., Ltd.	Fujian Nan'an Zuci Building Material Co., Ltd.
Xiamen Enrich Co., Ltd	Dongguan Lafite Quartz-Stone Co., Ltd.
Xiamen Enrich Co., Ltd	Quanzhou Yifeng Industries Corporation.
Xiamen Fortua (Hong Kong) Industry Co., Limited	Xiamen Fortua Industry & Trade Co., Ltd.
Xiamen Further Star Imp and Exp Co., Ltd	Quanzhou Yifeng Industries Corporation.
Xiamen Gofor Stone Co., Ltd	Huayao Stone Slab Factory.
Xiamen Good Time Stone Co., Ltd	One Stone Quartz Co., Ltd.
Xiamen Good Time Stone Co., Ltd	Lanling Jinzhao New Material Co., Ltd.
Xiamen Good Time Stone Co., Ltd	Thinking Industries Corporation Limited.
Xiamen Good Time Stone Co., Ltd	Xiamen Deyuan Panmin Trading Co., Ltd.
Xiamen Good Time Stone Co., Ltd	Quanzhou Yifeng Industries Corporation.
Xiamen Got Cheer Trading Co., Ltd. d.b.a. Xiamen Got Cheer Co., Ltd	Quanzhou Best Cheer Industry Co., Ltd.
Xiamen Got Cheer Trading Co., Ltd. d.b.a. Xiamen Got Cheer Co., Ltd	Xiamen Best Cheer Industry Co., Ltd.
Xiamen Got Cheer Trading Co., Ltd. d.b.a. Xiamen Got Cheer Co., Ltd	Best Cheer (Xiamen) Stone Works Co., Ltd.
Xiamen Honglei Imp. &. Exp. Co., Ltd. d.b.a. Honglei (Xiamen) Stone Co., Ltd.	Xiamen Honglei Imp. &. Exp. Co., Ltd. d.b.a. Honglei (Xiamen) Stone Co., Ltd.
Xiamen Injoy Import & Export Co., Ltd	Thinking Industries Corporation.
Xiamen Interock Stone Co., Ltd	Loyalty Enterprise Development (XinYang) Co., Ltd.
Xiamen Interock Stone Co., Ltd	Fujian Nan'an Zuci Building Material Co., Ltd.
Xiamen Jianming Rising Import & Export Co., Ltd	Thinking Industries Corporation.
Xiamen Jianming Rising Import & Export Co., Ltd	Nan'an Hanhua New Building Materials Co., Ltd.
Xiamen Luck Stone Co., Ltd	Foshan Opaly Composites Co., Ltd.
Xiamen Luck Stone Co., Ltd	Foshan Yixin Stone Co., Ltd.
Xiamen Luck Stone Co., Ltd	Heshan Biyu Stone Co., Ltd.
Xiamen Luck Stone Co., Ltd	Shandong Whitley New Materials Co., Ltd.
Xiamen Luck Stone Co., Ltd	Vemy Building Materials Co., Ltd.
Xiamen Maoshuang Stone Industry Co., Ltd	Fujian Panmin Quartz Co., Ltd.
Xiamen Northern Mining Stone Co., Ltd	Fujian Nanan Xietai Stone Co., Ltd.
Xiamen Northern Mining Stone Co., Ltd	Fujian Nanan Mao Tong Yuan Stone Co., Ltd.
Xiamen Northern Mining Stone Co., Ltd	Fujian Nanan Run Ze Stone Co., Ltd.
Xiamen Northern Mining Stone Co., Ltd	Shandong Horizon Group Co., Ltd.
Xiamen Northern Mining Stone Co., Ltd	Lanling Jinzhao New Material Co., Ltd.
Xiamen Northern Mining Stone Co., Ltd	Fujian Panmin Quartz Co., Ltd.
Xiamen Ogrand Stone Imp. & Exp. Co., Ltd	Quanzhou Yifeng Co., Ltd Nanan Branch.
Xiamen Oriental Stone Products Co., Ltd	Nanan City Shijing Town Stone Products Factory.
Xiamen Oriental Stone Products Co., Ltd	Fujian Nanan Lianhui Stone Products Co., Ltd.
Xiamen Orienti New Building Materials Ltd	Xiamen Orienti New Building Materials Ltd.
Xiamen Qinhui Import & Export Co., Ltd	Zhangzhou Qinhui Quartz Stone Co., Ltd.
Xiamen Qinhui Import & Export Co., Ltd	Fujian Quanzhou Qinhui Stone Co., Ltd.
Xiamen Realho Stone Co., Ltd	Thinking Industries Corporation.
Xiamen Realho Stone Co., Ltd	Shandong Whitley New Materials Co., Ltd.
Xiamen Realho Stone Co., Ltd	Quanzhou Yifeng Co., Ltd.
Xiamen Realho Stone Co., Ltd	Nan'an Fute Building Material Co., Ltd.
Xiamen Shihui Stone Product Co., Ltd	Guangdong Baoxin New Stone Products Co., Ltd.
Xiamen Shihui Stone Product Co., Ltd	Yunfu Honghai Investment Co., Ltd.
Xiamen Sinocau Import & Export Co., Ltd	Jinjiang Huabao Stone Co., Ltd.
Xiamen Smarter Stone Co., Ltd	Heshan Nande Quartz Stone Co., Ltd.
Xiamen Smarter Stone Co., Ltd	Fujian Quanzhou Runze Stone Co., Ltd.
Xiamen Smarter Stone Co., Ltd	Hongsheng Stone Co., Ltd.
Xiamen Stone Forest Co., Ltd	Quanzhou Yifeng Industries Corporation.
Xiamen Stone Forest Co., Ltd	Foshan Vemy Stone Building Material Co., Ltd.
Xiamen Stone Forest Co., Ltd	Foshan Rongguan Glass Material For Building Co., Ltd.
Xiamen Stone Forest Co., Ltd	Qingyuan Yuefeng Decoration Materials Co., Ltd.
Xiamen Stone Forest Co., Ltd	Lanling Jinzhao New Material Co., Ltd.
Xiamen Stone Forest Co., Ltd	Foshan Yixin Stone Co., Ltd.
Xiamen Stone Forest Co., Ltd	Xiamen Orienti New Building Materials Ltd.
Xiamen Stone Forest Co., Ltd	Dongguan Lafite Quartz-Stone Co., Ltd.
Xiamen Stone Forest Co., Ltd	Dongguan City Hongke Quartz Stone Co., Ltd.
Xiamen Stone Harbour Co., Ltd	Fujian PengXiang Industrial Co., Ltd.
Xiamen Stone Harbour Co., Ltd	Zhangzhou QinHui Quartz Co., Ltd.
Xiamen Stonelink Imp & Exp Co., Ltd	Fujian PengXiang Industrial Co., Ltd.
Xiamen Stonelink Imp & Exp Co., Ltd	Heshan Biyu Stone Co., Ltd.
Xiamen Stonevic Co., Ltd	Heshan Biyu Stone Co., Ltd.
Xiamen Stonevic Co., Ltd	Quanzhou Yifeng Industries Co., Ltd.

SEPARATE RATES COMPANIES—Continued

Exporter	Producer
Non-individually examined exporters receiving separate rates	Producers supplying the non-individually-examined exporters receiving separate rates
Xiamen Sun Young Corporation	Yifeng Industries Corporation.
Xiamen Sun Young Corporation	Heshan City Nande Stone Co., Ltd.
Xiamen Sun Young Corporation	Benyi New Materials Co., Ltd.
Xiamen Sun Young Corporation	Fujian Quanzhou Risheng Stone Co., Ltd.
Xiamen Sun Young Corporation	Nanan Chunjia Stone Co., Ltd.
Xiamen Terry Stone Co., Ltd	Heshan Biyu Stone Co., Ltd.
Xiamen Touch Stone Co., Ltd	One Stone Quartz Co., Ltd.
Xiamen Vatro Stone Imp. & Exp. Co., Ltd	Xiamen Vatro Stone Imp. & Exp. Co., Ltd.
Xiamen Vatro Stone Imp. & Exp. Co., Ltd	Shandong Whitley New Materials Co., Ltd.
Xiamen Vesen Imp. & Exp. Trade Co., Ltd	Nanan Xingli Stone Co., Ltd.
Xiamen Wanfu Trade Co., Ltd	Xiamen Wanfu Trade Co., Ltd.
Xiamen Wanfu Trade Co., Ltd	Thinking Industries Corporation.
Xiamen Wanfu Trade Co., Ltd	Yifeng Industries Corporation.
Xiamen Wanli Stone Decoration & Design Co., Ltd	Xiamen Wanlistone Stock Co., Ltd.
Xiamen Wanli Stone Decoration & Design Co., Ltd	Quanzhou Yifeng Co., Ltd.
Xiamen Wanli Stone Decoration & Design Co., Ltd	Nan'an Fengsheng Stone Co., Ltd.
Xiamen Wanli Stone Decoration & Design Co., Ltd	Thinking Industries Corporation Limited.
Xiamen Wanli Stone Decoration & Design Co., Ltd	One Stone Quartz Co., Ltd.
Xiamen Wanli Stone Decoration & Design Co., Ltd	Taking Luck (Xiamen) Granite & Marble Co., Ltd.
Xiamen Wanlistone Stock Co., Ltd	Xiamen Wanlistone Stock Co., Ltd.
Xiamen Winson Import and Export Co., Ltd	Xiamen Oulandi New Building Materail Co., Ltd.
Xiamen Yadonglong Imp & Exp. Co., Ltd	Quanzhou Yifeng Co., Ltd.
Xiamen Yadonglong Imp & Exp. Co., Ltd	Xiamen Orienti New Building Materials Ltd.
Xiamen Yadonglong Imp & Exp. Co., Ltd	Xinmingdu Building Materials (Xiamen) Co., Ltd.
Xiamen Yalitong Stone Industrial Co., Ltd	Fujian Nanan Xudong Building Materials Co., Ltd.
Xiamen Yalitong Stone Industrial Co., Ltd	Zhongci Wanjia Decoration Materials Co., Ltd.
Xiamen Yalitong Stone Industrial Co., Ltd	Quanzhou Yifeng Co., Ltd.
Xiamen Yeyang Import & Export Co., Ltd. (AKA Xiamen Yeyang Imp&Exp Co., Ltd.).	Fujian Nanan Yuanhong Construction Materails Co., Ltd.
Xiamen Yiqing Imp. & Exp. Co., Ltd	Fujian Nanan Yuanhong Construction Materails Co., Ltd.
Xiamen Zhongguanshi Stone Industry Co., Limited	Yunan Guanglai Stone Co., Ltd.
Xiamen Zhongguanshi Stone Industry Co., Limited	Foshan Devialef New Materials Co., Ltd.
Xiamen Zhongguanshi Stone Industry Co., Limited	Nan'an Guang Tai Xiang Stone Co., Ltd.
Xiamen Zhongguanshi Stone Industry Co., Limited	Wanfeng Compound Stone Technology.
Xiamen Zhongguanshi Stone Industry Co., Limited	Foshan Xinghe Quartz Stone Co., Ltd.
Xinyun Stone (Yunfu) Co., Ltd	Xinyun Stone (Yunfu) Co., Ltd.
Yekalon Industry Inc	Foshan Xinyixin Stone Company Limited.
Yunfu Andi Stone Co., Ltd	Yunfu Andi Stone Co., Ltd.
Yunfu Chuangyun New Meterail Co., Ltd	Yunfu Chuangyun New Meterail Co., Ltd.
Yunfu Dong Shan Stone Material Co., Ltd	Yunfu Dong Shan Stone Material Co., Ltd.
Yunfu Honghai Co., Ltd	Yunfu Honghai Co., Ltd.
Yunfu Jiuru Stone Ltd	Yunfu Jiuru Stone Ltd.
Yunfu Meiao Stone Co., Ltd	Yunfu Meiao Stone Co., Ltd.
Yunfu Wayon Stone Co., Ltd	Yunfu Wayon Stone Co., Ltd.
Yunfu Wayon Stone Co., Ltd	Guangdong Wayon Industrial Co., Ltd.
Yunfu Weibao Stone Co., Ltd	Yunfu Weibao Stone Co., Ltd.
Yunfu Weibao Stone Co., Ltd	Guangdong Wayon Industrial Co., Ltd.
Yunfu Wintop Stone Co., Ltd	Yunfu Wintop Stone Co., Ltd.
Yunfu Wintop Stone Co., Ltd	Guangdong Bosun Quartz Stone Co., Ltd.
Yunfu Wintop Stone Co., Ltd	Yunfu Runtai Stone Co., Ltd.
Yunfu Wintop Stone Co., Ltd	RongHuaFu Yunfu Stone Co., Ltd.
Zhangzhou OCA Furniture Co., Ltd	Fujian Panmin Co., Ltd.
Zhangzhou OCA Furniture Co., Ltd	Wanfu Building Materials Products Co., Ltd.
Zhaoqing Aibo New Material Technology Co., Ltd	Zhaoqing Aibo New Material Technology Co., Ltd.
Zhaoqing Aibo New Material Technology Co., Ltd	Shanghai Meiyang Stone Co., Ltd.
Zhaoqing Maxstone Com., Ltd	Zhaoqing Maxstone Com., Ltd.
Zhaoqing Uni Marble Co., Ltd	Vemy Quartz Co., Ltd.
Zhaoqing Uni Marble Co., Ltd	Guangdong Bosun Quartz Stone Co., Ltd.

[FR Doc. 2019–10800 Filed 5–22–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Uniform Formulary Beneficiary Advisory Panel; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Uniform Formulary Beneficiary Advisory Panel will take place.

DATES: Open to the public Wednesday, June 26, 2019, from 9:00 a.m. to 12:00 p.m.

ADDRESSES: The address of the open meeting is the Naval Heritage Center Theater, 701 Pennsylvania Avenue NW, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Colonel Paul J. Hoerner, USAF, 703–681–2890 (Voice), None (Facsimile), *dha.ncr.j-6.mbx.baprequests@mail.mil* (Email). Mailing address is 7700 Arlington Boulevard, Suite 5101, Falls Church, VA 22042–5101. Website: *https://health.mil/bap.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150.

The Panel will review and comment on recommendations made to the Director of the Defense Health Agency, by the Pharmacy and Therapeutics Committee, regarding the Uniform Formulary.

Purpose of the Meeting: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Uniform Formulary Beneficiary Advisory Panel will take place.

Agenda

1. Sign-In.
2. Welcome and Opening Remarks.
3. Scheduled Therapeutic Class Reviews (Comments will follow each agenda item).
   a. Proton Pump Inhibitors—Alternate Dosage Forms.
   b. Proton Pump Inhibitors—Capsules and Tablets.
   c. Pulmonary Arterial Hypertension—Endothelin Receptor Antagonists.
   d. Pulmonary Arterial Hypertension—Prostacyclin Nebulized Therapy.
   e. Pulmonary Arterial Hypertension—Prostacyclin Oral Therapy.
   f. Pulmonary Arterial Hypertension—Soluble Guanylate Cyclase Stimulator.
4. Newly Approved Drugs Review.
5. Pertinent Utilization Management Issues.
6. Panel Discussions and Vote.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b, as amended, and 41 Code of Federal Regulations (CFR) 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is limited and will be provided only to the first 220 people signing-in. All persons must sign-in legibly.

Written Statements: Pursuant to 41 CFR 102–3.140, the public or interested organizations may submit written statements to the membership of the Panel about its mission and/or the agenda to be addressed in this public meeting. Written statements should be submitted to the Panel's Designated Federal Officer (DFO). The DFO's contact information can be obtained previously in this announcement. Written comments or statements must be received by the committee DFO at least five (5) business days prior to the meeting so that they may be made available to the Panel for its consideration prior to the meeting. The DFO will review all submitted written statements and provide copies to all the committee members.

Dated: May 17, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–10740 Filed 5–22–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2019–OS–0030]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Policy, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by June 24, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Security Assistance Network (SAN); OMB Control Number 0704–0555.

Type of Request: Extension.

Number of Respondents: 1,784.

Responses per Respondent: 1.

Annual Responses: 1,784.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 446.

Needs and Uses: The Security Assistance Network (SAN) is a web based database used to exchange Security Cooperation training information between overseas Security Cooperation Offices, Geographical Combatant Commands, Military Departments, Defense Security Cooperation Agency, DoD Schoolhouses, Regional Centers, and International Host Nation Organizations. The Security Cooperation Training Management System (SC–TMS) is a tool used by the Security Cooperation community to manage International Military Student training data.

Affected Public: Individuals or households.

Frequency: As required.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: May 17, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–10756 Filed 5–22–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2019–OS–0005]

Submission for OMB Review; Comment Request

AGENCY: Defense Finance and Accounting Service (DFAS), DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by June 24, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Trustee Report; DD 2826; OMB Control Number 0730–0012.

Type of Request: Extension.

Number of Respondents: 200.

Responses per Respondent: 1.

Annual Responses: 200.

Average Burden per Response: 1 hour.

Annual Burden Hours: 200.

Needs and Uses: This form is used to report on the administration of the funds received on behalf of a mentally incompetent member of the uniformed services pursuant to 37 U.S.C. 602–604.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: May 17, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–10757 Filed 5–22–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Intelligence Agency National Intelligence University Board of Visitors; Notice of Federal Advisory Committee Meeting

AGENCY: Defense Intelligence Agency, National Intelligence University, DoD.

ACTION: Notice of closed meeting.

SUMMARY: The Department of Defense is publishing this notice to announce that the following Federal Advisory Committee meeting of the National Intelligence University Board of Visitors has been scheduled. The meeting is closed to the public.

DATES: Thursday, June 6, 2019 (7:30 a.m. to 5:15 p.m.) and Friday, June 7, 2019 (7:30 a.m. to 1:00 p.m.).

ADDRESSES: Defense Intelligence Agency, 7400 Pentagon, ATTN: NIU, Washington, DC 20301–7400.

FOR FURTHER INFORMATION CONTACT: Dr. J. Scott Cameron, President, National Intelligence University, Bethesda, MD 20816, Phone: (301) 243–2118.

SUPPLEMENTARY INFORMATION:

Purpose: The Board will discuss several current critical intelligence issues and advise the Director, DIA, as to the successful accomplishment of the mission assigned to the National Intelligence University.

Agenda: The following topics are listed on the National Intelligence University Board of Visitors meeting agenda: Welcome and Overview by Chair and NIU President; IC 2025/NIU22/Strategic Plan Crosswalk; Governance Transfer from SECDEF to DNI; Regional Accreditation Update; Working Lunch with Board members and University leadership; Introduction of New Provost; Review and Way Forward for Leadership and Management in the IC Certificate Program; NIU Strategic Initiatives and Partnerships; Faculty Roles and Responsibilities; Board Business; Executive Session; NIU Academic Program Updates; NIU Research Program Highlights; Board Business in Executive Session; Meeting Read-out by Board Chair to IC Senior Leaders.

The entire meeting is devoted to the discussion of classified information as defined in 5 U.S.C. 552b(c)(1) and therefore will be closed. Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written statements to the National Intelligence University Board of Visitors about its mission and functions.

Written statements may be submitted at any time or in response to the stated agenda of a planned meeting of the National Intelligence University Board of Visitors. All written statements shall be submitted to the Designated Federal Officer for the National Intelligence University Board of Visitors, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Designated Federal Officer can be obtained from the GSA's FACA Database—*http://www.facadatabase.gov/.*

Dated: May 17, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–10754 Filed 5–22–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Renewal of Department of Defense Federal Advisory Committees

AGENCY: Department of Defense.

ACTION: Renewal of Federal Advisory Committee.

SUMMARY: The Department of Defense is publishing this notice to announce that it is renewing the charter for the Board of Visitors, Marine Corps University (''the Board'').

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Board's charter is being renewed pursuant to 10 U.S.C. 8592(d) and in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix) and 41 CFR 102–3.50(a). The charter and contact information for the Board's Designated Federal Officer (DFO) are found at *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation.*

The Board provides the Secretary of Defense with independent advice and recommendations on matters pertaining to the Marine Corps University (the University). The Board shall provide advice and recommendations on academic and administrative matters critical to the full accreditation and successful operation of the University.

The Board shall be composed of at least seven and not more than 11 members who are eminent authorities in the fields of education, defense, management, economics, leadership, academia, national military strategy, or international affairs. The President of the University shall be a non-voting ex-officio member. Individual members will be appointed according to DoD policy and procedures, and members will serve a term of service of one-to-four years with annual renewals.

One member, according to DoD policy and procedures, will be appointed as Chair of the Board. No member, unless approved according to DoD policy and procedures, may serve more than two consecutive terms of service on the Board, to include its subcommittees, or serve on more than two DoD federal advisory committees at one time.

Members of the Board who are not full-time or permanent part-time Federal officers or employees will be appointed as experts or consultants, pursuant to 5 U.S.C. 3109, to serve as special government employee members. Board members who are full-time or permanent part-time Federal officers or employees will be appointed, pursuant to 41 CFR 102–3.130(a), to serve as regular government employee members.

All members of the Board are appointed to provide advice on the basis of their best judgment without representing any particular point of view and in a manner that is free from conflict of interest.

Except for reimbursement of official Board-related travel and per diem, members serve without compensation.

The public or interested organizations may submit written statements to the Board membership about the Board's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Board. All written statements shall be submitted to the DFO for the Board, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: May 17, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–10746 Filed 5–22–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2019–OS–0011]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by June 24, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Education Activity (DoDEA) Research Approval Process; DoDEA Form 1304.01–F1; OMB Control Number 0704–0457.

Type of Request: Revision.

Number of Respondents: 50.

Responses per Respondent: 1.

Annual Responses: 50.

Average Burden per Response: 1 hour.

Annual Burden Hours: 50.

Needs and Uses: The Department of Defense Education Activity (DoDEA) receives requests from researchers to conduct non-DoDEA sponsored research studies in DoDEA schools, districts, and/or areas. To review the proposed research requests, DoDEA is seeking renewal for the DoDEA ''Research Study Request'' Form 1. The DoDEA ''Research Study Request'' collects information about the researcher, the research project, audience, timeline, and the statistical analyses that will be conducted during the proposed research study. This information is needed to ensure that the proposed non-DoDEA sponsored research does not unduly interfere with the classroom instructional process or the regular operations of the school, district, and/or areas.

Affected Public: Individuals or Households.

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: May 17, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–10755 Filed 5–22–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice Inviting Postsecondary Educational Institutions To Participate in Experiments Under the Experimental Sites Initiative; Federal Student Financial Assistance Programs Under Title IV of the Higher Education Act of 1965, as Amended

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary invites institutions of higher education (institutions) that participate in the Federal Work-Study (FWS) Program authorized under title IV of the Higher Education Act of 1965, as amended (HEA), to apply to participate in a new institutional experiment under the Experimental Sites Initiative (ESI).

DATES: Letters of interest to participate in the experiment described in this notice must be received by the Department no later than July 8, 2019 to ensure that the Department considers the institution for participation in the experiment. Institutions that submit letters that are received after July 8, 2019 may, at the discretion of the Secretary, be considered as additional future participants on a rolling periodic basis.

ADDRESSES: Letters of interest must be submitted by electronic mail to the following email address: *experimentalsites@ed.gov.* For format and other required information, see ''Instructions for Submitting Letters of Interest'' under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Warren Farr, U.S. Department of Education, Federal Student Aid, 830 First Street NE, Washington, DC 20002. Telephone: (202) 377–4380. Email at: *Warren.Farr@ed.gov.*

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

SUPPLEMENTARY INFORMATION:

Instructions for Submitting Letters of Interest: Letters of interest must be submitted as an attachment in a Portable Document Format (PDF) to an email message sent to the email address provided in the **ADDRESSES** section of this notice. The subject line of the email should read ''ESI 2019—Federal Work-Study Experiment.'' The text of the email should include the name and address of the institution. The letter of interest must be on institutional letterhead and be signed by the institution's president or chancellor. The letter must include the institution's official name, its Office of Postsecondary Education Identification (OPEID) number, and the name of a contact person at the institution, along with a mailing address, email address, and telephone number of a contact person at the institution. The letter should also include the information described in the ''Application and Selection'' section in this notice. The letter must explain which offices or departments from the institution will participate in this experiment, and what role each will play. Upon receipt of a letter of interest, the Department will notify the institution by email that its letter of interest was received. This notification should be kept in the institution's records.

Background: Under the ESI, the Secretary has authority to grant waivers of certain title IV, HEA statutory or regulatory requirements to allow a limited number of institutions to participate in experiments to test alternative methods of administering the title IV, HEA programs. The alternative methods of title IV, HEA administration that the Secretary is permitting under this ESI experiment are designed to test how the following changes will increase partnerships between institutions and industry, improve student retention and completion, reduce student debt levels, and yield strong post-graduation employment outcomes: (1) Removing limits on the portion of an institution's FWS funds that may support students employed by private-sector companies; (2) increasing the number of hours per week an FWS student who is enrolled in a work-based learning program may work; (3) reducing the share of wages that must be covered by private-sector employers; and (4) allowing institutions to pay low-income students for work experiences required by their program, such as student teaching and clinical rotations. The Department is also interested in determining whether using FWS funds to supplement wages for private-sector employment will stimulate the creation or strengthening of employer-institution partnerships that engage employers in curriculum development and program evaluation, expand the number and kinds of off-campus job opportunities made available to students, and increase the number of formal work-based learning opportunities (such as apprenticeships) available to students. The Department also seeks to understand how FWS opportunities created under the experiment align with the academic programs or career goals of the student participants, including among students in liberal arts or humanities programs that may use an FWS to explore potential career options.

Apprenticeships, internships, and other work-and-learn opportunities can be beneficial to students, employers, and institutions. We wish to understand if, and to what extent, students who participate in program-related, paid, work experience enjoy improved graduation outcomes, accumulate less debt, and enjoy better post-graduation employment opportunities. In addition, students who earn wages while enrolled in a work-based learning program may be more likely to retain Pell eligibility if a portion of their wages are FWS wages since those earnings are not considered in the determination of a student's financial need.

Work-based learning programs benefit employers by helping them develop a pipeline of qualified workers and by engaging them in curriculum development or review to ensure that students graduate with strong workplace competencies. Employers also benefit when FWS wages offset a portion of the cost of work-based learning opportunities, thus reducing barriers to entry for employers that wish to start apprenticeship programs.

Institutions benefit from improved partnerships with business leaders, who can help inform academic programs and curricula to ensure that students are graduating with workplace competencies in addition to the subject matter expertise gained through their studies. These partnerships may also reduce the need for institutions to purchase expensive equipment or build specialized facilities, since private-sector companies may already have the equipment and facilities needed to instruct students.

The Department expects employers and institutions participating in this experiment to work together to coordinate schedules and minimize conflict between academic and employment activities. In addition, to the maximum extent possible, FWS-supported private-sector employment should be academically relevant, as required by section 443(c)(4) of the HEA and support the students' career goals. Employers must avoid the displacement of employed workers or the impairment of existing contracts for services and may not use funds made available under this experiment to pay any employee who would otherwise be employed by the organization. However, this does not prevent an employer who is engaged in apprenticeship from paying the student for hours worked in addition to the FWS-supported work if the

apprenticeship requires more on-the-job training than FWS wages can support or the employer wishes to pay wages to apprentices for the time they spend engaged in classroom learning. The Department also encourages sponsors of work-based learning programs to rely on, and provide financial support for, credit-bearing classroom instruction provided by colleges and universities for the classroom portion of those programs.

FWS is one of the oldest Federal Student Aid programs. Currently, it provides students with part-time employment to help pay higher education expenses, but institutions must navigate complicated requirements that limit the percentage of funds that can be used to support private sector employment. Current regulations also require private-sector employers to pay a higher proportion of wages as compared to on-campus employment or off-campus employment at non-profit organizations. Meanwhile, it is possible that smaller employers and start-up companies have fewer resources than well-established and well-supported non-profit organizations to provide paid learning opportunities for students.

While FWS could be an important means by which colleges and universities provide students with relevant program-related work experiences that could improve their subject matter expertise, enhance their classroom learning, and improve their job prospects after graduating, there is little indication the program is being used sufficiently in such a manner. Studies have shown that FWS jobs are often unrelated to a student's career goals or majors.[1] In addition, although campuses are permitted to use up to 10 percent of their FWS funds or $75,000 to support job development opportunities, few institutions use the available resources to pursue such opportunities for students.

As shown in Table 1, colleges and universities rarely provide students with employment opportunities that are located off-campus, despite the fact that few college graduates are destined to seek employment at an institution of higher education; instead most will work for private, for-profit firms.[2] During award year 2016–2017, over 3,000 colleges and universities provided over 600,000 students with FWS opportunities. In that year, 92 percent of FWS dollars supported students in on-campus employment, while less than one-tenth of one percent supported off-campus employment with private-sector employers.

TABLE 1—DISTRIBUTION OF FWS EARNINGS BY EMPLOYER TYPE

[2016–17]

On-campus	Off-campus nonprofit/government	Off-campus for-profit
$995,961,457 (91.76%)	$88,702,919 (8.17%)	$726,208 (0.07%)

Nearly all students believe that by earning a college credential, they will improve their employment opportunities and earnings.[3] While surveys show that students and faculty believe that college graduates are well prepared to enter the workforce, employers see things differently.[4] Many employers do not believe that college is preparing graduates to succeed in the workforce, and some are looking more carefully at an individual's work experience when making hiring decisions since degrees alone may no longer adequately signal an individual's intellectual capacity, resilience, and grit.[5] Therefore, it is important to expand the number and kinds of opportunities available to students so that they can gain experience in private-sector employment prior to graduation.

Internships, apprenticeships, and other work-and-learn opportunities provide high-quality educational opportunities that can serve as a primary or ancillary learning opportunity where theory and application are coordinated to lead to higher level competencies. However, there are insufficient numbers of apprenticeship opportunities available to students, especially in fields where apprenticeship has not historically been a common career pathway. Internship opportunities may be more plentiful, but many are low-paying or unpaid, meaning that these valuable opportunities are foreclosed to lower-income students who may need to earn wages to help pay for their education and other living expenses. Similarly, lower-income students may face tremendous challenges paying tuition and supporting themselves while engaged in required clinical rotations, externships, or student teaching, since outside work may be prohibited or discouraged during those times, or the student may simply not have enough time for both. As a result, these experiences, which should improve learning and lead to better career outcomes, can be detrimental to lower-income students by negatively affecting their educational outcomes, lengthening their time to completion, or increasing their reliance on loans.

Apprenticeships are especially effective in combining classroom and workplace learning in an interrelated and coordinated fashion. We are encouraged by the growing number of apprenticeship programs that rely on colleges and universities to provide classroom instruction that supports learning in the workplace. However, much more needs to be done to expand the number and kinds of apprenticeship programs available. Institutions that participated in the Department of Labor's American Apprenticeship Initiative grant program frequently reported at project meetings and accelerator sessions that despite strong letters of support from employers when developing their proposals, it was challenging to get employers to commit when it came time to develop structured workplace curricula or implement a full apprenticeship program. At those same meetings, employers often complained about the high cost of paying tuition and fees for apprentices to complete their classroom learning on a college campus. On the other hand, employers who participated on the President's Task Force on Apprenticeship Expansion explained that they find it difficult to identify institutions that are willing to provide classes at times and on a

[1] *www.insidehighered.com/views/2019/04/26/change-federal-work-study-program-so-it-encourages-useful-work-opinion;www.clasp.org/sites/default/files/public/resources-and-publications/publication-1/CPES_Federal WorkstudyFINAL.pdf;* and *compact.org/initiatives/federal-work-study/community/.*

[2] *www.bls.gov/opub/ted/2018/nonprofits-account-for-12-3-million-jobs-10-2-percent-of-private-sector-employment-in-2016.htm; www.bls.gov/emp/tables/employment-by-major-industry-sector.htm.*

[3] *www.newamerica.org/education-policy/edcentral/varying-degrees-2018/.*

[4] *www.insidehighered.com/news/2018/02/23/study-students-believe-they-are-prepared-workplace-employers-disagree.*

[5] *https://chronicle-assets.s3.amazonaws.com/5/items/biz/pdf/Employers%20Survey.pdf.*

schedule that does not interfere with workplace learning, or at a cost that is reasonable for an employer to cover.[6]

We wish to test in this experiment whether the opportunity to access FWS funds to pay or subsidize wages, and to allow students to be employed for more than 10 hours per week, provides the needed incentive to attract more businesses to participate in apprenticeships, and to do so in partnership with colleges and universities.

The President's Task Force on Apprenticeship Expansion pointed out during their deliberations and in their final report that employers may be reticent to engage in apprenticeship due to the cost of wages and classroom instruction, coupled with loss of productivity among the most qualified workers who divert time and energy from their primary job function in order to serve as mentors and instructors, and the possibility that another employer will ''poach'' well-prepared workers after the apprenticeship is over.[7] The Task Force called upon the Federal government to examine current workforce development programs to identify funding opportunities that would better support apprenticeship expansion. In its efforts to be responsive to the recommendations of the Task Force, the Department has identified FWS as an ideal candidate to provide such support.

There are additional ancillary benefits to consider. For example, since FWS funds are not included in the Federal need analysis calculation, a student engaged in paid work-based learning will be less likely to lose Pell eligibility if the wages are paid through the FWS program. In addition, since FWS funds are available only to students in credit-bearing programs, we believe that employers will be incentivized to require institutions to offer courses that yield college credit rather than relying on non-credit offerings at the institution to support employer-supported higher education. The Department also hopes that by off-setting a portion of wages, employers will be more likely to pay some or all of the costs of associated classroom learning, including if it takes place at an institution.

By leveraging FWS funds to support the creation or expansion of education-related jobs, paid internships, apprenticeships, student teaching, externships, and work-and-learn opportunities the Department seeks to ascertain whether this initiative should be considered for broader application. Broader application of the initiative could be justified if one or more of the following can be demonstrated: (1) The number and kinds of private-sector job and work-based learning opportunities, including apprenticeships, made available to FWS students increase; (2) student completion rates increase or time to degree completion decreases among FWS students who work in private-sector jobs or among students who receive FWS wages while completing required externships, clinical rotations, or student teaching; or (3) fewer Pell eligible students whose wages for work-based learning programs are paid for, or subsidized, with FWS funds lose their Pell eligibility.

The Experiment

Description

Institutions are permitted to utilize FWS funds to pay wages to students employed in on-campus, off-campus, and private sector jobs; however, over 90 percent of FWS wages are paid to students employed in on-campus jobs. This may be because of the added cost and complexity to institutions of cultivating private-sector FWS employment opportunities or complying with program regulations when private sector employment is involved, challenges in coordinating work and school schedules when off-campus employers are involved, the limitations on the number of hours an FWS student is permitted to work, and the higher percentage of wages that private-sector employers must pay as compared to non-profit or campus employers.

In addition, while students engaged in required externships, clinical rotations, or student teaching are clearly engaged in work-based learning, historically, institutions have not been permitted to pay FWS wages to students involved in these activities. This can be detrimental to low-income students who may have to resort to student loans in order to pay tuition and support themselves during periods of full-time non-paid work.

This experiment aims to determine whether, by reducing the difficulty to institutions of paying FWS wages to students employed by private-sector companies, increasing the number of hours an FWS student is permitted to work, and removing restrictions on allocations to on-campus, off-campus, and community service jobs, institutions can cultivate additional private-sector opportunities for employment of FWS students. In addition, the experiment aims to determine whether off-campus, private-sector FWS jobs improve student completion rates, reduce student borrowing, reduce time to degree completion, or lead to improved employment outcomes.

The experiment is also designed to assess whether paying FWS wages to students engaged in required externships, clinical rotations, student teaching, or similar work-based learning opportunities increases completion rates, reduces borrowing, and improves employment outcomes among FWS-eligible students.

The experiment also seeks to explore whether increased levels of Job Location and Development (JLD) funds enable institutions to develop more partnerships with employers that result in private-sector FWS opportunities, including apprenticeships. An institution is allowed to use part of the Federal funds it receives under the FWS Program to establish, administer, or expand a JLD Program. The JLD Program locates and develops off-campus job opportunities for students who are currently enrolled and who want jobs regardless of financial need. This means that jobs may be located and developed under the JLD Program for FWS and non-FWS eligible students. JLD jobs may be part-time or full-time, for either a for-profit or nonprofit employer.

In addition, an institution is permitted to use JLD funds to identify apprenticeship opportunities and help employers develop them, including the classroom and work-based learning components. An institution may use up to 10 percent of its annual FWS allocation, but no more than $75,000, to support its JLD Program. FWS funds can be used to pay up to 80 percent of the allowable costs to operate a JLD Program, such as staff salaries, supplies, and travel. The remaining costs (20 percent) are paid by an institution either in cash or in services. Institutions may enter into written agreements with other institutions or apprenticeship intermediaries to establish, fund, and operate a JLD Program for students enrolled at those institutions. Under such agreements, institutions may combine available JLD funds and resources.

Despite the availability of the JLD Program to assist institutions in developing off-campus employment opportunities for students, relatively few institutions take advantage of it. During Award Year 2016–2017, 338 institutions reported using about $11 million, or less than 1 percent, of their FWS allocations for JLD programs.

Institutions participating in this experiment will be encouraged to collaborate with local governments,

[6] *www.dol.gov/apprenticeship/docs/task-force-apprenticeship-expansion-report.pdf.*

[7] *www.dol.gov/apprenticeship/docs/task-force-apprenticeship-expansion-report.pdf.*

companies, trade and industry groups, non-profit organizations, unions, joint labor-management organizations, apprenticeship intermediaries, and others to develop relevant career-focused experiences for students. A particular emphasis will be placed on developing apprenticeships.

Participating institutions may be required to submit information to the Department or its contractor for an evaluation of the experiment (see Reporting and Evaluation section below).

Waivers

Institutions selected for this experiment will be granted flexibility in implementing the FWS and JLD programs. The following statutory and regulatory provisions would be waived:

- *34 CFR 675,* to the extent it restricts students in FWS programs to part-time employment. We propose waiving these restrictions to enable full-time employment opportunities related to the student's academic program (*e.g.,* relevant apprenticeships, clinical rotations, or student teaching).
- *34 CFR 675.23,* which limits the amount of an institution's FWS allocation and re-allocation for an award year to pay the compensation of FWS students employed by a private for-profit organization to 25 percent. We propose waiving this restriction entirely for institutions selected to participate in the experiment.
- *34 CFR 675.26(a)(3),* which limits the Federal share of the compensation to a student employed by a private for-profit organization to 50 percent. We propose increasing the Federal share amount to 75 percent for a small business, as defined in 13 CFR 121, which is the amount permitted for most non-profit or community service employment.
- *HEA section 442(a)(4)(A) and (B),* which permits the Secretary to allocate to eligible institutions up to 10 percent of the amount appropriated for FWS in excess of $700 million in any fiscal year. To encourage institutions to participate in the experiment in sufficient numbers to derive meaningful conclusions, we propose to use this authority to provide additional FWS funding to institutions participating in the experiment. This includes waiving the condition that they meet the statutory requirements for graduation or transfer of Pell Grant recipients since we believe that work-and-learn programs and apprenticeship programs can significantly improve graduation rates among low-income students.
- *34 CFR 675.32,* which caps the amount of an institution's FWS allocation to support a JLD Program at the lesser of $75,000 or 10 percent. We propose allowing an increase in the amount, in order to enable institutions to hire a coordinator or for other functions to further encourage institutions and employers to establish and expand paid internships, apprenticeships, and other work-and-learn opportunities. The institution's specific request for additional flexibility under this section must be detailed in its application and approved by the Department.
- *34 CFR 675.18(g),* which requires an institution to use at least seven percent of the sum of its initial and supplemental FWS allocations for an award year to compensate students employed in community service activities, including at least one reading tutoring project that employs one or more FWS students as reading tutors for children who are preschool age or are in elementary school or a family literacy project that employs one or more FWS students in family literacy activities. We propose waiving this requirement to provide maximum flexibility to institutions.

All other provisions and regulations of the title IV, HEA student assistance programs will remain in effect.

Reporting and Evaluation

The Department is interested in rigorously assessing the effectiveness of using FWS funds to expand private-sector job opportunities, including apprenticeships, and to support students engaged in program-required externships or student teaching. To meet this objective, the Department may randomly select from among all interested institutions a group of institutions that will be allowed to participate in the experiment. This random selection would take into account institutional characteristics such as total enrollment or the number of students participating in FWS, as well as the institutional priorities stated elsewhere. The institutions not selected may be invited to join the experiment in a subsequent academic year. This approach would allow the Department to assess the effects of the experiment by comparing the experiences and outcomes of students in participating versus non-participating institutions or in early- versus later-participating institutions.

Alternatively, the Department may require participating institutions to randomly assign certain parts of the waivers to eligible students; for example, to allow FWS to fund half (instead of all) of the eligible students engaged in program-required externships or student teaching or to give the higher Federal wage share for private-sector jobs to half (instead of all) of the eligible students who might seek one. This approach would enable the Department to rigorously assess the effects of those particular waivers on students' experiences and outcomes, even while the potential benefits of the experiment's other waivers would be available institution-wide.

Participating institutions will be required to collect, maintain, and report information about students involved in the experiment and to participate in the Department's evaluation. Information needed for the evaluation may include: (1) The identity of students eligible for FWS and those who choose to take advantage of the opportunities provided through the experiment, and (2) the characteristics associated with each student's FWS job or program-required work-based learning, including the number of hours worked (including hours not supported by FWS wages), the wages paid (including for non-FWS paid work with the same employer), and the identity of the employer. This information would likely come from databases institutions maintain to administer FWS and complete the Fiscal Operations Report and Application to Participate (FISAP) form annually. The Department may also require participating institutions to use a common form, provided by the Department at a later time, to collect qualitative information from students annually about their FWS-supported work opportunities.

Participating institutions will be required to respond to annual surveys or interviews that collect information about job development activities relevant to FWS students, including institutions with JLD funds, and any unforeseen challenges or opportunities identified in conjunction with administering the experiment. The Department's evaluation will also include information reported by institutions through the Department's regular data collection systems regarding the enrollment, completion, and withdrawal of students who receive title IV funds while enrolled at the institution during the student's participation in the experiment. In addition, the Department may obtain data on students' employment and earnings from other Federal agencies, such as the Internal Revenue Service, to better understand the effects of the experiment on students both before and after graduation.

The Department will finalize the specific evaluation and reporting requirements prior to the start of the

experiment in consultation with the Department's Institute of Education Sciences.

Application and Selection

Institutions are invited to apply to participate in the experiment described in this notice. From the institutions that submit letters of interest, the Secretary will select a limited number of institutions to participate in this experiment. When selecting institutions for participation in this experiment, the Secretary will consider—

1. Evidence that demonstrates a strong record in the administration of the title IV, HEA programs;

2. Evidence that demonstrates strong standards of financial responsibility, including that the institution's independent auditor does not express doubt as to the institution's ability to operate as a going concern or indicate an adverse opinion or a finding of material weakness related to financial stability;

3. The percentage of students enrolled at the institution who are Pell eligible or FWS eligible, such that institutions serving the largest percentage of these students will be given priority to participate in this experiment; and

4. The types of private-sector job opportunities, work-and-learn programs, or required externships or student teaching experiences that will be targeted by the institution as a result of the experiment and how the paid training experiences being targeted will be incorporated into the academic programs of study and the extent to which the experience is well structured and academically relevant to the student's program of study. The institution's commitment to target opportunities for students in high-need employment areas (based on State or local determinations or indications by the Department of Labor that an occupation is a ''bright outlook'' occupation [8]).

In the event that the Department must limit the number of institutions invited to participate, priority will be based on whether the institution proposes to identify or expand work-and-learn opportunities in communities certified by the Internal Revenue Service as Opportunity Zones authorized under the Tax Cuts and Jobs Act of 2017 and the proportion of enrolled students that are Pell Grant recipients, the level of demonstrated employer interest, and whether the institution proposes work-and-learn opportunities in academic programs that have higher than average non-completion rates.

[8] *www.onetonline.org/help/bright/.*

The Secretary's selection of institutions will be guided by the purpose of the experiment, which is to evaluate whether FWS funds can be used effectively to: Provide more private-sector FWS opportunities to students; develop work-and-learn programs such as apprenticeships, to improve completion rates and reduce borrowing among students enrolled in required externships or student teaching activities; and improve completion rates and post-graduation employment outcomes for students involved in the experiment. If a selected institution consists of more than one location (*e.g.,* the institution has additional locations or branch campuses), the institution or the Secretary may limit the experiment to a single location.

The Department will finalize the application and selection requirements prior to the start of the experiment. The Secretary will consult with those institutions that have been invited to participate in the experiment on the final design of the experiment through webinars or other outreach activities.

Institutions selected for participation in an experiment will have their Program Participation Agreement (PPA) with the Secretary amended to reflect the specific statutory or regulatory provisions that the Secretary has waived for participants in the experiment. The institution must acknowledge its commitment to adequately establish the procedures necessary to successfully administer the experiment. The amended PPA will also document the agreement between the Secretary and the institution about how the experiment will be conducted and will specify the evaluation and reporting requirements for the experiment.

Administration of the experiment is the responsibility of an institution's senior leaders since it is likely that multiple departments within an institution will need to collaborate to develop high-quality opportunities for students. The institution's president or chancellor will be required to acknowledge the institution's commitment to properly administer the experiment and to involve all departments, faculty, and staff required to support successful implementation.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* Braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

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

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

Program Authority: 20 U.S.C. 1094a(b).

Mark A. Brown,

Chief Operating Officer, Federal Student Aid.

[FR Doc. 2019–10811 Filed 5–22–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2114–301]

Public Utility District No. 2 of Grant County; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Shoreline Management Plan Update.

b. *Project No:* 2114–301.

c. *Date Filed:* April 18, 2019.

d. *Applicant:* Public Utility District No. 2 of Grant County (Grant PUD).

e. *Name of Project:* Priest Rapids Hydroelectric Project.

f. *Location:* The project is located on the mid-Columbia River, in portions of Grant, Yakima, Kittitas, Douglas, Benton, and Chelan Counties, Washington.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Shannon Lowry, Lands and Recreation Resources Manager, Grant PUD, PO Box 878, Ephrata, WA 98823; (509) 754–5088 ext. 2191 or *slowry@gcpud.org.*

i. *FERC Contact:* Hillary Berlin, (202) 502–8915, *Hillary.berlin@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* June 18, 2019.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using

the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2114–301. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* Grant PUD filed a six-year update to its Shoreline Management Plan (SMP) for the project, as required in the SMP approved by the Commission in 2013 under Article 419. Grant PUD proposes to refine allowable uses within each land-use classification, reclassify nine acres of shoreline land from Resource Management to Public Recreation Development, include a monitoring and compliance plan, and revise the schedule for updating the SMP to coordinate with the Recreation Resources Management Plan.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: May 16, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–10741 Filed 5–22–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0496; FRL–9993–94–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Area Sources: Asphalt Processing and Asphalt Roofing Manufacturing (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Area Sources: Asphalt Processing and Asphalt Roofing Manufacturing (EPA ICR Number 2352.05, OMB Control Number 2060–0634), 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 May 31, 2019. Public comments were previously requested, via the **Federal Register**, on May 30, 2018 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 neither conduct nor 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 June 24, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0496, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

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.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of

Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@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 National Emission Standards for Hazardous Air Pollutants (NESHAP) for Area Sources: Asphalt Processing and Asphalt Roofing Manufacturing (40 CFR part 63, subpart AAAAAAA) were proposed on July 9, 2009, promulgated on December 2, 2009, and amended on March 18, 2010. These regulations apply to existing facilities and new facilities that are Area Sources and that either process asphalt or manufacture asphalt roofing products. New facilities include those that commenced construction, modification or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart AAAAAAA.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Form Numbers: None.

Respondents/affected entities: Existing and new facilities that are area sources and that process asphalt or manufacture asphalt roofing products. New facilities include those that commenced construction, modification or reconstruction after the date of proposal.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart AAAAAAA).

Estimated number of respondents: 35 (total).

Frequency of response: Semiannually.

Total estimated burden: 1,410 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $161,000 (per year), which includes $525 in annualized capital/startup and/or operation & maintenance costs.

Changes in the estimates: There is a decrease in hours in the total estimated respondent burden compared with the ICR currently-approved by OMB. This is due to a decrease in EPA's estimate of the number of industry sources subject to this regulation, which is based on information collected during a recent analysis of asphalt processing and asphalt roofing major sources for a risk and technology review. The growth rate for the industry continues to be very low, negative or non-existent.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–10786 Filed 5–22–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9993–62–OA]

Request for Nominations of Candidates to the EPA's Science Advisory Board (SAB) and SAB Standing Committees

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites nominations of scientific experts from a diverse range of disciplines to be considered for appointment to the EPA Science Advisory Board (SAB) and four SAB committees described in this notice. Appointments will be announced by the Administrator and are anticipated to be filled by the start of Fiscal Year 2020 (October 2019).

DATES: Nominations should be submitted in time to arrive no later than June 24, 2019.

SUPPLEMENTARY INFORMATION: *Background:* The SAB is a chartered Federal Advisory Committee, established in 1978 under the authority of the Environmental Research, Development and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical peer review, consultation, advice and recommendations to the EPA Administrator on the scientific bases for EPA's actions and programs. Members of the SAB constitute distinguished bodies of non-EPA scientists, engineers, economists, and behavioral scientists who are nationally and internationally recognized experts in their respective fields. Members are appointed by the EPA Administrator for a three-year term and serve as Special Government Employees who provide independent expert advice to the agency. Additional information about the SAB is available at *http://www.epa.gov/sab.*

Expertise Sought for the SAB: The chartered SAB provides strategic advice to the EPA Administrator on a variety of EPA science and research programs. All the work of SAB committees and panels is conducted under the auspices of the chartered SAB. The chartered SAB reviews all SAB committee and panel draft reports and determines whether they are appropriate to send to the EPA Administrator. The SAB Staff Office invites the nomination of experts to serve on the chartered SAB in the following scientific disciplines as they relate to human health and the environment: *Analytical chemistry; benefit-cost analysis; causal inference; complex systems; ecological sciences and ecological assessment; economics; engineering; forestry geochemistry; health sciences; hydrology; hydrogeology; medicine; microbiology; modeling; pediatrics; public health; risk assessment; social, behavioral and decision sciences; statistics; toxicology; epidemiology; and uncertainty analysis.*

The SAB Staff Office is especially interested in scientists in the disciplines described above who have knowledge and experience in *air quality; agricultural sciences; atmospheric sciences; benefit-cost analysis; complex systems; drinking water; energy and the environment; epidemiological risk analyses; dose-response, exposure, and physiologically based pharmacokinetic (PBPK) modeling; water quality; water quantity and reuse; ecosystem services; community environmental health; sustainability; chemical safety; green chemistry; and waste management.* For further information about the chartered SAB membership appointment process and schedule, please contact Dr. Thomas Armitage, DFO, by telephone at (202) 564–2155 or by email at *armitage.thomas@epa.gov.*

The SAB Staff Office is also seeking nominations of experts for possible vacancies on four SAB standing committees: The Agricultural Science Committee, the Chemical Assessment Advisory Committee; the Drinking Water Committee; and the Radiation Advisory Committee.

(1) The SAB Agricultural Science Committee (ASC) provides advice to the chartered SAB on matters that have been determined to have a significant

direct impact on farming and agriculture-related industries. The SAB Staff Office invites the nomination of scientists with expertise in one or more of the following disciplines: *Agricultural science, including agricultural economics and valuation of ecosystem goods and services; agricultural chemistry; agricultural engineering; agronomy and soil science; animal science; aquaculture science; biofuel engineering; biotechnology; crop science and phytopathology; environmental chemistry; forestry; and hydrology.* For further information about the ASC membership appointment process and schedule, please contact Dr. Bryan Bloomer, DFO, by telephone at (202) 564–4222 or by email at *bloomer.bryan@epa.gov*.

(2) The SAB Chemical Assessment Advisory Committee (CAAC) provides advice through the chartered SAB regarding selected toxicological reviews of environmental chemicals. The SAB Staff Office invites the nomination of scientists with experience in chemical assessments and expertise in one or more of the following disciplines: *Toxicology, including, developmental/reproductive toxicology, and inhalation toxicology; carcinogenesis; biostatistics; uncertainty analysis; epidemiology and risk assessment.* For further information about the CAAC membership appointment process and schedule, please contact Dr. Suhair Shallal, DFO, by telephone at (202) 564–2057 or by email at *shallal.suhair@epa.gov.*

(3) The SAB Drinking Water Committee (DWC) provides advice on the scientific and technical aspects of EPA's national drinking water program. The SAB Staff Office is seeking nominations of experts with experience on drinking water issues. Members should have expertise in one or more of the following disciplines: *Environmental engineering; epidemiology; microbiology; public health; toxicology; uncertainty analysis; and risk assessment.* For further information about the DWC membership appointment process and schedule, please contact Dr. Bryan Bloomer, DFO, by telephone at (202) 564–4222 or by email at *bloomer.bryan@epa.gov.*

(4) The Radiation Advisory Committee (RAC) provides advice on radiation protection, radiation science, and radiation risk assessment. The SAB Staff Office invites the nomination of experts to serve on the RAC with demonstrated expertise in the following disciplines: *Radiation carcinogenesis; radiochemistry; radiation dosimetry; radiation epidemiology; radiation exposure; radiation health and safety; radiological risk assessment; uncertainty analysis; and radionuclide fate and transport.* For further information about the RAC membership appointment process and schedule, please contact Dr. Diana Wong, DFO, by telephone at (202) 564–2049 or by email at *wong.diana-m@epa.gov.*

Selection Criteria for the SAB and the SAB Committees Includes

—Demonstrated scientific credentials and disciplinary expertise in relevant fields;
—Willingness to commit time to the committee and demonstrated ability to work constructively and effectively on committees;
—Background and experiences that would help members contribute to the diversity of perspectives on the committee, *e.g.,* geographical, social, cultural, educational backgrounds, professional affiliations; and other considerations; and
—For the committee as a whole, the collective breadth and depth of scientific expertise is considered.

As the SAB and its standing committees undertake specific advisory activities, the SAB Staff Office will consider two additional criteria for each new activity: Absence of financial conflicts of interest and absence of an appearance of a loss of impartiality.

How to Submit Nominations: Any interested person or organization may nominate qualified persons to be considered for appointment to these advisory committees. Individuals may self-nominate. Nominations should be submitted in electronic format (preferred) using the online nomination form under the ''Nomination of Experts'' category at the bottom of the SAB home page at *http://www.epa.gov/sab.* To be considered, all nominations should include the information requested below. EPA values and welcomes diversity. All qualified candidates are encouraged to apply regardless of gender, race, disability or ethnicity.

Nominators are asked to identify the specific committee for which nominees are to be considered. The following information should be provided on the nomination form: Contact information for the person making the nomination; contact information for the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's *curriculum vitae;* and a biographical sketch of the nominee indicating current position, educational background; research activities; sources of research funding for the last two years; and recent service on other national advisory committees or national professional organizations. To help the agency evaluate the effectiveness of its outreach efforts, please indicate how you learned of this nomination opportunity. Persons having questions about the nomination process or the public comment process described below, or who are unable to submit nominations through the SAB website, should contact the DFO for the committee, as identified above. The DFO will acknowledge receipt of nominations and in that acknowledgement, will invite the nominee to provide any additional information that the nominee feels would be useful in considering the nomination, such as availability to participate as a member of the committee; how the nominee's background, skills and experience would contribute to the diversity of the committee; and any questions the nominee has regarding membership. The names and biosketches of qualified nominees identified by respondents to this **Federal Register** notice, and any additional experts identified by the SAB Staff Office, will be posted in a List of Candidates on the SAB website at *http://www.epa.gov/sab.* Public comments on each List of Candidates will be accepted for 21 days from the date the list is posted. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

Candidates invited to serve will be asked to submit the ''Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency'' (EPA Form 3110–48). This confidential form allows EPA to determine whether there is a statutory conflict between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a loss of impartiality, as defined by Federal regulation. The form may be viewed and downloaded through the ''Ethics Requirements for Advisors'' link on the SAB home page at *http://www.epa.gov/sab.* This form should not be submitted as part of a nomination.

Dated: May 3, 2019.

Khanna Johnston,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2019–10819 Filed 5–22–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0524; FRL–9993–88–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Stationary Combustion Turbines (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Stationary Combustion Turbines (EPA ICR Number 2177.07, OMB Control Number 2060–0582) 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 May 31, 2019. Public comments were previously requested, via the **Federal Register**, on May 30, 2018 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 neither conduct nor 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 June 24, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0524, to: (1) EPA online using *www.regulations.gov* (our preferred method), by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

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.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@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 New Source Performance Standards (NSPS) for Stationary Combustion Turbines (40 CFR part 60, subpart KKKK) were proposed on February 18, 2005, and promulgated on July 6, 2006. These regulations apply to new stationary combustion turbines with a heat input at peak load equal to or greater than 10.7 gigajoules (10 MMBtu) per hour, based on the higher heating value of the fuel. New facilities include those that commenced construction, modification or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 60, subpart KKKK.

In general, all NSPS standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NSPS.

Form Numbers: None.

Respondents/affected entities: Stationary combustion turbines.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart KKKK).

Estimated number of respondents: 730 (total).

Frequency of response: Initially and semiannually.

Total estimated burden: 76,100 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $8,670,000 (per year), which includes $0 in annualized capital/startup and/or operation & maintenance costs.

Changes in the estimates: There is an adjustment increase in burden hours and costs for both the respondents and the Agency as currently identified in the OMB Inventory of Approved Burdens. The increase is not due to any program changes. The increase is due to an adjustment in the number of new or modified sources. This ICR assumes the respondent universe subject to the regulation has continued to grow at a constant rate since the last ICR renewal. The increase in the number of respondents also results in an increase in the number of responses.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–10785 Filed 5–22–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0642; FRL–9994–28–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Chemical Preparations Industry (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Chemical Preparations Industry (EPA ICR Number 2356.05, OMB Control Number 2060–0636), 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 May 31, 2019. Public comments were previously requested, via the **Federal Register**, on May 30, 2018 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 neither conduct nor 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 June 24, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0642, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T,

1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

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.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@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, EPA 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 National Emission Standards for Hazardous Air Pollutants (NESHAP) for Chemical Preparations Industry (40 CFR 63, subpart BBBBBBB) were proposed on August 5, 2009, and promulgated on December 30, 2009. These regulations apply to both existing and new chemical preparation facilities that conduct the mixing, milling, blending or extruding of industrial chemicals and that are area sources of hazardous air pollutants (HAPs). Area sources are classified as sources that emit less than 10 tons per year of a single HAP or less than 25 tons per year of any combination of HAPs. New facilities include those that commenced construction or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart BBBBBBB.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Form Numbers: None.

Respondents/affected entities: Existing and new chemical preparation facilities that conduct the mixing, milling, blending or extruding of industrial chemicals and that are area sources of hazardous air pollutants (HAPs).

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart BBBBBBB).

Estimated number of respondents: 26 (total).

Frequency of response: Initially, annually and semiannually.

Total estimated burden: 2,210 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $252,000 (per year), which includes $390 in annualized capital/startup and/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. This is due to two considerations: (1) The regulations have not changed over the past three years and are not anticipated to change over the next three years; and (2) the growth rate for the industry is very low, negative or non-existent, so there is no significant change in the overall burden.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–10787 Filed 5–22–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[Regional Docket No. II–2016–3; FRL–9993–76–Region 2]

Clean Air Act Operating Permit Program; Petitions on State Operating Permit for Hyland Landfill

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final Order on Petitions on Clean Air Act title V operating permit.

SUMMARY: The Environmental Protection Agency (EPA) Administrator signed an Order dated April 10, 2019 denying two Petitions, each dated March 21, 2016, from Gudrun Scott and from Frederick Sinclair on behalf of the Concerned Citizens of Allegany County (CCAC). The Petitions relate to a Clean Air Act (CAA) title V operating permit issued by the New York State Department of Environmental Conservation (NYSDEC) to Hyland Facility Associates for the Hyland Landfill located in Allegany County, New York.

ADDRESSES: The EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view copies of the final Order, the Petitions, and other supporting information. You may review copies of the final Order, the Petitions, and other supporting information at the EPA Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866.

You may view the hard copies Monday through Friday, from 9:00 a.m. to 3:00 p.m., excluding federal holidays. If you wish to examine these documents, you should make an appointment at least 24 hours before the visiting day. Additionally, the final Order and Petitions are available electronically at: *https://www.epa.gov/title-v-operating-permits/title-v-petition-database.*

FOR FURTHER INFORMATION CONTACT: Suilin Chan, EPA Region 2, 212–637–4019, *Chan.Suilin@epa.gov.*

SUPPLEMENTARY INFORMATION: The CAA affords the EPA a 45-day period to review and object to, as appropriate, operating permits proposed by state permitting authorities under title V of the CAA. Section 505(b)(2) of the CAA authorizes any person to petition the EPA Administrator to object to a title V operating permit within 60 days after the expiration of the EPA's 45-day review period if the EPA has not objected on its own initiative. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or unless the grounds for the issues arose after this period.

The EPA received Petitions from Gudrun Scott and from Frederick Sinclair on behalf of the CCAC, each dated March 21, 2016, relating to the issuance of operating Permit No. 9–0232–00003/00012, issued by the NYSDEC to the Hyland Landfill, in Allegany County, New York. The Order more fully summarizes the issues raised in the Petitions. The Scott Petition expresses various concerns related to Hyland Landfill's acceptance of drill cuttings and other drilling wastes from natural gas drilling operations in Pennsylvania, and the possibility that the deposition of these wastes will ultimately result in air emissions of radon from the Hyland Landfill. The

CCAC Petition asserts that the permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or conditions of the permit.

On April 10, 2019, the EPA Administrator issued an Order denying the Petitions. The Order explains the basis for the EPA's decision.

Sections 307(b) and 505(b)(2) of the CAA provide that a petitioner may request judicial review of those portions of an order that deny issues in a title V petition. Any petition for review shall be filed in the United States Court of Appeals for the appropriate circuit no later than July 22, 2019.

Dated: May 6, 2019.

Peter Lopez,

Regional Administrator, Region 2.

[FR Doc. 2019–10818 Filed 5–22–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2015–0191; FRL–9993–87–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Miscellaneous Organic Chemical Manufacturing (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Miscellaneous Organic Chemical Manufacturing (EPA ICR Number 1969.07, OMB Control Number 2060–0533), 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 May 31, 2019. Public comments were previously requested, via the **Federal Register**, on May 30, 2018 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 neither conduct nor 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 June 24, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2015–0191, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

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.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@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, EPA 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 National Emission Standards for Hazardous Air Pollutants (NESHAP) for Miscellaneous Organic Chemical Manufacturing (40 CFR part 63, subpart FFFF) were proposed on April 4, 2002, and promulgated on July 14, 2006. These regulations apply to both existing facilities and new facilities that manufacture a miscellaneous organic chemical and that are located at, or are part of, major sources of hazardous air pollutant (HAP) emissions. New facilities include those that commenced construction, modification or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart FFFF.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Form Numbers: None.

Respondents/affected entities: Miscellaneous organic chemical manufacturing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart FFFF).

Estimated number of respondents: 202 (total).

Frequency of response: Initially and semiannually.

Total estimated burden: 327,000 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $41,600,000 (per year), which includes $4,310,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the estimates: There is an adjustment decrease in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens; this decrease is not due to any program changes. The decrease in burden is due to more accurate estimates of existing sources based on information gathered by EPA and confirmed by industry. The decrease in the number of respondents also results in a decrease in responses and operation and maintenance costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–10784 Filed 5–22–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request (OMB No. 3064–0190)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collection described below (3064–0190). On March 15, 2019, the FDIC requested comment for 60 days on a proposal to renew the information collection described below. No comments were received. The FDIC

hereby gives notice of its plan to submit to OMB a request to approve the renewal of this collection, and again invites comment on this renewal.

DATES: Comments must be submitted on or before June 24, 2019.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *https://www.FDIC.gov/regulations/laws/federal.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Counsel, MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: On March 15, 2019, the FDIC requested comment for 60 days on a proposal to renew the information collection described below. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of this collection, and again invites comment on this renewal.

Proposal to renew the following currently approved collection of information:

1. *Title:* Interagency Complaint Form.

OMB Number: 3064–0190.

Form Number: None.

Affected Public: Individuals, financial institutions and other private sector entities.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

Information collection description	Type of burden	Obligation to respond	Estimated number of respondents	Estimated frequency of responses	Estimated time per response (minutes)	Estimated annual burden (hours)
Interagency Appraisal Complaint Form ..	Reporting	Voluntary	40	On Occasion ..	30	20
Total Estimated Annual Burden	.....	.....	.....	.....	.....	20

General Description of Collection: As provided in section 1473(p) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act),[1] on January 12, 2011, the Appraisal Subcommittee (''ASC''), of the Federal Financial Institutions Examination Council (FFIEC) determined that no national hotline existed to receive complaints of non-compliance with appraisal standards. A notice of that determination was published in the **Federal Register** on January 28, 2011 (76 FR 5161). As required by the Dodd-Frank Act, the ASC established a hotline to refer complaints to appropriate state and Federal regulators. For those instances where the ASC determines the FDIC, OCC, FRB, or NCUA is the appropriate regulator, the agencies developed the Interagency Appraisal Complaint Form as a means to efficiently collect necessary information. The Interagency Appraisal Complaint Form is designed to collect information necessary for one or more agencies to take further action on a complaint from an appraiser, other individual, financial institution, or other entities. The FDIC will use the information to take further action on the complaint to the extent it relates to an issue within its jurisdiction.

[1] Dodd-Frank Wall Street Reform and Consumer Protection Act § 1473, Public Law 111–203, 124 Stat. 1376, July 21, 2010; 12 U.S.C. 3351(i) . . .

There is no change in the method or substance of the collection. The overall reduction in burden hours (from 100 hours to 20 hours) is the result of a change in the agency's estimate of the number of annual responses based on a review of the actual number of complaints received over the last three years. In particular, the estimated number of respondents has decreased from 200 to 40 while the estimated time per response and the frequency of response have remained the same.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the 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 through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, on May 20, 2019.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2019–10790 Filed 5–22–19; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request (OMB No. 3064–0178)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collection described below (3064–0178). On February 1, 2019, the FDIC requested comment for 60 days on a proposal to renew this information collection. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of this collection, and again invites comment on its renewal.

DATES: Comments must be submitted on or before June 24, 2019.

ADDRESSES: Interested parties are invited to submit written comments to

the FDIC by any of the following methods:

- *https://www.FDIC.gov/regulations/laws/federal.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Jennifer Jones (202–898–6768), Counsel, MB–3105, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jennifer Jones, Counsel, 202–898–6768, *jennjones@fdic.gov,* MB–3105, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: On February 1, 2019, the FDIC requested comment for 60 days on a proposal to renew this information collection. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of this collection, and again invites comment on its renewal.

Proposal to renew the following currently approved collection of information:

1. *Title:* Market Risk Capital Requirements.

OMB Number: 3064–0178.

Form Number: None.

Affected Public: Insured state nonmember banks and state savings associations.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

Information collection (IC) description	Type of burden	Obligation to respond	Estimated number of respondents	Estimated frequency of responses	Estimated time per response	Frequency of response	Total annual estimated burden
Identification of trading positions.	Recordkeeping	Mandatory ..	1	1	40	On Occasion	40
Trading and hedging strategies.	Recordkeeping	Mandatory ..	1	1	16	On Occasion	16
Active management of covered positions.	Recordkeeping	Mandatory ..	1	1	16	On Occasion	16
Review of internal models.	Recordkeeping	Mandatory ..	1	1	16	On Occasion	16
Internal audit report	Reporting	Mandatory ..	1	1	16	On Occasion	16
Backtesting adjustments to risk-based capital ratio calculations.	Recordkeeping	Mandatory ..	1	4	16	On Occasion	64
Demonstrate appropriateness of proxies.	Recordkeeping	Mandatory ..	1	1	8	On Occasion	8
Retention of subportfolio information.	Recordkeeping	Mandatory ..	1	1	24	On Occasion	24
Stressed Var-based measure quantitative requirements.	Reporting	Mandatory ..	1	4	40	On Occasion	160
Modeled specific risk ..	Reporting	Mandatory ..	1	4	88	On Occasion	352
Incremental risk model-prior approval.	Reporting	Mandatory ..	1	4	480	On Occasion	1,920
Comprehensive risk measurement-prior approval.	Reporting	Mandatory ..	1	4	480	On Occasion	1,920
Requirements of stress testing.	Recordkeeping	Mandatory ..	1	1	80	On Occasion	80
Securitization positions	Recordkeeping	Mandatory ..	1	4	120	On Occasion	480
Quantitative market risk disclosures.	Third-Party Disclosure.	Mandatory ..	1	4	8	On Occasion	32
Disclosure policy	Recordkeeping	Mandatory ..	1	1	40	On Occasion	40
Quantitative disclosures for each portfolio of covered positons.	Third-Party Disclosure.	Mandatory ..	1	4	8	On Occasion	32
Qualitative disclosures for each portfolio of covered positons.	Third-Party Disclosure.	Mandatory ..	1	1	12	On Occasion	12
Total Hourly Burden.	.....	.....	.....	.....	.....	.....	5,228

General Description of Collection

The FDIC's market risk capital rules (12 CFR part 324, subpart F) enhance risk sensitivity, increase transparency through enhanced disclosures and include requirements for the public disclosure of certain qualitative and quantitative information about the market risk of state nonmember banks and state savings associations (covered FDIC-supervised institutions). The market risk rule applies only if a bank

holding company or bank has aggregated trading assets and trading liabilities equal to 10 percent or more of quarter-end total assets or $1 billion or more (covered FDIC-supervised institutions). Currently, only one FDIC-regulated entity meets the criteria of the information collection requirements that are located at 12 CFR 324.203 through 324.212. The collection of information is necessary to ensure capital adequacy appropriate for the level of market risk.

Section 324.203(a)(1) requires covered FDIC-supervised institutions to have clearly defined policies and procedures for determining which trading assets and trading liabilities are trading positions and specifies the factors a covered FDIC-supervised institution must take into account in drafting those policies and procedures. Section 324.203(a)(2) requires covered FDIC-supervised institutions to have clearly defined trading and hedging strategies for trading positions that are approved by senior management and specifies what the strategies must articulate. Section 324.203(b)(1) requires covered FDIC-supervised institutions to have clearly defined policies and procedures for actively managing all covered positions and specifies the minimum requirements for those policies and procedures. Sections 324.203(c)(4) through 324.203(c)(10) require the annual review of internal models and specify certain requirements for those models. Section 324.203(d) requires the internal audit group of a covered FDIC-supervised institution to prepare an annual report to the board of directors on the effectiveness of controls supporting the market risk measurement systems.

Section 324.204(b) requires covered FDIC-supervised institutions to conduct quarterly backtesting. Section 324.205(a)(5) requires institutions to demonstrate to the FDIC the appropriateness of proxies used to capture risks within value-at-risk models. Section 324.205(c) requires institutions to develop, retain, and make available to the FDIC value-at-risk and profit and loss information on sub-portfolios for two years. Section 324.206(b)(3) requires covered FDIC-supervised institutions to have policies and procedures that describe how they determine the period of significant financial stress used to calculate the institution's stressed value-at-risk models and to obtain prior FDIC approval for any material changes to these policies and procedures.

Section 324.207(b)(1) details requirements applicable to a covered FDIC-supervised institution when the covered FDIC-supervised institution uses internal models to measure the specific risk of certain covered positions. Section 324.208 requires covered FDIC-supervised institutions to obtain prior written FDIC approval for including equity positions in its incremental risk modeling. Section 324.209(a) requires prior FDIC approval for the use of a comprehensive risk measure. Section 324.209(c)(2) requires covered FDIC-supervised institutions to retain and report the results of supervisory stress testing. Section 324.210(f)(2)(i) requires covered FDIC-supervised institutions to document an internal analysis of the risk characteristics of each securitization position in order to demonstrate an understanding of the position. Section 324.212 applies to certain covered FDIC-supervised institutions that are not subsidiaries of bank holding companies, and requires quarterly quantitative disclosures, annual qualitative disclosures, and a formal disclosure policy approved by the board of directors that addresses the approach for determining the market risk disclosures it makes.

The annual burden for this information collection is estimated to be 5,228 hours. This represents an increase of 1,300 hours from the current burden estimate of 3,928 hours. This increase is not due to any new requirements imposed by the FDIC. Rather, it is due to FDIC's reassessment of the number of respondents as well as the frequency of responses per respondent per year.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the 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 through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, on May 20, 2019.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2019–10795 Filed 5–22–19; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 19, 2019.

A. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Meta Financial Group, Inc., Sioux Falls, South Dakota;* to become a bank holding company upon the conversion of its federal savings bank subsidiary, MetaBank, Sioux Falls, South Dakota, into a national bank to be named MetaBank, National Association.

Board of Governors of the Federal Reserve System, May 20, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–10796 Filed 5–22–19; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[Notice-PBS–2019–04; Docket No. 2019–0002; Sequence No. 10]

Notice of Intent To Prepare an Environmental Impact Statement for Land Ports of Entry

AGENCY: Public Buildings Service (PBS), General Services Administration (GSA).

ACTION: Notice of intent; meeting.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) and GSA have partnered to develop a program of projects at a number of Land Ports of Entry (LPOEs) so that FMCSA agents can safely and effectively inspect both commercial truck and bus traffic. GSA intends to prepare an Environmental Impact Statement (EIS) to analyze the potential impacts from the proposed construction of six (6) inspection facilities at five (5) different LPOEs in both California and Arizona.

DATES: The views and comments of the public are necessary to help determine the scope and content of the environmental analysis. Interested parties are encouraged to attend and provide written comments regarding the scope of the EIS and the proposed facilities by Thursday, July 11, 2019.

Scoping meetings for the EIS will be held on four (4) separate dates listed below:

- *San Ysidro, CA & Otay Mesa, CA*
  Tuesday, June 18, 2019, 4:00 p.m. to 6:00 p.m., San Diego, CA.
- *Calexico East, CA*
  Thursday, June 20, 2019, 4:00 p.m. to 6:00 p.m., Calexico, CA.
- *San Luis II, AZ*
  Wednesday, June 26, 2019, 4:00 p.m. to 6:00 p.m., Yuma, AZ.
- *Nogales Mariposa, AZ*
  Thursday, June 27, 2019, 4:00 p.m. to 6:00 p.m., Nogales, AZ.

ADDRESSES: The meetings will be conducted in an open house format, where project information will be presented and distributed. Comments regarding the scope of the EIS and the proposed facilities may be sent to the point of contact listed in the **FOR FURTHER INFORMATION** section.

The meetings will be held at the following locations:

- *San Ysidro, CA & Otay Mesa Sites*
  The FRONT Arte Cultura, 147 W San Ysidro Blvd., San Diego, CA 92173, telephone (619) 428–1115.
- *Calexico East, CA Site*
  Holiday Inn Express Calexico, 2501 Scaroni Avenue, Calexico, CA 92231, telephone 760–768–6048.
- *San Luis II, AZ Site*
  Holiday Inn Express and Suites Yuma, 2044 S Avenue 3E, Yuma, AZ 85365, telephone 928–317–1400.
- *Nogales Mariposa, AZ Site*
  Holiday Inn Express Nogales, 850 W Shell Road, Nogales, AZ 85621, telephone 520–281–0123.

FOR FURTHER INFORMATION CONTACT:

- *Email:* Osmahn A. Kadri at *osmahn.kadri@gsa.gov.*
- *Mail:* Attn: Osmahn Kadri, NEPA Program Manager, 50 United Nations Plaza, 3345 Mailbox #9, San Francisco, CA 94102.
- *Telephone:* 415–522–3617 (Please also call this number if special assistance is needed to attend and participate in the public scoping meetings).

SUPPLEMENTARY INFORMATION:

Background

The FMCSA has been tasked with ensuring that commercial vehicles entering the United States (U.S.) and travelling on U.S. Highways are operating safely and within current U.S. standards. To achieve this mission and ensure safety on public highways, FMCSA must inspect commercial and bus traffic at points of destination or origin, the U.S.-Mexico Border being a main point of origin.

FMCSA inspectors currently inspect both bus and commercial truck traffic at multiple LPOEs along the U.S.-Mexico Border in both California and Arizona at facilities that were not built for their needs and at sites which do not allow for thorough, safe inspection of vehicles. In April of 2018, FMCSA received funding from the Committees of Congress to develop, design, and construct facilities that will allow them to meet their mission goals safely and effectively.

It has been determined that to achieve this mission, six (6) inspection facilities will be needed at five (5) different LPOEs in both California and Arizona:

- San Ysidro, CA (Bus Inspection)
- Otay Mesa, CA (Commercial Truck Inspection)
- Calexico East, CA (Bus and Commercial Truck Inspection)
- San Luis II, AZ (Commercial Truck Inspection)
- Nogales Mariposa, AZ (Commercial Truck Inspection)

Alternatives

The EIS will consider three Alternatives; a ''preferred build alternative'' for six (6) facilities at five (5) locations, a ''smaller footprint'' build alternative for six (6) facilities at the same five (5) locations, and a ''no action'' alternative. The alternatives for each location are described below:

San Ysidro LPOE, CA

The construction of a new bus inspection facility on a newly acquired federal site north of the LPOE. The proposed facility includes an existing single-story building and parking lot. Site work would require the clearing of the existing site and building, extension/relocation of existing utilities for electrical, sanitary sewer and water, paving of the bus path and realignment and partial paving of the parking lot and entry and exit access through the site. Facility construction would include an inspection canopy with pits and a ''Basic'' FMCSA administration building. The other build alternative would consist of a smaller facility footprint on the same location.

Otay Mesa LPOE, CA

The proposed truck inspection facility would be located to the east of the current and proposed Port of Entry, on a site currently owned and operated by the California Department of Transportation. The proposed site is linked to the Port of Entry by a frontage road that is already in place. Site work would require the clearing of the existing site, extension of existing utilities for electrical, sanitary sewer and water. Facility construction would include an inspection canopy with a pit and a ''Basic'' FMCSA administration building. The other build alternative would consist of a smaller facility footprint on the same location.

Calexico East LPOE, CA

The proposed truck inspection facility would be located beyond the northern edge of the LPOE property line, adjacent to California State Highway Patrol land and is accessed at the exit of the LPOE. Site work would require the clearing of the existing site, extension of existing utilities for electrical, sanitary sewer and water,and paving of the truck path. Facility construction would include an inspection canopy with pits and a ''Medium 1'' FMCSA administration building. The other build alternative would consist of a smaller facility footprint on the same location.

The proposed bus facility would be located on the northwestern edge of the LPOE property. Site work would require the extension of existing utilities for electrical, sanitary sewer and water, and paving of the bus path through the site. Facility construction would include an inspection canopy with pits and a ''Basic'' FMCSA administration building. The other build alternative

would consist of a smaller facility footprint on the same location.

San Luis II LPOE, AZ

The proposed truck inspection facility would be located on the northern edge of the LPOE property line. A portion of the site work would be constructed on newly acquired Federal land that will allow access from the site after hours. Site work would require the clearing of the existing site, extension of existing utilities for electrical, sanitary sewer and water, paving of the truck path, and relocating the existing CBP impound lot. Facility construction would include an inspection canopy with pits and a ''Medium 1'' FMCSA administration building. The other build alternative would consist of a smaller facility footprint on the same location.

Nogales Mariposa LPOE, AZ

The proposed truck inspection facility would be located on privately owned land, north of the existing LPOE. Site work would require the clearing of the existing site, extension of existing utilities for electrical, sanitary sewer and water, paving of the truck path. Facility construction would include an inspection canopy with pits and a FMCSA administration building. The other build alternative would consist of a smaller facility footprint on the same location.

The ''no action'' alternative assumes that no new facility would be constructed at any of the sites and the LPOEs and FMCSA operations would continue to operate under current conditions.

Dated: May 15, 2019.

Jared Bradley,

Director, Portfolio Management Division, Pacific Rim Region, Public Buildings Service.

[FR Doc. 2019–10783 Filed 5–22–19; 8:45 am]

BILLING CODE 6820–YF–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–284]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by June 24, 2019.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR*, Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Transformed—Medicaid Statistical Information System (T–MSIS); *Use:* The data reported in T–MSIS are used by federal, state, and local officials, as well as by private researchers and corporations to monitor past and projected future trends in the Medicaid program. The data provide the only national level information available on enrollees, beneficiaries, and expenditures. It also provides the only national level information available on Medicaid utilization. The information is the basis for analyses and for cost savings estimates for the Department's cost sharing legislative initiatives to Congress. The collected data are also crucial to our actuarial forecasts. *Form Number:* CMS–R–284 (OMB control number: 0938–0345); *Frequency:* Quarterly and monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 55; *Total Annual Responses:* 660; *Total Annual Hours:* 6,600. (For policy questions regarding this collection contact Connie Gibson at 410–786–0755.)

Dated: May 20, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–10792 Filed 5–22–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Sexual Risk Avoidance Education (SRAE) Program Performance Analysis Study (PAS)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

SUMMARY: The Office of Planning, Research, and Evaluation and the Family and Youth Services Bureau (FYSB) in the Administration for Children and Families propose data collection activities as part of the Sexual Risk Avoidance Education (SRAE) Program Performance Analysis Study (PAS). The goal of the study is to collect, analyze, and report on performance measures data for SRAE programs.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning 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 directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Description: The purpose of the SRAE program is to educate youth on ''how to voluntarily refrain from non-marital sexual activity and prevent other youth risk behaviors.'' Data will be used to determine if the SRAE grantees are meeting performance benchmarks related to their program's mission and priorities.

Respondents: Departmental (DSRAE), State (SSRAE), and Competitive (CSRAE) grantees, their subawardees, and program participants.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondents	Average burden hours per response	Annual burden hours
(1) Participant Entry Survey					
DSRAE participants	161,916	53,972	1	0.1333	7,195
SSRAE participants	1,108,456	369,485	1	0.1333	49,252
CSRAE participants	29,108	9,703	1	0.1333	1,293
(2) Participant Exit Survey					
DSRAE participants	129,948	43,316	1	0.2667	11,552
SSRAE participants	886,768	295,589	1	0.2667	78,834
CSRAE participants	22,871	7,624	1	0.2667	2,033
(3) Performance Reporting Data Entry Form—Grantees					
DSRAE grantees	150	50	2	16	1,600
SSRAE grantees	117	39	2	16	1,248
CSRAE grantees	144	48	2	16	1,536
(4) Performance Reporting Data Entry Form—Sub Awardees					
DSRAE subawardees	3,450	1,150	2	13	29,900
SSRAE subawardees	2,700	900	2	13	23,400
CSRAE subawardees	831	277	2	13	7,202

Estimated Total Annual Burden Hours: 215,045.

Authority: 42 U.S.C. 1310.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–10762 Filed 5–22–19; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1524]

Bedford Laboratories, et al.; Withdrawal of Approval of 24 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 24 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 24, 2019.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their

opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040524	Promethazine Hydrochloride (HCl) Injection USP, 25 milligrams (mg)/milliliter (mL) and 50 mg/mL.	Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146.
ANDA 070857	Trazodone HCl Tablets USP, 50 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 070987	Diazepam Tablets USP, 2 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233.
ANDA 070996	Diazepam Tablets USP, 5 mg	Do.
ANDA 071717	Flurazepam HCl Capsules USP, 15 mg and 30 mg	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520.
ANDA 071751	Methyldopa Tablets USP, 125 mg	Halsey Drug Co., Inc.
ANDA 071752	Methyldopa Tablets USP, 250 mg	Do.
ANDA 077190	Milrinone Lactate Injection, EQ 1 mg base/mL	Gland Pharma, Ltd., c/o INC Research, LLC, 4800 Falls of Neuse Rd., Suite 600, Raleigh, NC 27609.
ANDA 077703	Pamidronate Disodium for Injection USP, 30 mg/vial and 90 mg/vial.	Sun Pharma Global FZE, c/o Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512.
ANDA 080300	Prednisone Tablets USP, 5 mg	Halsey Drug Co., Inc.
ANDA 080961	Chlorpheniramine Maleate Tablets USP, 4 mg	Aurolife Pharma, LLC.
ANDA 083453	Niacin Tablets USP, 500 mg	Halsey Drug Co., Inc.
ANDA 083629	Kloromin (chlorpheniramine maleate) Tablets USP, 4 mg.	Do.
ANDA 083930	Dextroamphetamine Sulfate Tablets USP, 10 mg	Do.
ANDA 084676	Secobarbital Sodium Capsules USP, 100 mg	Do.
ANDA 085088	Hydralazine HCl Tablets USP, 50 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 085219	Hydrochlorothiazide Tablets, 50 mg	Aurolife Pharma, LLC.
ANDA 085923	Amitriptyline HCl Tablets USP, 10 mg	Halsey Drug Co., Inc.
ANDA 087279	Butalbital, Aspirin, and Caffeine Tablets	Sandoz, Inc., 227–15 North Conduit Ave., Laurelton, NY 11413.
ANDA 088116	Myfed (pseudoephedrine HCl and triprolidine HCl) Syrup, 30 mg/5 mL and 1.25 mg/5 mL.	USL Pharma, LLC, 301 South Cherokee St., Denver, CO 80223.
ANDA 088725	Chlorpropamide Tablets USP, 100 mg	Aurolife Pharma, LLC.
ANDA 089130	Hydralazine HCl Tablets USP, 25 mg	Halsey Drug Co., Inc.
ANDA 089178	Hydralazine HCl Tablets USP, 100 mg	Do.
ANDA 201484	Levofloxacin Tablets, 250 mg, 500 mg, and 750 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 24, 2019. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on June 24, 2019, may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10809 Filed 5–22–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Maternal and Child Health Bureau Performance Measures for Discretionary Grant Information System (DGIS), OMB No. 0915–0298—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than June 24, 2019.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal and Child Health Bureau Performance Measures for Discretionary Grant Information System (DGIS), OMB No. 0915–0298—Revision.

Abstract: This Information Collection Request is for continued approval of performance measures for HRSA's Maternal and Child Health Bureau (MCHB) discretionary grants, specifically, the continued use of reporting requirements for grant programs administered by MCHB in accordance with the ''Government Performance and Results Act of 1993'' (Pub. L. 103–62). This Act requires the preparation of an annual performance plan covering each program activity set forth in the agency's budget, which includes establishment of measurable goals that may be reported in an annual financial statement to support the linkage of funding decisions with performance. Performance measures for MCHB discretionary grants were initially approved in 2003, and the latest approval was obtained in 2016 for significant revisions. OMB approval is currently being sought to continue the use of performance measures with minor revisions. Most of these measures are specific to certain types of programs and are not required of all grantees. The measures are categorized by domains (Adolescent Health, Capacity Building, Child Health, Children with Special Health Care Needs, Lifecourse/Crosscutting, Maternal/Women Health, and Perinatal/Infant Health). In addition, there are some program-specific measures. Grant programs are assigned domains based on their activities. HRSA is proposing to make changes to the DGIS to more closely align data collection forms with current program activities. These revisions will facilitate more accurate reporting of descriptive information related to Long-term Trainees in Maternal and Child Health, as well as activities related to Technical Assistance for programs. Proposed changes include the following:

- Trainee Information (Long-term Trainees Only) form:
  - Changes will incorporate options and titles that were omitted from the final submission of the previous OMB package, providing clarification for the reporting of specific descriptive information about Long-term Trainees on the form.
  - Changes will list the following options for ''Type'': ''Non-Degree Seeking,'' ''Undergraduate,'' ''Masters,'' ''Doctoral,'' Post-doctoral,'' ''Other.''
  - Changes will list the title ''Student Status'' next to the options for ''Part-time student'' and ''Full-time student.''
- Technical Assistance/Collaboration form:
  - Add a field asking for the ''Total number of TA recipients.'' This change will allow for better alignment with this data that was previously collected by program, but omitted due to a DGIS paper form error.
  - Add an ''Other'' category to List B under ''Topic of Technical Assistance/Collaboration.'' This change would facilitate more accurate data reporting by providing programs an additional category to choose from if their current Technical Assistance activities do not closely align with the existing categories in List B.

A 60-day **Federal Register** Notice was published in the **Federal Register** on November 13, 2018 Vol. 83, No. 219, pp. 56353–54). No public comments were received.

Need and Proposed Use of the Information: The performance data collected through the DGIS serves several purposes, including grantee monitoring, program planning, performance reporting, and the ability to demonstrate alignment between MCHB discretionary programs and the Title V MCH Services Block Grant program. This revision will facilitate more accurate reporting of descriptive information related to Long-term Trainees in Maternal and Child Health, as well as activities related to Technical Assistance for programs.

Likely Respondents: The grantees for Maternal and Child Health Bureau Discretionary Grant Programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Grant Report	700	1	700	36	25,200
Total	700		700		25,200

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–10807 Filed 5–22–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Nominations to the Advisory Council on Alzheimer's Research, Care, and Services

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of HHS established the Advisory Council to provide advice and consultation to the Secretary on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. The Secretary signed the charter establishing the Advisory Council on May 23, 2011. *HHS is soliciting nominations for five (5) new non-Federal members of the Advisory Council to replace the five members whose terms will end September 30, 2019.* Nominations should include the nominee's contact information (current mailing address, email address, and telephone number) and current curriculum vitae or resume.

DATES: Submit nominations by email or USPS mail before COB on June 28, 2019.

ADDRESSES: Nominations should be sent by email to Helen Lamont at *helen.lamont@hhs.gov;* or sent by USPS mail to: Helen Lamont, Office of the Assistant Secretary for Planning and Evaluation, Room 424E, Humphrey Building, 200

Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Helen Lamont (202) 260–6075, *helen.lamont@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Council on Alzheimer's Research, Care, and Services meets quarterly to discuss programs that impact people with Alzheimer's disease and related dementias and their caregivers. The Advisory Council makes recommendations to Congress and the Secretary of Health and Human Services about ways to reduce the financial impact of Alzheimer's disease and related dementias and to improve the health outcomes of people with these conditions. The Advisory Council also provides feedback on a National Plan for Alzheimer's disease. On an annual basis, the Advisory Council evaluates the implementation of the recommendations through an updated National Plan. The National Alzheimer's Project Act, Public Law 111–375 (42 U.S.C. 11225), requires that the Secretary of Health and Human Services (HHS) establish the Advisory Council on Alzheimer's Research, Care, and Services. The Advisory Council is governed by provisions of Public Law 92–463 (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The Advisory Council consists of 22 members. Ten members are designees from Federal agencies including the Centers for Disease Control and Prevention, Administration for Community Living, Centers for Medicare and Medicaid Services, Indian Health Service, National Institutes of Health, National Science Foundation, Department of Veterans Affairs, Food and Drug Administration, Agency for Healthcare Research and Quality, and the Health Resources and Services Administration. The Advisory Council also consists of 12 non-federal members selected by the Secretary who represent 6 categories of people impacted by dementia: Dementia caregivers (2), health care providers (2), representatives of State health departments (2), researchers with dementia-related expertise in basic, translational, clinical, or drug development science (2), voluntary health association representatives (2), and dementia patient advocates, including an advocate who is currently living with the disease (2). At this time, the Secretary shall appoint one member for the researcher, voluntary health association, healthcare provider, patient advocate, caregiver categories to replace the five members whose terms will end on September 30th, 2019. After receiving nominations, the Secretary, with input from his staff, will make the final decision, and the new members will be announced soon after. Members shall be invited to serve 4-year terms. The member living with dementia will serve a 2-year term. A member may serve after the expiration of the member's term until a successor has taken office. Members will serve as Special Government Employees.

Dated: May 17, 2019.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.

[FR Doc. 2019–10775 Filed 5–22–19; 8:45 am]

BILLING CODE 4150–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development and Use of a Therapeutic STAT3 Inhibitor, GLG–302, in All Proliferative Diseases, Where STAT3 Is Present

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the (U.S.) Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to GLG Pharma LLC located in Jupiter, Florida, USA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before June 7, 2019 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Sidra Ahsan, Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702 Telephone: (240) 276–5530; Facsimile: (240) 276–5504 Email: *ahsans@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 62/481,960, filed April 5, 2017 and entitled ''Improved STAT3 Inhibitor Formulation'' [HHS Reference No. E–035–2017/0–US–01]; PCT Patent Application No. PCT/US2018/026228, filed April 5, 2018 and entitled ''STAT3 Inhibitor Formulation'' [HHS Reference No. E–035–2017/0–PCT–02]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to: ''The development and commercialization of a therapeutic STAT3 inhibitor, GLG–302, in all proliferative diseases, where STAT3 is present.''

This technology discloses the use of the STAT3 inhibitor GLG–302 with Trizma salts for preclinical anti-cancer and cancer preventive activity. GLG–302 is a proprietary compound developed by GLG Pharma LLC. Trizma salts allow GLG–302 to remain in solution for oral administration. This formulation has been demonstrated to be effective in the modulation of STAT3 signaling and proliferation in normal mammary ductal epithelium, and this formulation has demonstrated mammary cancer preventive efficacy in rat (ER+) and mouse (ER −) models. The technology provides improved sample handing and oral bioavailability suggesting that a therapeutic product derived from this technology would be applicable for the treatment of cancer where STAT3 is present.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the

Freedom of Information Act, 5 U.S.C. 552.

Dated: May 15, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019–10779 Filed 5–22–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: Hazardous Waste Worker Training Grantee Data Collection—42 CFR Part 65 (National Institute of Environmental Health Sciences)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Joseph T. Hughes, Jr., Director, Worker Training Program (WTP), Division of Extramural Research and Training (DERT), NIEHS, P.O. Box 12233 MD: K3–14, Research Triangle Park, NC 27709 or call non-toll-free number (984) 287–3271 or Email your request, including your address to: *hughes3@niehs.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on March 12, 2019, Vol. 84, No. 48 page 8883 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Hazardous Waste Worker Training Grantee Data Collection—42 CFR part 65 (NIEHS), 0925–0348, Expiration Date 03/31/2019 REINSTATEMENT WITHOUT CHANGE, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: This request for OMB review and approval of the information collection is required by regulation 42 CFR part 65(a)(6). The National Institute of Environmental Health Sciences (NIEHS) was given major responsibility for initiating a worker safety and health training program under Section 126 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) for hazardous waste workers and emergency responders. A network of non-profit organizations that are committed to protecting workers and their communities by delivering high-quality, peer-reviewed safety and health curricula to target populations of hazardous waste workers and emergency responders has been developed. In thirty-one years (FY 1987–2018), the NIEHS WTP has successfully supported 20 primary grantees that have trained more than 4.1 million workers across the country and presented over 245,830 classroom and hands-on training courses, which have accounted for over 50 million contact hours of actual training. Generally, the grant will initially be for one year, and subsequent continuation awards are also for one year at a time. Grantees must submit a separate application to have the support continued for each subsequent year. Grantees are to provide information in accordance with S65.4 (a), (b), (c) and 65.6(a) on the nature, duration, and purpose of the training, selection criteria for trainees' qualifications and competency of the project director and staff, cooperative agreements in the case of joint applications, the adequacy of training plans and resources, including budget and curriculum, and response to meeting training criteria in OSHA's Hazardous Waste Operations and Emergency Response Regulations (29 CFR 1910.120). As a cooperative agreement, there are additional requirements for the progress report section of the application. Grantees are to upload their information into the WTP Grantee Data Management System. The information collected is used by the Director through officers, employees, experts, and consultants to evaluate applications based on technical merit to determine whether to make awards and whether appropriate training is being conducted to support continuation of the grant into subsequent years.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 616.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Information Collection Questionnaire (Data Management System).	Grantee	22	2	14	616
Total	.....	22	44	.....	616

Dated: May 16, 2019.

Jane M. Lambert,

Project Clearance Liaison, NIEHS, NIH.

[FR Doc. 2019–10780 Filed 5–22–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7011–N–21]

Notice of Emergency Approval of an Information Collection: National Standards for the Physical Inspection of Real Estate (NSPIRE) Demonstration

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, HUD has requested from the Office of Management and Budget (OMB) emergency approval of the information collection described in this notice.

DATES: *Comments Due Date:* June 6, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: National Standards for the Physical Inspection of Real Estate (NSPIRE) Demonstration.

OMB Approval Number: 2577–Pending.

Type of Request: New Collection.

Form Number: N/A.

Description of the Need for the Information and Proposed Use: HUD's Real Estate Assessment Center (REAC) has developed a new inspection model entitled the National Standards for the Physical Inspection of Real Estate (NSPIRE). Prior to nationwide implementation, REAC will test NSPIRE through a multistage Demonstration to identify potential adjustments to standards, protocols, and processes. HUD will ask public housing agencies (PHAs), and owners and agents (OA) (collectively referred to as POAs) to participate in this Demonstration through a voluntary application process and plans to test this model with approximately 4,500 properties.

HUD is developing a standardized electronic system and data exchange standard for this collection and will distribute self-inspection software for properties to collect and submit this data electronically. Within the scope of this collection, HUD requests the following information from participating POAs: An annual self-inspection report or work order receipts, a property profile, copies of building system certificates, local code violations over the rolling calendar year, and participation in feedback sessions.

1. Many POAs have statutory, regulatory, or housing program contractual requirements to conduct annual self-inspections on all dwelling units. POAs will be provided with self-inspection software that will enable them to easily document and submit deficiencies that are present within dwelling units across the rolling calendar year. In lieu of submitting a self-inspection report, POAs can electronically submit work order receipts from across the rolling calendar year. This data provides reasonable assurance that every dwelling unit was evaluated for deficiencies and maintenance needs.

2. POAs will submit a property profile documenting the: Owner/company name, physical address, type of housing (*e.g.,* section 8), structure type, number of buildings, number of floors, number of units, existence of an attached garage, types of fuel-burning appliances, and an updated floor plan.

3. POAs will submit an electronic copy of the building system certificates, including elevators, fire alarm systems, sprinkler systems, boilers (HVAC or domestic water), and lead-based paint inspection reports. HUD believes that it is important for POAs to provide this information annually as the inoperability of these systems can have a substantial effect on residents.

4. POAs will submit a list of local code violations for which the property was cited over the rolling calendar year. HUD regulations at 24 CFR 5.703(g), requires HUD housing to adhere to local code. HUD believes that compliance (or non-compliance) with local code can serve as an important indicator as to whether a property is conducting regular maintenance and whether it is providing acceptable basic housing conditions.

5. Finally, HUD will ask 900 POAs to provide Demonstration feedback via one in-person listening session. With this information, HUD will be better able to refine inspection standards and protocols ensuring resident housing is decent, safe, sanitary, and in good repair.

Without the information on POA-conducted physical inspections, HUD's interests will not be protected, and HUD will not be able to easily identify risks due to neglected maintenance. Analyzing self-inspection data will allow HUD to better identify these risks and improve the accuracy of property assessments, the consistency of inspections, and ultimately to provide residents with quality affordable housing.

Respondents: POAs participating in the NSPIRE Demonstration.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
	60,000	Annually	4,500	2.7 hours/property	12,150	$22.76	$276,534

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses).

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: May 16, 2019.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2019–10821 Filed 5–22–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2019–N066; FXES11130800000–190–FF08E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before June 24, 2019.

ADDRESSES: *Document availability and comment submission:* Submit requests for copies of the applications and related documents and submit any comments by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* TEXXXXXX).

- *Email: permitsr8es@fws.gov.*
- *U.S. Mail:* Daniel Marquez, Endangered Species Program Manager, U.S. Fish and Wildlife Service, Region 8, 2800 Cottage Way, Room W–2606, Sacramento, CA 95825.

FOR FURTHER INFORMATION CONTACT: Daniel Marquez, via phone at 760–431–9440, via email at *permitsr8es@fws.gov,* or via the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits would allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered or threatened under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes such activities as pursuing, harassing, trapping, capturing, or collecting in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found in the Code of Federal Regulations at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

Application No.	Applicant, city, state	Species	Location	Activity	Type of take	Permit action
TE–86906B	Yosemite National Park, El Portal, California.	• Sierra Nevada yellow-legged frog (*Rana sierrae*).	CA	Educational activities	Capture, handle, and release.	Amend.
TE–37598D	Ivan Parr, Oakland, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*), • Longhorn fairy shrimp (*Branchinecta longiantenna*), • San Diego fairy shrimp (*Branchinecta sandiegonensis*), • Riverside fairy shrimp (*Streptocephalus woottoni*), • Vernal pool tadpole shrimp (*Lepidurus packardi*), • California tiger salamander (Santa Barbara County and Sonoma County Distinct Population Segments (DPSs)) (*Ambystoma californiense*)	CA	Survey	Capture, handle, release, and collect vouchers.	New.
TE–09375A	Laura Eliassen, Bradley, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*), • Longhorn fairy shrimp (*Branchinecta longiantenna*), • San Diego fairy shrimp (*Branchinecta sandiegonensis*), • Riverside fairy shrimp (*Streptocephalus woottoni*),	CA	Survey	Capture, handle, release, and collect vouchers.	Renew.

Application No.	Applicant, city, state	Species	Location	Activity	Type of take	Permit action
		• Vernal pool tadpole shrimp (*Lepidurus packardi*)				
TE–114928	John Howe, Sacramento, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*), • Longhorn fairy shrimp (*Branchinecta longiantenna*), • San Diego fairy shrimp (*Branchinecta sandiegonensis*), • Riverside fairy shrimp (*Streptocephalus woottoni*), • Vernal pool tadpole shrimp (*Lepidurus packardi*).	CA	Survey	Capture, handle, release, and collect vouchers.	Renew.
TE–37607D	Darcee Guttilla, Templeton, California.	• California tiger salamander (Santa Barbara County and Sonoma County Distinct Population Segments (DPSs)) (*Ambystoma californiense*).	CA	Survey	Capture, handle, and release.	New.
TE–37609D	Debi Fanucchi, Oakland, California.	• California tiger salamander (Santa Barbara County and Sonoma County Distinct Population Segments (DPSs)) (*Ambystoma californiense*).	CA	Survey and restore habitat.	Capture, handle, release, and habitat restoration.	New.
TE–37620D	Angelique Herman, Atascadero, California.	• Tipton kangaroo rat (*Dipodomys nitratoides nitratoides*) • Giant kangaroo rat (*Dipodomys ingens*)	CA	Survey	Capture, handle, and release.	New.
TE–821229	David Crawford, Camarillo, California.	• Unarmored threespine stickleback (*Gasterosteus aculeatus williamsoni*), • Tidewater goby (*Eucyclogobius newberryi*).	CA	Survey	Capture, handle, and release.	Renew.
TE–59890B	Olberding Environmental, Inc., Folsom, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*), • Longhorn fairy shrimp (*Branchinecta longiantenna*), • San Diego fairy shrimp (*Branchinecta sandiegonensis*), • Riverside fairy shrimp (*Streptocephalus woottoni*), • Vernal pool tadpole shrimp (*Lepidurus packardi*).	CA	Survey	Capture, handle, release, and collect vouchers.	Renew.
TE–76006B	Zoological Society of San Diego, San Diego, California.	• Mountain yellow-legged frog ((northern California DPS) (*Rana muscosa*)).	CA	Telemetry	Radio tag and track ...	Amend.
TE–196118	Julie Niceswanger Hickman, Ventura, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*), • Longhorn fairy shrimp (*Branchinecta longiantenna*), • San Diego fairy shrimp (*Branchinecta sandiegonensis*), • Riverside fairy shrimp (*Streptocephalus woottoni*), • Vernal pool tadpole shrimp (*Lepidurus packardi*).	CA	Survey	Capture, handle, release, and collect vouchers.	Renew/ Amend.
TE–37920D	Oregon State University, Corvallis, Oregon.	• Lost River sucker (*Deltistes luxatus*), • Shortnose sucker (*Chasmistes brevirostris*)	OR	Collect data	Capture, handle, fin clip, measure, insert PIT (passive integrated transponder) tag, and release.	New.
TE–13636B	Michaela Hoffman, Grover Beach, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*), • Longhorn fairy shrimp (*Branchinecta longiantenna*), • San Diego fairy shrimp (*Branchinecta sandiegonensis*), • Riverside fairy shrimp (*Streptocephalus woottoni*), • Vernal pool tadpole shrimp (*Lepidurus packardi*).	CA	Survey	Capture, handle, release, and collect vouchers.	Renew.
TE–027427	Jeff Alvarez, Sacramento, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*), • Longhorn fairy shrimp (*Branchinecta longiantenna*), • San Diego fairy shrimp (*Branchinecta sandiegonensis*), • Riverside fairy shrimp (*Streptocephalus woottoni*), • Vernal pool tadpole shrimp (*Lepidurus packardi*), • California tiger salamander (Santa Barbara County and Sonoma County Distinct Population Segments (DPSs)) (*Ambystoma californiense*).	CA	Survey, collect tissue, and conduct educational workshops.	Capture, handle, release, collect vouchers, and collect tissue.	Renew.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Peter Erickson,

Acting Chief of Ecological Services, Pacific Southwest Region, Sacramento, California.

[FR Doc. 2019–10825 Filed 5–22–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON00000–L18200000.XX0000–19X]

Meetings of the Northwest (Colorado) Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Northwest (Colorado) Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Northwest RAC is scheduled to meet June 13, 2019 and August 22, 2019. Each meeting will begin at 8 a.m. and adjourn at approximately 3:00 p.m.

ADDRESSES: The June 13 meeting will be held in Kremmling at the Allington Inn, 215 Central Avenue, and the August 22 meeting will be in Craig at the Center of Craig, 601 Yampa Avenue.

FOR FURTHER INFORMATION CONTACT: David Boyd, Public Affairs Specialist, Northwest District Office, 2300 River Frontage Road, Silt, CO 81652. Phone: (970) 876–9008. Email: *dboyd@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Northwest Colorado RAC advises the Secretary of the Interior, through the BLM, on a variety of public land issues in the Northwest District, which includes the Colorado River Valley, and the Kremmling, Little Snake, and White River field offices. Topics of discussion for these meetings include recreation, recreation fee proposals, fire management, land use planning, invasive species management, energy and minerals management, travel management, wilderness, wild horse herd management, land exchange proposals, cultural resource management, and other issues as appropriate. The June 13 agenda will include a specific campground fee proposal for the Colorado River Valley Field Office. Final agendas will be posted online at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/colorado/northwest-rac.*

The meetings are open to the public, and public comment periods will be held at 10 a.m. and 2 p.m. at each meeting. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited.

The public may also send written comments to David Boyd, Public Affairs Specialist, Northwest District Office, 2300 River Frontage Road, Silt, CO 81652. Phone: (970) 876–9008. Email: *dboyd@blm.gov.* All comments received will be provided to the Northwest RAC.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Detailed meeting minutes for the RAC meetings will be maintained in the Northwest District Office and will be available for public inspection and reproduction during regular business hours within thirty (30) days following the meeting. Previous RAC meeting minutes, membership information, and upcoming agendas are available at: *https://www.blm.gov/get-involved/resource-advisory-council/near-you/colorado/northwest-rac.*

Jamie Connell,

BLM Colorado State Director.

[FR Doc. 2019–10739 Filed 5–22–19; 8:45 am]

BILLING CODE 4310–JB–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–19–019]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: May 29, 2019 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.

2. Minutes.

3. Ratification List.

4. Vote on Inv. Nos. 701–TA–603–604 and 731–TA–1413–1414 (Final) (Glycine from China, India, and Japan). The Commission is currently scheduled to complete and file its determinations and views of the Commission by June 14, 2019.

5. Vote on Inv. Nos. 701–TA–447 and 731–TA–1116 (Second Review) (Circular Welded Carbon-Quality Steel Pipe from China). The Commission is currently scheduled to complete and file its determinations and views of the Commission by August 5, 2019.

6. *Outstanding action jackets:* None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: May 21, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–10919 Filed 5–21–19; 4:15 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On May 17, 2019, the Department of Justice lodged a proposed consent decree with the United States District Court for the Western District of Washington in the lawsuit entitled *United States* v. *Manke Lumber Company, Inc.,* Civil Action No. 3:17–cv–05257–RJB.

The United States, on behalf of the United States Environmental Protection Agency filed a Complaint against Manke Lumber Company, Inc. (Manke) alleging violations of the under the Clean Water Act (CWA). The Complaint alleges that Manke violated Section 301 of the Clean Water Act (''CWA''), 33 U.S.C. 1311; the conditions and limitations of the Industrial Stormwater General Permit (''General Permit'') issued to Manke by the Washington Department of Ecology (''Ecology'') under Section 402(a) of the CWA, 33 U.S.C. 1342(a); and the Spill Prevention, Control, and Countermeasure (''SPCC'') regulations promulgated by EPA pursuant to Section 311(j) of the CWA, 33 U.S.C. 1321(j) at its wood products facility in Tacoma, Washington.

The proposed Consent Decree provides for Manke to perform injunctive relief consisting of installation and implementation of stormwater treatment systems, as well as new environmental management system, training, and audits. The proposed Decree also requires that Manke pay a $320,000 penalty and perform a Supplemental Environmental Project (''SEP'').

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 entitled *United States* v. *Manke Lumber Company, Inc.,* D.J. Ref. No. 90–5–1–1–11580. 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 $36.75 (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 $14.75.

Susan M. Akers,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2019–10768 Filed 5–22–19; 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; Veterans Supplement to the Current Population Survey

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Bureau of Labor Statistics (BLS) sponsored information collection request (ICR) titled, ''Veterans Supplement to the Current Population Survey,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, 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 June 24, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201902-1220-001* (this link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–BLS, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Veterans Supplement to the Current Population Survey information collection. The Veterans Supplement to the Current Population Survey (CPS) is conducted annually. This supplement is co-sponsored by the U.S. Department of Veterans Affairs (VA) and by the U.S. DOL's Veterans Employment and Training Service (VETS). Data collected through this supplement is used by the co-sponsors to determine policies that better meet the needs of our Nation's veteran population. The supplement provides information on the labor force status of veterans with a service-connected disability, combat veterans, past or present National Guard and Reserve members, and recently discharged veterans. In addition, location of service questions separately identify Afghanistan, Iraq, and Vietnam veterans. Data are provided by period of service and a range of demographic characteristics. The supplement also provides information about veterans' participation in various transition and employment training programs. Respondents are veterans who are not currently on active duty or who are members of a household where a veteran lives. Title 29 U.S.C. 1–9 authorize this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB

Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1220–0102.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on August 31, 2019. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 6, 2019 (84 FR 8120).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1220–0102. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–BLS.

Title of Collection: Veterans Supplement to the Current Population Survey.

OMB Control Number: 1220–0102.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 7,800.

Total Estimated Number of Responses: 7,800.

Total Estimated Annual Time Burden: 423 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: May 16, 2019.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2019–10794 Filed 5–22–19; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

National Environmental Policy Act Implementing Procedures

AGENCY: National Endowment for the Humanities, National Foundation on the Arts and the Humanities.

ACTION: Notice of Final National Environmental Policy Act Implementing Procedures.

SUMMARY: This document contains the final National Endowment for the Humanities (''NEH'') procedures for compliance with the National Environmental Policy Act of 1969 (''NEPA''), as amended. This action is necessary to implement these procedures and make them available to the public on NEH's internet site.

DATES: These procedures are effective May 23, 2019.

FOR FURTHER INFORMATION CONTACT: Michael McDonald; (202) 606–8322; gencounsel@neh.gov.

SUPPLEMENTARY INFORMATION: NEH is an independent agency within the executive branch of the United States government, established by the National Foundation on the Arts and the Humanities Act of 1965. NEH extends financial assistance to individuals and organizations to support research, education, preservation, and public programs in the humanities. It also has statutory authority to extend financial assistance to cultural organizations to enable infrastructure development and capacity building, including through the design, purchase, construction, restoration, or renovation of facilities needed for humanities activities and historic landscapes.

NEPA and implementing regulations promulgated by the Council on Environmental Quality (''CEQ'') (40 CFR parts 1500–1508) established a broad national policy to use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare, as well as to create and maintain conditions under which man and nature can exist in productive harmony and fulfill the social, economic, and other requirements of present and future generations of Americans.

The CEQ regulations implementing the procedural provisions of NEPA are designed to ensure that this national policy, environmental considerations, and associated public concerns are given careful attention and appropriate weight in all decisions of the federal government. Section 102(2) of NEPA and 40 CFR 1505.1 and 1507.3 require federal agencies to develop and, as needed, revise implementing procedures consistent with the CEQ regulations. NEH is issuing the following NEPA implementing procedures that comply with NEPA and supplement the CEQ regulations. Per 40 CFR 1507.3, CEQ has reviewed these final implementing procedures for conformity with NEPA and the CEQ regulations, and considered NEH's responses to comments from the public.

The remaining sections of **SUPPLEMENTARY INFORMATION** will provide background and address comments NEH received in response to its proposed NEPA implementing procedures. Following the **SUPPLEMENTARY INFORMATION** is the text of the final procedures.

Background

On October 15, 2018, NEH published a notice in the **Federal Register** (83 FR 52235) advising the public of its intent to promulgate NEPA implementing procedures, including a list of ''categorical exclusions'' (*i.e.,* those actions which do not individually or cumulatively have a significant effect on the human environment and for which, in the absence of extraordinary circumstances, further environmental review and documentation is not required). NEH solicited public comments on its proposed procedures.

Consistent with CEQ regulations, NEH consulted with CEQ prior to making its proposed implementing procedures available for public review and comment. 40 CFR 1507.3. The comment period closed on November 15, 2018. NEH received comments from three individuals, which it posted to the NEH website at *https://www.neh.gov/public-comments-neh-rulemaking-and-other-notices.*

Comments

One commenter expressed concern that NEH intends to issue these procedures to inhibit its ability to fund humanities-related projects. That commenter also questioned whether an NEH-funded project would ever not receive a ''Finding of No Significant Impact.''

NEH has determined to issue these procedures because: (i) CEQ regulations require that agencies adopt procedures to ensure that their decision-making is consistent with the policies and purposes of NEPA (40 CFR 1505.1 and 1507.3); (ii) CEQ specifically advised NEH to adopt NEPA implementing procedures; and (iii) NEH identified a particular need to adopt such procedures in light of recent agency efforts to support projects involving the design, purchase, construction, restoration, and renovation of facilities and historic landscapes. These efforts, supported through NEH's Challenge Grant program, will strengthen the institutional base of the humanities by enabling infrastructure development and capacity building. NEH's NEPA implementing procedures, and in particular the categorical exclusions, will facilitate—rather than impede—NEH's grant making activities by creating a protocol through which NEH and its award recipients will assess whether and to what extent NEH-funded activities require heightened environmental review as mandated by NEPA.

It bears emphasizing that the majority of NEH grant-making activities (*i.e.,* those supporting research, education, preservation, and public programs in the humanities) are likely to fall under one of NEH's ''General Categorical Exclusions,'' as activities having no inherent potential for significant environmental impact, that require no further environmental documentation or review.

As for NEH-funded construction, restoration, and renovation projects, such projects must serve NEH's narrow statutory mission of promoting humanities excellence. Accordingly, such projects most often involve the construction or renovation of libraries, museums, and other facilities that house and advance scholarly research. To maximize public outreach, such NEH-funded construction activities often take place in already-developed areas. For these reasons, except for potential effects to historic sites, that NEH will evaluate under Section 106 of the National Historic Preservation Act (''NHPA''), NEH-funded construction and renovation projects generally pose minimal potential impact to the human environment. Accordingly, to the extent NEH has control and responsibility for such projects sufficient to implicate NEPA in the first instance, NEH anticipates that most of these projects are likely to fall under a Program Specific Categorical Exclusion.

The second commenter similarly requested that NEH not implement overly restrictive procedures that could otherwise impede the agency's work. As explained above, much of NEH's business falls under one or more ''General Categorical Exclusions,'' and NEH anticipates that most NEH-funded projects involving construction and renovation for which NEH has control and responsibility are likely to fall under a ''Program Specific Categorical Exclusion.''

It bears emphasizing that NEH drafted its proposed categorical exclusions with the dual goals of increasing administrative efficiency in NEPA compliance and avoiding misuse of categorical exclusions that could lead to non-compliance with NEPA requirements. Furthermore, it developed its categorical exclusions after (i) carefully considering each of its programs and activities; (ii) consulting with those NEH staff members responsible for administering NEH grants involving facility construction, restoration, renovation, and repair; (iii) canvassing the categorical exclusions used by other federal agencies; and (iv) consulting with CEQ. Based upon NEH's findings, which it documented in an ''Administrative Record for NEH Proposed Categorical Exclusions under NEPA,'' NEH does not believe its procedures are overly restrictive or will unduly impede its work.

The third commenter submitted a number of proposed edits to NEH's implementing procedures. The commenter explained that he based his comments on simplifying the NEPA documentation process to ensure that NEH invests its environmental analysis and documentation on those actions that may significantly affect the quality of the human environment and avoid unnecessary work. NEH addresses the commenter's specific proposed edits in turn below.

First, the commenter proposed that NEH add text to the ''Applicability'' section of its procedures (Section 2) clarifying those instances in which NEPA applies: Namely, (i) when NEH has a goal and is actively preparing to make a decision on one or more alternative means of accomplishing that goal and the effects can meaningfully be evaluated; (ii) the proposed action is subject to NEH control and responsibility; (iii) the proposed action would cause effects on the human environment as defined in 40 CFR 1508.14; and (iv) the proposed action is not statutorily exempt from the requirements of section 102(2)(C) of NEPA (42 U.S.C. 4332(2)(C)).

NEH agrees that it would be helpful to add such clarification to Section 2 of its implementing procedures. It notes that the limiting language closely follows that set forth in the CEQ regulations and that other agencies have included similar applicability guidelines within their NEPA implementing procedures: For example, the Department of the Interior (43 CFR 46.100) and the United States Forest Service (36 CFR 220.4).

Second, the commenter objected to NEH's proposal that actions otherwise meeting the criteria for Program Specific Categorical Exclusions require completion of a Record of Environmental Consideration (''REC'') documenting NEH's determination that the activity qualifies for a categorical exclusion. Although the commenter acknowledged that other agencies impose similar documentation requirements with respect to projects involving construction, renovation, rehabilitation or other ground disturbance, he asked that NEH consider making the documentation requirement for Program Specific Categorical Exclusions optional, and suggested that NEH retain discretion to complete such documentation based on ''risks.'' The commenter contended that the requirement that NEH complete an REC will increase the agency's paperwork burden with respect to actions that should otherwise be excluded from documentation.

NEH agrees that activities meeting the criteria set forth within its General Categorical Exclusions should require no further documentation, as such activities generally pose no inherent potential for significant environmental impacts. Accordingly, NEH did not propose completion of a REC for these activities. In addition, NEH concurs with the commenter's concern regarding the potential increase in burden that could result by using the REC attached in Appendix B, and has deleted it. NEH will document Program Specific Categorical Exclusions (Section B of Appendix A) in a manner that aligns with NEH's NEPA implementing procedures, but will not require the use of the REC to do so.

Specifically, for activities falling under a Program Specific Categorial Exclusion, NEH will document whether extraordinary circumstances exist, and in the absence of extraordinary

circumstances, NEH will require no further environmental documentation such as would be required to conduct an environmental assessment (''EA'') or an environment impact statement (''EIS''). Accordingly, NEH's determination that such activities qualify for a categorical exclusion will greatly reduce the documentation burden on NEH and its award recipients by obviating the need for further environmental review.

Third, the commenter proposed a series of edits to NEH's enumeration of the ''extraordinary circumstances'' in Section 10 of its implementing procedures that would require preparation of an EA or EIS. Consistent with CEQ regulations (40 CFR 1508.27), and for the sake of clarity, NEH agrees to define ''extraordinary circumstances'' as arising when a typically-categorically excluded action has the reasonable likelihood to result in individually or cumulatively significant impacts on the public health, public safety, or the environment.

Consistent with a number of federal court decisions, NEH further agrees to add text to Section 10 clarifying that the phrase ''highly controversial'' refers to a ''substantial'' and ''scientifically-verifiable'' controversy regarding a project's impact. In addition, NEH will eliminate from its list of potential ''extraordinary circumstances'' reference to ''scientifically controversial'' effects, which the above edit has made redundant.

The commenter further recommended that NEH delete from its list of potential ''extraordinary circumstances'' reference to activities reasonably likely to (i) have a greater scope or size than is normal for the category of action; (ii) degrade already existing poor environmental conditions or initiate a degrading influence, activity or effect in areas not already significantly modified from their natural conditions; and (iii) have a disproportionately high and adverse effect on low income or minority populations (see Executive Order 12898). The commenter questioned whether the presence of these circumstances alone constitute ''extraordinary circumstances,'' and doubted those items' utility as ''criterion for extraordinary circumstances.''

NEH notes that the situations listed in Section 10 of these procedures are not themselves ''criterion of extraordinary circumstances,'' but are rather examples of ''extraordinary circumstances.'' NEH believes that the language it has added to these procedures explaining that, to give rise to an ''extraordinary circumstance,'' an action must have a reasonable likelihood of causing a ''significant'' impact on public health, public safety, or the environment, helps clarify that the list of enumerated effects are illustrative of potential extraordinary circumstances, and are not themselves dispositive. Accordingly, NEH has determined to retain reference to degraded pre-existing conditions and disproportionate effects on low income or minority populations, as it has now made clear that such effects constitute ''extraordinary circumstance'' provided they otherwise have a significant impact on human health, safety or the environment.

NEH agrees with the commenter, however, that whether an activity is likely to have a greater scope or size than is normal for the category of action is not an especially helpful illustration of an activity giving rise to an extraordinary circumstance, and accordingly, NEH will delete that reference. Whether any particular action gives rise to ''extraordinary circumstances'' will necessarily depend on the action's potential for significant impacts, which will most likely depend in some measure on its scope or size relative to similar actions.

The commenter recommended that NEH delete the ''General Categorical Exclusions'' from Appendix A of these procedures on the ground that NEPA does not require that agencies ''establish categorical exclusions for actions that do not affect the natural and physical environment and the relationship of people with that environment.'' NEH disagrees. While CEQ has made clear that NEPA applies only to ''Major Federal Actions''—*i.e.,* those actions with effects that ''may be'' significant (40 CFR 1508.18)—it has also defined ''categorical exclusion'' to mean those actions that do not individually or cumulatively have a significant effect on the human environment (40 CFR 1508.4). In other words, it is through the process of evaluating and issuing categorical exclusions that agencies determine which of their actions will not affect the natural and physical environment and the relationship of people with that environment. As memorialized in its Administrative Record for NEH Proposed Categorical Exclusions under NEPA, NEH determined that the activities identified in its General Categorical Exclusions have very little inherent potential for significant environmental impact. Accordingly, NEH will not require preparation of an REC for such activities or consideration of potential extraordinary circumstances.

Moreover, NEH's inclusion within its General Categorical Exclusions of routine administrative and management activities, the preparation of regulations, and the approval and issuance of financial assistance to support research, education, preservation, and public programs in the humanities, is consistent with the categorical exclusions adopted by numerous other federal agencies: For example, the Denali Commission (45 CFR part 900, Appendix B), the Department of the Interior (43 CFR 46.210), the Department of Health and Human Services—Indian Health Services (58 FR 569), and the U.S. Forest Service (36 CFR 220.6 (adopting the categorical exclusions issued by the Department of Agriculture at 7 CFR part 1b.3)).

The commenter further noted that NEH's explanation in Appendix B that a categorical exclusion may only apply after NEH has determined that a particular construction, renovation or rehabilitation project is ''not reasonably likely to have a significant effect on historic properties'' is redundant of Section 10, in which NEH identified the ''significant effect on environmentally sensitive resources'' as a potential extraordinary circumstance. NEH included this language in Appendix B because the agency frequently supports projects involving renovation, repair and/or rehabilitation of historic properties. For such projects, NEH requires review under Section 106 of the NHPA. For this reason, and notwithstanding the fact that NEH has determined to delete Appendix B, NEH believes it is important that these NEPA implementing procedures expressly state that a categorical exclusion determination may not be made until after NEH has performed a review under Section 106 of the NHPA and determined that there exist no adverse effects to historic properties, or that any such effects can be mitigated effectively.

The commenter further recommended that NEH delete from the second Program Specific Categorical Exclusion those conditions requiring that (i) there is no evidence of community controversy; (ii) the proposed use will not substantially increase the number of motor vehicles at the facility or in the area; and (iii) the construction or improvement will not result in uses that exceed existing support infrastructure capacities (road, sewer, water, parking, etc.). The commenter recommended that each such condition be considered as a potential extraordinary circumstance rather than a condition to a categorical exclusion.

NEH agrees with the commenter's suggestion regarding ''community controversy.'' Because NEH will identify as a possible extraordinary circumstance effects that are ''highly controversial'' it would be redundant and potentially

confusing to condition application of the second Program Specific Categorical Exclusion on a lack of ''community controversy.'' Should a project have effects that are reasonably likely to be ''highly controversial,'' the presence of such extraordinary circumstances would preclude application of a categorical exclusion.

NEH will, however, retain all other conditions associated with the second Program Specific Categorical Exclusion, including those pertaining to motor vehicle presence and existing infrastructure capacity. Such conditions are consistent with those included in the categorical exclusions of numerous other federal agencies: For example, the Department of Commerce (74 FR 33204), the U.S. Missile Defense Agency (79 FR 46410), the National Capital Planning Commission (1 CFR 601.12), and the Department of Homeland Security (71 FR 16790).

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

Executive Orders 13563 and 12866 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, distribution impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. These procedures have not been designated a ''significant regulatory action'' because they do not: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in these Executive Orders. The text of the complete proposed procedures appears below.

Dated: May 17, 2019.

Michael McDonald,

General Counsel, National Endowment for the Humanities.

Table of Contents

The National Environmental Policy Act Procedures for NEH

1. Purpose

These procedures implement the provisions of NEPA, 42 U.S.C. 4321 *et seq.* They adopt and supplement the CEQ regulations implementing NEPA, 40 CFR parts 1500–1508, by establishing policy, directing environmental planning, and assigning responsibilities in NEH to prepare, review, and approve environmental documents, 40 CFR 1508.10, that comply with NEPA.

2. Applicability

These procedures apply NEPA to NEH programs and activities, including programs and activities carried out by state and local governments, federally-recognized tribal governments and non-governmental organizations with the use of NEH financial assistance, when the following apply:

(a) The NEH has a goal and is actively preparing to make a decision on one or more alternative means of accomplishing that goal and the effects can meaningfully be evaluated (40 CFR 1508.23);

(b) The proposed action is subject to NEH control and responsibility (40 CFR 1508.18);

(c) The proposed action would cause effects on the human environment, which CEQ has interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment (40 CFR 1508.14);

(d) The proposed action is not statutorily exempt from the requirements of section 102(2)(C) of the NEPA (42 U.S.C. 4332(2)(C)).

3. Environmental Policy

It is the policy of NEH to:

(a) Start the NEPA process at the earliest possible time as an effective decision-making tool while evaluating a proposed action;

(b) Comply with the procedures and policies of NEPA and other related environmental laws, regulations, and orders applicable to NEH actions;

(c) Provide guidance to applicants responsible for ensuring that proposals comply with all appropriate NEH requirements;

(d) Integrate NEPA requirements and other planning and environmental review procedures required by law or NEH practice so that all such procedures run concurrently rather than consecutively;

(e) Encourage and facilitate public involvement in NEH actions that affect the quality of the human environment;

(f) Use the NEPA process to identify and assess reasonable alternatives to proposed NEH actions to avoid or minimize adverse effects upon the quality of the human environment; and

(g) Use all practicable means consistent with NEPA and other essential considerations of national policy to restore or enhance the quality of the human environment and avoid, minimize, or otherwise mitigate any possible adverse effects of NEH actions upon the quality of the human environment.

4. Terms and Abbreviations

(a) For the purposes of this section, the definitions in the CEQ regulations, 40 CFR parts 1500 through 1508, are adopted and supplemented as set out in paragraphs (a)(i) through (vi) of this section. In the event of a conflict the CEQ regulations apply.

(i) *Action.* Action and Federal action as defined in 40 CFR 1508.18 include projects and programs entirely or partly financed, assisted, conducted, regulated, or approved by NEH.

(ii) *Applicant.* The state, local or federally-recognized tribal government or non-governmental partner or organization applying to NEH for financial assistance or other approval. An applicant may be an organization

already in receipt of NEH-awarded funds.

(iii) *Approving Official.* The NEH Chairman or an NEH staff member designated by the NEH Chairman to fulfill the responsibilities defined in Section 6 below, including overseeing development of and approval of the NEPA document.

(iv) *Finding of No Significant Impact (FONSI)* is a document by NEH briefly presenting the reasons why an action, not otherwise excluded as provided in Section 10 below, will not have a significant impact on the human environment and for which an EIS will not be prepared.

(v) *NEH Proposal (or Proposal).* A proposal, as defined at 40 CFR 1508.23, is an NEH proposal whether initiated by NEH, another federal agency or an applicant.

(vi) *NEH Chairman:* The Chairman of NEH, as established in Section 7 of the National Foundation on the Arts and the Humanities Act of 1965, 20 U.S.C. 956.

(b) The following abbreviations are used throughout these procedures:

(i) CATEX—Categorical exclusions;

(ii) CEQ—Council on Environmental Quality;

(iii) EA—Environmental assessment;

(iv) EIS—Environmental impact statement;

(v) FONSI—Finding of no significant impact;

(vi) NEPA—National Environmental Policy Act of 1969, as amended;

(vii) NOI—Notice of intent; and

(viii) ROD—Record of decision.

5. Federal and Intergovernmental Relationships

NEH occasionally partners with federal, state and local agencies, and federally-recognized tribal governments, and may depend on these governmental agencies for project management. Under such circumstances, NEH may rely on the expertise and processes already in use by partnering agencies to help prepare NEH NEPA analyses and documents.

(a) With federal partners, NEH will work as either a joint lead agency (40 CFR 1501.5 and 1508.16) or cooperating agency (40 CFR 1501.6 and 1508.5). NEH may invite other Federal agencies to serve as the lead agency, a joint lead agency, or as a cooperating agency.

(b) Consistent with 40 CFR 1508.5, NEH may invite state and local government partners, and federally-recognized tribal governments, to serve as cooperating agencies.

6. Applicant Responsibility

Applicants shall work under NEH direction provided by the Approving Official, and assist NEH in fulfilling its NEPA obligations by preparing NEPA analyses and documents that comply with the provisions of NEPA (42 U.S.C. 4321–4347), the CEQ regulations (40 CFR parts 1500 through 1508), and the requirements set forth in this part.

Applicants shall follow NEH direction when they assist NEH with the following responsibilities, among others:

(a) Prepare and disseminate applicable environmental documentation concurrent with a proposal's engineering, planning, and design;

(b) Create and distribute public notices;

(c) Coordinate public hearings and meetings as required;

(d) Submit all environmental documents created pursuant to these procedures to NEH for review and approval before public distribution;

(e) Participate in all NEH-conducted hearings or meetings;

(f) Consult with NEH prior to obtaining the services of an environmental consultant; in the case that an EIS is required, the consultant or contractor will be selected by NEH; and

(g) Implement mitigation measures included as voluntary commitments by the applicant or as requirements of the applicant in NEH decision documents (FONSI or ROD).

7. NEH Responsibility

(a) The NEH Chairman or his/her designee shall designate an Approving Official for each NEH proposal, and shall provide environmental guidance to the Approving Official;

(b) The Approving Official shall provide direction and guidance to the applicant as well as identification and development of required analyses and documentation;

(c) The Approving Official shall make an independent evaluation of the environmental issues, take responsibility for the scope and content of the environmental document (EA or EIS), and make the environmental finding;

(d) The Approving Official shall ensure mitigation measures included in NEH decision documents (FONSI or ROD) are implemented; and

(e) The Approving official shall be responsible for coordinating communications with cooperating agencies and other federal agencies.

8. Public Involvement

NEH will make diligent efforts to involve the public in preparing and implementing its NEPA procedures in accordance with 40 CFR 1501.4(b), 1506.6 and part 1503. When developing a plan to include the public and affected parties in the environmental analysis process, NEH will consider the following factors: (a) The magnitude of the environmental considerations associated with the proposal; (b) the extent of expected public interest; and (c) any relevant questions of national concern. NEH will specifically publish EAs and draft FONSIs on its website as provided in Section 11(c) below.

9. Environmental Review Process

The environmental review process is the investigation of potential environmental impacts to determine the environmental process to be followed and to assist in the preparation of the environmental document. NEH shall specifically determine whether any NEH proposal:

(a) Is categorically excluded from preparation of either an EA or an EIS;

(b) Requires preparation of an EA; or

(c) Requires preparation of an EIS.

10. Categorical Exclusions

(a) *General.* A categorical exclusion (''CATEX'') is defined in 40 CFR 1508.4 as a category of actions which do not individually or cumulatively have a significant effect on the human environment and for which, in the absence of extraordinary circumstances, neither an EA nor an EIS is required. Actions that meet the conditions in paragraph (b) of this section and are listed in section A of appendix A of these procedures can be categorically excluded from further analysis and documentation in an EA or EIS. Actions that meet the screening conditions in paragraph (b) of this section and are listed in section B of appendix A require documentation.

(b) *Conditions.* The following three conditions must be met for an action to be categorically excluded from further analysis in an EA or EIS.

(i) The action has not been segmented (too narrowly defined or broken down into small parts in order minimize its potential effects and avoid a higher level of NEPA review) and its scope includes the consideration of connected actions and, when evaluating extraordinary circumstances, cumulative impacts.

(ii) No extraordinary circumstances described in paragraph (c) of this section exist.

(iii) The proposed action fits within one of the categorical exclusions described in either section of Appendix A of this part.

(c) *Extraordinary Circumstances.* Any action that normally would be classified as a CATEX but could involve extraordinary circumstances will

require appropriate environmental review documented in an NEH CATEX checklist to determine if the CATEX classification is proper or if an EA or EIS should be prepared. Extraordinary circumstances to be considered include those reasonably likely to:

(i) Have effects on the environment that are highly controversial: *i.e.,* a controversy that is both substantial and scientifically-verifiable.

(ii) Have effects on the human environment that are highly uncertain, involve unique or unknown risks, or involve unresolved conflicts concerning alternative uses of available resources;

(iii) Establish a precedent for future action or represent a decision in principle about future actions with potentially significant environmental effects;

(iv) Relate to other actions with individually insignificant but cumulatively significant environmental effects;

(v) Degrade already existing poor environmental conditions or initiate a degrading influence, activity, or effect in areas not already significantly modified from their natural condition;

(vi) Have a disproportionately high and adverse effect on low income or minority populations (see Executive Order 12898);

(vii) Limit access to and ceremonial use of Indian sacred sites on federal lands by Indian religious practitioners or adversely affect the physical integrity of such sacred sites (see Executive Order 13007);

(viii) Threaten a violation of a federal, tribal, state or local law or requirement imposed for the protection of the environment;

(ix) Significantly affect subsistence activities; or

(x) Significantly affect environmentally sensitive resources, such as (A) properties listed, or eligible for listing, in the National Register of Historic Places; (B) species listed, or proposed to be listed, on the List of Endangered or Threatened Species, or their habitat; or (C) natural resources and unique geographic characteristics such as historic or cultural resources; park, recreation or refuge lands; wilderness areas; wild or scenic rivers; national natural landmarks; sole or principal drinking water aquifers; prime farmlands; special aquatic sites (defined under Section 404 of the Clean Water Act); floodplains; national monuments; and other ecologically significant or critical areas.

11. Environmental Assessments

An EA is required for all proposals, except those exempt from NEPA or categorically excluded under these procedures, and those requiring an EIS. An EA is not necessary if the NEH has decided to prepare an EIS. EAs provide sufficient evidence and analysis to determine whether to prepare an EIS or issue a finding of no significant impact (FONSI). In addition, an EA may be prepared on any action at any time in order to assist in planning and decision making, to aid in NEH's compliance with NEPA when no EIS is necessary, or to facilitate EIS preparation. EAs shall be prepared in accordance with these procedures and shall contain analyses to support conclusions regarding environmental impacts. If a FONSI is proposed, it shall be prepared in accordance with Section 11(e) below.

(a) Content

(i) The EA shall include brief discussions of the need for the proposal; of alternatives to the proposal as required by NEPA section 102(2)(E); and of the environmental impacts of the proposal and alternatives. The EA shall also include a listing of agencies and persons consulted in the preparation of the EA.

(ii) The EA may describe a broad range of alternatives and proposed mitigation measures to facilitate planning and decision-making.

(iii) The EA should also document compliance, to the extent possible, with all applicable environmental laws and Executive Orders, or provide reasonable assurance that those requirements can be met.

(iv) The EA should be a concise public document. The level of detail and depth of impact analysis will normally be limited to the minimum needed to determine the significance of potential environmental effects.

(b) General Considerations in Preparing Environmental Assessments

(i) *Adoption of an EA.* NEH may adopt an EA prepared for a proposal before NEH by another agency or an applicant when the EA, or a portion thereof, addresses the proposed NEH action and meets the standards for an adequate analysis under these procedures and relevant provisions of 40 CFR parts 1500 through 1508, provided that NEH makes its own evaluation of the environmental issues and takes responsibility for the scope and content of the EA in accordance with 40 CFR 1506.5(b).

(ii) *Incorporation by reference into the EA.* Any document may be incorporated by reference in accordance with 40 CFR 1502.21 and used in preparing an EA in accordance with 40 CFR 1501.4(b) and 1506.5(a), provided that NEH makes its own evaluation of the environmental issues and takes responsibility for the scope and content of the EA in accordance with 40 CFR 1506.5(b).

(iii) *Applicant responsibility.* The applicant shall assist NEH with preparing the EA. NEH remains responsible for compiling the public hearing summary or minutes, where applicable; and copies of any written comments received and responses thereto.

(c) Public Involvement

(i) In accordance with 40 CFR 1506.6, the Approving Official shall publish EAs and draft FONSIs on the NEH website and make such documents available for public comment for not less than 15 calendar days.

(ii) NEH will only take final action on an EA and draft FONSI after it reviews and considers public comments.

(d) Actions Resulting From Assessment

(i) *Accepted without modification.* NEH may accept a proposal without modifications if the EA indicates that the proposal does not have significant environmental impacts and a FONSI is prepared in accordance with Section 11(e) below.

(ii) *Accepted with modification.* If an EA identifies potentially significant environmental impacts, the proposal may be modified to eliminate such impacts. Proposals so modified may be accepted by NEH if the proposed changes are evaluated in an EA and a FONSI is prepared in accordance with Section 11(e) below.

(iii) *Mitigated FONSI.* If mitigation is required to reduce the impacts below significant the FONSI shall identify the mitigation and adopt applicable monitoring and enforcement measures that are necessary to ensure the implementation of the mitigation measures.

(iv) *Prepare an EIS.* NEH shall require that the proposal be evaluated in an EIS, prepared in accordance with Section 12 below, if the EA indicates significant environmental impacts that are not mitigated below a specified level of significance.

(v) *Rejected.* NEH may always elect to reject a proposal.

(e) Findings of No Significant Impact

(i) *Content.* A FONSI shall include the EA or a summary of it and shall note any other environmental documents related to it (40 CFR 1501.7(a)(5)). If the EA is included, the finding need not repeat any of the discussion in the assessment but may incorporate it by reference.

(ii) *Publication.* NEH shall make the final FONSI available to the public on the NEH website.

(f) Proposals Normally Requiring an EA

Proposals that normally require preparation of an EA include proposed actions that potentially result in significant changes to established land use.

12. Environmental Impact Statements

An EIS is required when the project is determined to have a potentially significant impact on the human environment.

(a) Notice of Intent and Scoping

NEH shall publish an NOI, as described in 40 CFR 1508.22, in the **Federal Register** as soon as practicable after NEH makes a decision to prepare an EIS. If there will be a lengthy period of time between NEH's decision to prepare an EIS and its actual preparation, NEH may defer publication of the NOI until a reasonable time before preparing the EIS, provided that NEH allows a reasonable opportunity for interested parties to participate in the EIS process. NEH and the applicant will coordinate during the time period prior to the publication of the NOI to identify: the scope of the action, potential modifications to the proposal, potential alternatives, environmental constraints, potential timeframes for the environmental review, and federal, state, or tribal entities that could be interested in the project, including those with the potential to become cooperating agencies. Through the NOI, NEH shall invite comments and suggestions on the scope of the EIS.

Publication of the NOI in the **Federal Register** shall begin the public scoping process. The public scoping process for an NEH EIS shall allow a minimum of 15 days for the receipt of public comments.

(b) Preparation and Filing of Draft and Final EISs

(i) *General.* EISs shall be prepared in two stages and may be supplemented.

(ii) *Format.* The EIS format recommended by 40 CFR 1502.10 shall be used unless NEH makes a determination on a particular project that there is a reason to do otherwise. In such a case, the EIS format must meet the minimum requirements prescribed in 40 CFR 1502.10, as further described in 40 CFR 1502.11 through 1502.18.

(iii) *Applicant role.* The draft or final EIS shall be prepared by NEH with assistance from the applicant under appropriate guidance and direction from the Approving Official.

(iv) *Third-party consultants.* A third-party consultant selected by NEH or in cooperation with a cooperating agency may prepare the draft or final EIS.

(v) *NEH responsibility.* NEH shall provide a schedule with time limits, provide guidance, participate in the preparation, independently evaluate, and take responsibility for the content of the draft and final EIS.

(vi) *Filing.* After a draft or final EIS has been prepared, NEH shall file the EIS with the Environmental Protection Agency (''EPA'') for publication of a notice of availability in accordance with 40 CFR 1506.9 and 1506.10.

(vii) *Draft to final EIS.* When a final EIS does not require substantial changes from the draft EIS, NEH may document required changes in errata sheets, insertion pages, and revised sections. NEH will then circulate such changes together with comments on the draft EIS, responses to comments, and other appropriate information as its final EIS. NEH will not circulate the draft EIS again; however, NEH will post the EIS on its website and provide the draft EIS if requested.

(viii) *Record of decision.* A record of decision (ROD) will be prepared in accordance with 40 CFR 1505.2 and 1505.3.

(c) Supplemental EIS

(i) Supplements to either draft or final EISs shall be prepared, as prescribed in 40 CFR 1502.9, when NEH finds that there are substantial changes proposed in a project that are relevant to environmental concerns, or when there are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts.

(ii) Where NEH action remains to be taken and the EIS is more than three years old, NEH will review the EIS to determine whether it is adequate or requires supplementation.

(iii) NEH shall prepare, circulate and file a supplement to an EIS in the same fashion (exclusive of scoping) as a draft and final EIS. In addition, the supplement and accompanying administrative record shall be included in the administrative record for the proposal. When an applicant is involved, the applicant shall, under the direction of the Approving Official, provide assistance.

(iv) An NOI to prepare a supplement to a final EIS will be published in those cases where a ROD has already been issued.

(d) Adoption

(i) NEH may adopt a draft or final EIS or portion thereof (see 40 CFR 1506.3), including a programmatic EIS, prepared by another agency.

(ii) If the actions covered by the original EIS and the proposal are substantially the same, NEH shall recirculate it as a final statement. Otherwise, NEH shall treat the statement as a draft and recirculate it except as provided in paragraph (iii) of this section.

(iii) Where NEH is a cooperating agency, it may adopt the EIS of the lead agency without recirculating it when, after an independent review of the EIS, NEH concludes that its comments and suggestions have been satisfied.

(iv) When NEH adopts an EIS which is not final within the agency that prepared it, or when the action it assesses is the subject of a referral under 40 CFR part 1504, or when the EIS's adequacy is the subject of a judicial action which is not final, NEH shall so specify.

(e) Proposals Normally Requiring an EIS

Given the nature of NEH activities, there are no proposals that would normally require use of an EIS. NEH would most likely use an EA in any given case to determine whether a project has a potentially significant impact on the human environment. The conclusion reached by NEH in the EA would dictate whether it would then prepare an EIS.

Appendix A to the National Environmental Policy Act Procedures for NEH

Actions consistent with any of the following categories are, in the absence of extraordinary circumstances, categorically excluded from further analysis in an EA or EIS:

A. General Categorical Exclusions

1. Routine administrative and management activities including, but not limited to, those activities related to budgeting, finance, personnel actions, procurement activities, compliance with applicable executive orders and procedures for sustainable or ''greened'' procurement, retaining legal counsel, public affairs activities (*e.g.,* issuing press releases, newsletters and notices of funding availability), internal and external program evaluation and monitoring (*e.g.,* site visits), database development and maintenance, and computer systems administration.

2. Preparing, revising, or adopting regulations, including those that implement without substantial change the regulations, instructions, directives, or guidance documents from other Federal agencies.

3. Routine activities undertaken by NEH to support its program partners, such as serving on task forces, ad hoc committees or representing NEH interests in other forums.

4. Approving and issuing financial assistance to support research, education, preservation, and public programs in the humanities, except where such assistance supports the construction, restoration, or renovation of facilities, including the purchase or lease of new infrastructure, or otherwise involves ground disturbing activity.

5. Approving and issuing financial assistance to support facility planning and design.

6. Approving and issuing grants to support the purchase or lease of preexisting infrastructure.

7. Nondestructive data collection, inventory, study, research, and monitoring activities.

B. Program Specific Categorical Exclusions

Actions consistent with any of the following categories are, in the absence of extraordinary circumstances, categorically excluded from further analysis and documentation in an EA or EIS. A categorical exclusion determination may only be made after NEH has, if necessary, performed a review under Section 106 of the National Historic Preservation Act (''NHPA'') and determined and documented that such action is not reasonably likely to have an adverse effect on historic properties.

1. Upgrade, repair, maintenance, replacement, or minor renovations and additions to facilities, grounds and equipment, including but not limited to, roof replacement, foundation repair, access ramp and door improvements pursuant to the Americans with Disabilities Act (''ADA''), weatherization and energy efficiency related improvements, HVAC renovations, painting, floor system replacement, repaving parking lots and ground maintenance, that do not result in a change in the functional use of the real property.

2. Construction, purchase or lease of new infrastructure, including, but not limited to, museums, libraries and other community buildings, and office space, that is similar to existing land use if the area to be disturbed has no more than two acres of new surface disturbance. The following conditions must be met:

a. The structure and proposed use are compatible with applicable Federal, tribal, state, and local planning and zoning standards.

b. The site and scale of the construction or improvement is consistent with those of existing, adjacent, or nearby buildings.

c. The proposed use will not substantially increase the number of motor vehicles at the facility or in the area.

d. The construction or improvement will not result in uses that exceed existing support infrastructure capacities (road, sewer, water, parking, etc.).

3. Construction, purchase or lease of new infrastructure, including, but not limited to, museums, libraries and other community buildings, and office space, where such construction, purchase or lease is for infrastructure of less than 12,000 square feet of useable space.

4. Demolition, disposal, or improvements involving buildings or structures when done in accordance with applicable regulations, including those regulations applying to removal of asbestos, polychlorinated biphenyls (PCBs), and other hazardous materials.

[FR Doc. 2019–10745 Filed 5–22–19; 8:45 am]

BILLING CODE 7536–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0230]

Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for comment; extension of comment period.

SUMMARY: On May 2, 2019, the U.S. Nuclear Regulatory Commission (NRC) requested comments on draft approaches regarding the training and experience (T&E) requirements for radiopharmaceuticals requiring a written directive. The public comment period was originally scheduled to close on June 3, 2019. The NRC is extending the comment period to July 3, 2019, to allow more time for stakeholders and members of the public to submit their comments.

DATES: The due date of comments requested in the notice published on May 2, 2019 (84 FR 18874) is extended. Comments should be submitted no later than July 3, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0230. Address questions about NRC 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: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6360, email: *Sarah.Lopas@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0230 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 *http://www.regulations.gov* and search for Docket ID NRC–2018–0230.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2018–0230 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 *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that 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. Discussion

On May 2, 2019, the NRC published a notice in the **Federal Register** (84 FR 18874) requesting comments on draft approaches the staff developed regarding the T&E requirements for radiopharmaceuticals requiring a written directive. The public comment period was originally scheduled to close on June 3, 2019. By letter dated May 13, 2019 (ADAMS Accession No. ML19136A236), the American College of Radiology, the American Society for Radiation Oncology, and the Society of Nuclear Medicine and Molecular Imaging jointly requested a 30-day extension to the public comment period. United Pharmacy Partners, Inc. also submitted a request for extension by letter dated May 14, 2019 (ADAMS Accession No. ML19136A238). Additional requests for an extension to the public comment period were also heard during a May 14, 2019, public comment meeting. The NRC is granting this request and will extend the public comment period until July 3, 2019, to allow more time for medical and regulatory stakeholders and members of the public to submit their comments.

Dated at Rockville, Maryland, this 17th day of May 2019.

For the Nuclear Regulatory Commission.

Andrea L. Kock,

Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2019–10760 Filed 5–22–19; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2019–138 and CP2019–152; MC2019–139 and CP2019–153; MC2019–140 and CP2019–154]

New Postal Product

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:* May 28, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

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 3007.301.[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 3010, and 39 CFR part 3020, 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 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2019–138 and CP2019–152; *Filing Title:* USPS Request to Add Priority Mail Contract 528 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 17, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* May 28, 2019.

2. *Docket No(s).:* MC2019–139 and CP2019–153; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & First-Class Package Service Contract 62 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 17, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* May 28, 2019.

3. *Docket No(s).:* MC2019–140 and CP2019–154; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 100 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 17, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* May 28, 2019.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2019–10822 Filed 5–22–19; 8:45 am]

BILLING CODE 7710–FW–P

[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).

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, & First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 23, 2019.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 17, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, & First-Class Package Service Contract 62 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–139, CP2019–153.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–10734 Filed 5–22–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice May 23, 2019.*

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 17, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 100 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–140, CP2019–154.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–10733 Filed 5–22–19; 8:45 am]

BILLING CODE 7710–12–P

PRIVACY AND CIVIL LIBERTIES OVERSIGHT BOARD

[Notice–PCLOB–2019–02; Docket No. PCLOB–2019–0002; Sequence No. 1]

Public Forum

AGENCY: Privacy and Civil Liberties Oversight Board.

ACTION: Notice of public forum; request for public comment.

SUMMARY: The Privacy and Civil Liberties Oversight Board will conduct a public forum to examine the USA FREEDOM Act and the government's call detail records (CDR) program under that law. During the forum, Board Members will hear a range of expert views on the USA FREEDOM Act—from its history and implementation, to present challenges and the path ahead.

DATES: The forum will be held on Friday, May 31, 2019, from 10:00 a.m. to 12:30 p.m. (Eastern Standard Time). Please submit comments on or before July 1, 2019.

ADDRESSES: Ronald Reagan Building, Horizon Room, 1300 Pennsylvania Ave. NW, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Jen Burita, Director of Legislative and Public Affairs, 202–331–1986.

SUPPLEMENTARY INFORMATION: Doors open at 9:30 a.m. The forum will begin promptly at 10:00 a.m.

Participant List

The Board will hear from these experts:

- Jamil N. Jaffer—Founder and Director of the National Security Institute and Director of the National Security Law and Policy Program, George Mason University, Antonin Scalia School of Law
- Susan Landau—Bridge Professor of Cyber Security and Policy in the Fletcher School of Law and Diplomacy and the School of Engineering, Department of Computer Science, Tufts University
- Jonathan Mayer—Assistant Professor of Computer Science and Public Affairs, Princeton University
- Julian Sanchez—Senior Fellow, Cato Institute
- Caroline Lynch—Founder and Owner of Copper Hill Strategies, former Chief Counsel of the House Judiciary Subcommittee on Crime, Terrorism, Homeland Security, and Investigations
- Michael Bahar—Partner, Eversheds Sutherland's Global Cybersecurity and Privacy Practice, former Minority Staff Director and General Counsel for the U.S. House Intelligence Committee.

Procedures for Public Observation

The event is open to the public. Pre-registration is not required. Members of the public will have an opportunity to offer comments and pose questions to the panelists. Individuals who plan to attend and require special assistance should contact Jen Burita, Public Affairs/Legislative Affairs Officer, 202–331–1986, at least 72 hours prior to the event.

Public Comments

The Privacy and Civil Liberties Oversight Board invites written comments of interested persons regarding privacy in the counterterrorism context. You may submit comments with the docket number PCLOB–2019–02 by the following method:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Please search by 'Notice PCLOB–2019–02' and follow the on-line instructions for submitting comments.
- Written comments may be submitted at any time prior to the closing of the docket at 11:59 p.m., EST, on July 1, 2019.

All comments will be made publicly available and posted without charge. Do not include personal or confidential information.

Dated: May 17, 2019.

Eric Broxmeyer,

General Counsel, Privacy and Civil Liberties Oversight Board.

[FR Doc. 2019–10788 Filed 5–22–19; 8:45 am]

BILLING CODE 6820–B5–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85895; File No. 265–30]

Fixed Income Market Structure Advisory Committee

AGENCY: Securities and Exchange Commission.

ACTION: Notice of meeting.

SUMMARY: Notice is being provided that the Securities and Exchange Commission Fixed Income Market Structure Advisory Committee will hold an open, public telephonic meeting on

Tuesday, June 11, 2019 beginning at 1:00 p.m. (ET). The meeting will include the consideration of a recommendation from the Technology and Electronic Trading Subcommittee. Members of the public may listen to the meeting by telephone at 1–800–260–0718, participant code 467607, or by webcast on the Commission's website at *www.sec.gov*. Persons needing special accommodations to take part because of a disability should notify the contact persons listed below. The public is invited to submit written statements to the Committee.

DATES: The public telephonic meeting will be held on June 11, 2019. Written statements should be received on or before June 6, 2019.

ADDRESSES: Written statements may be submitted by any of the following methods:

Electronic Statements

- Use the Commission's internet submission form (*http://www.sec.gov/rules/other.shtml*); or
- Send an email message to *rule-comments@sec.gov.* Please include File Number 265–30 on the subject line; or

Paper Statements

- Send paper statements in triplicate to Vanessa A. Countryman, Acting Federal Advisory Committee Management Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. 265–30. This file number should be included on the subject line if email is used. To help us process and review your statement more efficiently, please use only one method. The Commission will post all statements on the Commission's internet website at *http://www.sec.gov/comments/265-30/265-30.shtml.*

Statements also will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Room 1580, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All statements received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: David Dimitrious, Senior Special Counsel, at (202) 551–5131, or Benjamin Bernstein, Special Counsel, at (202) 551–5354, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington DC 20549–7010.

SUPPLEMENTARY INFORMATION: In accordance with Section 10(a) of the Federal Advisory Committee Act, 5 U.S.C.–App. 1, and the regulations thereunder, Brett Redfearn, Designated Federal Officer of the Committee, has ordered publication of this notice.

Dated: May 20, 2019.

Vanessa A. Countryman,

Acting Committee Management Officer.

[FR Doc. 2019–10810 Filed 5–22–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85889; File No. SR–NYSE–2019–20]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change Amending Section 302 of the Listed Company Manual To Provide Exemptions for the Issuers of Certain Categories of Securities From the Obligation To Hold Annual Shareholders' Meetings

May 17, 2019.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 6, 2019, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section 302 of the Listed Company Manual (the ''Manual'') to provide exemptions for the issuers of certain categories of securities from the obligation to hold annual shareholders' meetings. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Section 302 of the Manual provides that listed companies are required to hold an annual shareholders' meeting during each fiscal year.

Section 303A.00 of the Manual provides that preferred and debt listings, passive business organizations in the form of trusts (such as royalty trusts) and derivative and special purpose securities are not required to comply with certain of the corporate governance requirements set forth in Section 303A.[4] Section 303A.00 does not exclude the obligation to hold an annual meeting pursuant to Section 302 from those requirements with which such issuers must comply.

Holders of non-voting preferred and debt securities, securities of passive business organizations (such as royalty trusts) and derivative and special purpose securities either do not have the right to elect directors at annual meetings or have the right to elect directors only in very limited circumstances. For example, holders of non-voting preferred securities may have the right to temporarily elect directors if dividends on such securities have not been paid for a specified period of time. Absent such special circumstances, in no event do holders of the securities listed above elect directors on an annual basis. Despite the fact that there is no matter with respect to which holders of these securities have an annual voting right under state law or their governing documents, NYSE rules currently do not exclude the issuers of

[4] To the extent that Rule 10A–3 under the Act applies to (i) companies listing only preferred or debt securities, or (ii) passive business organizations, such entities are required to comply with the requirements of Section 303A.06 (Audit Committee) and certain provisions of 303A.12(b) (Certification Requirements).

such securities from the requirement that they hold an annual meeting of shareholders.

The Exchange now proposes to amend Section 302 to provide that issuers of these securities would not be required to hold an annual meeting. Specifically, Section 302 as amended would specify that the annual meeting requirement does not apply to companies whose only securities listed on the Exchange are non-voting preferred and debt, passive business organizations (such as royalty trusts), or securities listed pursuant to Rules 5.2(j)(2) (Equity Linked notes), 5.2(j)(3) (Investment Company Units), 5.2(j)(4) (Index-Linked Exchangeable Notes), 5.2(j)(5) (Equity Gold Shares), 5.2(j)(6) (Equity Index-Linked Securities, Commodity-Linked Securities, Currency-Linked Securities, Fixed Income Index-Linked Securities, Futures-Linked Securities and Multifactor Index-Linked Securities), 8.100 (Portfolio Depositary Receipts), 8.200 (Trust Issued Receipts), 8.201 (Commodity-Based Trust Shares), 8.202 (Currency Trust Shares), 8.203 (Commodity Index Trust Shares), 8.204 (Commodity Futures Trust Shares), 8.300 (Partnership Units), 8.400 (Paired Trust Shares), 8.600 (Managed Fund Shares) and 8.700 (Managed Trust Securities). The Exchange is also amending the rule text to make clear that, if an issuer also lists common stock or voting preferred stock, or their equivalent, such issuer must still hold an annual meeting for the holders of that common stock or voting preferred stock, or their equivalent.[5]

The Exchange notes that the listing rules of NYSE Arca, Inc. (''NYSE Arca''), the NASDAQ Stock Market LLC (''NASDAQ''), Cboe BZX Exchange, Inc. (''Cboe BZX'') and NYSE American LLC (''NYSE American'') all provide exclusions for issuers of ETFs and other derivative securities products from the annual meeting requirements in their rules.[6] The following are rules for derivative and special purpose securities listed on the Exchange and, in each case, a reference to a rule of either NYSE Arca, NYSE American or NASDAQ providing for the listing of similar securities on NYSE Arca, NYSE American or NASDAQ that are explicitly excluded from the annual meeting requirement on such exchange:

- NYSE Rule 5.2(j)(2) (Equity Linked Notes): NYSE Arca Rule 5.2–E(j)(2) (Equity Linked Notes) and NYSE American Company Guide Section 107B (Equity Linked Term Notes);
- NYSE Rule 5.2(j)(3) (Investment Company Units): NYSE Arca Rule 5.2–E(j)(3) (Investment Company Units) and NYSE American Rule 1002A (Index Fund Shares);
- NYSE Rule 5.2(j)(4) (Index-Linked Exchangeable Notes): NYSE Arca Rule 5.2–E(j)(4) (Index Linked Exchangeable Notes) and NYSE American Company Guide Section 107C (Index Linked Exchangeable Notes);
- NYSE Rule 5.2(j)(5) (Equity Gold Shares): NYSE Arca Rule 5.2–E(j)(5) (Equity Gold Shares) and NASDAQ Marketplace Rule 5711(b) (Equity Gold Shares);
- NYSE Rule 5.2(j)(6) (Equity Index-Linked Securities, Commodity-Linked Securities, Currency-Linked Securities, Fixed Income Index-Linked Securities, Futures-Linked Securities and Multifactor Index-Linked Securities): NYSE Arca Rule 5.2–E(j)(6) (Index Linked Securities) and NYSE American Company Guide Sections 107D (Index-Linked Securities, 107E (Commodity-Linked Securities), 107F (Currency-Linked Securities), 107G (Fixed Income-Linked Securities), 107H (Futures-Linked Securities), and 107I (Combination-Linked Securities);
- NYSE Rule 8.100 (Portfolio Depositary Receipts): NYSE Arca Rule 8.100–E (Portfolio Depositary Receipts) and NYSE American Rule 1000A [sic] (Portfolio Depository Receipts);
- NYSE Rule 8.200 (Trust Issued Receipts): NYSE Arca Rule 8.200–E (Trust Issued Receipts) and NYSE American Rule 1202 (Trust Issued Receipts);
- NYSE Rule 8.201 (Commodity-Based Trust Shares): NYSE Arca Rule 8.201–E (Commodity Based Trust Shares) and NYSE American Rule 1200A (Commodity Based Trust Shares);
- NYSE Rule 8.202 (Currency Trust Shares): NYSE Arca Rule 8.202–E (Currency Trust Shares) and NYSE American Rule 1202B (Currency Trust Shares);
- NYSE Rule 8.203 (Commodity Index Trust Shares): NYSE Arca Rule 8.203–E (Commodity Index Trust Shares) and NASDAQ Marketplace Rule 5711(f) (Commodity Index Shares);
- NYSE Rule 8.204 (Commodity Futures Trust Shares): NYSE Arca Rule 8.204–E (Commodity Futures Trust Shares) and NASDAQ Marketplace Rule 5711(g)(Commodity Futures Trust Shares);
- NYSE Rule 8.300 (Partnership Units): NYSE Arca Rule 8.300–E (Partnership Units) and NYSE American Rule 1502 (Partnership Units);
- NYSE Rule 8.400 (Paired Trust Shares): NYSE Arca Rule 8.400–E (Paired Trust Shares) and NYSE American Rule 1402 (Paired Trust Shares);
- NYSE Rule 8.600 (Managed Fund Shares): NYSE Arca Rule 8.600–E;
- NYSE Rule 8.700 (Managed Trust Securities): NYSE Arca Rule 8.700–E.

Shareholders of ETFs and derivative securities products listed on the Exchange receive regular disclosure documents describing the pricing mechanism for their securities and detailing how they can value their holdings. Moreover, the net asset value of the categories of ETFs and other derivative securities products listed above is determined by the market price of each fund's underlying securities or other reference asset. Because shareholders can value their investments on an ongoing basis, the Exchange believes that there is less need for shareholders to engage management at an annual meeting. In addition, while holders of such securities may have the right to vote in certain limited circumstances, they do not have the right to vote on the annual election of a board of directors, further eliminating the need for an annual meeting.

Notwithstanding the existence of an exemption from the Exchange's annual shareholder meeting requirement as proposed to be amended, issuers of listed securities will remain subject to any applicable state and federal securities laws with respect to the holding of annual meetings; as a result, an issuer that lists one or more of the types of securities that the Exchange proposes to exclude from its annual meeting requirement may still be required to hold annual shareholder meetings in accordance with such state and federal securities laws. In addition, the Exchange notes that issuers of NYSE-listed securities, including the types of securities that the Exchange proposes to exclude from its annual meeting requirement, remain subject to state and federal securities laws that may require other types of shareholder meetings, such as special meetings of shareholders. For example, exchange-traded funds are registered under, and remain subject to, the Investment Company Act of 1940 (''Investment Company Act''), which imposes various shareholder-voting requirements that may be applicable to such funds.[7]

[5] This proposed clarifying language is identical to that used in the NYSE Arca and NASDAQ annual meeting rule. *See* NYSE Arca Rule 5.3–E(e) and NASDAQ Marketplace Rules IM–5620.

[6] *See* Exchange Act Release No. 83324 (SR–NYSEArca–2018–31) (May 24, 2018); 83 FR 25076 (May 31, 2018) (approving [sic] amendments to NYSE Arca Rule 5.3(e)–E). *See also* NASDAQ Marketplace Rules IM–5620, Cboe BZX Rule 14.10, Interpretations and Policies 15; and NYSE American Company Guide Section 704, Commentary .01.

[7] See, *e.g.,* Section 16 of the Investment Company Act, which requires, among other things, an

Lastly, the Exchange notes that any security listed under Section 703.19 of the Manual (''Other Securities'') that has the attributes of common stock or voting preferred stock, or their equivalents will still be subject to the Exchange's annual meeting requirements.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Exchange Act,[9] in particular in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed amendment is consistent with the protection of investors, as the holders of non-voting preferred stock, bonds, the listed shares of passive business organizations (such as royalty trusts), ETFs and certain other derivative and special purpose securities do not have voting rights with respect to the election of directors except in very limited circumstances as required by state law or their governing documents. In addition, the net asset value of the categories of ETFs and other derivative securities products that the Exchange proposes to exclude from its annual meeting requirement is determined by the market price of each fund's underlying securities or other reference asset. Shareholders of such ETFs and derivative securities products listed on the Exchange receive regular disclosure documents describing the pricing mechanism for their securities and detailing how they can value their holdings. Accordingly, holders of such securities can value their investment on an ongoing basis. Because of these factors, the Exchange believes there is no need for the issuers of such securities to hold annual shareholder meetings.

Further, notwithstanding the existence of an exemption from the Exchange's annual shareholder meeting requirement as proposed to be amended, issuers of listed securities will remain subject to any applicable state and federal securities laws with respect to the holding of annual meetings; as a result, an issuer that lists one or more of the types of securities that the Exchange proposes to exclude from its annual meeting requirement may still be required to hold annual shareholder meetings in accordance with such state and federal securities laws. In addition, the Exchange notes that issuers of NYSE-listed securities, including the types of securities that the Exchange proposes to exclude from its annual meeting requirement, remain subject to state and federal securities laws that may require other types of shareholder meetings, such as special meetings of shareholders.

Lastly, the Exchange notes that any security listed under Section 703.19 of the Manual (''Other Securities'') that has the attributes of common stock or voting preferred stock, or their equivalents will still be subject to the Exchange's annual meeting requirements.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed amendments will not impose any burden on competition, as they simply conform the Exchange's rules to those of its competitors in the market for the listing of the specified types of securities.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up [sic] to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2019–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2019–20. 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/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2019–20 and should be submitted on or before June 13, 2019.

investment company's initial board of directors to be elected by the shareholders at an annual or special meeting. 15 U.S.C. 80a–16(a).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–10753 Filed 5–22–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85887; File No. SR–NYSENAT–2019–12]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Fees and Rebates

May 17, 2019.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 8, 2019, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Schedule of Fees and Rebates to (1) increase the current adding tier fees (Adding Tier 1, Adding Tier 2, Adding Tier 3, and Adding Tier 4) for adding displayed liquidity in Tape A, Tape B and Tape C securities and renumber the tiers in order of favorability; and (2) adopt a new Step Up Adding Tier 1 that would set forth fees for displayed and non-displayed orders that add liquidity to the Exchange and renumber the current Step Up Adding Tier. The Exchange proposes to implement the rule change on May 8, 2019. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Schedule of Fees and Rebates to (1) increase the current adding tier fees (Adding Tier 1, Adding Tier 2, Adding Tier 3, and Adding Tier 4) for adding displayed liquidity in Tape A, Tape B and Tape C securities and renumber the tiers in order of favorability; and (2) adopt a new Step Up Adding Tier 1 that would set forth fees for displayed and non-displayed orders that add liquidity to the Exchange and renumber the current Step Up Adding Tier.

The Exchange proposes to implement the rule change on May 8, 2019.[4]

Proposed Changes To Adding Tiers

Current Adding Tier 1 (Proposed Adding Tier 4)

Under current Adding Tier 1, the Exchange offers the following fees for transactions in stocks with a per share price of $1.00 or more when adding liquidity to the Exchange if the ETP Holder has at least 0.015% of Adding average daily volume (''ADV'') as a percent of US consolidated ADV (''CADV'') [5]:

- $0.0020 per share for displayed orders in Tapes B and C securities and $0.0022 per share for displayed orders in Tape A securities;
- $0.0018 per share for orders that set a new Exchange BBO in Tapes B and C securities and $0.0020 per share in Tape A securities;
- $0.0022 per share for non-displayed orders in Tapes B and C securities and $0.0024 per share for non-displayed orders in Tape A securities; and
- $0.0005 per share for MPL orders, which would remain unchanged.

The Exchange proposes to amend the Adding Tier 1 fees as follows:

- $0.0023 per share for displayed orders in Tapes B and C securities and $0.0025 per share for displayed orders in Tape A securities;
- $0.0021 per share for orders that set a new Exchange BBO in Tapes B and C securities and $0.0023 per share in Tape A securities;
- $0.0025 per share for non-displayed orders in Tapes B and C securities and $0.0027 per share for non-displayed orders in Tape A securities; and
- $0.0005 per share for MPL orders, which would remain unchanged.

Current Adding Tier 1 would be renumbered and become Adding Tier 4. As noted, the current Adding Tier 1 volumes are waived. Footnote * of the Schedule of Fees and Rebates would be amended to reflect the renumbering of current Adding Tier 1.[6]

Adding Tier 2 (Proposed Adding Tier 1)

Under current Adding Tier 2, the Exchange offers the following fees for transactions in stocks with a per share price of $1.00 or more when adding liquidity to the Exchange if the ETP Holder quotes: (i) At least 5% of the NBBO [7] in 1,000 or more symbols on an average daily basis, calculated monthly, and 0.20% or more Adding ADV as a percentage of US CADV, or (ii) at least 5% of the NBBO in 2,500 or more symbols on an average daily basis, calculated monthly, and 0.10% or more Adding ADV as a % of US CADV:

- $0.0005 per share for adding displayed orders in Tape B and C securities and $0.0008 per share in Tape A securities;
- $0.0005 per share for orders that set a new Exchange BBO in Tape B and C securities and $0.0008 per share in Tape A securities;
- $0.0007 per share for adding non-displayed orders in Tape B and C securities and $0.0010 per share in Tape A securities; and
- $0.0005 per share for MPL orders, which would remain unchanged.

The Exchange proposes to amend the Adding Tier 2 fees as follows:

- $0.0008 per share for adding displayed orders in Tape B and C securities and $0.0011 per share in Tape A securities;
- $0.0008 per share for orders that set a new Exchange BBO in Tape B and C

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange originally filed to amend the Schedule of Fees and Rebates on April 30, 2019 (SR–NYSENAT–2019–11). SR–NYSENAT–2019–11 was subsequently withdrawn and replaced by this filing.

[5] The Adding Tier 1 volumes are currently waived. *See* footnote * in the current Schedule of Fees and Rebates.

[6] *See* note 4, *supra.*

[7] *See* footnote ** in the current Schedule of Fees and Rebates.

securities and $0.0011 per share in Tape A securities;

• $0.0010 per share for adding non-displayed orders in Tape B and C securities and $0.0013 per share in Tape A securities; and

• $0.0005 per share for MPL orders, which would remain unchanged.

Current Adding Tier 2 would also be renumbered and become Adding Tier 1.

Adding Tier 3 (Proposed Adding Tier 2)

Under current Adding Tier 3, the Exchange offers the following fees for transactions in stocks with a per share price of $1.00 or more when adding liquidity to the Exchange if the ETP Holder quotes at least 5% of the NBBO in 2000 or more symbols on an average daily basis, calculated monthly, and executes 0.10% or more Adding ADV as a percentage of US CADV:

• $0.0009 per share for adding displayed orders in Tape B and C securities and $0.0012 per share in Tape A securities;

• $0.0009 per share for orders that set a new Exchange BBO in Tape B and C securities and $0.0012 per share in Tape A securities;

• $0.0011 per share for adding non-displayed orders in Tape B and C securities and $0.0014 per share in Tape A securities; and

• $0.0005 per share for MPL orders, which would remain unchanged.

The Exchange proposes to amend the Adding Tier 3 fees as follows:

• $0.0012 per share for adding displayed orders in Tape B and C securities and $0.0015 per share in Tape A securities;

• $0.0012 per share for orders that set a new Exchange BBO in Tape B and C securities and $0.0015 per share in Tape A securities;

• $0.0014 per share for adding non-displayed orders in Tape B and C securities and $0.0017 per share in Tape A securities; and

• $0.0005 per share for MPL orders, which would remain unchanged.

Current Adding Tier 3 would be renumbered and become Adding Tier 2.

Adding Tier 4 (Proposed Adding Tier 3)

Under current Adding Tier 4, the Exchange offers the following fees for transactions in stocks with a per share price of $1.00 or more when adding liquidity to the Exchange if the ETP Holder quotes at least 5% of the NBBO in 600 or more symbols on an average daily basis, calculated monthly:

• $0.0012 per share for adding displayed orders in Tape B and C securities and $0.0014 per share in Tape A securities;

• $0.0012 per share for orders that set a new Exchange BBO in Tape B and C securities and $0.0014 per share in Tape A securities;

• $0.0014 per share for adding non-displayed orders in Tape B and C securities and $0.0016 per share in Tape A securities; and

• $0.0005 per share for MPL orders, which would remain unchanged.

The Exchange proposes to amend the Adding Tier 4 fees as follows:

• $0.0015 per share for adding displayed orders in Tape B and C securities and $0.0017 per share in Tape A securities;

• $0.0015 per share for orders that set a new Exchange BBO in Tape B and C securities and $0.0017 per share in Tape A securities;

• $0.0017 per share for adding non-displayed orders in Tape B and C securities and $0.0019 per share in Tape A securities; and

• $0.0005 per share for MPL orders, which would remain unchanged.

Current Adding Tier 4 would be renumbered and become Adding Tier 3.

Proposed Step Up Adding Tier 1

The Exchange proposes a new Step Up Adding Tier 1 for displayed and non-displayed orders in securities priced at or above $1.00.

Under the proposed Step Up Adding Tier 1, the Exchange would offer the following fees for transactions in stocks with a per share price of $1.00 or more when adding liquidity to the Exchange if the ETP Holder has 0.07% or more of Adding ADV as a percentage of US CADV over the ETP Holder's Adding ADV as a % of US CADV in November 2018:

• $0.0012 per share for adding displayed orders in Tapes B and C securities and $0.0015 per share in Tape A securities;

• $0.0012 per share for orders that set a new Exchange BBO[8] in Tapes B and C securities and $0.0015 per share in Tape A securities;

• $0.0014 per share for adding non-displayed orders in Tapes B and C securities and $0.0017 per share in Tape A securities; and

• $0.0005 per share for MPL orders.

For example, in a given month of 20 trading days, assume that an ETP Holder adds liquidity of an ADV of 3.8 million shares in a month where CADV is 7.6 billion shares, or 0.05% of US CADV in November 2018 (the ''Baseline''). Further assume that the ETP Holder adds liquidity of an ADV of 9.5 million shares in the relevant billing month with the same US CADV of 7.6 billion shares, or 0.125% of US CADV. That ETP Holder would qualify for the proposed Step Up Adding Tier 1 based on their 0.075% step up as a percent of US CADV over the ETP Holder's Baseline.

Finally, the existing Step Up Adding Tier would be renumbered Step Up Adding Tier 2.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that ETP Holders would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[10] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

Proposed Changes To Adding Tiers

The Exchange believes that the proposed changes to the tiered adding requirements for displayed and non-displayed orders in Tape A, Tape B and Tape C securities priced at or above $1.00 are reasonable, equitable and not unfairly discriminatory, as follows.

The proposed changes to the Adding Tier 1, Adding Tier 2, Adding Tier 3, and Adding Tier 4 fees for adding liquidity in Tapes A, B and C securities for ETP Holders meeting the current requirements for each tier, which the Exchange does not propose to change, are reasonable because the proposed fee will incentivize submission of additional liquidity to a public exchange, thereby benefiting all ETP Holders by achieving higher tiers. Specifically, the Exchange believes that higher charges would incentivize ETP Holders to send additional liquidity to the Exchange in order to avoid the proposed fee by meeting the Adding Tier liquidity requirements.

The proposed fees are also equitable and not unfairly discriminatory because those fees would be consistent with or lower than the applicable rate on other marketplaces that charge for adding liquidity. For example, Cboe BYX charges a standard fee of $0.0019 per share, and their lowest fee for adding is

[8] The term ''BBO'' is defined in Rule 1.1 to mean the best bid or offer that is a Protected Quotation on the Exchange. The term ''BB'' means the best bid that is a Protected Quotation on the Exchange and the term ''BO'' means the best offer that is a Protected Quotation on the Exchange.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) & (5).

$0.0012, while Cboe EDGA charges a standard fee of $0.0030 per share, and their lowest fee for adding is $0.0022. In addition, the Exchange believes that the proposed Adding Tier fees are equitable and not unfairly discriminatory as all similarly situated market participants will be subject to the same fees on an equal and non-discriminatory basis.

Proposed Step Up Adding Tier 1

The Exchange believes that the proposed Step Up Adding Tier 1 fees for ETP Holders with 0.07% or more Adding average daily volume as a percentage of US CADV in addition to the ETP Holder's Adding ADV as a percentage of US CADV in November 2018 is reasonable because the proposed tier would further contribute to incentivizing ETP Holders to bring additional order flow to a public market. In particular, the Exchange believes that the proposed new tiered rates will provide an incentive for more active ETP Holders, including those that meet the current Step Up Adding Tier 2 as well as those that do not, to add displayed liquidity to the Exchange in excess of the current Step Up Adding Tier 2 level, to the benefit of the investing public and all market participants. In addition, the Exchange believes that the proposed Step Up Adding Tier 1 fees are equitable and not unfairly discriminatory because all similarly situated market participants who would submit additional liquidity to the Exchange in order to qualify for the fees would be subject to the same fees on an equal and non-discriminatory basis.

The Exchange also believes that the proposed non-substantive renumbering changes would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from increased clarity and transparency, thereby reducing potential confusion.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[11] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for ETP Holders. The Exchange believes that this could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As a result of all of these considerations, the Exchange does not believe that the proposed changes will impair the ability of ETP Holders or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[12] of the Act and subparagraph (f)(2) of Rule 19b–4[13] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSENAT–2019–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2019–12. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are

[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(2).

[14] 15 U.S.C. 78s(b)(2)(B).

cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2019–12 and should be submitted on or before June 13, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–10751 Filed 5–22–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85888; File No. SR–NYSEARCA–2019–37]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Equities Fees and Charges To Adopt a Higher Credit for the Tier 2 Pricing Tier

May 17, 2019.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 10, 2019, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Fees and Charges (''Fee Schedule'') to adopt a higher credit for the Tier 2 pricing tier. The Exchange proposes to implement the fee changes effective May 10, 2019.[4] The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to adopt a higher credit for Tier 2. The Exchange proposes to implement the fee changes effective May 10, 2019.

The Exchange proposes to adopt a higher credit for a current pricing tier—Tier 2—for securities with a per share price $1.00 or above.

Currently, a Tier 2 credit of $0.0029 per share for orders in Tape A and Tape C Securities that provide liquidity to the Book, and a credit of $0.0022 per share for orders in Tape B Securities[5] that provide liquidity to the Book, applies to ETP Holders and Market Makers that either (1) provide liquidity an average daily share volume per month of 0.30% or more, but less than 0.70% of the US CADV or (2) provide liquidity of 0.10% of more of the US CADV per month, and are affiliated with an OTP Holder or OTP Firm that provides an ADV of electronic posted Customer and Professional Customer executions in all issues on NYSE Arca Options (excluding mini options) of at least 1.50% of total Customer equity and ETF option ADV as reported by The Options Clearing Corporation (''OCC'').

The Exchange proposes to adopt a higher credit of $0.0031 per share for orders that provide liquidity in Tape A and Tape C Securities, and $0.0024 per share for orders that provide liquidity in Tape B Securities. The proposed higher credit would be applicable for orders that provide displayed liquidity to the Book for ETP Holders and Market Makers that meet the requirements of Tier 2 described above and, for the billing month, (1) execute providing volume equal to at least 0.30% of US CADV, (2) execute removing volume equal to at least 0.285% of US CADV, and (3) execute Market-On-Close and Limit-On-Close Orders executed in a Closing Auction of at least 0.075% of US CADV.

For example, assume an ETP Holder posts an order for 1,000 shares that provides liquidity to the Book. Assume further that 600 shares, from the 1,000 shares that are posted and therefore are adding liquidity, trade against an incoming order which would be removing liquidity. The 600 share execution would be a product of two orders interacting, one that provided liquidity and the contra order that removed liquidity. The remaining 400 shares of that ETP Holder's adding order would remain posted on the Book. The 600 shares of the adding order that executed and added liquidity would count towards the executed adding volume requirement of 0.30% of US CADV, the first prong of the requirement. The 400 shares of that adding order that remain unexecuted would not count towards the requirement.

Further, assume the same ETP Holder sends an Immediate or Cancel (''IOC'') order of 1,000 shares to the Exchange, of which 600 shares execute against an order that was already resting on the Book. The 600 share execution would be a product of two orders interacting, one that provided liquidity and the contra order that took liquidity. The 400 shares remaining of that IOC order that did not immediately execute would cancel back to the ETP Holder that submitted the 1,000 share order. The 600 shares of the IOC order that executed and removed liquidity would count towards the executed removing volume requirement of 0.285% of US CADV, the second prong of the requirement. The 400 shares of that IOC order that did not execute and was canceled would not count towards the requirement.

Additionally, assume an ETP Holder sends a Market-On-Close (''MOC'') order of 2,000 shares to the Exchange for execution in the Closing Auction. Further assume that 1,200 shares of that MOC order executed in the Closing Auction, and the remaining 800 shares did not execute and were canceled after the Closing Auction. The 1,200 shares of that MOC order that executed and traded in the Closing Auction would count towards the Market-On-Close and Limit-On-Close Orders executed in a

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange originally filed to amend the Fee Schedule on April 30, 2019 (SR–NYSEArca–2019–31) and withdrew such filing on May 10, 2019.

[5] An additional credit applies to ETP Holders and Market Makers affiliated with LMMs that provide displayed liquidity to the Book based on the number of Less Active ETP Securities in which the LMM is registered as the LMM. *See* LMM Transaction Fees and Credits on the Fee Schedule for the applicable tiered credits.

Closing Auction requirement of at least 0.075% of US CADV, the third prong of the requirement. The 800 shares of that MOC order that were canceled would not count towards the requirement.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any significant problems that market participants would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[7] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed modification to adopt a higher Tier 2 credit is reasonable because the proposed credit is designed to encourage increased trading by ETP Holders and Market Makers. The Exchange notes that ETP Holders and Market Makers that do not meet the requirements to qualify for the higher credit may still qualify for current Tier 2 credits if they meet the Tier 2 requirements. The Exchange further believes that the higher credit will encourage ETP Holders and Market Makers to provide higher volumes of MOC and Limit-On-Close (''LOC'') Orders, which will contribute to the quality of the Exchange's Closing Auction and provide ETP Holders and Market Makers that submit MOC and LOC Orders greater opportunity for execution.

The Exchange further believes the proposed higher credit is reasonable and appropriate in that it is based on the amount of business transacted on the Exchange. The Exchange believes the proposed increased credit for adding liquidity is also reasonable because it will encourage liquidity and competition in securities quoted and traded on the Exchange.

The Exchange also believes the proposed higher credit is equitable and not unfairly discriminatory because it is open to all ETP Holders and Market Makers on an equal basis and provides discounts that are reasonably related to the value to the Exchange's market quality associated with higher volumes. The Exchange further believes that the proposed increased credit is not unfairly discriminatory because the magnitude of the additional credit is not unreasonably high in comparison to the credit paid with respect to other displayed liquidity-providing orders. For example, for ETP Holders and Market Makers that provide liquidity an average daily share volume per month of 0.70% or more of the US CADV receive a Tier 1 credit of $0.0031 per share for orders that provide liquidity in Tape A Securities, $0.0023 per share for orders that provide liquidity in Tape B Securities, and $0.0032 per share for orders that provide liquidity for Tape C Securities.

The Exchange does not believe that it is unfairly discriminatory to offer increased credits to ETP Holders and Market Makers as these participants would be subject to additional volume requirements.

The Exchange believes that the proposed fee change is equitable and not unfairly discriminatory because providing incentives for orders in exchange-listed securities that are executed on a registered national securities exchange (rather than relying on certain available off-exchange execution methods) would contribute to investors' confidence in the fairness of their transactions and would benefit all investors by deepening the Exchange's liquidity pool, supporting the quality of price discovery, promoting market transparency and improving investor protection.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[8] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the proposal to adopt incremental credits for an existing pricing tier would encourage the submission of additional liquidity to a public exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for ETP Holders and Market Makers. The Exchange believes that this could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As a result of all of these considerations, the Exchange does not believe that the proposed change will impair the ability of ETP Holders or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[9] of the Act and subparagraph (f)(2) of Rule 19b–4[10] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[11] of the Act to

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4) and (5).

[8] 15 U.S.C. 78f(b)(8).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(2).

[11] 15 U.S.C. 78s(b)(2)(B).

determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2019–37 on the subject line.

Paper Comments

- *Send paper comments in triplicate to:* Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2019–37. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2019–37 and should be submitted on or before June 13, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–10752 Filed 5–22–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85883; File No. SR–ISE–2019–14]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Rules Governing the Give Up of a Clearing Member

May 17, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 3, 2019, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules governing the give up of a Clearing Member [3] by a Member on Exchange transactions.

The text of the proposed rule change is available on the Exchange's website at *http://ise.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its requirements in Rule 707 related to the give up of a Clearing Member by a Member on Exchange transactions. This proposed rule change is substantially similar [4] to a recently-approved rule change by the Exchange's affiliate, Nasdaq PHLX LLC (''Phlx''),[5] and serves to align the rules of Phlx and the Exchange.[6]

By way of background, to enter transactions on the Exchange, a Member must either be a Clearing Member or must have a Clearing Member agree to accept financial responsibility for all of its transactions. In particular, Rule 707 currently provides that a Member must give up the name of the Clearing Member through whom the transaction will be cleared. Rule 712(b) provides, in relevant part, that every Clearing Member shall be responsible for the clearance of Exchange transactions of such Clearing Member and of each Member who gives up such Clearing Member's name pursuant to a letter of authorization, letter of guarantee or other authorization given by such Clearing Member to such Member, which authorization must be submitted to the Exchange. Additionally Rule 808(a) provides that no Market Maker (*i.e.,* Primary Market Makers and Competitive Market Makers) shall make any transactions on the Exchange unless a Letter of Guarantee has been issued for such Member by a Clearing Member and filed with the Exchange.[7]

Recently, certain Clearing Members, in conjunction with the Securities

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Clearing Member'' means a Member that is self-clearing or an Electronic Access Member that clears Exchange Transactions for other Members of the Exchange. *See* Rule 100(a)(10).

[4] Specifically, ISE is not adopting sections (c)(i) and (c)(ii) of Phlx Rule 1037, which relate to how the Phlx trading system will enforce unauthorized Give Ups for floor trades and electronic trades, respectively. With respect to electronic trades, Phlx will block the order from the outset whereas ISE will automatically default to the Member's guarantor. *See* proposed ISE Rule 707(c).

[5] *See* Securities Exchange Act Release No. 85136 (February 14, 2019) (SR–Phlx–2018–72) (Approval Order).

[6] The other Nasdaq, Inc.-owned options markets, Nasdaq BX, Nasdaq GEMX, Nasdaq MRX, and The Nasdaq Options Market (collectively, ''Nasdaq HoldCo Exchanges''), will file similar rule change proposals based on the Phlx filing.

[7] Furthermore, the Exchange previously issued guidance on designating Give Ups in Regulatory Information Circular 2001–13. This rule change supersedes the Exchange's previous interpretation.

Industry and Financial Markets Association (''SIFMA''), expressed concerns related to the process by which executing brokers on U.S. options exchanges (''Exchanges'') are allowed to designate or 'give up' a clearing firm for purposes of clearing particular transactions. The SIFMA-affiliated Clearing Members have recently identified the current give up process as a significant source of risk for clearing firms, and subsequently requested that the Exchanges alleviate this risk by amending Exchange rules governing the give up process.[8]

Proposed Rule Change

Based on the above, the Exchange now seeks to amend its rules regarding the current give up process in order to allow a Clearing Member to opt in, at The Options Clearing Corporation (''OCC'') clearing number level, to a feature that, if enabled by the Clearing Member, will allow the Clearing Member to specify which Members are authorized to give up that OCC clearing number. Accordingly, Rule 707 will be retitled as ''Authorization to Give Up,'' and the current rule text will be replaced by new language. Specifically, proposed Rule 707 will provide that for each transaction in which a Member participates, the Member may indicate, at the time of the trade or through post trade allocation, any OCC number of a Clearing Member through which a transaction will be cleared (''Give Up''), provided the Clearing Member has not elected to ''Opt In,'' as defined in paragraph (b) of the proposed Rule, and restrict one or more of its OCC number(s) (''Restricted OCC Number''). A Member may Give Up a Restricted OCC Number provided the Member has written authorization as described in paragraph (b)(ii) (''Authorized Member'').

Proposed Rule 707(b) provides that Clearing Members may request the Exchange restrict one or more of their OCC clearing numbers (''Opt In'') as described in subparagraph (b)(i) of Rule 707. If a Clearing Member Opts In, the Exchange will require written authorization from the Clearing Member permitting a Member to Give Up a Clearing Member's Restricted OCC Number. An Opt In would remain in effect until the Clearing Member terminates the Opt In as described in subparagraph (iii). If a Clearing Member does not Opt In, that Clearing Member's OCC number may be subject to Give Up by any Member.

Proposed Rule 707(b)(i) will set forth the process by which a Clearing Member may Opt In. Specifically, a Clearing Member may Opt In by sending a completed ''Clearing Member Restriction Form'' listing all Restricted OCC Numbers and Authorized Members.[9] A copy of the proposed form is attached in Exhibit 3. A Clearing Member may elect to restrict one or more OCC clearing numbers that are registered in its name at OCC. The Clearing Member would be required to submit the Clearing Member Restriction Form to the Exchange's Membership Department as described on the form. Once submitted, the Exchange requires ninety days before a Restricted OCC Number is effective within the System. This time period is to provide adequate time for the member users of that Restricted OCC Number who are not initially specified by the Clearing Member as Authorized Members to obtain the required written authorization from the Clearing Member for that Restricted OCC Number. Such member users would still be able to Give Up that Restricted OCC Number during this ninety day period (*i.e.,* until the number becomes restricted within the System).

Proposed Rule 707(b)(ii) will set forth the process for Members to Give Up a Clearing Member's Restricted OCC Number. Specifically, a Member desiring to Give Up a Restricted OCC Number must become an Authorized Member.[10] The Clearing Member will be required to authorize a Member as described in subparagraph (i) or (iii) of Rule 707(b) (*i.e.,* through a Clearing Member Restriction Form), unless the Restricted OCC Number is already subject to a Letter of Guarantee that the Member is a party to, as set forth in Rule 707(d).

Pursuant to proposed Rule 707(b)(iii), a Clearing Member may amend the list of its Authorized Members or Restricted OCC Numbers by submitting a new Clearing Member Restriction Form to the Exchange's Membership Department indicating the amendment as described on the form. Once a Restricted OCC Number is effective within the System pursuant to Rule 707(b)(i), the Exchange may permit the Clearing Member to authorize, or remove authorization for, a Member to Give Up the Restricted OCC Number intra-day only in unusual circumstances, and on the next business day in all regular circumstances. The Exchange will promptly notify the Members if they are no longer authorized to Give Up a Clearing Member's Restricted OCC Number. If a Clearing Member removes a Restricted OCC Number, any Member may Give Up that OCC clearing number once the removal has become effective on or before the next business day.

Proposed Rule 707(c) will provide that the System will not allow an unauthorized Member to Give Up a Restricted OCC Number. Specifically, if an unauthorized Give Up with a Restricted OCC Number is submitted to the System, the System will process that transaction using the Member's default OCC clearing number.

Furthermore, the Exchange proposes to adopt paragraph (d) to Rule 707 to provide, as is the case today, that a clearing arrangement subject to a Letter of Guarantee would immediately permit the Give Up of a Restricted OCC Number by the Member that is party to the arrangement. Since there is an OCC clearing arrangement already established in this case, no further action is needed on the part of the Clearing Member or the Member.

The Exchange also proposes to adopt paragraph (e) to Rule 707 to provide that an intentional misuse of this Rule is impermissible, and may be treated as a violation of Rule 400, titled ''Just and Equitable Principles of Trade,'' or Rule 401, titled ''Adherence to Law.'' This language will make clear that the Exchange will regulate an intentional misuse of this Rule (*e.g.,* sending orders to a Clearing Member's OCC account without the Clearing Member's consent), and that such behavior would be a violation of Exchange rules.

In light of the foregoing proposal, the Exchange also proposes to amend Rule 712(b), which addresses the Clearing Member's financial responsibility for the Exchange transactions of Members who give up the name of such Clearing Member pursuant to, for example, a letter of guarantee. In particular, the Exchange proposes to add that every Clearing Member shall be responsible for the clearance of the Exchange transactions of each Member who gives up such Clearing Member's name pursuant to a written authorization to become an Authorized Member under Rule 707. Lastly, the Exchange proposes two technical changes in the same provision: First, to capitalize Letter of Guarantee for consistency throughout its Rulebook and second, to delete an

[8] *See* note 5 above.

[9] This form will be available on the Exchange's website. The Exchange will also maintain, on its website, a list of the Restricted OCC Numbers, which will be updated on a regular basis, and the Clearing Member's contact information to assist Members (to the extent they are not already Authorized Members) with requesting authorization for a Restricted OCC Number. The Exchange may utilize additional means to inform its members of such updates on a periodic basis.

[10] The Exchange will develop procedures for notifying Members that they are authorized or unauthorized by Clearing Members.

obsolete reference to the letter of authorization.[11]

Implementation

The Exchange proposes to implement the proposed rule change no later than by the end of Q3 2019. The Exchange will announce the implementation date to its Members in an Options Trader Alert.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(5) of the Act,[13] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

Particularly, as discussed above, several clearing firms affiliated with SIFMA have recently expressed concerns relating to the current give up process, which permits Members to identify any Clearing Member as a designated give up for purposes of clearing particular transactions, and have identified the current give up process (*i.e.,* a process that lacks authorization) as a significant source of risk for clearing firms.

The Exchange believes that the proposed changes to Rule 707 help alleviate this risk by enabling Clearing Members to 'Opt In' to restrict one or more of its OCC clearing numbers (*i.e.,* Restricted OCC Numbers), and to specify which Authorized Members may Give Up those Restricted OCC Numbers. As described above, all other Members would be required to receive written authorization from the Clearing Member before they can Give Up that Clearing Member's Restricted OCC Number. The Exchange believes that this authorization provides proper safeguards and protections for Clearing Members as it provides controls for Clearing Members to restrict access to their OCC clearing numbers, allowing access only to those Authorized Members upon their request. The Exchange also believes that its proposed Clearing Member Restriction Form allows the Exchange to receive in a uniform fashion, written and transparent authorization from Clearing Members, which ensures seamless administration of the Rule.

The Exchange believes that the proposed Opt In process strikes the right balance between the various views and interests across the industry. For example, although the proposed rule would require Members (other than Authorized Members) to seek authorization from Clearing Members in order to have the ability to give them up, each Member will still have the ability to Give Up a Restricted OCC Number that is subject to a Letter of Guarantee without obtaining any further authorization if that Member is party to that arrangement. The Exchange also notes that to the extent the executing Member has a clearing arrangement with a Clearing Member (*i.e.,* through a Letter of Guarantee), a trade can be assigned to the executing Member's guarantor. Accordingly, the Exchange believes that the proposed rule change is reasonable and continues to provide certainty that a Clearing Member would be responsible for a trade, which protects investors and the public interest. Finally, the Exchange believes that adopting paragraph (e) of Rule 707 will make clear that an intentional misuse of this Rule (*e.g.,* sending orders to a Clearing Member's OCC account without the Clearing Member's consent) will be a violation of the Exchange's rules, and that such behavior would subject a Member to disciplinary action.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose an unnecessary burden on intramarket competition because it would apply equally to all similarly situated Members. The Exchange also notes that, should the proposed changes make ISE more attractive for trading, market participants trading on other exchanges can always elect to become Members on ISE to take advantage of the trading opportunities.

Furthermore, the proposed rule change does not address any competitive issues and ultimately, the target of the Exchange's proposal is to reduce risk for Clearing Members under the current give up model. Clearing firms make financial decisions based on risk and reward, and while it is generally in their beneficial interest to clear transactions for market participants in order to generate profit, it is the Exchange's understanding from SIFMA and clearing firms that the current process can create significant risk when the clearing firm can be given up on any market participant's transaction, even where there is no prior customer relationship or authorization for that designated transaction.

In the absence of a mechanism that governs a market participant's use of a Clearing Member's services, the Exchange's proposal may indirectly facilitate the ability of a Clearing Member to manage their existing customer relationships while continuing to allow market participant choice in broker execution services. While Clearing Members may compete with executing brokers for order flow, the Exchange does not believe this proposal imposes an undue burden on competition. Rather, the Exchange believes that the proposed rule change balances the need for Clearing Members to manage risks and allows them to address outlier behavior from executing brokers while still allowing freedom of choice to select an executing broker.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the

[11] ISE recently updated its forms to combine the Electronic Access Member letter of authorization and Market Maker guarantee into one Letter of Guarantee applicable to all Members.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2019–14 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2019–14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2019–14 and should be submitted on or before June 13, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–10750 Filed 5–22–19; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 10778]

Determination Under Section 7070(c)(1) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2018 and Section 7047(c)(1) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2019

Pursuant to section 7070(c)(1) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2018 (Div. K, Pub. L. 115–141) and section 7047(c)(1) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2019 (Div. F, Pub. L. 116–6), and pursuant to delegated authority, I hereby determine that the Government of Nicaragua has recognized the independence of, or has established diplomatic relations with, the Russian occupied Georgian territories of Abkhazia and Tskhinvali Region/South Ossetia.

This determination shall be published in the **Federal Register** and on the Department of State website and, along with the accompanying Memorandum of Justification, shall be reported to Congress.

John J. Sullivan,

Deputy Secretary of State.

[FR Doc. 2019–10817 Filed 5–22–19; 8:45 am]

BILLING CODE 4710–29–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36188]

Wilmington Terminal Railroad, Limited Partnership—Temporary Trackage Rights Exemption—CSX Transportation, Inc.

On May 8, 2019, Wilmington Terminal Railroad, Limited Partnership (WTRY) filed a request under 49 CFR 1180.2(d)(8) for a one-year extension of the temporary overhead trackage rights previously granted in this docket over a line of railroad of CSX Transportation, Inc. (CSXT), between the Port of Wilmington in Wilmington, NC, at CSXT milepost ACB 249.74 and the switch at CSXT milepost ACB 243.96, and between the switch at CSXT milepost ACB 243.96 and the switch at CSXT's Davis Yard in Navassa, NC, at CSXT milepost SE 359.79, a distance of approximately 10.0 miles (the Line).

WTRY was authorized to acquire these trackage rights over the Line by notice of exemption served and published in the **Federal Register** on May 18, 2018 (83 FR 23,324). The purpose of the trackage rights is to allow WTRY to bridge loaded and empty trains containing containers or trailers in intermodal service in connection with CSXT's ''Queen City Express'' service. The rights are scheduled to expire on June 3, 2019.

Under 49 CFR 1180.2(d)(8), the parties may, prior to the expiration of the temporary trackage rights, file a request for a renewal of the temporary rights for an additional period of up to one year, including the reasons for the extension. WTRY states that the service has been beneficial to WTRY and CSXT and to the shippers being served, and WTRY and CSXT wish to extend the service for an additional year so that WTRY can continue to handle the intermodal traffic movements likely to be tendered during the upcoming year.

WTRY filed a copy of an executed amendment to the temporary trackage rights agreement with its request for the one-year extension. WTRY also acknowledges that any further extension of these rights, or a conversion to a longer term, would require a separate notice of exemption pursuant to 49 CFR 1180.4(g).

In accordance with 49 CFR 1180.2(d)(8), WTRY's temporary trackage rights over the Line will be extended for one year and will expire on June 3, 2020. The employee protective conditions imposed in the May 18, 2018 notice remain in effect. Notice of the one-year extension will be published in the **Federal Register**.

It is ordered:

1. WTRY's temporary trackage rights over the Line are extended for one year and will expire on June 3, 2020.

2. Notice will be published in the **Federal Register**.

3. This decision is effective on its service date.

Decided: May 17, 2019.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–10743 Filed 5–22–19; 8:45 am]

BILLING CODE 4915–01–P

[16] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Hood River-White Salmon Bridge Replacement Project; Notice of Intent To Prepare a Supplemental Draft Environmental Impact Statement

AGENCY: Federal Highway Administration, DOT.

ACTION: Notice of intent.

SUMMARY: The Federal Highway Administration (FHWA) is issuing this notice to advise that a Supplemental Draft Environmental Impact Statement will be prepared for a proposed bridge replacement project of the Hood River-White Salmon Bridge across the Columbia River between Hood River, Oregon and White Salmon, Washington.

FOR FURTHER INFORMATION CONTACT: Emily Cline, Federal Highway Administration, 530 Center Street NE, Suite 420, Salem, OR 97301; Telephone: (503) 316–2547 or Kevin Greenwood, Port of Hood River, 1000 E Port Marina Drive, Hood River, OR 97031; Telephone: (541) 436–0797.

SUPPLEMENTARY INFORMATION: FHWA, with the Port of Hood River (the Port) and the Oregon Department of Transportation (ODOT) as joint lead agencies, will prepare a Supplemental Draft Environmental Impact Statement (EIS) for the Hood River-White Salmon Bridge Replacement Project (formerly named the SR–35 Columbia River Crossing Project) to replace the existing Hood River-White Salmon Bridge between Hood River, Oregon, and White Salmon, Washington. The primary purpose of this project is to improve multi-modal transportation of people and goods across the Columbia River between the Hood River and White Salmon/Bingen communities by replacing the existing Hood River-White Salmon bridge. The need for the project is to rectify current and future transportation and structural inadequacies and deficiencies of the bridge.

The SR–35 Columbia River Crossing Draft EIS was issued in December 2003. The Draft EIS evaluated four alternatives, including the no action alternative, and documented the project's impacts and benefits to the community and environment and identified a preliminary preferred alternative. All build alternatives would replace the existing movable span bridge with a fixed span bridge, retain the current two travel lanes on the bridge, add shoulders, add a pedestrian and bicycle facility, resolve all height, width and weight restrictions currently in place on the existing bridge, and provide a wider clearance for navigation. The Draft EIS disclosed proposed measures to avoid, minimize, or mitigate impacts to the community and environment, summarized agency and public engagement to date, and described how and when the public and agencies could submit comments. The 45-day comment period included a public open house/hearing on January 22, 2004. The environmental review phase of the project was put on hold shortly after the comment period ended.

In 2017, the Port of Hood River secured state funding (Oregon House Bill 2017) to continue the bridge replacement project and complete the environmental review process in compliance with the National Environmental Policy Act (NEPA). The Port of Hood River restarted the project in 2018, including holding a public open house on December 10, 2018 and an online survey conducted through January 31, 2019. Attendees and survey respondents indicated continued support for the project and the previously identified purpose and need statement, range of alternatives, and preliminary preferred alternative.

The Supplemental Draft EIS will provide updated information on the affected environment, environmental consequences, and mitigation measures for the same alternatives studied in the 2003 Draft EIS; coordination activities and input from Federal, State and local agencies; consultation with Tribes; and public involvement. The Supplemental Draft EIS will be available for public and agency review and comment prior to a public hearing.

Authority: 23 U.S.C. 315; 49 CFR 1.48.

Issued On: May 15, 2019.

Phillip A. Ditzler,

Division Administrator, Federal Highway Administration, Oregon Division.

[FR Doc. 2019–10770 Filed 5–22–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2015–0221]

60-Day Notice of Request for Renewal of a Previously Approved Collection

AGENCY: Office of the Secretary (OST), Department of Transportation (Department) or (DOT).

ACTION: Notice and request for comments.

SUMMARY: The OSDBU invites public comments about our intention to request the Office of Management and Budget's (OMB) approval to renew an information collection. The collection involves the following form with an expiration date of May 20, 2022, and is presently in use.

DATES: Please submit comments by July 22, 2019.

ADDRESSES: You may submit comments [identified by Docket No. DOT–OST–2015–0221] through one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail or Hand Delivery:* U.S. Department of Transportation, Dockets Management Facility, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590.
- *Agency website: http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Michelle Harris, 202–366–1930 ext 62253, Office of Small and Disadvantaged Business Utilization, Office of the Secretary, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W56–444, Washington, DC 20590. Office hours are from 9:00 a.m. to 5:00 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: SBTRC Regional Field Offices Intake Form (DOT F 4500).

OMB Control Number: 2105–0554.

Background: In accordance with Public Law 95–507, an amendment to the Small Business Act and the Small Business Investment Act of 1953, OSDBU is responsible for the implementation and execution of DOT activities on behalf of small businesses, in accordance with Section 8, 15 and 31 of the Small Business Act (SBA), as amended. The Office of Small and Disadvantaged Business Utilization also administers the provisions of Title 49, of the United States Cole, Section 332, the Minority Resource Center (MRC) which includes the duties of advocacy, outreach, and financial services on behalf of small and disadvantaged businesses and those certified under CFR 49 parts 23 and or 26 as Disadvantaged Business Enterprises (DBE).

SBTRC's Regional Field Offices will collect information on small businesses, which includes Disadvantaged Business Enterprise (DBE), Women-Owned Small Business (WOB), Small Disadvantaged Business (SDB), 8(a), Service Disabled Veteran Owned Business (SDVOB), Veteran Owned Small Business (VOSB), HubZone, and types of services they

seek from the Regional Field Offices. Services and responsibilities of the Field Offices include business analysis, general management & technical assistance and training, business counseling, outreach services/ conference participation, short-term loan and bond assistance. The cumulative data collected will be analyzed by the OSDBU to determine the effectiveness of services provided, including counseling, outreach, and financial services. Such data will also be analyzed by the OSDBU to determine agency effectiveness in assisting small businesses to enhance their opportunities to participate in government contracts and subcontracts.

We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995, Public Law 104–13.

Title: Small Business Transportation Resource Center Regional Field Office Intake Form (DOT F 4500).

Form Numbers: DOT F 4500.

Type of Review: Renewal of an information collection.

The Regional Field Offices Intake Form, (DOT F 4500) is used to enroll small business clients into the program in order to create a viable database of firms that can participate in government contracts and subcontracts, especially those projects that are transportation related. Each area on the fillable pdf form must be filled in electronically by the Field Offices and submitted every quarter to OSDBU. The Offices will retain a copy of each Intake Form for their records. The completion of the form is used as a tool for making decisions about the needs of the business, such as; referral to technical assistance agencies for help, identifying the type of profession or trade of the business, the type of certification that the business holds, length of time in business, and location of the firm. This data can assist the Field Offices in developing a business plan or adjusting their business plan to increase its ability to market its goods and services to buyers and potential users of their services.

Respondents: SBTRC Regional Field Offices.

Estimated Number of Respondents: 100.

Frequency: The information will be collected quarterly.

Estimated Number of Responses: 100.

Estimated Total Annual Burden on Respondents: 600 hours per year.

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 proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information collection; and (d) ways to minimize the burden of the collection of information on respondents, by the use of electronic means, including the use of automated collection techniques or other forms of information technology. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1:48.

Issued in Washington, DC, on May 20, 2019.

Michelle Harris,

Manager, Regional Assistance Division, Office of Small and Disadvantaged Business Utilization.

[FR Doc. 2019–10789 Filed 5–22–19; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application, Reports, and Recordkeeping for the Social Impact Partnerships To Pay for Results Act (SIPPRA) Grant Program

AGENCY: Departmental Offices, U.S. 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 June 24, 2019.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8142, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Quintana by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application, Reports, and Recordkeeping for the Social Impact Partnerships to Pay for Results Act (SIPPRA) Grant Program.

OMB Control Number: 1505–0260.

Type of Review: Revision of a currently approved collection.

Abstract: Authorized under the Bipartisan Budget Act of 2018, the Social Impact Partnerships to Pay for Results Act (SIPPRA), amends Title XX of the Social Security Act, 42 U.S.C. 1397 *et seq.,* to provide $100 million in funding to implement ''Social Impact Partnership Demonstration Projects'' (projects) and feasibility studies to assist states and local governments in applying for project funding. SIPPRA authorizes the Secretary of the Treasury (Secretary) to enter into award agreements with state or local governments for projects addressing entrenched social problems. SIPPRA requires Treasury to conduct a request for proposals for projects, make award decisions, and enter into project award agreements. Treasury is publishing a Notice of Funding Availability (NOFA) seeking applications for projects, and anticipates that ten or more persons will respond to its notice announcing availability of funding for SIPPRA projects.

Although Treasury is asking applicants to use the SF–424 family of common forms for their applications, in order to effectively and efficiently assess and evaluate applications and ensure that projects comply with statutory requirements, Treasury is also soliciting additional detailed information from applicants. This request only includes the burden for this additional information. The burden for the SF–424 forms is covered under OMB Control Numbers 4040–0004, 4040–0006, 4040–0007, 4040–0008, 4040–0009 and 4040–0013. The additional information includes the following components:

- Notice of Intent to Apply;
- Project Narrative, to include an Executive Summary;
- Project Narrative Attachments, to include project budget, partnership agreements, partner qualifications, independent evaluator qualifications, evaluation design plan, independent evaluator contract, outcome valuation (for which Treasury's SIPPRA website will provide a tool to assist applicants), legal compliance, and (optional) additional supporting documentation such as a preexisting feasibility study;
- DUNS Number and SAM registration;

• Copy of application proposing privileged or confidential information to be redacted;
• Administrative Reporting, including Annual Performance Report, Evaluation Progress Reports, and Final Evaluation Report;
• Records Retention

Form: SIPPRA Grant Application, Recordkeeping, and Reports.

Affected Public: State, Local, and Tribal Governments.

Estimated Total Annual Burden Hours: 2,190.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: May 17, 2019.

Jennifer P. Quintana,

Treasury PRA Clearance Officer.

[FR Doc. 2019–10747 Filed 5–22–19; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

United States Mint

Establish Pricing for 2019 United States Mint Numismatic Product

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint is announcing pricing for a new United States Mint numismatic product in accordance with the table below:

Product	2019 retail price
Pride of Two Nations Limited Edition Two-Coin Set™	$139.95

FOR FURTHER INFORMATION CONTACT: Derrick Griffin, Marketing Specialist, Sales and Marketing; United States Mint; 801 9th Street NW, Washington, DC 20220; or call 202–354–7579.

Authority: 31 U.S.C. 5111, 5112, 5132 & 9701.

Dated: May 20, 2019.

David J. Ryder,

Director, United States Mint.

[FR Doc. 2019–10824 Filed 5–22–19; 8:45 am]

BILLING CODE 4810–37–P

FEDERAL REGISTER

Vol. 84 Thursday,
No. 100 May 23, 2019

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423
Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4180–F]

RIN 0938–AT92

Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to support health and drug plans' negotiation for lower drug prices and reduce out-of-pocket costs for Part C and D enrollees. These amendments will improve the regulatory framework to facilitate development of Part C and Part D products that better meet the individual beneficiary's healthcare needs and reduce out-of-pocket spending for enrollees at the pharmacy and other sites of care.

DATES: These regulations are effective on January 1, 2020, except for the amendments to §§ 422.629, 422.631, 422.633, 423.128, and 423.160, which are effective January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Joella Roland, (410) 786–7638 or Christian Bauer, (410) 786–6043, Part D Issues.

Marty Abeln, (410) 786–1032, Jelani Murrain, (410) 786–2274, or Brandy Alston, (410) 786–1218, Part C Issues.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Purpose

This final rule amends regulations to support Medicare health and drug plans' negotiation for lower drug prices and to reduce out-of-pocket costs for Part C and D enrollees. Although satisfaction with the MA and Part D programs remains high, these provisions are responsive to input we received from stakeholders while administering the programs, as well as through our requests for comment.

The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 16, 2018, 83 FR 22692) sought to find out more information about lowering drug pricing using these four strategies: Improved competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs. We are finalizing a number of provisions that implement these four strategies in an attempt to lower out-of-pocket costs. There is also a particular focus in this final rule on strengthening negotiation leverage for MA and Part D plans and increasing competition in the market for prescription drugs. We are finalizing policies that provide more tools to MA plans that negotiate with manufacturers of Part B drugs, so these plans are equipped with similar negotiation capabilities that group health plans and issuers have in the commercial market. We sought to drive robust competition among health plans and pharmacies, so consumers can shop based on quality and value. These provisions align with the Administration's focus on the interests and needs of beneficiaries, providers, MA plans, and Part D sponsors. We are also finalizing policies that will increase transparency of drug pricing and drug price increases, giving beneficiaries and prescribers tools to help improve adherence, lower prescription drug costs, and minimize beneficiary out-of-pocket costs.

B. Summary of the Major Provisions

1. Providing Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi))

Except in limited circumstances, current Part D policy requires Part D sponsors to include on their formularies all Part D drugs in six categories or classes: (1) Antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics. We proposed three exceptions to this protected class policy that would allow Part D sponsors to: (1) Implement broader use of prior authorization (PA) and step therapy (ST) for protected class Part D drugs, including to determine use for protected class indications; (2) exclude a protected class Part D drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class Part D drug from a formulary if the price of the drug increased beyond a certain threshold over a specified lookback period. This regulatory provision finalizes one of the three proposed exceptions with modifications: The first exception related to PA and ST.

The first exception permits Part D sponsors to use PA and ST for protected class Part D drugs. We are finalizing this exception with modifications. As modified, the exception is a codification of existing policy and does not place additional limits on beneficiary access to medications. Specifically, the exception will permit PA and ST only for new starts (that is, enrollees initiating therapy), including to confirm the use is for a protected-class indication, for five of the six protected classes (that is, all protected classes except for antiretroviral medications). PA and ST will not be permitted for antiretrovirals under this exception. This exception will permit indication-based formulary design and utilization management for new starts in five of the six protected classes, allowing Part D sponsors to exclude a protected class Part D drug in these five classes from the formulary for non-protected class indications only. As is required for all other Part D drug categories or classes, these formulary design and utilization management edits will be subject to CMS review and approval as part of our annual formulary review and approval process, which includes reviews of PA and ST edits that restrict access, ST criteria, PA outliers, and PA criteria. (For an extensive description of our annual formulary checks see section II.A.1. of this final rule.)

The second exception would have permitted Part D sponsors to exclude from the formulary a protected class Part D drugs that is a new formulation of a protected class Part D drug, even if the older formulation is removed from the market. That is, Part D sponsors would have been permitted to exclude from their formularies a protected class Part D drug that is a new formulation that does not provide a unique route of administration, regardless of whether the older formulation remains on the market. Based on comments, we are not finalizing this exception.

The third exception would have permitted Part D sponsors to exclude from the formulary any protected class Part D drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation calculated based on the Consumer Price Index for all Urban Consumers (CPI–U). Based on comments, we are not finalizing this exception.

2. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160)

This final rule requires under section 1860D–4(e)(2)(D) of the Social Security Act (Act) that Part D plan sponsors implement an electronic real-time benefit tool (RTBT) capable of integrating with at least one prescriber's electronic prescribing (eRx) system or

electronic health record (EHR). We believe that this requirement is appropriate given the Act's support of interactive real-time standards whenever feasible, and for standards that improve the cost-effectiveness of the Part D benefit. RTBTs currently used in the industry have the ability to make beneficiary-specific drug coverage and cost information visible to prescribers who want to consider that information at the point-of-prescribing. Because there currently are no industry-wide electronic standards for RTBTs, we are finalizing a requirement that each Part D plan implement at least one RTBT of its choosing that is capable of integrating with at least one prescriber's eRx system or EHR to provide prescribers who care for its enrollees complete, accurate, timely and clinically appropriate patient-specific real-time formulary and benefit (F&B) information (including cost, formulary alternatives and utilization management requirements) by January 1, 2021. However, we strongly encourage plans to start implementing this provision prior to 2021.

3. Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, and 422.619)

This final rule provides requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs and adopts new adjudication timeframe requirements for organization determinations and plan reconsiderations related to requests for Part B drugs. In addition, CMS will incorporate the shorter adjudication timeframes for Part B drug requests into the contract deadlines that apply to Part C Independent Review Entity (IRE) reconsiderations under § 422.592(b). In this final rule, we reaffirm MA plans' existing authority to implement appropriate utilization management and prior authorization programs (meaning policies and procedures) for managing Part B drugs to reduce costs for both beneficiaries and the Medicare program. The use of utilization management tools, such as step therapy, for Part B drugs enhances the ability of MA plans to negotiate Part B drug costs and ensures that taxpayers and MA enrollees face lower per unit costs or pay less overall for Part B drugs while maintaining access to medically-necessary Medicare-covered services and drugs. In order to make sure enrollees maintain access to all medically necessary Part B covered drugs, we are modifying the Part C adjudication time periods for organization determinations and appeals involving Part B drugs.

C. Summary of Costs and Benefits

TABLE 1—COSTS AND BENEFITS FOR THE MAJOR PROVISIONS

Provision	Description	Impact
Providing Plan Flexibility to Manage Protected Classes (§ 423.120(b)(2)(vi)).	We allow the following exception related to protected class Part D drugs: Use of PA and ST for new starts of five of the six protected classes, including to determine use for protected class indications.	We estimate neither cost nor savings from this provision.
E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160).	We require each Part D plan sponsor to implement one or more RTBTs of its choosing that are capable of integrating with at least one provider's e-Rx system or EHR and delivering complete, accurate, timely and clinically appropriate patient-specific real- time F&B information beginning on 01/01/2021.	This provision is scored as a qualitative savings. Based on commenter response we do not believe there will be significant cost to implement RTBT since i) Based on informal conversations with plans and commenter response, 30 percent–90 percent of plans are estimated as already supporting an RTBT tool and ii) plans that do not have it are most likely to use existing intermediaries. Commenters were overwhelmingly enthusiastic on the savings potential due to reduced drug costs arising from cheaper alternatives. The Trust Fund and enrollees will save. However, this savings is classified as a transfer since a cheaper drug is being substituted for a more expensive one. Because of the complexity of prescription drug usage we are unable to meaningfully quantify this savings.
Part D Explanation of Benefits (§ 423.128).	We require the inclusion of negotiated drug pricing information and lower cost alternatives in the Part D Explanation of Benefits beginning on 01/01/2021. The intent of the provision is to provide enrollees with greater transparency, thereby encouraging lower costs.	There is an estimated cost of $4.7 million in the first year of implementation for programmers to update systems. There is an annual estimated cost in all years (including the first) of $5.7 million arising from the cost of paper, printer toner, and postage for mailing one extra page in the Part D EOB with added information about alternatives.
Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, and 422.619).	We added certain new requirements for when MA plans may apply step therapy as a utilization management tool for Part B drugs.	The estimated savings to enrollees due to reduced out-of-pocket costs are between $5 and $8 million for 2020–2029 resulting in an aggregate savings of $62 million over 10 years. The savings to the Trust Fund are between $145 and $240 million for 2020–2029, resulting in an aggregate savings over 10 years of 1.9 billion. There is a modest cost to the government and its contractors of $1 to $1.3 million in 2020–2029 due to a projected increased in appeals, resulting in an aggregate cost of $11.2 million cost over 10 years. These estimates reflect the impact of allowing step therapy for MA organizations in 2020 and future years.

D. Background

In the proposed rule titled ''Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses'' which appeared in the November 30, 2018 **Federal Register** (83 FR 62152 through 62201), we proposed revisions to the Medicare Advantage program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations that

will have the effect of lowering the cost of medications and reducing out-of-pocket costs for enrollees in the Part C and D programs. The changes, as finalized in this rule, will also streamline different aspects of the Part D program and reduce associated burden on the government and sponsoring organizations of MA plans and Part D plans.

In response to the proposed rule, we received 7,898 timely pieces of correspondence containing multiple comments each. Although we are not finalizing all of our proposals to provide plan flexibility to manage protected classes, we are finalizing all other provisions with changes varying from minor clarifications to more significant modifications, based on the comments received. We also sought comment on the possibility of adopting a new definition of ''negotiated price'' under which plan sponsors would be required to pass through all pharmacy price concessions at the point of sale. We will carefully review all input received from stakeholders on this issue as we continue our efforts to meaningfully address rising prescription drug costs for beneficiaries. We also note that some of the public comments received were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate headings.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Providing Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi))

Section 1860D–4(b)(3)(G) of the Act requires Part D sponsors to include in their formularies all covered Part D drugs in classes and categories of clinical concern identified by the Secretary using criteria established through rulemaking. The statute specifies that until such time as the Secretary establishes the criteria to identify drug categories or classes of clinical concern through rulemaking, the following drug categories or classes shall be identified as categories or classes of clinical concern: Anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. This policy is frequently called the ''protected class'' policy in the Part D program, with the drug categories or classes of clinical concern being the ''protected classes.'' Section 1860D–4(b)(3)(G) of the Act permits the Secretary to establish exceptions that permit a Part D sponsor to exclude from its formulary (or to otherwise limit access to such a drug, including through PA or utilization management) a particular covered Part D drug that is otherwise required to be included in the formulary. The Secretary must engage in rulemaking to establish these exceptions. Section 423.120(b)(2)(vi) currently provides three regulatory exceptions to the protected class policy that permit Part D sponsors to: (1) Exclude from their formulary therapeutically equivalent drugs, (2) apply utilization management (UM) edits for safety, and (3) exclude other drugs that CMS specifies through a medical and scientific process which also permits public notice and comment.

The protected class policy, inclusive of its current limitations on PA, is unique to the Medicare Part D program and does not appear elsewhere in other Federal programs, such as the Veterans Health Administration (VA), TRICARE, the Federal Employees Health Benefits Program (FEHBP), the Patient Protection and Affordable Care Act Essential Health Benefits (EHB) Benchmark Plans, or in commercial private health plans. We are concerned that requiring essentially open coverage of certain drug categories or classes in Part D presents both enrollee cost and welfare concerns, as well as increased costs for the Part D program as a result of overutilization (for example, antipsychotics used for sedation) and increased drug prices due to lack of competition between manufacturers to achieve inclusion on plan formularies. In our January 2014 proposed rule entitled, ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 1918, hereinafter referred to as the ''January 2014 proposed rule''), we detailed concerns that the policy potentially facilitates the overutilization of drugs within the protected classes (79 FR 1938). Despite some formulary flexibility and ability to use drug UM techniques for protected class Part D drugs, Part D sponsors are not able to negotiate rebates across the protected classes at levels commensurate with other Part D drugs or prescription drugs covered in the commercial market.

Consequently, although we did not propose to eliminate any of the protected classes, we proposed to use the authority under section 1860D–4(b)(3)(G) of the Act to revise § 423.120(b)(2)(vi). Specifically, we proposed to use the authority under section 1860D–4(b)(3)(G) of the Act to establish additional exceptions to the requirement that all drugs in a protected class be included in the formulary and to permit additional use of UM. We proposed to revise § 423.120(b)(2)(vi) to permit Part D sponsors to implement PA and ST requirements for protected class Part D drugs for broader purposes than allowed currently. We also proposed to allow Part D sponsors to exclude specific protected class Part D drugs from their formularies if they are a single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration or to exclude single-source drugs or biological products that have certain price increases beyond a certain threshold over a specified look back period. However, we noted that these exceptions will apply only to the requirement that the drug be included on the formulary because it is a protected class Part D drug. In other words, an exception from the protected class policy will not supersede our other formulary requirements in § 423.120(b)(2).

We received the following comments and our response follows:

Comment: Many commenters stated that all three of our proposals greatly compromised access to needed therapy (that is, delays and/or interruptions in therapy) for patients taking protected class Part D drugs, which would lead to adverse health outcomes for these enrollees, and, in the case of HIV, endanger public health.

Response: In considering whether to propose these exceptions, CMS took our other enrollee access protections into account, which have successfully protected beneficiary access to needed medications in the more than 12 years the Part D program has been operational. There are five such enrollee protections, which include formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the expedited coverage determination and appeals processes.

The first protection is our requirement for formulary transparency to beneficiaries. Part D sponsors are required to provide comprehensive formulary drug listings to the public through their own websites and printed materials, as well as to CMS for access through the online interactive drug plan comparison tool, the Medicare Plan Finder (Plan Finder). Beneficiaries or

their representatives can complete a personalized search on the Plan Finder to locate and select a Part D plan that covers their drugs. Thus, beneficiaries who review plan formularies can select plans that cover their current medications.

The second type of protection is the Part D formulary requirements (§ 423.120(b)(2)). Our annual formulary review and approval process is designed to ensure that Part D formularies do not substantially discourage enrollment by certain beneficiaries and that the formularies include adequate representation of all necessary Part D drug categories or classes for the Medicare population. The formulary review and approval process includes the following:

- Category and Class Review (§ 423.272(b)(2)). Distinct from our other formulary checks, CMS reviews and approves drug lists that are consistent with best practice formularies currently in widespread use today. CMS evaluates the sufficiency of a Part D sponsor's formulary drug categories or classes in conjunction with the plan's formulary drug list to ensure that the formulary provides access to an acceptable range of Part D drug choices.
- Two Drugs Requirement (§ 423.120(b)(2)(i)). Each submitted formulary is reviewed for the inclusion of at least two distinct drugs from each of the submitted categories or classes, except as provided in § 423.120(b)(2)(ii).
- Formulary Tier Review (Medicare Prescription Drug Benefit Manual, Chapter 6, section 30.2.7). The tiering structure of each formulary is reviewed to ensure that each category or class generally has at least one drug in a preferred tier.
- Common Medicare Drugs Review (§ 423.120(b)(2)(iii)). Formularies are reviewed for inclusion of the drugs or drug classes that are most commonly utilized by the Medicare population. We use prior years' data to identify the drugs or drug classes with the highest utilization in Medicare Part D, and use these drugs or drug classes as the basis for our review in this area.
- Treatment Guidelines [1] Review (§ 423.120(b)(2)(iii)). We analyze formularies to determine whether appropriate access is afforded to drugs or drug classes included in widely accepted treatment guidelines.
- Vaccines Review (§ 423.100). Each formulary submission is reviewed to ensure the formulary includes Part D vaccines.
- Specialty Tier Review (§ 423.578(a)(7)). For formularies using a specialty tier, we perform an extensive review of the composition of each specialty tier. We apply a standard outlined in the annual Call Letter to determine whether drugs placed in specialty tiers meet the relevant cost criteria.
- Quantity Limits (QL) Amount Review (§ 423.153(b)). QL restrictions are reviewed for appropriateness. The standard for the review is generally based on the maximum recommended dose when such dosage limits are identified in the Food and Drug Administration (FDA)—approved labeling.
- Restricted Access Review (§ 423.153(b)). Formularies are reviewed for use of PA and ST edits across drug categories or classes. We decline to approve UM for entire drug classes, other than for those categories or classes where the UM edits are considered to be consistent with best practices, for example, for erythropoietin stimulating agents (ESAs), due to the high likelihood of Part B versus Part D coverage issues, as well as a boxed warning in the FDA labeling that warns of significant adverse events when these drugs are used outside of their approved indications and therapeutic targets.
- Step Therapy Criteria Review (§ 423.153(b)). The ST requirements are reviewed to ensure that the ST algorithms are consistent with best practices, including prerequisite drugs, current industry standards and appropriate treatment guidelines.
- Prior Authorization Criteria Review (§ 423.153(b)). We review the criteria for drugs requiring PA on the formulary submissions. We look to existing best practices, current industry standards, and appropriate treatment guidelines to check that the Part D plans' use of PA is consistent with such best practices. Submitted criteria are also compared to recognized compendia (that is, those compendia described in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information and DRUGDEX Information System) and FDA-approved indications.
- Mid-year formulary change restrictions (§ 423.120(b)(5)); Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 30.3.3). Except when: (1) The FDA deems a Part D drug unsafe, (2) a manufacturer removes a Part D drug from the market, or (3) in the circumstances described under § 423.120(b)(5)(iv) when a new generic drug becomes available, a Part D sponsor may not remove a covered Part D drug from its formulary, or make any adverse change in preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with the annual coordinated election period. However, prescription drug therapies are constantly evolving, and new drug availability, medical knowledge, and opportunities for improving safety and quality in prescription drug use at a lower cost will inevitably occur over the course of the year. As recognized in regulation, these new developments may require formulary changes during the year in order to provide high-quality, affordable prescription drug coverage. Moreover, CMS will not approve mid-year changes, other than the three types of changes listed here, unless the Part D sponsor grandfathers coverage for the remainder of the plan year for enrollees that are already taking the drug being removed (or subjected to an adverse change in preferred or tier cost sharing) at the time of the change.

Thus, in summary, our formulary rules both ensure that all Part D formularies contain sufficient drugs to treat all disease states in the Medicare population and protect enrollees from significant changes in formularies during the course of a coverage year.

The third type of enrollee protection is the annual notice to reassigned enrollees required under section 3305 of the Patient Protection and Affordable Care Act (PPACA, Pub. L. 111–148). Effective January 1, 2011, we provide individuals who receive the Low Income Subsidy (LIS individuals) who are reassigned to a different Part D plan with information on the differences under the new plan formulary, as well as information on the enrollee's grievance and appeal rights in the new plan. Thus, (in order to maintain access to a $0 premium) any individual who has his or her plan selection decision made through our reassignment process receives detailed coverage status information for each drug for which he or she filled a prescription between January and August of the previous year. With regard to the new plan, this notice describes for each drug whether it is on the formulary, whether the brand or generic version is covered, and whether UM may be applied. Moreover, the notice also provides a list of other available plans into which the enrollee can enroll with no premium if they

[1] The World Health Organization (WHO) defines a standard treatment guideline as a systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances (available at *http://www.who.int/medicines/technical_briefing/tbs/10-PG_Standard-Treatment-Guidelines_final-08.pdf*).

would prefer not to remain in the plan where they were reassigned. We send notices after the individual's reassignment and in time to allow for the LIS individual to make a voluntary selection of another plan effective January 1. Thus, any reassigned LIS individual receives advance notice of any change in formulary coverage of their medications in plenty of time to work with their prescribers if they wish to remain in the new plan, or to select a different Part D plan.

The fourth type of enrollee protection is our unique transition supply and notice requirements. A Part D sponsor must provide for an appropriate transition process for Part D drugs that are not on its formulary with respect to: (1) The transition of new enrollees into prescription drug plans following the annual coordinated election period; (2) the transition of newly-eligible Medicare beneficiaries from other coverage; (3) the transition of individuals who switch from one plan to another after the start of the contract year; and (4) in some cases, current enrollees affected by formulary changes from one contract year to the next (see § 423.120(b)(3) Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 30.4). Within the first 90 days of an enrollee's enrollment in a new plan, plans must provide a temporary fill of at least an approved month's supply when the enrollee requests a fill of a non-formulary drug or a Part D drug that is on a plan's formulary but requires PA or ST under a plan's UM rules. This requirement applies beginning on an enrollee's first effective date of coverage, regardless of whether this is within the first 90 days of the contract year. Additionally, if a Part D sponsor cannot determine at the point of sale (POS) whether an enrollee is currently taking a drug (for example, a new enrollee filling a prescription for the first time), we instruct the Part D sponsor to provide the enrollee with a transition supply.

A successful transition process is contingent not only upon providing the transitional drug supply, but also upon informing affected enrollees, their caregivers, and their prescribers about the enrollee's options for ensuring that his or her medical needs are safely accommodated within a Part D sponsor's formulary. For this reason, when providing a temporary supply of non-formulary Part D drugs or Part D drugs that are on a plan's formulary but require PA or ST under a plan's UM rules, Part D sponsors must provide enrollees and their prescribers with written notice within three business days after adjudication of the temporary fill that they are receiving a transition supply and that they must take action. The temporary fill and written notice provide enrollees with a reasonable amount of time during which they and their prescribers can address the issue (by requesting a formulary exception or transitioning to a formulary drug) and prevents them from having to abruptly change or go without their medication (see Transition notice requirements (to enrollees and providers) [§ 423.120(b)(3)(iv and v); Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 30.4.10]). Thus all enrollees and their prescribers have advance notice of any issue with continued coverage of a previously initiated therapy and sufficient time to resolve those issues without any lapse in appropriate therapy. The preceding formulary review and transition requirements are described in Chapter 6 of the Medicare Prescription Drug Benefit Manual (located at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf*).

The fifth enrollee protection we took into account is the requirement for a robust coverage determination and appeal process, including the right of an enrollee or his or her prescriber to request an exception to the plan's UM criteria, tiered cost-sharing structure, or formulary. Part D sponsors are required to issue a coverage decision and notify the enrollee (and the prescriber, as appropriate) in writing in accordance with strict regulatory timeframes. In general, consistent with § 423.578, a plan must grant a tiering or formulary exception (for example, provide coverage for a non-formulary drug or a formulary exception to the UM criteria) when it determines that the requested drug is medically necessary, consistent with the prescriber's supporting statement indicating that preferred alternatives(s) would not be as effective and/or would have adverse effects.

We have established by regulation both an expedited adjudication timeframe if the plan or prescriber believes that applying the standard timeframe may jeopardize the enrollee's health, and a requirement that plans must issue all coverage decisions as expeditiously as the enrollee's health condition requires. The requirements at § 423.568 for coverage determinations and § 423.572 for expedited coverage determinations state that the plan must notify the enrollee ''as expeditiously as the enrollee's health condition requires, but no later than [72 or 24 hours, respectively] after receiving the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.'' That is to say, if an enrollee's health condition requires a response in less than 24 hours, the plan is obligated to provide one.

If, based on the initial review of the request, the Part D sponsor expects to issue a partially or fully adverse decision based on medical necessity, the coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the Part D sponsor issues the decision on the coverage determination. If the Part D sponsor makes an adverse coverage determination, the required written notice must explain the specific reason(s) for the denial and include a description of the enrollee's right to a standard or expedited redetermination by the plan, and the rest of the five-level appeals process, including the right to request independent review. At the redetermination level of appeal, when the issue is the denial of coverage based on a lack of medical necessity, the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. If a plan fails to make a coverage decision and notify the enrollee within the required timeframe, the request must be forwarded to the independent review entity (IRE) to be adjudicated.

Moreover, while we do not treat a claim transaction as a coverage determination, we require Part D sponsors to arrange with network pharmacies to provide enrollees with a written copy of the Office of Management and Budget (OMB)-approved standardized pharmacy notice (''Notice of Denial of Medicare Prescription Drug Coverage,'' CMS–10146) when the enrollee's prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the point-of-sale (POS). The notice instructs the enrollee on how to contact his or her plan and explains the enrollee's right to request a coverage determination. Thus, all enrollees immediately receive clear, concise instructions on how to pursue their right to request a coverage determination when a prescription cannot be filled at POS. For additional information on the coverage determination, appeals, and grievance process, including information about the pharmacy notice, see 42 CFR part 423, subparts M and U, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available at *https://www.cms.gov/Medicare/Appeals-and-*

Grievances/MedPrescriptDrugApplGriev/index.html.

CMS will be monitoring appeals activity to ensure Part D enrollees' requests are appropriately evaluated. Additionally, we also plan to implement a protected class-specific Complaints Tracking Module (CTM) monitoring project in 2020 to monitor access to protected class Part D drugs. Finally, as discussed elsewhere in this final rule, CMS is taking steps in 2020 and future rulemaking to include e-prescribing improvements such as real time benefit tools (RTBTs) and Part D electronic prior authorization (ePA) as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271), which could reduce the need for coverage determinations and appeals. Taken together, these initiatives and the five beneficiary access protections described previously will help to protect enrollees from any unnecessary or inappropriate delay in access to medically necessary drugs.

Comment: Several commenters stated that Part D sponsors already have enough tools to manage protected class Part D drugs, including PA on new starts, formulary tiering, and generic utilization. Some commenters added that by using these tools, Medicare currently only covers two-thirds of protected class Part D drugs, and plans already use PA on nearly one half of protected class Part D drugs. However, many other comments that we received expressed support for additional formulary management tools.

Response: It is unclear on what basis commenters are making the assertions regarding Medicare only covering two-thirds of protected class Part D drugs and plans already using PA on nearly one-half of protected class Part D drugs, as plans are required to include all protected class Part D drugs on their formularies, with limited exceptions as specified at § 423.120(b)(2)(vi), and the use of PA has been limited to new starts under our existing policy. Although we are not able to speak to the actual rebate values, our internal analyses of rebate data reported by Part D sponsors generally support the assertion that Part D sponsors obtain substantially smaller rebates for protected class Part D drugs than they do for non-protected class Part D drugs. Due to restrictions on disclosure of rebate data, CMS is not able to release this analysis to the public.

Comment: Some commenters claimed that proposing exceptions without previously or concurrently proposing clinical criteria is out of order, and not allowed by the plain reading of the statute.

Response: Section 1860D–4(b)(3)(G)(ii) of the Act specifies that subject to section 1860D–4(b)(3)(G)(iv) of the Act, the Secretary ''shall identify, as appropriate,'' categories or classes the Secretary determines are of clinical concern, using criteria the Secretary establishes. Section 1860D–4(b)(3)(G)(iv) of the Act states that until such time as the Secretary establishes the criteria, the existing protected class categories ''shall be identified'' under section 1860D–4(b)(3)(G)(ii) of the Act. The statute clearly contemplates that the existing protected classes—that is, those set forth in section 1860D–4(b)(3)(G)(iv) of the Act—are the identified classes for purposes of section 1860D–4(b)(3)(G)(ii)(II) of the Act, as well as section 1860D–4(b)(3)(G)(i)(I) of the Act, and therefore the Secretary need not establish criteria for identifying new or different protected classes before establishing exceptions.

Comment: Some commenters claimed that CMS's protected class proposals violate the statutory non-discrimination provision, particularly with respect to enrollees who take high-cost drugs in the protected classes. Other commenters asserted that HIV patients, LIS enrollees, and dually-eligible enrollees (particularly children) would be disproportionately affected by our proposals.

Response: The non-discrimination provision and the protected class provision are not at odds. Non-discrimination applies to all Part D enrollees, while the protected class provision establishes additional requirements for drugs in protected classes. Section 1860D–4(b)(3)(G) of the Act authorizes formulary exclusion and UM for protected class Part D drugs, which indicates that non-discriminatory formulary exclusion and UM are contemplated by the statute. Therefore, excluding a protected class drug from the formulary or imposing UM criteria would not be discriminatory in itself. Our approach to approving PA and ST criteria for protected class Part D drugs will be consistent with our discrimination analysis for all other categories or classes—that is, to ensure that these criteria, as applied, would not substantially discourage enrollment by certain Part D eligible individuals. As described previously, we conduct a discrimination review to ensure that plans' formulary designs are not likely to substantially discourage enrollment by certain Part D eligible individuals. We will conduct the same review with respect to the protected class drugs that plans wish to exclude from the formulary or for which they wish to impose PA or ST, in each case only as permitted under the exceptions we are finalizing in this rule. Moreover, there are other, non-protected categories and classes of drugs that consist of high-cost therapies (for example, drugs used to treat hepatitis C) for which CMS has been able to ensure a benefit design that is not likely to substantially discourage enrollment by certain Part D eligible individuals.

Comment: Some commenters asserted that CMS's proposals are inconsistent with Congressional intent and in conflict with our regulation. Specifically, commenters pointed to the language we adopted at § 423.120(b)(2)(vi)(C) specifying that any exception to the criteria is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV–1-infected Adults and Adolescents).

Response: Section 1860D–4(b)(3)(G)(i)(II) of the Act specifically allows the Secretary to establish exceptions that permit a Part D sponsor to exclude from its formulary a particular covered Part D drug in a category or class that is otherwise required to be included in the formulary, or to otherwise limit access to such a drug, including through PA or UM. Our existing exception at § 423.120(b)(2)(vi)(C) was adopted after enactment of the Medicare Improvements for Patients and Providers Act (MIPPA) (section 176 of Pub. L. 110–275). However, the PPACA (section 3307 of Pub. L. 111–148) removed this statutory requirement. While our existing regulations at § 423.120(b)(2)(vi)(C) discuss an exception for protected class Part D drugs that is ''based upon scientific evidence and medical standards of practice (and in the case of antiretroviral medications is consistent with the [HHS] Guidelines for the Use of antiretroviral Agents in HIV–1 Infected Adults and Adolescents),'' this is a separate and distinct exception from the exceptions proposed in this rulemaking. In other words, these exceptions can exist contemporaneously, and are not in conflict with each other.

Comment: Stakeholders provided alternative policies to lower drug prices, such as allowing copay assistance cards for Part D enrollees and other federal healthcare program beneficiaries, encouraging Part D plans to institute benefit designs that include ''select care'' tiers that would cover drugs with low or no patient cost sharing (including antineoplastic drugs), exploring new ways to encourage Part D

plans to offer supplemental benefits for enrollees, further developing demonstration models that provide supplemental benefits or reduced cost sharing for patients with specific conditions or needs, or proposing an exception that would permit Part D sponsors to exclude protected class Part D drugs when therapeutic alternatives exist.

Response: We thank commenters for their suggestions.

We are finalizing our proposal to redesignate the existing paragraph that appears at § 423.120(b)(vi)(C) that permits CMS to exempt other drugs that CMS specifies. However, because we are not finalizing our proposed exceptions regarding new formulations and price increases, paragraph § 423.120(b)(vi)(C) will be redesignated as paragraph (D), instead of (F) as originally proposed.

1. Broader Use of Prior Authorization for Protected Class Part D Drugs

Under section 1860D–4(b)(3)(G)(i)(II) of the Act, the Secretary can establish exceptions to permit a Part D sponsor to exclude from its formulary, or otherwise limit access through PA or UM, a particular Part D drug that is otherwise required to be on the formulary because it is in a protected class. This authority is specific to Part D drugs, and moreover, applies without regard to whether an enrollee is initiating therapy (new starts) or is currently taking a drug (existing therapy).

Part D coverage is limited to those drugs that meet the definition of a Part D drug in § 423.100. Therefore, regardless of a drug's potential status as a protected class drug, Part D sponsors are responsible for ensuring that coverage is limited to Part D drugs. In order to accomplish this, Part D sponsors use PA [2] on drugs that have a high likelihood of: (1) Coverage that is available under Parts A or B (versus D) for the drug as prescribed and dispensed or administered; (2) exclusion from Part D coverage (for example, a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D as defined in section 1927(d)(2) of the Act); or (3) use other than for a medically accepted indication as defined in section 1860D–2(e)(4) of the Act, in the Part D sponsor's experience or as directed by CMS, consistent with sections 10.6 and 30.2.2.3 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. Additionally, relative to medically accepted indications, consistent with section 10.6.1 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, Part D sponsors may retrospectively identify and confirm—either as part of their retrospective review programs required under § 423.153, or incident to another UM review—that a dispensed drug, including when dispensed as a transition supply, was not prescribed for a medically accepted indication for a particular individual. CMS does not consider the use of CMS-approved PA requirements for these purposes to be subject to section 1860D–4(b)(3)(G) of the Act because section 1860D–4(b)(3)(G) of the Act is specific to Part D drugs. Consequently, consistent with current policy, CMS will continue to permit Part D sponsors to apply PA for potential protected class drugs to determine whether such drugs can be covered under Part D, for both new starts and existing therapy, for those drugs with a high likelihood of being excluded from Part D for the reasons provided previously, subject to CMS review and approval.

Using the authority under section 1860D–4(b)(3)(G)(i)(II) of the Act, which applies without regard to new starts or existing therapy, we proposed to permit Part D sponsors to apply PA and ST requirements to new starts and existing therapy of protected class Part D drugs that are implemented to confirm use is intended for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. We also solicited comment on whether PA and ST of protected class Part D drugs should be limited to new starts only.

We received the following comments and our response follows:

Comment: A number of commenters supported the proposal to expand the use of PA and ST for protected class Part D drugs from new starts only to new starts and existing therapy to confirm use is intended for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval.

Response: We thank the commenters for their support.

Comment: Many commenters asserted that treatments in the protected classes are neither interchangeable nor ''one-size-fits-all,'' adding that patients need access to the full range of therapies in these classes, and prescribers need the autonomy to make the best decision for each patient as an individual. Several commenters asserted that while clinical practice guidelines are publicly available, they are not intended to drive policy decisions. These commenters further added that while guidelines are important to give clinicians a starting point in the care of patients, it is ultimately up to the clinician who knows the full history of the individual patient to tailor treatments that will result in the best outcomes for that patient. Some commenters added that PA and ST policies intended to restrict access to physician-directed care unnecessarily prolong ineffective treatment and prevent individuals from immediately starting the treatment their prescribers believe is best. Some commenters suggested that ST requirements should not be ironclad, but instead should be suggested clinical care pathways to provide clinical decision support. Other commenters added that the lack of autonomy damages the doctor-patient relationship.

Response: Consistent with § 423.120(b)(2)(iii) and § 423.153(b), CMS conducts treatment guideline, ST criteria, and PA criteria reviews as part of the annual formulary review and approval process. CMS uses the FDA-approved labeling and widely accepted treatment guidelines to determine clinical appropriateness before approving PA or ST criteria. As discussed previously in this preamble, we will only approve PA and ST criteria that are clinically supported. These beneficiary protections, and specifically the limits we place on Part D sponsors' ability to apply PA and ST, differentiate Part D from other prescription drug benefits and help prevent the negative consequences (that is, prolongation of ineffective therapy and delaying accesses to appropriate therapy) suggested by the commenters and are designed to preserve the doctor-patient relationship. Moreover, ST requirements are not ironclad because, consistent with § 423.578, prescribers can request a formulary exception, and provided it meets the requirements at § 423.578, the supporting statement provided by a physician or other prescriber is given great weight when reviewing an exception request.

Comment: Some commenters expressed concern that CMS has not provided specificity about the clinical criteria that will be applied to its formulary review or any additional oversight and monitoring that would be appropriate to ensure the well-being of Part D enrollees with chronic conditions. Commenters recommended a system whereby CMS signs off on ST

[2] Consistent with section 10.6 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, Part D sponsors should consistently use prior authorization (PA) for those drugs with the highest likelihood of non-Part D covered uses unless plans are able to reliably use tools other than PA to determine appropriate coverage for the drug.

programs for protected classes based on certain defined criteria, including that the program is evidence-based, or for areas where adequate evidence is lacking, is based on accepted standards or best clinical practice. Additionally, commenters suggested CMS should create a specialty council with expertise in the fields of the various protected class indications to review formulary decisions.

Response: As noted in response to the previous comment, consistent with § 423.120(b)(2)(iii) and § 423.153(b), CMS conducts treatment guideline, ST criteria, and PA criteria reviews as part of the annual formulary review and approval process. CMS uses the FDA-approved labeling and widely accepted treatment guidelines to determine clinical appropriateness before approving PA or ST criteria. We will only approve PA or ST criteria that are clinically supported. Please see section II.A. of the preamble to this final rule for an extensive description of our formulary review process. Consistent with § 423.578, prescribers can also request a formulary exception if a desired outcome is not met with current formulary alternatives. Additionally, the CMS formulary team reviewing Part D formularies and related PA and ST criteria is composed of pharmacists who are board-certified pharmacotherapy specialists with extensive clinical experience reviewing PA and ST criteria. These pharmacists use the FDA-approved labeling and widely accepted treatment guidelines when considering PA and ST criteria for disease states.

Comment: A number of commenters expressed concern that PA and ST policies can lead to patients' not filling their prescriptions or underutilizing medications, which leads to non-adherence. Commenters expressed concern that non-adherence, in turn, can lead to interruptions in therapy across the six classes, and in the case of HIV, would endanger public health because it is a communicable disease which can rapidly mutate and become resistant to therapy.

Response: CMS acknowledges that PA and ST requirements can potentially cause the issues cited when they are implemented without the protections provided under the Part D program. However, we believe such concerns have been mitigated in Part D based upon our more than 12 years of experience with the Part D program, including our existing policy that allows for PA and ST for new starts of protected class Part D drugs (except antiretrovirals), and the other unique Part D protections that are more robust than in comparable programs. For example, in all other Part D drug categories and classes, where wide use of PA and ST has been allowed since the beginning of the Part D program, subject to our other formulary requirements, we have no evidence to suggest that Part D enrollees routinely experience interruptions in therapy as a result of PA and ST requirements. Moreover, CMS is advancing improvements in price transparency, interoperability, and e-prescribing, such as RTBTs and Part D ePA as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271), that could help mitigate the kinds of administrative burdens sometimes associated with PA and ST that commenters claim could lead to underutilization.

Comment: Several commenters asserted that the PA process is complicated and labor intensive, and also, given the high approval rate—particularly for protected class Part D drugs—PA requirements do not reduce medication utilization and thus simply impose unnecessary burdens on patient care. Some commenters added that this proposal is counter to CMS's Patients over Paperwork initiative.

Response: We are concerned that the current policy potentially facilitates the overutilization of drugs within the protected classes, particularly antipsychotics.[3] [4] [5] By limiting the ability of Part D sponsors to implement UM tools (for example, PA or ST requirements) for an entire category or class, we also limit their ability to prevent the misuse or abuse of drugs that are not medically necessary. Inappropriate use of Part D drugs can lead to adverse effects that can harm the enrollee and require medical treatment that will otherwise not have been necessary, thus increasing overall Medicare costs.[6] We remain concerned there may be a link between the profitability of products not subject to normal price negotiations as the result of protected class status, such as antipsychotics, and overutilization, particularly off-label overutilization, of some of these drugs. Additionally, as discussed elsewhere in this final rule, CMS is advancing improvements in price transparency, interoperability, and e-prescribing, such as RTBTs, and Part D ePA as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271), that could help mitigate the kinds of administrative burdens sometimes associated with PA and ST and aligns this proposal with the Patients over Paperwork initiative.

Comment: Commenters were divided over whether we should continue to allow PA and ST for UM purposes for new starts only. Some commenters strongly supported the idea. Many commenters expressed concern that requiring enrollees to undergo ST requirements after they have already been stabilized on a treatment regimen can cause disruptions to the overall success of the enrollee's treatment and create negative treatment health care outcomes. However, other commenters opposed to limiting PA and ST for new starts only, as contrasted to permitting PA and ST for new starts and existing therapy, expressed concern that data limitations for PDP sponsors to discern new starts from existing therapy at the POS would create operational issues that would ultimately cause them not to use this exception, which would sufficiently undermine the exception and render it ineffective.

Some commenters suggested that rebate differences between the protected classes would yield greater cost savings for some protected classes, such as antipsychotics, antidepressants, and anticonvulsants, than the other protected classes (antiretrovirals, antineoplastics, and immunosuppressants). These commenters asserted that certain protected classes, like antiretrovirals to

[3] A May 2011 Department of Health and Human Services Office of Inspector General report found that of 2.1 million elderly persons who lived in nursing homes in the first 6 months of 2007, almost 305,000 had a prescription for at least one atypical antipsychotic drug. Eighty-eight percent of these prescriptions were for off-label, medically unacceptable uses and/or were associated with a specific FDA Black Box warning against their use by elderly persons with dementia. In all, unapproved uses and improperly documented claims for these drugs cost Medicare $116 million in one 6-month period. Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents. OEI–07–08–00150. *https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf* Accessed April 17, 2019.

[4] The percentage of long-term nursing home residents being given antipsychotic drugs dropped from about 24 percent in late 2011 to under 15 in the third quarter of 2018. National Partnership to Improve Dementia Care in Nursing Homes: Antipsychotic Medication Use Data Report (January 2019). *https://www.nhqualitycampaign.org/files/Antipsychotic_Medication_Use_Report.pdf.* Accessed May 10, 2019.

[5] Advocates say even the lower rate of antipsychotic usage is excessive, given federal warnings that elderly people with dementia face a higher risk of death when treated with such drugs. February 5, 2018. Crary D. Associated Press. "New Report Details Misuse of Antipsychotics in Nursing Homes" *https://www.statnews.com/2018/02/05/antipsychotics-nursing-homes-elderly/* Accessed May 10, 2019.

[6] Prescription Drug Workgroup; American Academy of Actuaries. Issue Brief: Prescription Drug Spending the in US Healthcare System, an Actuarial Perspective. March 2018. *https://www.actuary.org/content/prescription-drug-spending-us-health-care-system* Accessed April 12, 2019.

treat HIV, do not have significant branded competition and therefore would not be expected to see significant rebating, even absent the protected classes policy.[7] Other commenters suggested that CMS should introduce automatic permission for a 7-day temporary supply while approval is sought.

Response: CMS' current policy permits PA and ST for new starts only for protected class Part D drugs, except antiretroviral medications.

We proposed to broaden the permissible use of PA and ST for protected class Part D drugs by permitting PA and ST for enrollees on existing therapy. Our goal was to provide additional flexibility so that Part D sponsors could better manage the benefit from a clinical as well as a cost savings perspective. We believe that the existing beneficiary protections, including our extensive clinical formulary review and approval process, would adequately protect enrollees from the inappropriate application of PA and ST requirements. Moreover, we would effectively limit most ST criteria to new starts as best practice, except when a change in therapy is clinically supported by the recognized compendia or widely accepted treatment guidelines. When step therapy is applied, we would expect to approve PA or ST requirements with initial treatment that is comparably supported by recognized compendia or widely accepted treatment guidelines.

Nevertheless, CMS is persuaded by comments that expressed significant concern for the potential disruption of ongoing therapy of protected class Part D drugs used for protected class indications and, after considering all the comments, we conclude that the risks associated with inappropriately interrupting therapy for stabilized patients receiving protected class drugs for protected class indications by potentially subjecting them to PA or ST requirements outweighs the potential clinical benefits that some enrollees could gain from switching therapies that might be more appropriate and the potential cost savings that would accompany the additional formulary management flexibility. Therefore, we are finalizing a codification of existing policy that allows Part D sponsors to apply PA and ST requirements for protected class Part D drugs, except for antiretroviral medications, only for new starts, to determine if a drug's intended use is for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. PA and ST will continue to be prohibited for antiretroviral medications. Because the statutory protected class provision applies only to Part D drugs, Part D sponsors may continue to use coverage determinations, including PA or other reliable tools, to determine a drug's status as a Part D drug irrespective of such drug's status as a new start or existing therapy. However, we clarify that for enrollees on existing therapy, Part D sponsors may not require PA to confirm that a drug's intended use is for a protected class indication if the drug otherwise does not have a high likelihood of use intended for a non-medically accepted indication that would not be coverable under Part D. In other words, sponsors generally will need to rely on alternative approaches, such as retrospective DUR, to confirm the intended use is for a protected class indication for enrollees on existing therapy.

CMS thanks the commenters for their suggestion about the 7-day supply. However, because of our transition policy, which requires at least a month's approved supply, a 7-day supply is not necessary.

Comment: Some commenters expressed concern that expanded use of PA and ST will limit access to protected class Part D drugs for important uses that may not be considered a protected class indication, for example, enrollees who take various protected class Part D drugs for conditions like chronic pain or lupus. Commenters asserted that access limitations based on purported ''protected'' versus ''non-protected'' uses would be divorced from the clinical realities that exist for patients with complex and chronic conditions.

Some commenters expressed concern that expanded use of PA and ST will limit access to protected class Part D drugs that have more than one protected class indication, for example, antidepressants with dual use as anxiolytics (antianxiety medications) or antipsychotics and vice versa, or as another example, anticonvulsants with use as adjunct anxiolytics or antidepressants. Other commenters added that the proposal does not protect off-label prescribing within a protected class, for example, tacrolimus for lung transplants.

Response: A number of protected class Part D drugs have medically accepted indications for non-protected class uses. As discussed in the proposed rule, we are clarifying that we consider medically accepted indications consistent with the identified drug categories or classes of the protected classes to be ''protected class indications.'' In other words, when a Part D drug is used for a protected class indication, we consider it to be a protected class Part D drug. Using the commenter's example, tacrolimus for lung transplants would still be considered to be used for a protected class indication if use in lung transplant is a medically accepted indication. In addition, Part D drugs with multiple medically accepted protected class indications are protected for each such protected class indication, even if the indications are in more than one protected class. For example, aripiprazole has an FDA-labeled indication for acute and maintenance treatment of schizophrenia, and an FDA-labeled indication for adjunctive treatment of major depressive disorder; both of these uses are considered to be protected class indications.

As discussed in the proposed rule at 83 FR 62158, CMS is concerned that unless a Part D sponsor can use PA to determine the indication for which the drug has been prescribed, there is the potential to increase Part D program costs when there may be a less expensive alternative available to treat a particular non-protected indication that would be clinically appropriate. Therefore, we will permit Part D sponsors to use PA only for new starts in the protected classes, except for antiretrovirals, to determine if such drugs' intended use is for non-protected class indications. For those drugs that have both protected class and non-protected class indications, we may permit different PA requirements or formulary inclusion for non-protected class indications than those used for protected class indications, depending upon the clinical appropriateness and consistent with the July 25, 2018 and August 29, 2018 HPMS memos about indication-specific UM and formulary design. Additionally, to the extent that treatment guidelines for non-protected class indications include drugs with both protected class and non-protected class indications, plans will still be required to meet all established Part D formulary criteria regarding access to such drugs for non-protected class uses.

For example, for an enrollee who is a new start on topiramate, an anticonvulsant, the PA criteria used for topiramate could determine coverage and establish appropriate use in the following scenarios:

[7] See PEW Comments on Proposals to Modernize Medicare Drug Payments. *https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2019/01/25/pew-comments-on-proposals-to-modernize-medicare-drug-payments* Accessed April 12, 2019.

• If use is for weight loss (an excluded, use under Part D), the Part D sponsor would deny coverage. (We remind Part D sponsors that they may deny coverage for excluded use under Part D irrespective of the enrollee's status as a new start or continuing existing therapy);

• If use is as an anticonvulsant (a protected class indication), the plan would cover the drug; or

• If use is for migraine prophylaxis (a non-protected class, indication), the Part D sponsor could—

++ Deny coverage (if this use is not on formulary) and require the enrollee to seek an exception to obtain coverage; or

++ Apply another set of PA or ST requirements for this indication.

We expect that all such issues or questions would be addressed during the coverage determination to avoid the possibility of enrollees needing to submit multiple coverage determination requests for the same drug.

Application of PA criteria to determine use for weight loss, as an anticonvulsant, or for migraine prophylaxis would be consistent with our July 25, 2018 Health Plan Management System (HPMS) memorandum entitled, ''Indication-Based Utilization Management'' and our August 29, 2018 HPMS memorandum entitled, ''Indication-Based Formulary Design Beginning in Contract Year (CY) 2020.''

Finally, in their formulary materials, we would expect Part D sponsors to note differential formulary inclusion for drugs with regard to protected class versus non protected class indications.

Comment: A few commenters suggested that, while they did not support our proposal to allow broader use of UM for protected class Part D drugs, one area in which they did support the use of such tools in the protected classes was to reduce the inappropriate prescribing of antipsychotics in the long-term care setting.

Response: We share the commenters' concerns about inappropriate prescribing of antipsychotics in the long-term care setting. Allowing PA and ST for new starts of antipsychotics will help to limit overutilization of these drugs for non-protected class indications (for example, antipsychotic use for sedation in nursing homes).

Comment: Some commenters expressed concern that expanded use of PA and ST will limit or delay access to more than one drug for an indicated use, asserting that individuals sometimes require more than one drug, or a specific combination of drugs, for a particular condition, and that this is particularly salient within the protected classes.

Response: To the extent that the FDA labeling, recognized compendia, or treatment guidelines discuss the use of multiple drugs, or a particular combination of drugs, within the protected classes for a given protected class indication, consistent with our existing formulary requirements, plans will still be required to provide coverage of such drugs for those patients. Additionally, UM and retrospective drug utilization review (DUR) can be used to ensure that combinations are clinically appropriate and comport with treatment guidelines, even if such combination is not first-line therapy, for example, retrospective DUR to ensure the use of combination therapies of HIV medications comport with the HHS HIV Guidelines.

Comment: Several commenters expressed concern that ST is not appropriate for protected class Part D drugs, particularly antineoplastics, antiretrovirals, and immunosuppressants.

Response: We agree that in most circumstances of clinically appropriate care, ST would not be appropriate for protected class Part D drugs. However, as a general statement, we disagree with the commenters. Our more than 12 years of experience with the Part D program has provided evidence of inappropriate prescribing within the protected classes, across all of the classes, and particularly for antipsychotics. Additionally, we have recently seen evidence of fraudulent prescribing and diversion of antiretrovirals. Although we are taking a more limited approach to our application of PA and ST than we proposed and excluding antiretrovirals from the exception we are finalizing at § 423.120(b)(vi)(C), we continue to believe that PA and ST are important tools to ensure clinically appropriate use of drugs, including those in the protected classes.

Comment: Some commenters suggested that CMS should require plans to list all drugs that require PA and ST.

Response: Plans are required to submit this information in their bids. Additionally, this information is available when beneficiaries search for plans by inputting their drugs into the Medicare Plan Finder. This information is also required to be available in the printed formulary, on the formulary on the plan's website, and available by calling the plan.

Comment: Some commenters noted that the Emergency Medical Treatment and Labor Act (EMTALA) requirements preclude emergency physicians from asking patients about their insurance coverage before a medical screening examination is completed, and therefore, emergency physicians do not know which type of plan and formulary the patient may have at the point of prescribing. These commenters asserted that the urgency of treatment in the emergency setting requires emergency services personnel to provide medications that may not be on a Part D plan's formulary and suggested that CMS exempt prescriptions that originate in emergency settings from this exception.

Response: Part D enrollees may be started on non-formulary medications as inpatients or in emergency settings that are subject to PA or ST requirements if continued upon discharge. If an enrollee who presented to the pharmacy a new prescription was started on protected class drugs in such a scenario, we would expect Part D sponsors to consider such enrollee to be continuing existing therapy. Additionally, as detailed previously, our transition requirements and exceptions and appeals process provides the necessary protection for enrollees that need to remain on such medications. Although Part D enrollees and prescribers may need to avail themselves of our exceptions and appeals processes, as discussed previously in this preamble and consistent with section 30.4.7 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, we remind Part D sponsors that they are required to make coverage determinations and redeterminations as expeditiously as the enrollee's health condition requires.

Comment: A commenter requested that CMS allow MA plans, through a step therapy edit, to require the use of a Part B drug prior to the use of a protected class Part D drug starting in 2020.

Response: We noted in the proposed rule that the combination of our proposal to specify additional exceptions to the formulary requirements for protected class Part D drugs (section II.A. of the proposed rule, ''Broader Use of Prior Authorization for Protected Class Part D Drugs'') and our proposal for step therapy for Part B drugs (section II.F of the proposed rule, ''Medicare Advantage and Step Therapy for Part B Drugs'') would allow MA–PD plans to require step therapy of a Part B drug before a Part D drug. However, step therapy of a Part B drug before a Part D protected class drug would be allowed only under the circumstances outlined in this regulation (for example, only for new starts of five of the six protected classes) and subject to our Part D formulary review process.

We thank stakeholders for their comments on the proposed expansion of PA and ST for protected class drugs. We are redesignating the existing paragraph at § 423.120(b)(2)(vi)(C) as paragraph (D) and adding a new exception at paragraph (C), which we are modifying in response to comments: For enrollees that are not on existing therapy on the protected class covered Part D drug, and except for antiretroviral medications, PA and ST requirements that are implemented to confirm that the intended use is for a protected class indication, to ensure clinically appropriate use, to promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. As modified, the exception is a codification of existing policy and does not place additional limits on beneficiary access to medications.

2. New Formulations

We proposed two changes to our protected class exceptions to address new formulations. First, we proposed a change to the existing exception at § 423.120(b)(2)(vi)(A) to reflect the forthcoming introduction of interchangeable biological products to the market by specifying drug or biological products that are rated as—(1) therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' also known as the Orange Book); or (2) interchangeable (under the FDA's most recent publication of the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations).'' Second, we proposed to add a new exception at new paragraph § 423.120(b)(2)(vi)(D) that would have specified that, in the case of a single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration, the new formulation may be excluded from a Part D sponsor's formulary. Under our existing policy, Part D sponsors are not required to include a new formulation of a drug on their formularies when the older formulation is still available.

We received the following comments and our response follows:

Comment: Many commenters requested that CMS define the term ''new formulation.''

Response: We declined to propose a definition for ''new formulation'' because we believe Part D sponsors will be better able to make these determinations more quickly, and we saw merit and benefit in providing Part D sponsors with the flexibility to determine whether they will exclude the drug or negotiate with the manufacturer for formulary inclusion and placement.

Comment: A few commenters asked CMS to expand the application of the proposed exception for new formulations beyond brand drugs to include generic drugs.

Response: Multiple-source drugs that are therapeutic equivalents already can be excluded from the formulary in accordance with the existing exception at § 423.120(b)(5)(vi)(A).

Comment: Several commenters wanted CMS and not, as we proposed, Part D sponsors, to track which drugs would be eligible for exclusion under this exception and to publish a list of applicable drugs. Manufacturers largely wanted to limit the applicability of the exception, and plans generally wanted CMS to make the determinations for them.

Response: We did not propose that CMS publish a list of such drugs because we believed Part D sponsors will be better able to make these determinations more quickly, and we saw merit and benefit in providing Part D sponsors with the flexibility to determine whether they will exclude the drug or negotiate with the manufacturer for formulary inclusion and placement.

Comment: Some commenters expressed concern that CMS was attempting to fix a problem that has not happened yet, as there have been no instances of new formulations that that meet the proposed criteria for an exception within the protected classes. Other commenters further suggested that, while they understood CMS's attempts to fix a potential problem, our proposal, if finalized, would leave vulnerable enrollees without access to needed drugs.

Response: The purpose of our proposed exception was to specify that even if a new formulation of a single-source drug or biological product in the protected class became the only formulation available, Part D sponsors would have been able to exclude it from their formularies, except as required by our other formulary requirements in § 423.120(b)(2) and subject to our review and approval, as part of our annual formulary review process. Under our existing policy, which will still apply, Part D sponsors are not required to include a new formulation of a drug on their formularies when the older formulation is still available. CMS was persuaded by the commenters' argument because under our proposed policy, in a scenario where our other formulary requirements did not require Part D sponsors to have the new formulation on their formulary, a Part D enrollee who is stable on the old formulation could be left without access to the new formulation. Consequently, we decline to finalize this exception.

Comment: Several commenters asserted that the exception for new formulations is unnecessary if the exception for PA and ST is finalized.

Response: We thank the commenters for their suggestion. We note that we are not finalizing the new formulations exception.

Receiving no comments on the proposed change to the existing exception at § 423.120(b)(2)(vi)(A) to reflect the forthcoming introduction of interchangeable biological products to the market, we are finalizing a change to § 423.120(b)(2)(vi)(A) to allow an exception for interchangeable biological products, in addition to our existing policy of an exception for therapeutically equivalent generic drugs. We are not finalizing the proposed exception to specify that, in the case of a single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration, the new formulation may be excluded from a Part D sponsors' formulary.

3. Pricing Threshold for Protected Class Part D Drug Formulary Exclusions

To address Part D sponsors' assertion that they have limited ability to negotiate manufacturer rebates and achieve appreciable savings relative to drugs within the protected classes, as well as price increases for such drugs, CMS proposed, effective for plan years starting on or after January 1, 2020, to permit Part D sponsors to exclude from their formularies any single-source drug or biological product that is a protected class Part D drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation. We proposed the rate of inflation would be calculated using the Consumer Price Index for all Urban Consumers (CPI–U), and the price would be defined as the Wholesale Acquisition Cost (WAC).

We received many comments regarding this proposal, including commenters that supported this proposed exception, and agreed with CMS that this flexibility would allow plans more negotiation power with manufacturers on protected class Part D drugs. However, we also received many

comments urging us not to finalize this proposed exception highlighting concerns with beneficiary access, and inability to adequately address rising launch prices, among other concerns. Based on the comments and responses summarized below, we are not finalizing this proposed exception.

We received the following comments and our response follows:

Comment: Several commenters supported this exception, and agreed with CMS that this flexibility would allow plans more negotiation power with manufacturers on protected class Part D drugs.

Response: While we are not finalizing the exception, we thank commenters for their support.

Comment: Many commenters stated that all three of our proposals greatly compromised access to needed therapy (that is, delays and/or interruptions in therapy) for patients taking protected class Part D drugs, which would lead to adverse health outcomes for these enrollees, and, in the case of HIV, endanger public health.

Response: In considering whether to propose these exceptions, CMS took our other enrollee access protections into account, which have successfully protected beneficiary access to needed medications in the more than 12 years the Part D program has been operational. There are five such enrollee protections, which include formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the expedited coverage determination and appeals processes. While we believe our current enrollee access protects are sufficient, we appreciate commenters concerns regarding beneficiary access and protections and as a result we are not finalizing the pricing threshold exception.

Comment: Several commenters asserted that this proposed exception, since it is based on cost considerations rather than scientific evidence, medical standards, or clinical practice, represents an unexplained departure from established policy that would create discrimination in Part D. Commenters further asserted that basing exceptions to the protected classes on cost considerations is neither supported by statute nor our existing regulations at § 423.120(b)(2)(vi)(C).

Response: While a price increase could have triggered a formulary exclusion, the exception we proposed would not have superseded our other formulary requirements, including our annual clinically and scientifically based formulary review and approval process, which includes extensive checks to ultimately ensure adequate representation of all necessary Part D drug categories or classes for the Medicare population.

We would also like to clarify that we do not view an exception based on a pricing threshold as a departure from current policy. While our existing regulations at § 423.120(b)(2)(vi)(C) discuss an exception for protected class Part D drugs that is ''based upon scientific evidence and medical standards of practice (and in the case of antiretroviral medications is consistent with the [HHS] Guidelines for the Use of Antiretroviral Agents in HIV–1-Infected Adults and Adolescents),'' this is a separate and distinct exception from the exceptions we proposed in this rulemaking. In other words, these exceptions can exist contemporaneously, and are not in conflict with each other.

Finally, we remind commenters that CMS conducts a discrimination review to ensure that plans' formulary designs are not likely to substantially discourage enrollment by certain Part D eligible individuals.

Comment: Some commenters suggested that this exception policy was based on the erroneous belief that prices of protected class Part D drugs are increasing rapidly and that plans need additional leverage to negotiate prices for protected class Part D drugs, citing evidence from MedPAC's March 2017 report [8] that shows plans' ability to adequately manage utilization of protected class Part D drugs and drive enrollees toward use of generic drugs.

Response: MedPAC's finding that Part D plans ''have had success at moving enrollees toward generic drugs, which helps to slow the growth in prices, even when a drug has protected status,'' does not negate the unsustainable growth in protected class Part D drug prices or a Part D sponsor's limited ability to negotiate rebates for such drugs. For example, in addition to Part D sponsors' limited ability to negotiate rebates for protected class drugs, internal CMS analysis has also shown price trends for brand drugs are consistently higher for drugs in protected classes than such drugs in non-protected classes. On the whole, protected class drug prices have increased more than other, non-protected drug classes between 2012 and 2017. More recently, the allowed cost per days' supply increased by 24 percent for protected class brand drugs between 2015 and 2016 and by 14 percent between 2016 and 2017. In contrast, the allowed cost per days' supply increased by 16 percent for non-protected class brand drugs from 2015 to 2016, and showed no growth for such drugs from 2016 to 2017. In addition, in the March 2017 MedPAC report, MedPAC also stated ''[the drug's protected class status] may limit the amount of rebates plan sponsors are able to obtain from manufacturers in these classes,'' which supports the basis for which we proposed this exception. Although we are not finalizing the proposed exception, we remain concerned about the pricing dynamics for protected class drugs.

Comment: Some commenters suggested that if CMS finalized the exception to broaden use of PA and ST in the protected classes, then finalizing the exception based on a pricing threshold would not be necessary.

Response: As discussed earlier in this rule, we are only finalizing the exception that exists under current policy, related to the use of utilization management in the protected classes, which we believe will continue to provide Part D sponsors with the flexibility to use PA and ST in the protected classes and help them achieve negotiating leverage to realize cost savings for their enrollees. We agree that, at that this time, the pricing threshold exception is not a necessary addition to the exceptions we are finalizing.

Comment: A commenter suggested this policy exception was dangerously close to price fixing.

Response: Although we are not finalizing, this proposed policy would not have placed restrictions on how manufacturers may price their products. We also note that Part D sponsors would not have been required to exclude a protected class Part D drug from formulary under this exception, rather, we were simply proposing to provide the sponsor the flexibility to do so. However, as discussed further below, concern over whether Part D sponsors would be motivated to exercise this flexibility is one reason why we are not adopting this exception in this final rule.

Comment: Several commenters agreed with the proposal, but noted it would not limit growth in the launch prices of new drugs, which have been found to drive spending increases among specialty drugs, and might even lead to higher launch prices moving forward. Commenters also noted the potential for gaming by manufacturers to circumvent their drug being eligible for formulary exclusion under this exception.

Response: We agree with commenters that there may be an incentive for

[8] MedPAC, Report to the Congress: Medicare Payment Policy (March 2017). p. 412.

manufacturers to come in at higher launch prices for protected class Part D drugs as a result of this exception. In light of this concern and others noted previously, we are not finalizing this exception.

Comment: A commenter noted that Part D sponsors' contracts with manufacturers may include price protections, and as such, may be protected from any change in WAC during the contract year. Thus, Part D sponsors' motivation to apply this exception may be muted.

Response: We understand that all Part D sponsors may not be motivated to use this exception, particularly considering the limited savings associated with this exception. In light of this comment, we are not finalizing this exception as proposed.

Comment: We received many comments in response to these requests for comment on several specific technical and operational elements of the exception, some in support of the proposed operational and technical components of the exception, and others that suggested alternative approaches to those proposed.

Response: We thank commenters for their responsiveness to the comment solicitation, but we are not finalizing this proposed exception.

Comment: A commenter suggested that, in order to discourage potential gaming for drugs not yet on the market as of September 1, 2019, CMS establish a reference baseline price for drugs new to the market consistent with the inflation-adjusted launch prices of leading therapeutic alternatives in the class rather than allowing the manufacturer to establish its own baseline price.

Response: CMS shares the commenter's concern over the risk of potential gaming, and, thus, we are not finalizing this exception while we continue to consider how best to align incentives to encourage manufacturers to keep drug prices low of their own volition, as was intended with the proposed exception.

Comment: A commenter recommended that CMS apply this exception more broadly to include all National Drug Codes (NDCs) assigned to single-source brand drugs, single-source generic drugs, and generic drugs, as well as both protected class and non-protected class Part D drugs and biological products. The commenter asserted that if only protected class Part D drugs are excluded based upon price increases beyond a certain threshold, that over time, manufacturers will have the ability to apply egregious price increases to an NDC that applies to more than one drug, as well as non-protected classes in order to make up for any lost compensation.

Response: While we are not finalizing this exception, we remind the commenter that Part D sponsors already have the flexibility to exclude non-protected class Part D drugs from their formularies or apply PA and ST requirements to such drugs, unless the drug is required to be on formulary to be compliant with our formulary requirements. As discussed earlier in the preamble, this exception—which would have applied only to the requirement that all protected class Part D drugs be included on the formulary—does not supersede our formulary requirements at § 423.120(b)(2). Regarding multiple-source generic drugs, as discussed in the proposed rule (83 FR 62160), we declined to apply this exception to such drugs given the wide use of maximum allowable cost (MAC) pricing for such drugs which yields changes in list prices such as WAC meaningless.

Regarding potential price increases for an NDC related to multiple drugs, it is unclear what the commenter means by referring to ''an NDC that applies to more than one drug'' because an NDC is specific to a drug, the manufacturer, strength, dosage form, and quantity. However, if the commenter simply means that manufacturers will increase prices for multiple other non-protected class Part D drugs to offset limiting price increases on a specific protected class drug or drugs to the cumulative change in CPI–U, we share those concerns. Based on the comments received, we are not finalizing this proposed exception.

4. Solicitation of Comment for Special Considerations

In considering whether exceptions to the added protections afforded by the protected class policy are appropriate, we took other enrollee protections in the Part D program into account. As detailed earlier in section II.A of this final rule, there are five such enrollee protections which include formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the expedited exception, coverage determination, and appeals processes. Our formulary review and approval process includes a formulary tier review, and for PA and ST, we also conduct restricted access, ST criteria, PA outlier, and PA criteria reviews. Additionally, our formulary review and approval process takes into consideration the applicable indication, proposed applicability to new or continuing therapy, and likelihood of comorbidities when reviewing PA and ST criteria submitted to CMS by Part D sponsors. We noted that best practice UM practices do not require an enrollee who has been stabilized on an existing therapy of a protected class Part D drug for a protected class indication to change to a different drug in order to progress through ST requirements, and we would not have expected Part D sponsors to require, nor would CMS have been likely to approve such requirements, unless clinically warranted (for example, an enrollee was started on clinically inappropriate therapy or received second- or third-line therapy for initial treatment of a condition, as described by the recognized compendia). Moreover, we believe our current approach, which ensures at least one drug within the class is offered on a preferred tier and free of PA and ST, is working well and should be maintained. Currently, Part D formularies frequently have more than one protected class Part D drug at a preferred cost sharing level, especially in classes with significant generic penetration, without any PA or ST requirement, and we do not expect that this policy will prompt Part D sponsors to stop including protected class Part D drugs on tiers with preferred cost sharing.

Finally, our transition policy will continue to require Part D sponsors to provide all new enrollees with at least an approved month's supply if the Part D sponsor cannot determine at the point of sale whether the enrollee is currently taking such protected class Part D drug. (For a detailed discussion of our transition requirements, see section II.A. of this final rule and regulations at § 423.120(b)(3).)

Nonetheless, it was our intent to make certain that the three proposed exceptions to the protected class policy (that is, broader use of PA, new formulations, and pricing thresholds) would not introduce interruptions for enrollees on existing therapy of protected class Part D drugs for protected class indications.

We solicited comment on whether there are additional considerations that will be necessary to minimize: (1) Interruptions in existing therapy of protected class Part D drugs for protected class indications during PA processes; and (2) increases in overall Medicare spending from increased utilization of services secondary to adverse events from interruptions in therapy. These could include, but are not limited to, for example, special transition considerations for on-formulary protected class Part D drugs for which the Part D sponsor has

established PA requirements, or as another example, for transitioning some enrollees taking protected class Part D drugs for protected class indications to alternative Part D drugs. If so, we sought comment on why our current requirements and protections are inadequate, or could be improved. In addition, we solicited comment on what specific patient population(s), individual patient characteristic(s), specific protected class Part D drugs or individual protected drug classes will require such additional special transition or other protections and how such population(s) can be consistently identified. Finally, we solicited comment on other tools that could be used to minimize interruptions in existing therapy of protected class Part D drugs for protected class indications during PA processes, for example, wider use of diagnosis codes on prescriptions, ePA during e-prescribing, targeting protected class Part D drugs in Medication Therapy Management (MTM) programs, or, as another example, expanded use of a data-sharing tool to exchange information for enrollees transitioning from one plan to another.

We received the following comments and our response follows:

Comment: Several commenters expressed concerns that our proposals would increase costs for Medicare Part D enrollees, the Part D program, and Medicare overall due to increased utilization of other healthcare services, for example, emergency department visits and inpatient admissions. Some commenters requested that we exempt various protected class indications or enrollees in LTC settings or served by LTC pharmacies from the application of the proposed exceptions, asserting these enrollees will have higher hospital admission and readmission rates due to complications from ineffective medications and consequent needs for additional treatment.

Response: CMS solicited comment on whether there are additional considerations that will be necessary to minimize increases in overall Medicare spending from increased utilization of services secondary to adverse events from interruptions in therapy but did not receive suggestions, apart from exempting virtually all of the applicable enrollees from the exceptions, to abate these concerns.

We understand the importance of access and continuity of care with these as well as all classes and will take that into consideration when approving PA and ST criteria. Our annual formulary review and approval process includes extensive checks to ensure appropriate representation of drugs for all necessary Part D drug categories or classes for the Medicare population. Our process has been working well to ensure that enrollees have access to the drugs they need for their medical conditions. Formularies will still be subject to the entire CMS formulary review criteria, and our formulary review criteria look at widely accepted treatment guidelines.

As discussed previously, we are finalizing one exception to the protected classes formulary inclusion requirements. We are finalizing an exception, consistent with current policy, to allow Part D sponsors to apply PA and ST requirements for protected class Part D drugs, except antiretrovirals, for new starts only to confirm intended use is for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof. Under this exception, PA and ST will continue to be prohibited for antiretroviral medications. Any PA or ST requirements implemented under this exception will be subject to CMS review and approval.

Comment: Several commenters expressed support for our existing transition requirements.

Response: We thank the commenters for their support.

Comment: We received comments in support of our suggestions on other tools that could be used to minimize interruptions in existing therapy of protected class Part D drugs for protected class indications during PA processes, for example, wider use of diagnosis codes on prescriptions, ePA during e-prescribing, targeting protected class Part D drugs in Medication Therapy Management (MTM) programs (including mandatory MTM for Part D enrollees in nursing homes on protected class Part D drugs), or, as another example, expanded use of a data-sharing tool to exchange information for enrollees transitioning from one plan to another. Additionally, a commenter urged improvements to electronic health records and claims processing.

Response: We thank the commenters for their support. As discussed previously, CMS is taking steps to provide e-prescribing improvements such as RTBTs, and Part D electronic prior authorization as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271). CMS could explore the generation of reports through data sharing platforms. Regarding electronic health records and claims processing, we thank the commenter and welcome more input on this suggestion.

Comment: A number of commenters claimed that existing protections do not reliably ensure access to medically appropriate protected class Part D drugs. Some commenters in support of the proposals also encouraged CMS to improve enrollee protections, namely the appeals and exceptions processes. Commenters disputed our claim that our appeals and exceptions processes are mature and have proven workable, asserting that Medicare Part D enrollees afflicted with conditions addressed by protected class drugs continue to have considerable difficulty in navigating Part D, even after the improvements that CMS has recently taken to assist Medicare beneficiaries with selecting a plan and navigating the appeals and grievance processes. Commenters added that this is particularly concerning given that the proposal does not make mention of any additional CMS resources (such as additional staff or appropriations) to ensure that enrollees who need access to drugs within the protected classes are able to obtain their medications in a timely manner. Some commenters suggested that CMS should establish an expedited exceptions process that functions in less than 24 hours. Other commenters added that broader PA and ST should not be implemented without improvements to electronic health records (EHRs) and claims processing.

Response: CMS disagrees with the assertion that existing appeals processes are inadequate to ensure access to needed to medically-appropriate protected class Part D drugs, and commenters provided no evidence to support statements that Part D enrollees with protected class indications have difficulty navigating Part D. To that end, under the exceptions we are finalizing in this rule, the appeals process will work as it does today. If the enrollee's plan will not cover a drug the enrollee needs, or it will cover the drug at a higher cost than they believe they are required to pay, the enrollee or their prescriber can request a coverage determination (for example, a PA or tiering exception) from their plan. If their plan denies their request, they have the right to appeal that decision to obtain a redetermination. Additionally, the requirements at § 423.568 for coverage determinations and § 423.572 for expedited coverage determinations state that the plan must notify the enrollee ''as expeditiously as the enrollee's health condition requires, but no later than [72 or 24 hours, respectively] after receiving the request, or, for an exceptions request, the physician's or other prescriber's

supporting statement.'' That is to say, if an enrollee's health condition requires a response in less than 24 hours, the plan is obligated to provide one. Therefore, our existing appeals requirements already provide for timeframes of less than 24 hours when warranted.

CMS will continue to closely monitor appeals activity through audits and our Complaints Tracking Module (CTM) to ensure enrollees' requests are appropriately evaluated and that Part D sponsors are adhering to regulations. While we have confidence in our appeals process, CMS continues to take steps to improve the Part D Appeals process. Additionally, e-prescribing improvements such as real-time benefit tools (RTBTs) and Part D electronic prior authorization as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271) could reduce the need for appeals. CMS will take steps to further improve and strengthen the appeals process in response to any issues that arise.

Finally, CMS does not foresee a need to augment its clinical review staff because we already review PA and ST in the protected classes for new starts.

Comment: Some commenters claimed that the existing formulary review and approval process is inadequate to ensure non-discriminatory PA and ST requirements that would limit access to protected class Part D drugs, and the only way to ensure access to drugs in these classes is to maintain the policy as it exists today. Commenters asserted that our outlier analysis is an insufficient tool to provide oversight against potential discriminatory practices, particularly against enrollees who take high-cost drugs in these classes, HIV patients, LIS enrollees, and dually-eligible enrollees (particularly children). Commenters added that an outlier analysis is simply a test to determine if a certain plan is being more discriminatory than other plans but would not identify common discriminatory practices across plans. However, other commenters highlighted industry practices that are not currently allowed in Part D and were concerned that such practices would be allowed in Part D under our proposed modifications to the protected class policies. For example, some commenters expressed concern that we would allow PA for Truvada® which is indicated for prevention of HIV transmission. Other commenters cited commercial plans' requirements to use multi-tablet regimens for HIV, which are known to reduce medication adherence.

Response: We conduct a discrimination review consistent with § 423.272(b)(2) to ensure that plans' formulary designs are not likely to substantially discourage enrollment by certain part D eligible individuals. Our clinical checks are intended to ensure that formularies are robust and do not substantially discourage enrollment by certain beneficiaries. Our outlier analysis is an additional step that allows us to further question why a specific formulary either has additional or fewer UM requirements than most other plans (for example, an outlier because a Part D sponsor has not imposed PA where most other Part D sponsors require PA, or an outlier because a Part D sponsor requires PA when most other Part D sponsors do not). Being an outlier in and of itself does not mean a formulary substantially discourages enrollment (it might be just the opposite), but rather ensures the plan can justify the basis for its additional or fewer UM requirements compared to other plans.

All of our formulary requirements, when taken together, have resulted in CMS' ability, in its twelve-year experience implementing the benefit, to prevent formularies that are likely to substantially discourage enrollment by certain Part D-eligible individuals under plans. This includes protected class Part D drugs, due to our existing allowance of PA and ST for new starts. We do not anticipate that adoption of this policy will change our ability to prevent formularies that are likely to substantially discourage enrollment by certain Part D-eligible individuals under plans now. We are not aware of any industry-wide practices that would result in formularies that are likely to substantially discourage enrollment by certain Part D-eligible individuals under plans that would also meet the totality of our formulary requirements.

Comment: Some commenters expressed frustration that coverage determinations, exceptions, and appeal approvals are usually only granted for the duration of 1 plan year. Other commenters added that immunosuppressant approvals, specifically, should be extended to match the life of the transplanted organ.

Response: Part D benefits operate on a plan year for 1 calendar year. While extended-duration (that is, longer than 1 calendar year) approvals may be possible for Part D enrollees who stay with a plan across multiple plan years, we recognize such approvals present challenges when Part D enrollees switch plans. CMS has instituted the Additional Beneficiary Information Initiatives (ABII) web portal to facilitate data sharing from Medicare Part A claims data relative to Medicare-covered transplants to aid Part D sponsors in making these determinations; plans may request access to ABII to receive this information about their enrollees. If a Part D enrollee switches plans, the transition policy would apply and plans would be required to provide the medication for at least an approved month's supply. As discussed previously, CMS could explore the generation of additional pertinent reports through secure data-sharing platforms.

Comment: Related to the pricing threshold exception, a commenter suggested that enrollees doing well on a therapy should not lose their ability to take that therapy, and enrollees on an existing therapy should be grandfathered such that they do not lose the ability to continue on that therapy. In addition, for enrollees not eligible for grandfathering, Part D sponsors should be required to notify enrollees of their decision to exclude a therapy any time they do so pursuant to this exception.

Response: We appreciate the concerns raised by these commenters and, as noted previously, will not be finalizing this proposal.

We are finalizing the first exception with the modification to allow Part D sponsors to apply PA and ST requirements for protected class Part D drugs, except antiretrovirals, only for new starts to confirm intended use is for a protected class indication, to ensure clinically appropriate use, to promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. PA and ST will continue to be prohibited for antiretroviral medications under this exception. As such, we also allow indication-based formulary design and utilization management for new starts of protected class Part D drugs, which would allow Part D sponsors to exclude the protected class Part D drug from the formulary for non-protected class indications. As is required for all other Part D drug categories or classes, these formulary design and utilization management edits will be subject to CMS review and approval as part of our annual formulary review and approval process, which includes reviews of PA and ST edits that will restrict access, step therapy criteria, PA outliers, and PA criteria. (For an extensive description of our annual formulary checks see section II.A.1. of this final rule.) We also are finalizing a change to permit exclusion of interchangeable biological products. As modified, the exception is a codification of existing policy and does not place additional limits on beneficiary access to medications.

In response to comments, we are not finalizing the proposed exceptions to (1) allow Part D sponsors to exclude a protected class Part D drug from a formulary if it is a new formulation of a single-source drug or biological product with the same active ingredient of moiety that does not provide a unique route of administration, regardless of whether the other formulation is removed from the market; and (2) to permit Part D sponsors to exclude from their formularies any single-source drug or biological product that is a protected class Part D drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation.

B. Prohibition Against Gag Clauses in Pharmacy Contracts (§ 423.120(a)(8)(iii))

In October 2018, Congress enacted the ''Know the Lowest Price Act of 2018'' (Pub. L. 115–262). The measure, which amends section 1860D–4 of the Act by adding a paragraph (m), prohibits Medicare Part D plan sponsors from restricting their network pharmacies from informing their Part D plan enrollees of the availability of prescription drugs at a cash price that is below what that the enrollee will be charged (either the cost sharing amount or the negotiated price when it is less than the enrollee's cost sharing amount) for the same drug under the enrollee's Part D plan. In effect, the legislation prohibits Part D sponsors from including in their contracts with their network pharmacies ''gag clauses'', a term used within the prescription drug benefit industry that refers to provisions of drug plan pharmacy contracts that restrict the ability of pharmacies to discuss with plan enrollees the availability of prescriptions at a cash price that is less than the amount the enrollee will be charged when obtaining the prescription through their insurance. The measure becomes effective with the plan year starting January 1, 2020.

To make the Part D regulations consistent with the statute governing the Part D program, we proposed to incorporate the new requirement into the Part D regulations. Specifically, we proposed to amend the set of pharmacy contracting requirements at § 423.120(a)(8) by adding a paragraph (iii) that provides that a Part D sponsor may not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D plan enrollee of the availability at that pharmacy of a prescribed medication at a cash price that is below the amount that the enrollee will be charged to obtain the same medication through the enrollee's Part D plan.

Comment: A number of commenters expressed strong support and appreciation for our effort to incorporate into the Part D regulations the provisions of the ''Know the Lowest Price Act'' promptly after enactment of the legislation.

Response: We thank the commenters for their support.

Comment: Several commenters requested that CMS address additional issues related to beneficiaries' opting to purchase their prescriptions outside their Part D plan. Specifically, they suggested that CMS adopt policies to make it easier for plan enrollees to have their cash purchases reported electronically and automatically to their Part D plan sponsors, allowing the payment amounts to be counted toward beneficiaries' TrOOP and benefit deductible accumulations. Commenters also expressed their concern that prescriptions obtained outside the Part D benefit are not subject to plans sponsors' drug utilization review and medication therapy management tools, creating potential health and safety risks for beneficiaries who pay out of pocket for a covered medication. Some of these commenters urged CMS to take steps to ensure beneficiaries are made aware of this particular risk.

Response: We thank the commenters for their perspectives, though their suggestions are outside the scope of this rule. We have previously advised in sub-regulatory guidance (Chapter 5, Section 30.1 of the Medicare Prescription Drug Benefit Manual) that sponsors should accept paper claims for prescriptions their enrollees obtain without using their Part D benefit so that the sponsor can make the appropriate determinations concerning reimbursement, total gross covered drug cost, and TrOOP. Also, in our guidance, we have affirmed that it is in the best interests of beneficiaries to have their claims processed through their Part D sponsor so that concurrent drug utilization review can be performed (Chapter 14, Section 50.4.3 of the Medicare Prescription Drug Benefit Manual). We will continue to evaluate the impact on the Part D program of Part D plan enrollees filling their prescriptions outside their benefit plan and may consider proposing regulatory changes to address identified concerns in the future.

Comment: A commenter noted that the language of the proposed rule did not exactly mirror the language of the underlying statute. Specifically, the statute states that a sponsor may not restrict a pharmacy from informing a beneficiary of a ''lower price the individual would pay for the drug'' if obtained without using insurance while the rule refers to a ''cash price'' that is below the amount that would be charged to obtain the drug through insurance. The commenter states that the term ''cash price'' is not used in the statute and therefore, to promote uniformity in practical application of the requirement throughout the payer and provider industry, it should not be used in the corresponding rule.

Response: We appreciate the comment, though we believe that while a rule must reflect the meaning of its underlying statute, it need not simply re-state the statutory language. The commenter has not indicated how the use of the term ''cash price'' changes the meaning of the statute or could create confusion in its application. We have used the term ''cash price'' in previous Part D guidance addressing the issue of beneficiaries obtaining drugs outside their Part D benefit plans, including manual chapters and the May 2018 memorandum issued by the Administrator advising Part D sponsors that they should not include gag clauses in their pharmacy contracts. The term ''cash price'' is a term understood within the industry to mean a price charged by a pharmacy to customers not using insurance to obtain a prescription drug and its use in the rule promotes clarity in the statement of the new prohibition.

For the reasons sets forth in the proposed rule and our response to the related comments, we are finalizing the proposed regulation at § 423.120(a)(8)(iii) without modification.

C. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160)

1. Legislative Background

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) requires the adoption of Part D E-Prescribing (eRx) standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement eRx. However, prescribers and dispensers who electronically transmit and receive prescription and certain other information for 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.

For a further discussion of the statutory basis for this final rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. of the eRx and the Prescription Drug Program February 2005 proposed rule (70 FR 6256).

2. Regulatory History

Part D eRx standards are periodically updated to take new knowledge, technology, and other considerations into account. CMS currently requires providers and dispensers to utilize the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard, Implementation Guide Version 10.6, which was approved November 12, 2008, to provide for the communication of a prescription or prescription-related information for certain named transactions. However, as of January 1, 2020, prescribers and dispensers will be required to use the NCPDP SCRIPT standard, Implementation Guide Version 2017071, which was approved July 28, 2017 to provide for the communication of prescription or prescription-related information between prescribers and dispensers for the old named transactions and a handful of new transactions named at § 423.160(b)(2)(iv). We also currently require (under § 423.160(b)(5)) Medicare Part D plan sponsors and prescribers to convey electronic formulary and benefits information amongst themselves using Version 3 Release 0 (Version 3.0), from April 2012 of the NCPDP Formulary and Benefits Standard Implementation Guides. (For a detailed discussion of the regulatory history of eRx standards see the November 2017 proposed rule (82 FR 56437 and 56438)).

The NCPDP SCRIPT eRx standards (SCRIPT) and the NCPDP Formulary and Benefits standards (F&B) have become critical components of the Part D program. In the 2018 calendar year, over 66 percent of Part D prescriptions were transmitted electronically using the applicable SCRIPT standard, and all Part D plans implemented electronic F&B files using the adopted standard. Prescribers can use electronic F&B transactions during the eRx process. F&B is a batch mode transaction standard by definition, and therefore does not provide real-time information. A batch transaction allows plans to send the information nightly, weekly or even monthly. As plans make routine changes in their formularies, they may or may not be captured on the batch formulary files. In addition, F&B provides information on a contract level, rather than a patient level, and consequently could not provide out-of-pocket costs for a given patient at a given point in time, since costs and applicability of utilization management could vary significantly for individual beneficiaries depending on a variety of factors. For example, a contract may have a prior authorization (PA) requirement on a drug and that requirement would be listed on F&B data. However, if a particular beneficiary has already completed that PA requirement, RTBT would erroneously indicate that PA would be required in order for the plan to pay for the drug as prescribed. Likewise, F&B data could display outdated information about beneficiary-specific out-of-pocket costs based on the applicable phase of the benefit. For example, it would not indicate the out of pocket costs for a particular beneficiary when the deductible has been exhausted.

We proposed a real-time benefit tool (RTBT) to serve as a critical adjunct to the existing SCRIPT and F&B electronic standards. Should prescribers chose to implement electronic prescribing, the existing SCRIPT standard allows them a means to conduct electronic prescribing, while the F&B standard allows a prescriber to see what is on the plan's formulary. However, neither of those standards can convey patient-specific real-time cost or coverage information that includes formulary alternatives or utilization management data to the prescriber at the point of prescribing. We proposed RTBT to be layered on top of F&B data to gain a more complete view of the beneficiary's prescription benefit information. It can augment the information available in F&B because, though F&B is useful, it is a batch mode transaction standard by definition and therefore does not provide real-time information.

As described in more detail in the next section, we believe requiring plans to make one or more RTBTs available to prescribers will lead to higher prescriber use of F&B information during the eRx process. To be eligible for selection by a Part D sponsor, we proposed to require that the RTBT be capable of integrating with at least one prescriber's eRx and EMR system(s) the latter of which will hereinafter be referred to as an electronic health record or EHR for consistency with current Departmental terminology) and providing patient-specific coverage information at the point of prescribing to enable the prescriber and patient to collaborate in selecting a medication based on clinical appropriateness, coverage and cost.

We believe that furthering prescription price transparency is critical to lowering overall drug costs and patients' out-of-pocket costs, and anticipate improved medication adherence, as well as support for the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.

3. Adoption of a Real-Time Benefit Tool

As we explained in the proposed rule (83 FR 62152), the Medicare Part D program allows contracted entities that offer coverage through the program latitude to design plan benefits, provided these benefits comply with all relevant requirements. This flexibility results in variation in Part D plans' benefit design, cost-sharing amounts, utilization management tools (that is, prior authorization, quantity limits, and step therapy), and formularies (that is, covered drugs). We are aware of several Part D prescription drug plans that have begun to offer RTBT inquiry and response capabilities to some physicians to make beneficiary-specific drug coverage and cost data visible to prescribers who wish to use such data at the point-of-prescribing. We have reviewed multiple RTBT software solutions and have found that they are generally designed to provide patient-specific clinically appropriate information on lower-cost alternative therapies through the prescribers' eRx or EHR systems, if available, under the beneficiary's prescription drug benefit plan. However, for those software solutions that are capable of providing such decision support, based on our current experience, we understand that the prescribers will only embrace the technology if the prescriber finds the information to be readily useful. Thus, we stated in the proposed rule that to ensure success, we believe that the Part D sponsor must present prescribers with formulary options that are all clinically appropriate and accurately reflect the costs of their patient's specific formulary and benefit options under their drug benefit plan. In addition, as stated in the proposed rule, those who use plans' current RTBT technology report that prescribers are most likely to use the information available through RTBT transactions if the information is integrated into the eRx workflow and electronic health record (EHR) system. This will allow the prescriber and patient, when appropriate, to choose among clinically acceptable alternatives while weighing coverage and costs. Since eRx is generally performed within the provider's EHR system, integration of the RTBT function within the EHR generally, and the eRx workflow

specifically, appears to be critical for the successful implementation of the technology. However, we recognize that without an industry standard for RTBT, prescribers may be offered multiple technologies, which may overwhelm and create burden for EHR vendors. We also recognized that without a standard, the RTBT tool provided may not be integrated with a prescriber's EHR, thus limiting its utility.

As stated in the proposed rule (83 FR 62152), we are interested in fostering the use of these real-time solutions in the Part D program, given their potential to lower prescription drug spending and minimize beneficiary out-of-pocket costs. Not only can program spending and beneficiary out-of-pocket costs be reduced, but evidence suggests that reducing medication cost also yields benefits in patients' medication adherence. As mentioned in the proposed rule, a 2012 review of studies found that 85 percent of studies demonstrated that increasing patient cost-share for a medication was associated with a significant decrease in medication adherence.[9] This review also revealed that 86 percent of these studies demonstrated that increased medication adherence was associated with improved clinical outcomes. With respect to studies that directly measured the impact of out-of-pocket costs on outcomes, 76 percent found that increased medication out-of-pocket costs was associated with adverse non-medication related outcomes such as additional medical costs, office visits, hospitalizations, and other adverse events. Subsequently published studies continue to reflect similar findings.[10] [11]

Therefore, we proposed that each Part D sponsor be required to implement one or more RTBT capable of integrating with at least one prescriber's eRx and EHR systems to provide complete, accurate, timely, clinically appropriate and patient-specific real-time formulary and benefit information to the prescriber. We also encouraged plans to use RTBTs to promote full drug cost transparency by showing each drug's full negotiated price (as defined in § 423.100), in addition to the beneficiary's out-of-pocket cost information.

We also stated that health care providers using the RTBT should ensure that individuals are aware that information about services or treatment, such as a future prescription, may be disclosed to the plan by the tool, and effectuate the individual's disclosure restriction request by refraining to use the tool in instances in which the patient intends to self-pay in full. We encouraged covered health care providers to discuss with the individual whether the individual desires the prescriber to use the RTBT as doing so will generally eliminate the beneficiary's ability to request disclosure restrictions as the plan will already be in possession of the query data regarding the desire to prescribe something for a specified condition.

We sought comments on our proposal, including the feasibility for plans to meet the proposed January 1, 2020 deadline, and how our proposal may or may not expedite our goal of giving each Part D enrollee and the clinicians who serve them access to meaningful decision support through RTBT. We also sought relevant feedback about RTBT standardization efforts; this includes the planned fulfillment of any milestones that standardization bodies have already met, or are likely to meet in advance of the proposed January 1, 2020 deadline. We noted that we would consider retraction of our rule if we received feedback indicating that it would be contrary to advancing RTBT within Part D, or if a standard has been voted upon by an accredited Standard Setting Organization or there were other indications that a standard would have been available before the proposed 2020 effective date. In such case, we indicated that we would review such standard, and if we find it suitable for the Part D program consider proposal of that standard as a requirement for implementation in our 2021 rulemaking, effective January 1, 2021. We also solicited comments regarding the impact of the proposal on plans and providers, including overall interoperability and the impact on medical record systems. Finally, we solicited comments regarding the impact of the proposed effective date on the industry and other interested stakeholders.

We received approximately 194 comments on this proposal. Following are summaries of the comments we received and responses to these comments.

Comment: Commenters expressed widespread conceptual support for our proposal as a way to accelerate use of electronic Real-time Benefit Tools (RTBT) in the Part D program. These commenters believed that the provision of patient-specific price and coverage transparency at the point of prescribing will enable patients and providers to make more informed decisions about medication therapy.

Response: We thank commenters for their support.

Comment: We received numerous comments relating to the proposed January 1, 2020 implementation date. Although several commenters stated that the 2020 deadline was achievable, the majority of comments expressed concern. Most commenters believed that it would be prudent to delay the implementation date until an industry standard was available with some commenters characterizing the proposed time frame as overly aggressive or unrealistic given the level of effort required to implement RTBT.

Response: These comments have persuaded us that implementing RTBT will take substantial effort and that a 2020 deadline may be too difficult to achieve for those plans that have not yet begun to implement a real time solution. Given the considerable level of effort involved in developing RTBT we are delaying the required implementation date until January 1, 2021. However, given the potential benefits of RTBT, we strongly encourage plans to facilitate earlier use of RTBT when possible and start implementing prior January 1, 2021.

Comment: Many commenters stated that requiring RTBT in absence of an industry standard will impede integration of real-time information into EHRs and eRx systems. Many commenters urged CMS to continue to work with the industry through the National Council for Prescription Drug Programs (NCPDP) to develop a national standard that could meet the Part D program's needs. A few commenters asked CMS to wait a year or two after a standard becomes available in order to give the industry time to implement it. They noted that the cost of integrating multiple RTBT systems into EHRs will be prohibitive and may be passed on to prescribers through fees to the providers. A commenter suggested that CMS require that RTBT be provided to prescribers free of charge.

Response: CMS continues to support interoperability as a way to reduce the burden on health care providers and, as noted in our proposed rule, we would have preferred to consider and name a single industry standard for use in Part D. However as an industry standard is not yet available and we wish to bring the benefits of RTBT to the Part D

[9] Eaddy, M. T., Cook, C. L., O'Day, K., Burch, S. P., & Cantrell, C. R. (2012). How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review. Pharmacy and Therapeutics, 37(1), 45–55.

[10] Hershman, D.L., Tsui, J., Meyer, J., et al. (2014). The change from brand-name to generic aromatase inhibitors and hormone therapy adherence for early-stage breast cancer. Journal of the National Cancer Institute. 106(11), dju319.

[11] Chen SY, Shah SN, Lee YC, et al. (2014). Moving branded statins to lowest copay tier improves patient adherence. American Journal of Managed Care. 20, 34–42.

market as soon as feasible, we are finalizing the provision that each plan implement an RTBT of its choosing. Should a suitable RTBT standard emerge sometime in the future, we can consider it for future rulemaking. We also note that prescribers will be unlikely to use RTBT tools that impose a significant financial burden on their practices. We therefore encourage plans to work with those responsible for their real-time solutions to make sure that they present value to prescribers. The Department of Health and Human Services will continue to engage with standards development organizations, such as NCPDP to encourage the development of standards.

Comment: Several commenters cautioned that holding plan sponsors solely accountable for implementation of RTBT places an unfair burden on the plans and will not result in furthering CMS's goals of widespread use of the technology. Other commenters asked if a Part D sponsor would be considered compliant with this provision if their RTBT only integrates with one EHR.

Response: Though we believe that EHR and eRx providers will adopt well-developed RTBT solutions, we recognize that such acceptance is not always in the Part D plan's control. The proposed and final regulatory language make it clear that the Part D plan is responsible for supporting an RTBT capable of integrating with at least one EHR or eRX system, but stops short of placing the responsibility for widespread prescriber adoption on the plan. We are only requiring compatibility with at least one prescriber's eRx or EHR, since CMS realizes that without an industry-adopted standard, it would be operationally unattainable for a plan to support an RTBT capable of integrating with all EHR or eRx systems that prescribers are potentially using. And, although Part D plans can make sure that the RTBT system is capable of integrating with an EHR or eRx system, the decision to integrate the RTBT with specific prescriber-facing systems is out of the plan's control. Since this rule addresses Part D requirements, we can only address the plan's readiness for integration at this point.

Comment: Some commenters sought guidance about what features and information would satisfy the requirement for a RTBT. Commenters suggested that RTBT include information on the drug that the physician intends on prescribing along with formulary alternatives; they asked if RTBT should include drugs' applicable cash price, beneficiary copayment, any drug utilization controls, or side effects of alternative therapies presented. Some commenters believe that presenting negotiated prices to the prescriber would provide value to the RTBT process, while most commenters believe that that information was either not relevant or was considered proprietary information that should not be widely shared. Some commenters believed that RTBT should include information with respect to all available pharmacy and delivery options while others believe that only the prices of alternatives available at member's selected pharmacy should be populated by the RTBT.

Response: Our proposed regulation indicated that the goal of RTBT is to provide decision support to prescribers by presenting them with relevant details about formulary information and alternatives to the drug which the provider intends on prescribing. Although we encourage the inclusion of the negotiated price in RTBT, we are not mandating it at this time as the majority of commenters opposed its inclusion stating that the information was proprietary and overly confusing. Provider groups opposed its inclusion, since it was outside the scope of their responsibility. However, we believe that RTBT must include some minimal data points that will enable a prescriber and patient to make informed medication choices at the point of prescribing. These include benefit information about the drug which the provider intends on prescribing, enrollee cost-sharing information, and comparable information on formulary alternatives (meaning those medications that may have a different copayment or coinsurance amount than the medication about to be prescribed but may have the same therapeutic efficacy). The benefit information should include patient-specific utilization requirements (such as prior authorization or step therapy requirements) that have yet to be satisfied at the time when the prescription is written, and copayment or coinsurance (or negotiated price values if included) at the patient's selected pharmacy.

Comment: Some commenters expressed concerns that the data populated in the RTBT would not be reliable, that the data would be inaccurate or that it would be used for purposes other than to provide decision support to the prescriber. Commenters stated that existing real-time solutions vary in their functionality and reliability. One provider group pointed out that prescribers are already seeing that some of the RTBT systems are not providing useful information. They report that these systems are causing more effort on the part of the prescriber without providing useful decision support. Other providers noted that the quality of the information provided by multiple vendors is variable, and suggested that CMS assess the outcomes of the alternative vendors.

Response: CMS expects that data presented through RTBT will be patient-specific, timely, and accurate. Part D plans must make sure that they comply with these requirements. We are unsure what commercial purposes were of concern to commenters and how they would adversely impact the intended functionality. Should CMS become aware that RTBTs are being used in ways that are contrary to the Part D program goals, we will address the issues as they arise. Further, we believe that Part D plans are in the best position to assess the effectiveness of the RTBT solutions, since they have a financial stake in ensuring that their enrollees have access to the most cost-effective medications. We expect that widespread adoption of RTBT will, over time, facilitate improved functionality and administrative ease of using the tools in clinical practice. However, if such concerns are not mollified, we would expect that EHR vendors would offer feedback to the plans.

Comment: A few commenters suggested that we refer to RTBTs using other terms, such as real-time pharmacy benefit check or real-time pharmacy benefit transaction to more clearly describe our proposal. A commenter requested that we refer to the technology as a benefit check and not a tool.

Response: We understand that some terms may be clearer to certain readers. However, the ubiquity of the term RTBT leads us to believe that it is the correct term to use. In addition, the suggested terms were sufficiently close to our proposed term that we are convinced that RTBT is an accurate description of our regulatory requirement.

Comment: We received a number of comments objecting to our proposal that providers receive explicit patient consent before reviewing RTBT solutions. Commenters explained to us that requiring affirmative consent would result in providers having to modify their workflow and systems to capture such explicit consent. These systematic changes would require at least 18 months to adopt, implement, test, and remedy any issues. Educating providers across the country on this requirement and implementing the system changes would take at least another three months, which calls into question the ability to fulfill this requirement prior to January 1, 2020. Though one commenter

appreciated the proposed level of protection, all other commenters who addressed the issue stated that the proposed requirement would be a serious obstacle to the real-time process. For example, making system changes that normally require at least 18 months to make, within less than 6 months would require the hiring of significant amounts of new staff and put a burden on their systems to implement prior to the January 1, 2020 deadline.

Response: We are committed to ensuring that RTBT implementation happens as smoothly as possible. The RTBT regulation requires that each Part D plan implement one or more real-time benefit tools, but does not specify the circumstances under which a prescriber should use the technology. We expect that prescribers will only use RTBT when the information provided is useful. As the intent of the RTBT is to help the clinician know if a medication will be covered under a patient's prescription benefit coverage, we do not expect that prescribers will use the tool in those rare instances when a patient has expressed a desire to buy the medication outside of the insurance benefit. Yet, given the importance of protecting an individual from unauthorized disclosure of health information, we considered requiring patient consent before the RTBT was being used just to make sure that patients are fully cognizant that RTBT will be used.

However, on further reflection, under the current RTBT scheme, we believe that requiring that patients provide explicit affirmative consent before each use of an RTBT is unnecessary. In most instances, we expect that the choice about what prescription to prescribe will happen when a beneficiary is present, because the current ePrescribing standard requires the beneficiary to choose where the prescription is to be sent. This means they will be aware that their data will likely be transmitted to parties other than the prescriber. Furthermore, beneficiaries have the opportunity to ask their prescribers about what data is being sent over to the pharmacy.

We conducted more detailed research into how RTBTs would function in the Part D context, and we discovered that after the prescriber finishes consulting with the RTBT, they typically transmit the prescription to the pharmacy electronically. If the enrollee decides to private pay at a pharmacy, the pharmacy is required to send a failed claim notice if a beneficiary decides to pay for the prescription out of pocket, rather than all the information about the prescribed medication. This failed claim notice satisfies the § 423.120(c)(3) requirement for pharmacies to submit claims to the Part D sponsors or its intermediary whenever the Part D member ID card is presented or is on file at the pharmacy, which is a requirement without RTBT use. Thus, we encourage providers to discuss with the individual whether the individual desires to self-pay as after the prescriber uses the RTBT the patient will no longer be able to withhold information about the prescription from their plan under 45 CFR 164.522(a)(1)((vi) (allowing the beneficiary to request disclosure restrictions if they pay for their prescription).

After reviewing the comments, we weighed these potential privacy concerns against the potential disruptions to effective adoption of RTBT raised by commenters. Especially since pharmacy benefit information is generally already available to prescribers and pharmacies under typical patient interactions, we believe that RTBT use will fall within the category of health care treatment disclosures making the disclosure of health care data generally permissible without patient authorization. Nonetheless, we encourage prescribers to use RTBT judiciously and must always allow an individual enrolled in a Part D plan to instruct a prescriber not to use the system for any or all prescriptions, and prescribers should heed that instruction.

Comment: Several commenters suggested that CMS work with the Office of the National Coordinator for Health Information Technology (ONC) to develop incentives for integration of RTBT products into EHRs.

Response: CMS thanks the commenters for this suggestion. However, we do not believe that these incentives are required. Based on our research, we believe many EHRs are moving to integrate RTBTs into prescribers' works flows. In addition, since RTBTs are variable in their functionality it would be difficult for ONC to incentivize use of RTBT until an industry standard is implemented and tested.

Comment: A few commenters suggested that the F&B standards are no longer necessary and others asked us to clarify the role that the F&B standard should play in the future.

Response: In our proposed rule we clarified that F&B remains an important component of the Part D electronic prescription standard and plans must continue to support it. However, the future interaction between RTBT and the F&B standards are out of scope of this regulation.

Comment: A commenter requested that long-term care facilities be exempt from having to use a RTBT.

Response: CMS intends this regulatory requirement to apply solely to Part D plans. Although we encourage the use of RTBTs among providers, guidance for providers is outside of the scope of this final rule.

Comment: A few commenters suggested that CMS require Part D plans to develop a patient tool to provide prescription cost information to patients in addition to, or instead of, the prescriber facing tool we proposed.

Response: We appreciate the comments. However, our proposal was for a prescriber facing tool. A patient tool is outside the scope of this rule.

We are finalizing the proposal for each Part D plan to implement an RTBT of its choosing, effective January 1, 2021. We strongly encourage plans to start implementing this provision prior to 2021. We are removing the proposed requirement that covered health care providers obtain explicit beneficiary consent prior to using the RTBT.

D. Part D Explanation of Benefits (§ 423.128)

Section 1860D–4(a)(4)(A) of the Act requires Part D sponsors to furnish to each of their enrollees a written explanation of benefits (EOB) and, when the prescription drug benefits are provided, a notice of the benefits in relation to the initial coverage limit and the out-of-pocket threshold for the current year. We codified this EOB and notice requirement at § 423.128(e) by requiring the Part D EOB to include specific information written in a form easily understandable to enrollees. Part D sponsors must provide enrollees with an EOB no later than the end of the month following any month in which the enrollee utilized their prescription drug benefit.

Information about negotiated price changes for each of the prescription drugs covered for a beneficiary, including information about lower cost therapeutic alternatives, is not required to be in the EOB under the current regulation. Based on comments received, we are finalizing our proposal that sponsors must include negotiated price increases and lower cost therapeutic alternatives in their beneficiaries' Part D EOBs.

The Part D EOB is one of the principal documents that beneficiaries can rely on to understand where they are in the benefit phases and their changing out-of-pocket costs throughout the year. This document is provided to beneficiaries every month for the immediately preceding month that the

Part D benefit is used. As a retroactive monthly report, the EOB is the means by which beneficiaries can monitor their benefit utilization and prescription costs on a regular and frequent basis.

We received approximately 79 comments on this proposal. We have included a summary of the comments and our responses.

Comment: Commenters unanimously supported increasing drug pricing transparency for beneficiaries.

Response: We thank the commenters for their support. Lowering prescription drug costs is of critical and immediate concern to beneficiaries and the Administration.

Comment: Many commenters voiced concern that including drug pricing information on the EOB would be ineffective for the following reasons: (1) Its retroactive nature makes the price information not meaningful or actionable for the beneficiary; (2) its timing during a benefit year makes it not actionable by the beneficiary because of limitations on enrollment changes; (3) the nature of acute prescriptions means the information is not useful for short-term medications; and (4) this information is not discernable without being read with the prescriber. While asserting different reasons, these commenters generally agreed that the drug cost information would not be meaningful, actionable or useful for the beneficiary due to the enumerated circumstances.

Response: Despite the EOB being a retroactive report, the information provided will allow beneficiaries to engage with their prescriber at their next point of care and discuss their choices in medication. This may lead to beneficiaries switching to a lower cost drug. Even if a beneficiary is not able to change plans mid-year based on the EOB information, the information may still be useful to the beneficiary in the situation we just described—to engage with their prescriber about their medication choices within their existing plan. To address the comments concerning acute prescriptions, we note that on the EOB as it is written today an acute prescription filled one time is not carried over on multiple EOBs. However, we believe there is no harm in including a negotiated price increase and a lower cost alternative for an acute prescription claim, when available. This additional information empowers the beneficiary and provides them with a holistic approach when reviewing their Part D benefit. We believe this, in turn, will ultimately spark dialogue between the beneficiary and their prescriber(s) about lower cost therapeutic alternatives in the future. Thus, we conclude that the EOB will empower the beneficiary with information about drug costs that the beneficiary does not currently have. This initiative will support CMS' commitment to promoting drug price transparency in the Medicare Part D program.

Comment: Many commenters suggested that drug pricing information will be more useful if provided through a prospective tool, such as a real-time benefit tool (RTBT) at the time of prescribing, rather than the EOB. They highlighted that beneficiary knowledge would be more accurate with real-time information on which decisions could be made with their prescriber at the point of care.

Response: Implementing a real-time benefit tool for beneficiaries is an effective way to provide beneficiary-specific information about drug costs (for additional discussion about RTBTs, please see the previous section of this final rule). However, the EOB provides a different method of communicating drug pricing information directly to beneficiaries. Both are valuable price transparency tools.

Comment: Multiple commenters were concerned that displaying the percentage change in negotiated price would not be a helpful metric for beneficiaries when evaluating their Part D benefits. The commenters asserted that the negotiated price is not the correct price to display as it may not change throughout the benefit year, or if it does change, it may not impact the cost-sharing for the beneficiary. However, commenters did not provide alternative pricing that would be of greater impact to the beneficiary.

Response: We do not agree and believe providing this information to the beneficiary is valuable. The negotiated price information required to be included in the EOB is the percentage increase in the total cost for each prescription, when there is an increase, since the first claim of the current benefit year for each prescription drug claim in the EOB, which would display under each medication. Currently and under this new requirement, the EOB would still display the price paid by the beneficiary, plan and any other payer. While increases in negotiated prices may or may not be directly proportionate to a change in a beneficiary's cost-sharing for a variety of reasons, we believe that ensuring beneficiary access to information about changes in drug pricing in the context of their specific use of the benefit will allow them to better assess the value they receive from their Part D benefit.

Comment: Multiple commenters pointed out the Part D EOB is meant to be a brief document but is lengthy and complex. As such, these commenters pointed out that including additional details would only make the document longer, thereby paradoxically making a beneficiary less inclined to read the document thoroughly. Therefore, our EOB proposal would defeat the intent of requiring additional information in it. Some commenters also mentioned that the EOB is not the appropriate document to disseminate the pricing information and will inevitably lead to increased beneficiary confusion. Commenters suggested improving the functionality of the Medicare Plan Finder and other beneficiary-facing tools to convey this information.

Response: We find the current structure of the EOB to be well-suited to include additional information on individual prescription drug claims. Other beneficiary materials are delivered on an annual basis, and are geared toward assisting Part D beneficiaries make enrollment decisions whether to remain with their current prescription drug plan or switch to another. By including these negotiated price increases and lower cost alternatives on a monthly basis in EOBs, beneficiaries will be in greater control of their prescription drug benefits and, with their prescribers, will be able to make more informed decisions about their care. Beneficiaries will have documented drug pricing information and will be able to seek assistance from their prescribers, pharmacists, SHIPs, and family members.

Comment: A few commenters believed that the proposed rule did not provide sufficient definition of a lower cost therapeutic alternative.

Response: The lower cost therapeutic alternatives will be determined by the sponsor based on its formulary, not by CMS. As such, any drug may be identified as a lower-cost therapeutic alternative for another drug if a Part D sponsor reasonably determines it to be so. As stated in the preamble of the proposed rule, lower-cost therapeutic alternatives (meaning drugs with lower cost-sharing or lower negotiated prices) will not be limited to therapeutically-equivalent generic drugs if the original prescription fill is for a brand drug.

Comment: A few commenters wrote that the estimated implementation cost with respect to this proposal was understated in the proposed rule. These commenters also provided an estimate of their increased costs, citing that the programming would be more than CMS estimated, and also that these changes would contribute to increasing the length of the EOB document, thereby increasing printing and mailing costs for

plans. Commenters did not provide alternative solutions for including the drug pricing information and/or lower-cost therapeutic alternatives.

Response: We thank the commenters for providing us with their cost estimates. We have revised the estimated cost to implement the EOB updates; however, we still believe that these updates are necessary for adhering to the Administration's goal of drug price transparency and lowering beneficiary out-of-pocket costs. We will work with stakeholders to improve the model EOB to include this information in the most efficient and effective manner for beneficiaries and sponsors.

Comment: Many commenters wrote that amending the Part D EOB to include this information for the upcoming contract year, beginning January 1, 2020, was unreasonable and too burdensome.

Response: We thank the commenters for their concerns, and acknowledge that there will be administrative and programmatic costs to implement these changes. Given the level of effort involved in updating the Part D EOB, we are delaying the implementation date until January 1, 2021. However, given the potential benefits of these changes, we strongly encourage plans to begin implementing this requirement prior to January 1, 2021.

After consideration of comments received, we are finalizing the reassignment of paragraphs (e)(5) and (e)(6) of § 423.128(e) as paragraphs (e)(6) and (e)(7) to add a new paragraph (e)(5) that will require sponsors to include information about negotiated price increases, if any, and lower-cost therapeutic alternatives in the Part D EOBs. Based on comments received, as to information about negotiated drug price increases, we will require that Part D sponsors include the cumulative percentage increase, if any, in the negotiated price since the first claim of the current benefit year for each prescription drug claim in the EOB.

Second, CMS will require that Part D sponsors provide information about drugs that are therapeutic alternatives with lower cost-sharing, from the applicable approved plan formulary for each prescription drug claim, when such therapeutic alternative are available as determined by the plan. Also, the plan may include therapeutic alternatives with the same copayments if the negotiated price is lower.

Part D sponsors will be permitted and encouraged by CMS to take into consideration relevant beneficiary-specific information, such as diagnosis, the indication for the prescription and completed step therapy or exception requests, when providing formulary therapeutic alternatives in the EOB that have lower cost-sharing. For example, if a plan is aware that a beneficiary has already fulfilled step therapy requirements and the beneficiary's physician has attested that the beneficiary is not able to tolerate a formulary alternative, that formulary alternative does not need to be included on the EOB for that beneficiary.

E. Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, 422.619, 422.629, 422.631, 422.633)

1. Medicare Advantage and Step Therapy for Part B Drugs: General Requirements

In a HPMS memo released August 7, 2018,[12] CMS announced that under certain conditions beginning in contract year 2019, MA plans may use utilization management tools such as step therapy for Part B drugs; such utilization management tools, including prior authorization, can be used by MA organizations to both prevent overutilization of medically unnecessary health services and control costs. CMS proposed requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs and affirmed, based on our reinterpretation of the applicable statute, MA plans' authority to implement appropriate utilization management tools, including prior authorization, for managing Part B drugs in a manner to reduce costs for both enrollees and the Medicare program. Under Part B, traditional Medicare generally pays based on a statutory formula—average sales price plus a 6-percent add-on—for drugs and biological products that are not usually self-administered, such as injections and infusions. We stated in the proposed rule how we believe there is minimal negotiation between MA plans and drug manufacturers to reduce the price of these drugs. Prior to the August 7, 2018, HPMS memo and subsequent FAQs, [13] CMS interpreted existing law to prohibit MA plans from using step therapy for Part B drugs because there was a concern that such utilization management tools could have created an unreasonable barrier to coverage of and access to Part B benefits that MA plans must provide under the law. However, as we explained in the proposed rule, CMS recognizes that utilization management tools, such as step therapy, can provide the means for MA plans to better manage and negotiate the costs of providing Part B drugs. Based on this and for the reasons explained in more detail in this final rule, CMS rescinded the prior guidance prohibiting step therapy for Part B drugs and services in MA, and we are finalizing our proposal to allow MA plans to use step therapy for Part B drugs, subject to certain parameters. In the proposed rule, we explained how we believe the flexibility to use step therapy programs for Part B drugs would considerably assist MA plans in negotiating on behalf of enrollees to get better value for Part B drug therapies. Using internal bid data, excluding MA employer group plans, CMS estimates $9 billion in spending by MA plans for Part B drugs furnished during contract year 2018.

As discussed in the proposed rule, we believe that these tools will better enable MA organizations to take steps to ensure that MA plans and MA enrollees pay less overall or per unit for Part B drugs which could result in lower MA capitation payments by the government to MA organizations and lower average sales prices for Part B drugs, on which Medicare FFS payments for such drugs are based, while also maintaining access to medically necessary Medicare-covered drugs and services. These goals—reducing costs across the Medicare program while ensuring access to medically-necessary Medicare-covered benefits—underlie this final rule. We proposed adding a new regulation, at § 422.136, entitled ''Medicare Advantage and Step Therapy for Part B Drugs.''

Sections 1852(c)(1)(G) and (c)(2)(B) of the Act, and the MA regulations at § 422.4(a)(1)(ii) expressly reference a MA plan's application of utilization management tools, like prior authorization and other ''procedures used by the organization to control utilization of services and expenditures.'' This indicates that MA plans are not prohibited by the statute from implementing utilization management tools such as step therapy. In light of this, we proposed to define step therapy in § 422.2 and adopt requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs. We solicited comments concerning the impact that allowing step therapy for Part B drugs will have on MA plans and enrollees.

We clarified that for contract year 2020 and subsequent years, coupling

[12] Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage (August 2018). *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.*

[13] Available online at: *https://dpapportal.lmi.org/DPAPMailbox/Documents/Part%20B%20Step%20Therapy%20Questions%20FAQs_8-29-18.pdf.*

drug management coordination with rewards and incentives was not part of our proposal. While MA plans may still offer rewards and incentives programs, savings realized from Part B step therapy must be reflected in the plan's bid, as such savings would reduce the revenue necessary for MA plans to provide basic benefits that MA plans must furnish enrollees and supplemental benefits that MA plans may opt to offer. Additional Part C rebate dollars associated with the lower bid, as with all Part C rebate dollars, must be used to provide supplemental benefits and/or lower premiums for the plans' enrollees.

We noted that existing requirements in §§ 422.112(b) and 422.152 for care coordination activities are sufficient to promote positive health outcomes for both drugs and services; we relied on this and did not propose text at § 422.136 that an MA plan must offer a drug management program. We also recognized that we issued the August 7, 2018 memo that announced our reinterpretation of the statute after bids were submitted for the 2019 plan year and therefore expected plans to utilize the drug management program as a means to pass 2019 savings on to enrollees through rewards and incentives. Because we are finalizing this rule prior to the 2020 bid deadline, MA plans must include savings from implementing Part B step therapy in their bids for 2020 and future years, as the savings will affect the revenue necessary to provide benefits (see § 422.254).

We acknowledged in the proposed rule the potential for utilization management tools like step therapy to create administrative burden and process challenges for network providers. We also explained how, in light of that, we expect MA plans to work closely with the provider community and to adopt best practices that streamline requirements and minimize burden. We also encouraged continued development and advancement of electronic prior authorization processes to more efficiently administer this process. We solicited comment whether our proposed regulation text imposing education and information responsibilities in combination with existing regulations on care coordination are sufficient to ensure that MA organizations specifically address step therapy programs for Part B drugs as part of those care coordination responsibilities and if we should finalize a provision in § 422.136 that addresses the administrative burden imposed on network providers by MA plans.

We proposed and this final rule adopts a number of safeguards that ensure enrollees have timely access to all medically necessary Medicare Part B medications. MA plans will be required to administer the existing organization determination and appeals processes under new time frames that are similar to the timeframes applicable in Part D for coverage determinations; enrollees will be able to seek organization determinations in advance—or when the MA (or MA–PD) plan first starts the step therapy protocol for the enrollee—if the enrollee (typically after consultation with their health care provider) believes they need direct access to a Part B drug that will otherwise only be available after trying an alternative drug. We explained that MA plans will adjudicate these organization determinations based on medical necessity criteria. If an enrollee is dissatisfied with the plan's organization determination, the enrollee has the right to appeal. We noted that CMS monitors organization determination and appeals activity through the audit process and regular discussions with the Part C Independent Review Entity (IRE) to ensure enrollee requests are appropriately evaluated and processed within applicable timeframes.

As discussed in the proposed rule, our existing disclosure requirements at § 422.111 would require MA plans that apply step therapy to Part B drugs to disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) (when initially adopted or subsequently changed) and Evidence of Coverage (EOC) documents. In the ANOC, this information must be included under the Changes to Benefits and Costs for Medical Services. In the EOC, this information must be included in the Medical Benefits Chart under ''Medicare Part B prescription drugs.'' Under existing requirements at § 422.202(b), MA plans must establish policies and procedures to educate and fully inform contracted health care providers concerning plan policies on utilization management, which will include the plan's step therapy policies. We proposed to also include a requirement at § 422.136(a)(2) for plans to establish policies and procedures to educate and inform health care providers and enrollees specifically concerning its step therapy policies. We noted in the proposed rule that preferred provider organization plans (PPOs) are required, as part of the definition of a PPO at section 1852(e)(3)(A)(iv)(II) of the Act and under the MA regulation at § 422.4(a)(1)(v)(B), to reimburse or cover benefits provided out of network; while higher cost sharing is permitted, PPOs are prohibited from using prior authorization or preferred item restrictions in connection with out of network coverage. As such, PPOs must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization or step therapy requirements. We solicited comment whether the final rule should include a specific regulatory provision clarifying this issue.

We proposed at § 422.136 (a)(3), that MA plans will be required to use a Pharmacy and Therapeutics (P&T) committee to review and approve step therapy programs (meaning policies and procedures); we explained that this is necessary to ensure medically appropriate implementation of step therapy for Part B drugs. We explained how we believe the burden of this requirement will be limited because MA–PD plans and MA plans would be authorized to use any existing Part D P&T committees established by the MA–PD plan (or an MA–PD plan under the same contract as an MA-only plan) to comply with part 423 requirements for the Part D benefit. The Paperwork Reduction Act listing for P&T committee record keeping is OMB Control Number 0938–0964. We noted that P&T committee decisions are not public information. We proposed, in the introductory text of proposed paragraph (b), that a MA organization must establish or utilize an existing P&T committee prior to implementation of a Part B step therapy program so that the P&T committee reviews Part B step therapy programs. In addition, we noted in the proposed rule how we continued to actively consider expanding the role of MA P&T committees. Therefore, we solicited comments on our proposal that MA plans with Part B step therapy programs will be required to have P&T committees and, in addition, whether the requirement for this MA P&T committee should be expanded to all MA plans that have any utilization management policy (such as prior authorization or dosage limits) applicable to Part B drugs, and whether there are other options that will meet the policy goal of ensuring that Part B step therapy programs are medically appropriate underlying the P&T committee proposal. We proposed to codify P&T committee requirements for MA plans in § 422.136(b).

Our proposal for the P&T committee mirrors the Part D requirements for such committees currently codified at

§ 423.120(b) with regard to membership, scope, and responsibilities. We explained our position that existing Part D P&T requirements at § 423.120(b) are adequate to ensure MA plans implement step therapy for Part B drugs that is medically appropriate. We note that if necessary we may release subregulatory guidance concerning application of the P&T committee requirements in the context of Part B drugs.

We proposed requirements in § 422.136(b) that would be consistent with Part D requirements for a P&T committee. Specifically, we proposed that the majority of members comprising the P&T committee will be required to be practicing physicians or practicing pharmacists. The committee will be required to include at least one practicing physician member and at least one practicing pharmacist; these specific individuals will be required to be independent and free of conflict with the MA organization, the MA plan, and pharmaceutical manufacturers. In addition, the plan will be required to include at least one practicing physician member and one practicing pharmacist who are experts in the care of elderly and disabled persons. We also encourage MA plans to select P&T committee members representing various clinical specialties (for example, geriatrics, behavioral health) to ensure that all conditions are adequately considered in the development of step therapy programs. We proposed provisions for the responsibilities and scope of the P&T Committee at § 422.136(b)(4) through (11) that would mirror the current regulation text applicable to Part D P&T Committees under § 423.120(b)(1)(iv) through (xi), with minor revisions to tailor the proposed MA regulation to the Part B drug step therapy programs offered by MA plans. We reiterated in the proposed rule how our proposal was to substantially align the requirements of a P&T committee reviewing Part B drugs with Part D requirements because the Part D requirements have proved sufficient in ensuring that plans implement medically appropriate step therapy and utilization management protocols in Part D.

CMS proposed, as a beneficiary protection, to limit Part B step therapy requirements to only new starts of Part B drug therapies. CMS explained in the proposed rule that we believe new step therapy requirements should not disrupt ongoing Part B drug therapies for enrollees. In order to ensure that step therapy requirements do not disrupt ongoing Part B drug therapies, we proposed under § 422.136(a)(1), that step therapy may not disrupt enrollees' ongoing Part B drug therapies. Specifically, we proposed that step therapy only be applied to new prescriptions or administrations of Part B drugs for enrollees who are not actively receiving the affected medication; we proposed to require MA plans to use a lookback period of 108 days, in order to be consistent with established Part D policy with respect to transition requirements for new prescriptions, to determine if the enrollee is actively taking a Part B medication. In the proposed rule, we explained how the Part D lookback period was created with clinical and pharmaceutical input and that CMS believed the same criteria were appropriate to use in setting a lookback period for Part B drugs. We proposed that an MA plan would have to use the lookback period when an enrollee elects a new MA plan (regardless of whether previously enrolled in a MA plan, traditional Medicare, or new to Medicare) to determine whether the enrollee has taken the Part B drug (that will otherwise be subject to step therapy) within the past 108 days.

We explained that under our proposal, if the enrollee is actively taking the Part B drug, such enrollee will be exempted from the plan's step therapy requirement concerning that drug. We proposed to allow MA plans flexibility in implementing step therapy for Part B drugs within specific parameters. Specifically, we proposed that MA plans would be able to use a step therapy program to ensure that an enrollee who is newly diagnosed with a particular condition will begin treatment with a cost-effective biological product licensed under section 351(k) of the Public Health Service Act or generic medication before progressing to a more costly drug therapy if the initial treatment is ineffective or if there are adverse effects. We did not propose that § 422.136 specifically address the standard for exemptions or movement within a step therapy program because, as we explained in the proposed rule, we interpret the MA plan's responsibility to provide all medically necessary covered services and items covered under the original Medicare program to mean that ineffectiveness or adverse effects of a treatment required in a step therapy program would be sufficient basis to grant an exemption or move an enrollee to a higher step in the protocol.

Consistent with existing Part D guidelines, we proposed at § 422.136(c) to permit MA plans to require an enrollee to try and fail an off-label medically accepted indication (that is, an indication supported by one or more citations in the statutory compendia) before providing access to a drug for an FDA-approved indication (on-label indication). However, we proposed that using off-label drugs in step therapy will only be permitted in cases where the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers best practices. We solicited comments on our proposal to permit MA plans to use off-label drugs in a Part B step therapy program only when such drugs are supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices.

We also proposed, at § 422.136(d), that a step therapy program must not include as a component of a step therapy protocol or other condition or requirement any drugs not covered by the applicable MA plan as a Part B drug or, in the case of an MA–PD plan, a Part D drug. Specifically, we proposed § 422.136(d) to prohibit an MA organization from using a non-covered drug as a step in the step therapy program (that is, as a condition to coverage). Under our proposal, each step in a step therapy program would have to be another drug covered by the MA plan (another Part B drug) or MA–PD plan (another Part B drug or a Part D drug) to ensure that step therapy programs are not, intentionally or unintentionally, barriers to services that must be covered by the MA plan pursuant to section 1852 of the Act. Therefore, at § 422.136(d), we proposed regulation text to clarify that only Medicare covered Part B drugs (plus for MA–PD plans, Part D drugs) may be used in a step therapy program. We explained in the proposed rule that we intended to permit an MA plan to require one Part B drug be used before a different Part B drug and to permit MA plans that also offer prescription drug coverage (also known as ''MA–PD plans'') to use step therapy to require a Part D drug therapy prior to allowing a Part B drug therapy because the Part D drug will be covered by the plan.

Additionally, we noted in the proposed rule that the combination of our proposal to specify additional exceptions to the formulary requirements for protected class Part D drugs (section II.A.1 of the proposed rule, ''Broader Use of Prior Authorization for Protected Class Part D Drugs'') and our proposal for step therapy for Part B drugs (section II.F. of the proposed rule, ''Medicare Advantage and Step Therapy for Part B Drugs'') would allow MA–PD plans to require use of a Part B drug before a Part D drug as part of a step therapy program. Our

proposal about Part D protected class drugs is being finalized with modifications in this final rule. As noted previously, we are permitting the use of step therapy for protected class Part D drugs (other than antiretrovirals) for enrollees that are not already using the drug for a protected class indication (that is, ''new starts''), and therefore MA–PD plans may, starting in 2020, require step therapy of Part B drugs before Part D drugs for the protected classes as well, consistent with the requirements we are adopting at § 423.120(b)(2)(vi)(C). MA–PD plans that use cross-benefit step therapy programs must ensure that these requirements are clearly outlined in the Part D prior authorization criteria for the affected Part D drugs and are otherwise consistent with Part D requirements. We also stated in the preamble, as is required for all other drug categories or classes in Part D coverage, that Part D step therapy requirements will be subject to CMS review and approval, as part of our annual Part D formulary review and approval process, which includes formulary tier review, and relative to prior authorization and step therapy, restricted access, step therapy criteria, prior authorization outlier, and prior authorization criteria reviews.

We also solicited comments on the following aspects of our proposal:

- The restriction of step therapy to new starts of Part B drugs.
- The new requirement for a P&T committee for MA plans that implement step therapy and the use of that P&T committee.
- The prohibition on using non-covered drugs, and in certain circumstances, off-label drugs, in the step therapy programs.

We thank commenters for helping inform CMS's Medicare Advantage and Step Therapy for Part B drugs policy. We received approximately 153 comments on this proposal; we summarize them and our responses follow:

Comment: Some commenters strongly encouraged CMS to issue operational guidance for allowing step therapy for Part B drugs more quickly following the finalization of the Medicare Advantage and Step Therapy for Part B drugs final rule. These commenters argued that quickly finalizing this rule will allow for better compliance with CMS requirements.

Response: CMS appreciates commenters concerns regarding finalizing this rule and issuing operational guidance in a timely manner. The step therapy regulation we are finalizing here will be effective for plan years and coverage beginning on and after January 1, 2020. We will continue to work with MA stakeholders to ensure that any additional Part B step therapy program guidance, which may follow the rule, is timely, transparent, and geared to producing positive health care outcomes for enrollees.

Comment: Many commenters expressed concern that the step therapy for Part B drugs proposal would lead to negative health outcomes as a result of restricted access to care or delayed care. Commenters also expressed concern that CMS has not demonstrated how it will ensure that plans' step therapy policies are clinically appropriate and do not impede access to needed care. Some commenters urged CMS to study the effectiveness of step therapy on cost savings and its impact on health outcomes before finalizing this policy. A few commenters supported allowing step therapy as a cost effective utilization management tool.

Response: CMS appreciates commenters' feedback regarding the impact of this rule, including those who expressed concern that the Part B step therapy program will lead to negative health outcomes as a result of restricted access to care or delayed care. MA plans must comply with the statutory requirement that they provide enrollees with access to all medically necessary Part A and Part B benefits available in Original Medicare, as provided at section 1852(a)(1) of the Act. This final rule does not change or limit this requirement for MA plans. Accordingly, step therapy or other utilization management policies may not be used as an unreasonable barrier to deny coverage of medically necessary services or as a means to eliminate access to medically necessary Part B covered benefits. CMS has included a number of safeguards to ensure that access to medically necessary Part B services is maintained for MA enrollees who are subject to step therapy for Part B drugs. We note that consistent with MA regulations at 42 CFR 422.206, MA plans may not restrict the ability of a treating physician to advise enrollees about their treatment options. Thus, if a treating physician believes, based on their own medical judgment, that an MA enrollee should not be subject to step therapy for a Part B drug for medical reasons, the health care provider can furnish advice consistent with that and advocate on behalf of the enrollee. The treating physician can request an organizational determination under § 422.566(c) and the MA plan will make a formal determination of medical necessity that if denied, will require that the enrollee be notified of their right to a timely appeal. Pre-service reconsiderations of a plan denial may also be requested by a treating physician under § 422.578.

CMS appreciates commenters' recommendations that more study is needed to ensure that enrollees' health is not compromised. Although we are finalizing the step therapy policies, we will continue to monitor MA plan's use of Part B step therapy policies and will conduct oversight to ensure compliance with these rules. CMS will conduct audits that target pre-service organization determination and appeal cases related to requests for Part B drugs, monitor the Complaints Tracking Module (CTM) for access concerns, and closely monitor the implementation and operation of step therapy programs.

We believe that this final rule also contains adequate protections to ensure that step therapy policies are clinically appropriate and do not impede access to medically necessary care. This final rule will require that P&T committees have a majority of members who are practicing physicians or pharmacists in order to bring adequate clinical experience to the committee. The P&T committee requirements finalized at § 422.136(b)(2) require that P&T committee members must be free of conflict relative to the MA organization, the MA plan, and pharmaceutical manufacturers. Further, pursuant to § 422.136(b)(5), clinical decisions of the P&T committee must be based on the strength of scientific evidence and standards of practice, including assessing research literature and data as appropriate. We believe P&T committee requirements finalized at paragraph (b)(6) will help ensure MA plans' Part B step therapy policies are based on objective decisions that meet the needs of enrollees, by considering whether a Part B drug included in a step therapy program has therapeutic advantages in terms of safety and efficacy, while allowing practicing providers a role in developing and implementing Part B step therapy program guidance. This final rule, at § 422.136(b)(8), requires an annual reevaluation and analysis of the step therapy protocols and procedures. P&T committees must, pursuant to § 422.136(b)(9), document their decisions, which we believe must show how the committee complies with the regulation. These requirements will ensure that P&T committees' decisions with respect to Part B step therapy are conducted in a manner that is documented, evidenced-based, free from conflict of interest, and subject to CMS oversight. Finally, CMS will hold plans' P&T committees accountable by requesting written documentation, as

needed, regarding the development and revision of step therapy programs.

Comment: Some commenters expressed concern that MA plan step therapy policies would focus more on cost (as opposed to clinical appropriateness), interfere in personalized care, and interfere with provider autonomy. A few commenters expressed concern that this proposal would lead to increased administrative burden, which will frustrate physicians and cause them to leave the practice of medicine.

Response: CMS acknowledges the potential for step therapy programs to create administrative burden and process challenges for network providers. We remind readers that MA PPO plans may not impose limits like prior authorization or step therapy on benefits furnished by out-of-network providers. In a previous rulemaking (70 FR 4616 through 4617), CMS interpreted section 1852(e)(3)(A)(iv) of the Act and 42 CFR 422.4(a)(1)(v)(B) as precluding PPO plans from requiring enrollees to obtain as a condition of coverage pre-certification or pre-authorization, or a coverage determination before receiving a covered service out-of-network. The requirement that both local and regional PPO plans cannot require prior authorization as a condition for out-of-network coverage of services is also described in CMS guidance in Chapter 4, § 110.4 of the Medicare Managed Care Manual. We expect MA plans to work closely with providers to adopt best practices that streamline operations and minimize burden. We consider such efforts consistent with the obligation, under § 422.202, of MA plans to establish a mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures. We also encourage continued development and advancement of electronic prior authorization processes to more efficiently administer Part B step therapy programs.

With respect to clinical concerns and interference with provider care, we reiterate that step therapy or other utilization management policies may not be used as unreasonable means to deny coverage of medically necessary services or to eliminate access to medically necessary Part B covered drugs. The requirements in this rule, in combination with current MA program regulations, ensure access to Part B drugs and limit the potential for step therapy policies to interfere with medically necessary care. Specifically, MA plans must ensure access, consistent with the requirements at § 422.100(a) and § 422.101(a) and (b), to all medically necessary Part A and Part B benefits that are available in Original Medicare. Further, we are not changing or eliminating the existing requirements that MA plans must comply with national and local coverage determinations and guidelines. Organizations have been and remain subject to the MA regulations and must comply with national and applicable local coverage determinations. Step therapy protocols cannot be stricter than an NCD or LCD with specified step therapy requirements. Based on how §§ 422.100 and 422.101 will interact with § 422.136, if an NCD or LCD prohibits or establishes step therapy programs in connection with coverage of a Part B drug, the MA plan must comply with the applicable NCD or LCD.

As finalized in § 422.136(a)(1), Part B drug step therapy requirements may not apply to ongoing courses of Part B drug therapies. This limitation is designed to prevent interference with the provision of care to patients who have already started a drug treatment. As noted in the proposed rule, we recognize that negative health outcomes can arise from disruptions in existing treatment regimens and wish to avoid such occurrences.

Further, the MA regulation at § 422.206 prohibits an MA plan from interfering with health care professionals' medical advice to enrollees. Therefore, a provider's statement in support of a pre-service organization or appeal for access to a Part B drug cannot be prohibited by an MA plan. We expect MA plans to give weight to a provider's medical judgment and expertise when making organization determinations and deciding appeals related to access to Part B drugs that are subject to step therapy protocols; we remind MA plans that under §§ 422.566(d) and 422.590(g)(2), all denials of coverage based on medical necessity—which we expect will be the crux of requests by enrollees to avoid step therapy programs—must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. We note as well that under this final rule, the adjudication time periods for Medicare Advantage organization determinations are being shortened for cases related to coverage of Part B drugs. The ability for providers and enrollees to receive a pre-service decision regarding coverage on a Part B drug on this shortened timeframe will greatly reduce the potential for delay in access to medically necessary Part B drugs.

Furthermore, MA plans using step therapy must ensure that step therapy programs are clinically appropriate under this rule and existing rules governing the MA program. Pursuant to § 422.202(b)(1), MA organizations must formally consult with contracted physicians when developing utilization management guidelines, so that policies like step therapy are based on reasonable medical evidence or consensus of medical professionals, consider the needs of enrollees, and are reviewed and updated; taken together these standards mean that step therapy programs, like other utilization management policies, are clinically appropriate. As we stated previously, we are requiring that P&T committees must have a majority of members who are participating physicians or pharmacists and they must follow the requirements at § 422.136(b)(5) through (10) in review, evaluation and approval of step therapy policies. We believe this will help ensure that a MA plan's Part B step therapy policies will be clinically driven and that practicing providers, including network providers, will have a voice as practice guidelines are developed and implemented.

Comment: Some commenters stated Part B Step Therapy conflicted with section 1852(a)(1) of the Act. Specifically, these commenters argued that section 1852(a)(1) of the Act which requires MA plans to cover all Part A and Part B benefits (except for specifically excluded benefits like hospice), means that MA plan coverage policies not be more restrictive than Original Medicare and that CMS cannot allow plans to impose additional restrictions to Part B drug coverage. The commenters argued step therapy amounts to a denial of access to Part B benefits.

Response: As referenced in the proposed rule, CMS's reinterpretation of section 1852 of the Act means that MA plans' may implement appropriate utilization management tools, including prior authorization and step therapy, for managing Part B drugs in a manner to reduce costs for both enrollees and the Medicare program while not denying access to medically necessary services. Section 1852(a)(1) of the Act requires MA plans to provide coverage of items and services for which benefits are available under parts A and B of the Medicare statute, except for hospice care and, beginning 2021, excludes organ acquisitions costs for kidney

transplants. Although CMS previously interpreted this as requiring MA coverage of Part A and Part B benefits to be no more restrictive than coverage in Original (FFS) Medicare, the need to control drug costs prompted our review of the authority and CMS changed this interpretation with respect to utilization management programs applied to Part B drugs upon more careful consideration of the statute as a whole. As discussed in the proposed rule, we expect the use of step therapy for Part B drugs to lead to lower costs for the government and Medicare beneficiaries; lowered costs are undoubtedly a means to ensure the continued health of the Medicare program and a reasonable basis for revisiting the statute to evaluate whether there is authority to provide more flexibility to MA plans in connection with utilization management policies.

Section 1852, in imposing the requirement that MA plans furnish or cover Part A and Part B benefits, does not expressly prohibit the use of utilization management. To the contrary, sections 1852(c)(1)(G) and (c)(2)(B) of the Act expressly reference an MA plan's application of utilization management tools, like prior authorization and other ''procedures used by the organization to control utilization of services and expenditures.'' This clearly indicates that MA plans are not expressly prohibited by the statute from implementing utilization management tools such as step therapy. Although some commenters disagreed that step therapy is a utilization management tool, characterizing it instead as a limitation or restriction on coverage, we believe that it is such a tool and that the reasonable limits these protocols place on when a drug is covered are the means of controlling utilization and cost. All Part B drugs must be covered by the MA plan when medically necessary, for example, when a stepped drug is not effective or appropriate for the patient, the patient must be allowed direct access to an alternative Part B drug. We disagree with commenters that characterize these limits as meaning that certain Part B drugs are no longer covered by the MA plan; these limits on coverage do not eliminate coverage, rather they ensure the most cost effective, clinically appropriate treatment is provided. This is consistent with our current interpretation of the requirement in section 1852 of the Act that MA plans must furnish or cover medically necessary Part A and Part B services, excluding hospice and, beginning 2021, excluding kidney acquisition costs.

Further, we do not believe that the statute must list every possible procedure or policy that controls utilization of services or expenditures for the statute to authorize their use. Section 1860D–4(c) of the Act does not expressly refer to step therapy, but because it is an appropriate method for managing drug costs, we have historically permitted Part D plans to use step therapy as a utilization management program authorized by the statute. Section 1852(c)(1)(G) and (c)(2)(B) of the Act contemplates that MA plans will use utilization management policies that are not used in Original Medicare. If the statute permitted only prior authorization, requiring disclosure of ''procedures used by the organization to control utilization of services and expenditures'' would be unnecessary because subsection (c)(1)(G) already requires disclosure of prior authorization policies. Our interpretation gives meaning to both provisions and reasonably interprets the reference to controlling utilization of services and costs as including step therapy policies.

Further, we have explained our reinterpretation consistently. In the August 7, 2018 HPMS memo [14] and subsequent FAQs,[15] CMS recognized that utilization management tools, such as step therapy, can provide the means for MA plans to better manage and negotiate the costs of providing Part B drugs. In the proposed rule, we explained how we do not believe that MA plans subject to our prior guidance and interpretation engaged in negotiation over the cost of Part B drugs. As previously noted using internal bid data, excluding MA employer group plans, CMS estimates $9 billion in spending by MA plans for Part B drugs during contract year 2018. By providing a basis on which MA plans may more effectively negotiate the price they pay for Part B drugs, this reinterpretation of the statute allows for more cost-effective coverage of these drugs. Further, by using policies that promote the use of more cost effective drugs first when such drugs adequately and appropriate treat an enrollee's condition, step therapy programs can result in lower utilization while ensuring consistent beneficial outcomes.

Because the statute contemplates MA plans use of utilization management policies and procedures and because Part B drugs are accessible and covered when medically necessary (such as if other medications that are used first in a step therapy program are not effective), we have concluded that an MA plan may fulfill its obligations to furnish Part B benefits even if a step therapy program is used. As discussed elsewhere in response to comments, new § 422.136 contains beneficiary protections and limits on how step therapy can be used in order to ensure access to medically necessary Part B drugs. CMS reiterates that MA plans must comply with the statutory requirement that they provide enrollees with access to all medically necessary Part A and Part B benefits available in Original Medicare, as provided section 1852(a)(1) of the Act. This final rule does not contravene this statutory requirement for MA plans.

Comment: Several commenters expressed concerns that the proposal did not include adequate oversight from CMS. Several commenters argued that CMS cannot guarantee consistent enforcement and provide enrollees clinically appropriate Part B medication. Some commenters recommended CMS establish procedures, similar to Part D, in which plans are required to submit step therapy policies for CMS review and approval prior to implementation and use. Commenters also recommended that CMS actively monitor plans to ensure that plan policies and procedures are implemented in a manner that does not violate CMS rules. Commenters also suggested CMS closely monitor the extent to which organization determinations and appeals are being sought so that CMS can assess the need for additional patient protections.

Response: Although § 422.136 does not explicitly address monitoring and enforcement, CMS will leverage its existing oversight programs to include targeted monitoring of the Part B step therapy programs implemented by MA plans.

CMS will monitor beneficiary complaints and organization determinations and appeals related to Part B drug step therapy programs. CMS has regularly scheduled meetings with the Part C IRE contractor; during these meetings, CMS and the IRE contractor identify and evaluate systemic problems with coverage decisions that rise to the IRE based on denials at the plan level. When systemic coverage issues are

[14] Available online at: *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.*

[15] Available online at: *https://dpapportal.lmi.org/DPAPMailbox/Documents/Part%20B%20Step%20Therapy%20Questions%20FAQs_8-29-18.pdf.*

identified, CMS takes steps with the MA plan, or the industry as a whole, to ensure correction of the problem. CMS will also monitor compliance with organization determination and appeal adjudication timeframes, both existing and those adopted in this final rule, by MA plans. When MA plans are selected for audit, CMS will target sample pre-service organization determination and appeals related to requests for Part B drugs to ensure compliance with § 422.136, particularly the beneficiary protection requirements like the lookback period and the requirements to educate and inform health care providers and enrollees concerning its step therapy policies. CMS will also monitor step therapy related complaints it receives from stakeholders to learn how MA plans are implementing step therapy programs, including whether plan communications explaining the program and involvement of contracted providers, as we have outlined elsewhere in this final rule, are consistent with program requirements. Finally, when CMS identifies concerns about a step therapy program, CMS may request written documentation from the plan's P&T committee under authority in § 422.136(b)(9) and any other related plan information CMS deems necessary, in accordance with § 422.504(f)(2), in order to assess and evaluate the MA plan's step therapy program and ensure compliance with CMS requirements.

We note that CMS interprets its authority to review Part C bids and plan designs as the authority under which we could review MA plans use of Part B drug step therapy programs. However, given all of these oversight means and tools, we believe CMS can effectively monitor MA plan step therapy programs without reviewing all of the coverage policies and procedures an MA plan adopts for step therapy in advance. As discussed elsewhere in the final rule, P&T committees are responsible for reviewing and implementing Part B step therapy programs that are clinically appropriate and are based in scientific evidence and standards of practice. CMS does not review other utilization management practices (that is, prior authorization) for Part B items or services in advance of implementation by an MA plan. We will continue to hold plans accountable for ensuring coverage of medically necessary Medicare covered items and services through CMS's oversight activities.

CMS solicited comment on the rule's restriction to new medication starts only.

Comment: Some commenters requested CMS remove the new start restriction and allow step therapy for all Part B drug therapies. Several commenters requested that CMS increase the lookback period to determine if the enrollee is actively taking a Part B medication from 108 to 365 days to better ensure uninterrupted care. These commenters pointed out that there are many clinical differences in the drugs covered under Part B compared to those covered under Part D and noted that the FDA-approved dosage period for many Part B drugs exceeds 108 days. One commenter highlighted the following drugs (and their dosage periods) specifically:

- Zoledronic acid for osteoporosis is 1 year
- Denosumab for osteoporosis is 6 months
- Hyaluronic acid injections for knee osteoarthritis are 6 months
- Rituximab for rheumatoid arthritis is dosed at two infusions repeated every 4 to 6 months

Given these examples, these commenters and others recommended a 365-day lookback period to better ensure uninterrupted care, noting that a disruption in therapy could result in poorer disease control including relapse of symptoms and other bad outcomes, such as hospitalization and death, depending on the drug and condition. Commenters also reasoned that a 108 day lookback period may not be clinically appropriate for some disease states, as many patients receive less frequent infusions that may not be captured in this short time period.

Response: Although we proposed that MA plans would be required to have a lookback period of 108 days to determine if the enrollee is actively taking a Part B medication, we explained in the proposed rule how the purpose of the look back period was to determine if an enrollee were actively taking a Part B drug. We stated our belief that consistency with the Part D lookback period, which was created with clinical and pharmaceutical input, would be appropriate. As commenters have pointed out that the FDA-approved dosage periods for some Part B drugs exceeds 108 days, we now believe that in order to fully ensure that an MA enrollee is not already taking a Part B drug, a longer lookback period is appropriate and necessary. Therefore, in order to ensure continuity of care, we are finalizing § 422.136(a)(1) with a lookback period of 365 days as recommended by commenters. Based on this information about the dosage periods for Part B drugs, the justification for the 108-day lookback period used for Part D drugs is not applicable to Part B drugs. In Part D, 108 days is a considered sufficient because PDPs are allowed to provide 90-day supplies. The 108 day period allows for some flexibility beyond 90 days (18 days or 20% of 90 days) if the beneficiary does not refill a prescription exactly 90 days after the first fill. This scenario is not applicable to Part B drugs because Part B drugs are not administered based on a 90-day supply and, as the commenters indicated, may have dosage periods of up to a year. As discussed in the proposed rule, CMS believes new step therapy requirements must not disrupt ongoing Part B drug therapies for enrollees. In order to ensure that step therapy requirements do not disrupt ongoing Part B drug therapies, we proposed, and are finalizing at § 422.136(a)(1), that step therapy may not disrupt enrollees' ongoing Part B drug therapies. The regulation, at § 422.136(a)(1), permits MA plans to apply a step therapy program only to new administrations of Part B drugs, using a minimum lookback period. We believe a 365 day look back period will mean that MA plans identify enrollees who may be using a drug with a longer dosage period and thus better ensure uninterrupted care. Therefore, the final regulation text specifies a 365 day lookback period.

Comment: Commenters also stated that new start protections must be allowed for new MA enrollees as well as enrollees who switch MA plans.

Response: We agree that step therapy programs should be limited to new administrations for all enrollees. We proposed that step therapy should not be permitted to disrupt enrollees' ongoing Part B drug therapies and noted in the proposed rule how we intended the restriction to new starts and the use of the look back period to apply to current enrollees and when an enrollee elects a new MA plan. We clarify here that an enrollee's ongoing Part B drug therapy may not be disrupted even when an enrollee switches plans. MA plans must use the lookback period when an enrollee elects a new MA plan (regardless of whether previously enrolled in a MA plan, traditional FFS Medicare, or new to Medicare) to determine whether the enrollee has taken the Part B drug (that will otherwise be subject to step therapy) within the past 365 days. We are finalizing the requirement in § 422.136(a)(1) that step therapy only be applied to new prescriptions or administrations of Part B drugs, using a 365 day lookback period. This limitation must be applied to all enrollees and means step therapy for a Part B drug may be used only for an enrollee who is not receiving the

medication currently or has not previously received the medication within the lookback period. MA plans must therefore take steps to request and review information as necessary to identify whether an enrollee has used the applicable Part B drug during the lookback period.

Comment: Several commenters urged CMS to include in the final rule an exemption or waiver policy for individuals subject to Part B step therapy. Commenters argued that some beneficiaries have conditions that are too sensitive to be subject to the increased restrictions that step therapy would impose. Commenters reasoned that in some cases a patient being required to first ''fail'' on a plan preferred medication or to wait through a delay due to an appeal can to lead to adverse health outcomes, especially if the patient's condition is stable due to the enrollees' use of prescription drugs already selected by the prescribing health provider. Commenters stated that step therapy requirements prevent patients from adhering to their treatment plans and, therefore, are not in their best interests. Commenters also suggested CMS develop a more expansive exemption or waiver policy for individuals that should not be subject to Part B drug step therapy requirements.

Response: We reiterate that plans cannot deny medically necessary care and enrollees and/or providers may request a pre-service organization determination in order to receive plan approval to bypass the step therapy requirement, but we are not adopting specific regulation text to create additional exemptions from step therapy other than the limits we proposed (meaning, the limits regarding new administrations of a Part B drug, use of only covered drugs, and use of off-label indications). We believe that a request for a pre-service determination, particularly in light of the amendments to the deadlines for responding to requests for organization determinations about coverage of Part B drugs, is an adequate safeguard to ensure enrollee access to medically necessary care. In addition, an enrollee may request an expedited organization determination and reconsideration if necessary. We are also requiring that step therapy be limited to new starts with a 365 day look back period so continuing treatments are not affected. CMS limited step therapy to new starts because a disruption in successful MA enrollee therapy could result in poorer disease control, relapse of symptoms and other bad outcomes including hospitalization and death, depending on the drug and condition.

This final rule includes a number of safeguards that ensure timely access to all medically necessary Part B medications, including the following: (1) Requiring that step therapy only be applied to new prescriptions or administrations of Part B drugs for enrollees who are not actively receiving the affected medication with a lookback period of 365 days to determine if the enrollee is actively or during the lookback period was taking a Part B medication; (2) requiring that MA plans issue organization determinations and decisions on appeals under timeframes similar to those used in the Part D program when the issue is about coverage of a Part B drug; and (3) requiring that plans use a P&T committee to review and approve step therapy programs to ensure medically appropriate implementation of step therapy for Part B drugs.

Comment: Some commenters urged CMS to require that step therapy protocols be aligned with clinical practice guidelines and adhere to recognized standards of care. Other commenters urged CMS to require MA plans to establish processes to evaluate the clinical appropriateness of their step therapy protocols. Some commenters suggested that plan step therapy policies should be supported by evidence-based clinical guidelines and best practices that are based on robust research and publicly available overutilization data.

Response: CMS appreciates commenters' feedback about requiring P&T committees to establish processes to evaluate the step therapy policies developed by MA plans and that these policies be supported by evidence-based clinical guidelines and best practices. We believe that our proposal for P&T committees and the standards they would be required to use in reviewing and approving step therapy programs for Part B drugs are consistent with the commenters' recommendations. CMS is finalizing its proposal at § 423.136(b)(5), that requires P&T committees base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other information as is determines appropriate. This regulation will allow P&T committees discretion to determine the scientific evidence and standards of practice on which their clinical decisions are based, although CMS can monitor this process through review of P&T committee records. CMS is also finalizing regulation text at § 423.135(b)(9) that each P&T committees must document in writing its decisions regarding the development and revision of and utilization management activities and make this document available to CMS upon request. Accordingly, CMS may monitor compliance with (and, as necessary take enforcement and/or compliance action regarding) the P&T committee requirements in § 422.136(b) through requesting written documentation regarding Part B step therapy programs and evaluating whether clinical decisions and criteria are evidence-based and appropriate in terms of safety and efficacy. We may also release subregulatory guidance concerning the application of the P&T committee requirements in the context of Part B drugs.

Comment: A few commenters requested that CMS carefully consider the development of further guidance on how step therapy should align with existing care coordination programs.

Response: We evaluated existing requirements in §§ 422.112 and 422.152 that require care coordination activities and determined that changes to these rules are not needed to include care coordination activities related to Part B step therapy. We may consider further requirements in the future, as needed, and note that CMS is not finalizing a requirement in § 422.136 that an MA plan must offer a drug management care coordination program in conjunction with Part B step therapy. We believe full disclosure to enrollees regarding a plan's Part B step therapy program and good communication between providers and enrollees undergoing step therapy are important features of care coordination. We expect this disclosure to include informing enrollees of their appeal rights and confirming whether enrollees have used the stepped medication within the last year. While all of the care coordination requirements are important, we emphasize that plans should ensure that treating providers consider beneficiary input into the provider's proposed treatment plan, as described at 42 CFR 422.112(a)(6)(iii). We also expect MA plans to ensure that providers closely monitor patients undergoing step therapy to ensure that the prescribed medication is meeting clinical expectations.

Comment: Some commenters expressed concern that the additional education and information responsibilities in this proposal are insufficient and do not adequately inform enrollees and providers of plan step therapy policies. These commenters encouraged CMS to provide greater transparency to enrollees and

providers of step therapy policies by requiring that plans disclose the name of each Part B drug subject to step therapy in the annual notice of changes (ANOC) and explanation of benefits (EOC).

Response: With regard to the comments on the sufficiency of our proposal regarding education and information provided to providers and enrollees, CMS believes transparency and informed beneficiaries and providers are critical to a well-coordinated and efficient utilization management program. We are finalizing the requirement that MA plans establish policies and procedures to educate and inform health care providers and enrollees concerning step therapy policies at § 422.136(a)(2). In addition, we note that existing disclosure requirements in § 422.111 will apply to step therapy programs. We are still considering how to apply and interpret the requirements in § 422.111 regarding the ANOC and EOC to step therapy programs in light of the new requirement we are finalizing here at § 422.136(a)(2), that MA plans establish policies and procedures to educate and inform providers and enrollees about step therapy programs. Subregulatory guidance will be provided §§ 422.111 and 422.136(a)(2) and CMS intends to seek comment in its development of such guidance about whether step therapy requirements should be displayed in a drug-specific manner in the ANOC/EOC documents provided to beneficiaries.

Comment: Some commenters expressed concern that the requirements under this proposal are burdensome and not necessary to administer a drug benefit.

Response: CMS appreciates commenters concerns regarding the administrative burden imposed on network providers by MA plans. CMS encourages MA plans to work closely with providers to adopt best practices that streamline operations and minimize burden. We also encourage continued development and advancement of electronic prior authorization processes to more efficiently administer Part B step therapy programs and potentially minimize burden on health care providers. CMS believes that Part B step therapy programs can reduce medical costs by replacing more expensive drugs with less costly drugs when it is medically appropriate to do so.

Comment: Several commenters expressed concern about the disclosure requirements and argued that beneficiaries should receive more detailed information about drugs subject to Part B step therapy. Commenters suggested that beneficiaries should be able to review step therapy protocols and medications subject to step therapy prior to enrolling in the plan. Commenters recommended increased transparency of plan step therapy requirements, including having plans explain why step therapy is required for a specific medication, how the process works, and what recourse the beneficiary has to appeal. Furthermore, several commenters urged CMS to prohibit mid-year additions to step therapy programs or mid-year implementation of step therapy, noting that such restrictions should only be established in advance of a plan year so that beneficiaries will have access to all plan information prior to making enrollment decisions.

Response: As previously discussed, CMS believes transparency and informed beneficiaries and providers are critical to a well-coordinated and efficient utilization management program. The regulation at § 422.111 requires that MA plans disclose information covered by the plan, including applicable conditions and limitations, premiums, cost-sharing, and any other conditions associated with receipt or use of benefits in the plan's ANOC (when initially adopted or subsequently changed) and EOC documents, which are provided annually to plan enrollees. In the past, we interpreted the regulation to mean that plans must identify that covered services may be subject to utilization management tools, like prior authorization. In light of the comments regarding transparency and the need for enrollees to have detailed information about step therapy programs, we are considering whether § 422.111 should be interpreted to require more detailed disclosure, particularly as we are finalizing a requirement at § 422.136(a)(2) that MA plans establish policies and procedures to educate and inform providers and enrollees about step therapy programs. We intend to seek comment through sub-regulatory guidance as to whether step therapy requirements should be displayed in a drug-specific manner in the ANOC/EOC documents and how MA plans should be required to display this information so that enrollee elections can be made based on all necessary information.

With respect to mid-year changes to implementation of step therapy programs, we note that under § 422.111(d)(3), MA plans must inform all enrollees at least 30 days before the intended effective date of changes in plan rules. Utilization management tools like prior authorization and step therapy are plan rules within the scope of this provision so MA plans must inform enrollees of changes to rules described in the ANOC/EOC consistent with § 422.111(d).

Comment: Some commenters supported the use of P&T committees as an effective mechanism to ensure that step therapy and other utilization policies are clinically appropriate. Other commenters noted that MA plans utilize a Medical Policy committee, which reviews and evaluates drugs covered under the medical, rather than the pharmacy benefit. The commenters suggested CMS should allow MA plans to utilize these committees to develop and review plan step therapy policies instead of a P&T committee, which reviews and approves the Part D drug benefit.

Response: CMS appreciates commenters who shared both opposition and support of the P&T committee requirement. CMS will require MA plans that elect to use Part B step therapy programs to have a P&T committee review and approve such step therapy programs. This regulation affirms our reinterpretation of section 1852 of the Act, and the MA regulations governing benefit coverage and utilization management policies (for example, § 422.4(a)(1)(ii)) to allow MA plans to use utilization management tools such as step therapy for Part B drugs to prevent overutilization of medically unnecessary health services and control costs, subject to limitations finalized in § 422.136. We are finalizing the paragraph (b) provisions requiring use of P&T committees, but are limiting the P&T committee responsibilities to review and approval of Part B step therapy programs only. Our proposed regulation text in paragraphs (b)(6), (b)(7), and (b)(9) referred to utilization management policies and programs and proposed paragraph (b)(10) referred to ''clinical prior authorization criteria;'' we are not finalizing these references, but are limiting the regulation text to step therapy programs. The final rule does not require P&T committee review and approval of Part B utilization management policy other than step therapy programs; MA plans are permitted to use P&T committees more broadly to review and approve other utilization management programs and protocols, but are not required to by § 422.136 as finalized here. Limiting P&T committee responsibilities to step therapy programs is in line with our proposal. As explained in the proposed rule, § 422.136 is specific to step therapy programs applicable to Part B drugs, our reinterpretation permitting such programs, and the appropriate limits on MA plans using such

programs. Our proposal was not explicitly to impose new limits on existing utilization management programs. Although we solicited comments, we did not receive any comments recommending that P&T committee requirements be extended to other programs.

We believe the P&T committee requirements being finalized in this rule are necessary to ensure medically appropriate implementation of step therapy for Part B drugs. P&T committees will promote safe, effective, and cost-effective Part B drug therapy by reviewing and approving the policies and procedures for step therapy. CMS is not adopting any requirements for use of Medical Policy committees because, as discussed in the proposed rule, we believe it is appropriate to substantially align the requirements of a P&T committee reviewing Part B drugs with Part D requirements for administrative efficiency between Part C and Part D programs. P&T committee membership and regulatory requirements are specifically designed to ensure that adequate standards and considerations be used in reviewing step therapy programs for drugs. A medical policy committee's scope would not necessarily be limited to Part B drug review and, therefore, impose unnecessary burden to MA plans. Additionally, Part D requirements for P&T committees have proven sufficient in ensuring that plans implement medically appropriate step therapy and utilization management protocols in Part D.

Comment: Some commenters expressed concern about CMS's requirements regarding the sufficiency of the P&T committee's composition. These commenters believe MA plans should require, rather than encourage, P&T committees to include more specialists, nurse practitioners, and beneficiary representation.

Response: CMS appreciates commenters concerns regarding P&T committee composition. In response to commenters' suggestions that P&T committee composition include more specialists, practitioners, and beneficiary representation, CMS notes that this final rule requires P&T committees include a majority of members who are practicing physicians or pharmacists. Although P&T committees must include a majority of members who are physicians and pharmacists, plans have the discretion to include specialists, nurse practitioners, and beneficiaries as members. We do not believe that adopting different or revised composition requirements will necessarily further our goals for the use of the P&T committee while they could impose additional burden on MA plans, which would not be able to immediately implement use of an existing P&T committee established for the Part D program, if additional members must be added to the committee. As noted in the proposed rule, we believe that using the same rules as apply in the Part D program are appropriate because of the demonstrated success in that context.

Comment: A few commenters expressed concern that this proposal would lead to higher out-of-pocket (OOP) costs for beneficiaries. Some expressed concern that allowing plans to step a Part D drug before a Part B drug would lead to increased OOP costs for beneficiaries due to the differences in cost sharing rules between Part B and Part D drugs. A few commenters urged CMS to allow plans to cross-manage Part B and Part D drugs to enable plans to better manage Part B and Part D drug costs.

Response: CMS acknowledges that in some narrow instances beneficiaries may be financially disadvantaged and experience higher cost sharing if for example, a Part B step therapy program uses a Part D drug as a step to the Part B drug for an enrollee who had reached their MA plans maximum out-of-pocket limit (MOOP). MA enrollee out-of-pocket costs for Part D drugs are not included in the MOOP limit imposed on enrollee out of pocket costs under §§ 422.100(f) and 422.101(d), but enrollee costs for Part B drugs are; therefore, an enrollee who has reached the catastrophic limit would not have any cost sharing charged for a Part B drug, but would have to pay cost sharing for a Part D drug. However, we believe the majority of MA enrollees will realize reduced cost sharing as a result of the step therapy policy finalized in this rule because the enrollees will be directed to a clinically appropriate and more cost effective drug treatment. We expect that the implementation of step therapy will result in lower plan bids, because the cost of furnishing Part A and Part B benefits will be lower. If a plan reduces its bid relative to the benchmark, the plan should be able to charge a lower premium or provide supplemental benefits at a lower (or potentially no) premium.

Comment: Some commenters recommended that CMS permit plans to provide a two-tiered Part B preferred drug list with differential cost-sharing and requested that CMS use its authority through the Annual Rate Notice and Call Letter to permit MA plans to establish non-preferred Part B drug cost sharing greater than 20 percent.

Response: We thank commenters for their suggestions. We note that CMS does not have the authority to make such changes through the annual Call Letter. Section 3202 of the Affordable Care Act amended section 1852 of the Act to establish new standards for MA plans' cost sharing. Specifically, section 1852(a)(1)(B) of the Act was amended by the addition of new clause (iii) that limits cost sharing under MA plans so that it cannot exceed the cost sharing imposed under Original Medicare for specific services identified in new clause (iv). New section 1852(a)(1)(B)(iv) of the Act lists the three service categories for which cost sharing in MA plans may not exceed that required in Original Medicare (chemotherapy administration services, renal dialysis services, skilled nursing care) and section 1852(a)(1)(B)(iv)(IV) of the Act specifies that this limit on cost sharing also applies to such other services that the Secretary determines appropriate. CMS must use rulemaking to identify additional services to which this provision would apply to limit how much cost sharing is charged to an MA enrollee.

As stated in the CY 2012 Call Letter, MA plans and 1876 Cost Plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration including chemotherapy drugs and radiation therapy integral to the treatment regimen, skilled nursing care, and renal dialysis services (§§ 417.454(e) and 422.100(j)). In addition, in order to ensure that cost sharing is consistent with both §§ 422.254(b)(4) and 422.100(f)(2) and (6), CMS evaluates actuarial equivalent cost sharing limits separately for all Part B drugs. Therefore, the 20 percent limit applies to both Part B drugs-Chemo and Part B Drugs-Other.

Comment: Some commenters also suggested CMS allow plans' utilization management protocols to supersede national coverage determinations (NCDs) and local coverage determinations (LCDs). Specifically, it was suggested that CMS provide guidance that grants plans flexibility in implementing step therapy on Part B drugs with LCDs or NCDs. We also received a comment that encouraged CMS to review NCDs and revise those policies that impose barriers on the utilization of biosimilars.

Response: MA organizations have been and remain subject to § 422.101(b), which requires compliance with national and in some cases, local, coverage determinations. Part B step

therapy protocols for a given drug cannot be stricter than the step therapy provisions specified in an NCD or LCD. For example, if the NCD or LCD has specified Part B step therapy requirements for that particular drug, then the Part B step therapy protocols of an MA plan cannot be stricter than those protocols. We would further note that when NCDs or LCDs do not preclude MA step therapy, we believe that Part B step therapy can be an effective utilization management tool. Where an LCD or NCD addressing coverage of a Part B drug does not address or include a step therapy protocol, this regulation will permit the MA plan to adopt a step therapy for that Part B drug. As we have discussed elsewhere in this final rule, one significant policy goal in allowing Part B step therapy is to enable MA plans to reduce unnecessary drug spending and, in turn, reduce costs for beneficiaries and the Medicare program. MA plans must provide coverage of all Part A and Part B benefits, therefore, MA plans must provide coverage of all Part B drugs. If an NCD specifies that a biosimilar is not covered under Part B, it cannot be used under the Part B drug step therapy program.

Comment: Some commenters requested CMS clarify whether all of the projected savings resulting from step therapy may be incorporated in the bid amount, instead of offering incentives only to those enrollees subject to step therapy who completed specified care management activities, beginning in 2020.

Response: Effective January 1, 2020, MA plans must incorporate anticipated savings in the plan's bid amount; therefore, coupling step therapy with rewards and incentives will not be a requirement in 2020 or future years for MA plans (as it is in 2019) that use a step therapy program for one or more Part B drugs. Pursuant to § 422.254(b), MA bids for the basic benefit are required to reflect the revenue requirements for an MA plan to cover all Part A and Part B benefits; when use of a step therapy program means that the MA plan projects lower utilization or lower pricing (such as due to pricing negotiation with drug manufacturers), that will necessarily result in lower revenue needs to provide the Part B drugs that are subject to the step therapy program. CMS reminds plans that additional Part C rebate dollars associated with the lower bid, as with all Part C rebate dollars, must be used to provide supplemental benefits and/or lower premiums for the plans' enrollees.

We explained in the proposed rule how preferred provider organization plans (PPOs), because of the requirement in § 422.4(a)(1)(v)(B) to reimburse or cover benefits provided out of network without use of restrictions on coverage, would not be able to impose prior authorization or step therapy requirements on out-of-network provision of Part B drugs. We solicited comment on whether the final rule should include a specific regulatory provision clarifying whether preferred provider organization plans (PPOs) can apply step therapy out of network.

Comment: Some commenters requested that CMS allow PPOs to apply step therapy out of network.

Response: We clarify that PPOs are required, as part of the definition of a PPO at section 1852(e)(3)(A)(iv)(II) of the Act and under the MA regulations at § 422.4(a)(1)(v)(B), to reimburse or cover benefits provided out of network; while higher cost sharing is permitted, PPOs are prohibited from using prior authorization or preferred items restrictions in connection with out of network coverage. (70 FR 4616 through 4617). As such, PPOs must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization or step therapy requirements. Therefore, PPO plans may only use step therapy or prior authorization when a Part B drug is provided by an in-network provider.

Comment: Some commenters requested that all step therapy policy, including CMS operational guidance, be subject to advance public notice and an opportunity to provide comment.

Response: CMS thanks commenters for the suggestion and will consider soliciting comment on draft operational guidance related to § 422.136 and its requirements for Part B step therapy in the future. However, we do not believe that we are required to do so. Because of timing factors, as well as other policy considerations, we may release guidance without first soliciting comment.

Comment: Some commenters urged CMS to evaluate and revise existing subregulatory guidance and update relevant Medicare manual chapters to maximize the time plans have to design and implement step therapy programs and incorporate them in their bid applications for CY 2020.

Response: CMS will continue to evaluate and update Part B and Part D subregulatory guidance to ensure accuracy and consistency with new regulations. CMS appreciates that plans need to prepare bid submission and will work to provide additional Part B subregulatory guidance in a timely manner. This final rule provides significant discussion of § 422.136 and the requirements for Part B step therapy. Additional guidance before the bid deadline for CY2020 may not be possible.

Comment: Some commenters supported the proposal to permit MA plans to use off-label drugs in a step therapy program only when such drugs are supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices. Some commenters requested that CMS clarify what it considers to be ''best practices'' or ''widely used treatment and clinical literature'' in this regard. Others expressed caution that the use of off-label drugs as proposed could limit further investment in developing therapies and could provide disincentives to seeking FDA approval of additional indications. Some commenters expressed concern that the proposed regulation text does not explicitly require that an off-label use meet the definition of a medically accepted indication. Commenters also expressed concern that reliance upon compendia standards as the criteria for off-label coverage is insufficient to determine clinical appropriateness and could undermine the FDA and its role to review and approve investigational uses of approved drugs. Other commenters recommended CMS prohibit step therapy through an off-label medicine, particularly if there is an on-label medicine available.

Response: We thank commenters for their feedback. In order to ensure the medically appropriate use of off-label drugs, CMS's finalized rule prohibits an MA plan from including in step therapy protocols a drug supported only by an off-label indication unless the off-label indication is supported by widely used treatment guidelines or clinical literature. For example, an example of widely used treatment guidelines that would be relevant for Part B drugs would be the National Cancer Center Network (NCCN), which has separate guidelines for different types of cancer, as well as a compendium for cancer drugs.

Comment: A commenter asked whether the policies in our proposed rule allow a MA plan to require the use of a Part D protected class drug prior to the use of a Part B drug (that is., as a step to a Part B drug on a Part B step therapy program). The commenter also asked how the Part B step therapy program would impact enrollees' access to Part D protected class drugs.

Response: This final rule, at § 422.136(d), provides that only Medicare covered Part B drugs (and, for MA–PD plans, also Part D drugs) may be

used in a step therapy program for a Part B drug. A Part B step therapy program used by an MA plan must not include as a step or other component of the program any drugs not covered by the MA plan as a Part B drug, or, in the case of an MA–PD plan, a Part D drug. In addition to requiring one Part B drug be used before a different Part B drug, MA plans that also offer prescription drug coverage (MA–PD plans) may use step therapy to require a Part B drug or a Part D drug therapy, including a protected class Part D drug, prior to allowing a Part B drug therapy because the Part D drug will also be covered by the plan. MA–PD plans may also apply step therapy to require a Part B drug therapy prior to allowing a Part D drug therapy, including, for new starts only, a protected class Part D drug (other than an antiretroviral), as part of a Part D step therapy program or utilization management program; however, MA–PD plans must ensure that these requirements are clearly outlined in the Part D prior authorization criteria for the affected Part D drugs and are otherwise consistent with Part D requirements, including the requirements for the use of prior authorization and step therapy for protected class Part D drugs that we are finalizing elsewhere in this rule.

As discussed previously, after careful consideration of all comments received, and for the reasons set forth in the final rule and in our responses to the related comments, we are adopting a new regulation at § 422.136, substantially as proposed but with some modifications. Specifically, we are making the following changes from the proposal:

- In the proposed regulation text § 422.136(a) (1), we are finalizing a lookback period of 365 days instead of 108 days.'' Thus, § 422.136(a) (1) reads as follows: ''Apply step therapy only to new administrations of Part B drugs, using at least a 365 day lookback period.''
- In the introductory text in § 422.136(b), we are correcting a typographic error in the proposed regulation text to use ''an existing Part D P&T committee'' in place of ''an existing Part D P&T committees.''

We are also amending the P&T committee requirements at § 422.136(b) to clarify that P&T committee responsibilities apply to review and approval of Part B drug step therapy programs, and do not extend to all utilization management policies for Part B items or services. Therefore, we are making the following modifications:

- In the regulation text § 422.136(b)(6), we are replacing ''a utilization management programs, such as'' with ''program''. Thus, we are finalizing § 422.136(b)(6) to read as follows: ''Consider whether the inclusion of a particular Part B drug in a step therapy program has any therapeutic advantages in terms of safety and efficacy.''
- In the regulation text § 422.136(b)(7), we are not finalizing the language ''utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange'' and are finalizing language that refers to step therapy. Thus, we are finalizing § 422.136(b)(7) as follows: ''Review policies that guide exceptions and other step therapy processes.''
- In the regulation text § 422.136(b)(9), we are not finalizing ''and'' and ''utilization management.'' Thus, we are finalizing § 422.136(b)(9), to read as follows: ''Document in writing its decisions regarding the development and revision of step therapy activities and make this documentation available to CMS upon request.''
- In the regulation text § 422.136(b)(10), we are removing ''clinical prior authorization criteria'' and ''protocols and quantity limit restrictions.'' Thus we are revising § 422.136(b)(10), to read as follows: ''Review and approve all step therapy criteria applied to each covered Part B drug.''

2. Medicare Advantage and Step Therapy for Part B Drugs: Adjudication Timeframes

We proposed to amend a number of regulations related to the timeframe for an MA plan to make expedited and standard organization determinations and reconsiderations regarding coverage of Part B drugs. We also received comments on our proposal that requests for Part B drugs, including Part B drugs subject to step therapy, be processed under the same adjudication timeframes as used in the Part D drug program. As we stated in the proposed rule, we believe the clinical circumstances that typically accompany requests for Part B drugs warrant application to coverage decisions regarding Part B drugs of the shorter adjudication timeframes that apply in Part D. In keeping with this rationale, we did not propose to permit MA plans to extend adjudication timeframes for organization determinations and appeals related to Part B drug requests. We explained that our proposal to change the adjudication timeframes applies through the Part C IRE level of review. We did not propose to change how Part C appeals, whether for Part A, Part B or supplemental benefits, are processed by the Office of Medicare Hearings and Appeals (OMHA) and the Medicare Appeals Council (Council) which is housed within the Departmental Appeals Board (DAB).

Specifically, we proposed the following amendments regarding the organization determination and appeal procedures for Part B drugs:

- Add adjudication timeframes at §§ 422.568, 422.572(a), and 422.590(c) and (e)(2) for, respectively, standard organization determinations, expedited organization determinations, standard reconsiderations, and expedited reconsiderations related to coverage of Part B drugs that are the same as the timeframes for these appeal stages for Part D drugs under §§ 423.568, 423.572, and 423.590.
- Add references to determinations regarding Part B drugs to §§ 422.568(d) and (e)(4), 422.584(d), 422. 618(a) and (b), and 422.619(a), (b) and (c).
- Specify in §§ 422.568(b)(2), 422.572(a), and 422.590(c) and (e)(2) that the rules related to extending the adjudication timeframe related to requests for medical services and items (at §§ 422.568(b)(1)(i), 422.572(b) and redesignated § 422.590(f)) do not apply to the timeframes for resolving standard organization determinations, expedited organization determinations, standard reconsiderations, and expedited reconsiderations for Part B drugs.
- Make conforming changes that reference the applicable proposed timeframes and deadlines for determinations regarding Part B drugs and update cross-references in §§ 422.570(d)(1), 422.584(d)(1), and 422.618(a).
- Add a reference to an ''item'' to regulation text to clarify that the scope covers services and items at §§ 422.568(b), (d), and (e); 422.572(a) and (b), 422.590(a), (e), and (f); and 422.619(a) and (b).
- Redesignate existing regulatory paragraphs at § 422.568(b)(1) and (2) to § 422.568(b)(1)(i) and (ii), at § 422.590(c)–(f) to § 422.590(d)–(f), and at § 422.619(c)(2) to § 422.619(c)(3), without substantive change.

We explained in the proposed rule our intent to balance goals of cost savings and efficiencies with enrollee access, enhanced quality of care, and due process protections. We also solicited comments on our proposals related to organization determination and appeals timelines and processes that will be applicable to Part B drugs. Specifically, we solicited comments on our proposal to not permit MA organizations to extend the proposed timeframes for requests for Part B drugs and whether we overlooked an appeal

procedure or timeframe that should also be addressed in order to meet our goal of aligning organization determinations and appeals related to Part B drugs with the procedures and timeframes currently applicable to coverage determinations and appeals for Part D drugs under part 423. For more detail about the proposal, we direct readers to the proposed rule, 83 FR 62171 through 62174.

We explained in our proposal that, in a separate proposed rule, CMS–4185–P, entitled ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021'' and appeared in the **Federal Register** on November 1, 2018 (83 FR 54982), we proposed integrated grievance and appeal provisions for certain D–SNPs with aligned enrollment with Medicaid managed care plans. We also solicited comment on whether the proposed timeframes for organization determinations and appeals of coverage of Part B drugs should be incorporated into the integrated appeals procedures for certain D–SNPs.

We received 13 comments on our proposal related to organization determination and appeals timeframes for Part B drug requests:

Comment: Several commenters expressed support for the proposal to mirror Part D adjudication timeframes for Part B drug requests. Commenters stated that they appreciate CMS' efforts to clarify the appeals process and to establish greater consistency in how Part B and Part D drug requests are adjudicated. In expressing support for the adjudication timeframes for Part B drugs, one commenter stated that delays in treatment can have devastating health implications and noted that requiring plans to meet the Part D timeframe of 72 hours for standard organization determinations and 24 hours for expedited organization determinations will help ensure that these adverse outcomes are avoided.

Response: We thank the commenters for their support for this proposal. CMS believes that applying Part D adjudication timeframes to requests for Part B drugs establishes greater clarity and consistency in the coverage determination and appeals processes across the two programs. We believe the approach of applying shorter adjudication timeframes affords the most protection for beneficiaries. In addition, utilizing the timeframes that already exist in the Part D program minimizes changes to program operations for many plans since MA–PD plans are already familiar with and use the Part D timeframes.

Comment: Several commenters supported the proposed changes to the adjudication timeframes, but expressed concern that these beneficiary safeguards may not be strong enough to counter the negative effects of the proposed use of step therapy and utilization management tools. These commenters believe use of utilization management tools undermine patient access to clinically necessary and critical drugs, treatments, and therapies.

Response: We thank the commenters for sharing these concerns. CMS believes that mirroring the Part B adjudication timeframes with those shorter timeframes in Part D provides the best protection for enrollees who need a Part B drug. In all cases, the MA organization must notify the enrollee, and the physician or other prescriber involved, of its decision as expeditiously as the enrollee's health condition requires, but no later than the applicable adjudication timeframe. As we stated in the proposed rule, the rules on disclosure of utilization management requirements and individualized medical necessity determinations, coupled with the right to request an organization determination, ensure that an enrollee is informed about applicable step therapy requirements and has an opportunity for an individualized medical necessity determination related to a Part B drug step therapy requirement. Further, an MA organization has the discretion to establish an evaluation process for the appropriateness of enforcing its step therapy protocols on an enrollee when the enrollee's healthcare provider's assessment of medical necessity for the Part B drug indicates that the lower or earlier steps in the step therapy protocol are not clinically appropriate for that enrollee; this final rule does not prohibit MA organizations from working with their network providers to develop processes that eliminate the necessity for an enrollee to file a request for an organization determination in such cases. However, to the extent an MA organization develops an evaluation process for the appropriateness of enforcing its Part B step therapy protocols as described previously, the MA organization must ensure that the right of the enrollee to request an organization determination is not circumvented by such a process and that organization determination requests are processed in accordance with the requirements in Part 422, Subpart M.

Comment: Some commenters stated that they do not believe the appeals process is adequately responsive to patients with urgent treatment needs as it can be burdensome and slow for patients and their providers attempting to obtain drugs that are not on formulary. Other commenters noted concern about the complexity of the MA appeals process and how the process may be difficult for some beneficiaries to navigate. One commenter stated that the Part D appeals process is too deeply flawed to serve as a model for adopting changes to the MA appeals process for the purpose of providing protections to enrollees affected by plans' use of step therapy programs for Part B drugs. Another commenter stressed that, unlike Part D drugs, Part B drugs are almost exclusively administered to the sickest patients and require a patient to go to their doctor to receive treatment. This commenter indicated that it is critical that any request for direct access to a Part B drug that would otherwise only be available after trying an alternative drug be addressed as promptly as possible, and suggested that MA plans be required to make all decisions about Part B drugs within a 24-hour timeframe rather than a 72 hour timeframe as proposed.

Response: We thank commenters for their concerns and suggestions. We believe that application of shorter adjudication timeframes to requests for Part B drugs compared to the adjudication deadlines for other MA-covered services affords the best protection to enrollees who have an urgent need for the requested drug. As finalized in this rule, the MA organization must notify the enrollee, and the physician or other prescriber involved, of its decision regarding coverage of a Part B drug as expeditiously as the enrollee's health condition requires, but no later than 24 hours for expedited organization determination requests and 72 hours for standard organization determination requests for a Part B drug. We believe this medical exigency standard, coupled with the shorter timeframes, constitute meaningful beneficiary protections for those with urgent treatment needs. We believe that applying the same adjudication timeframes to all drug requests will increase consistency in the Part C and Part D coverage decision processes.

We disagree with the comment that every Part B drug request be adjudicated in a 24-hour period. We believe it is important to provide some flexibility in how MA plans allocate resources so that truly urgent requests are given the requisite level of consideration. As

noted in the proposed rule, we believe applying the 72-hour timeframe to standard Part B drug requests affords appropriate protection for enrollees and we reiterate that, in all cases, the plan must notify the enrollee of its decision as expeditiously as the enrollee's health condition requires. In other words, the plan must notify an enrollee of a decision even more quickly in a case where there is a medical need to do so and we expect plans to triage requests in a manner that ensures that this medical exigency standard is satisfied. In addition, under existing rules, an enrollee or a physician may request that an MA organization expedite an organization determination if an enrollee is waiting to receive a drug. For a request made by an enrollee, the MA organization must provide an expedited decision if it determines that applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. For a request made or supported by a physician, the MA organization must provide an expedited decision if the physician indicates that applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

Comment: One commenter stated that they believed that the current review time for Part B drugs is appropriate and allows for adequate physician coordination of services and drugs concurrently, and that expediting the Part B determinations would pose no advantage. In a similar vein, another commenter was opposed to the proposed changes to the adjudication timeframes and noted a preference to keep timeframes for Part B and Part D distinct and separate to maintain consistency with current processes; this commenter also indicated that restricting the ability to extend the timeframes would severely constrain their capacity to obtain the necessary and appropriate information to make informed determinations, exacerbating denial rates and adding costs to plans through increased administrative burdens.

Response: We thank the commenters for sharing their perspectives, but believe that the clinical circumstances that typically accompany requests for Part B drugs warrant application of the shorter adjudication timeframes that apply in Part D. As stated in the proposed rule, applying the shorter Part D adjudication timeframes to requests for Part B drugs establishes greater clarity and consistency in the coverage determination and appeals processes across the two programs and affords appropriate protections for enrollees requesting Part B drugs, including those subject to step therapy or other utilization management requirements. In keeping with the rationale that the clinical circumstances that typically accompany requests for Part B drugs warrant application of shorter adjudication timeframes, this final rule does not permit extension of the adjudication timeframes for Part B drug requests, as is allowed for other Part B organization determinations and appeals. With respect to the comment on increased administrative burdens, we believe utilizing the timeframes that already exist in the Part D program will minimize administrative burdens and changes to program operations for many plans since MA–PD plans are already familiar with and use the Part D timeframes.

We did not receive comments specific to our solicitation regarding whether to finalize different timeframes for Part B drug coverage decisions made as part of the integrated grievance and appeal provisions for certain D–SNPs with aligned enrollment with Medicaid managed care plans. As explained below, we are finalizing provisions to require applicable integrated plans to use the same Part B organization determination and appeals timeframes set forth in this rule. CMS finalized integrated appeals procedures for certain D–SNPs with aligned enrollment with Medicaid managed care plans in the final rule CMS–4185–F, Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021. This final rule appeared in the April 16, 2019 **Federal Register** (84 FR 15680). A significant part of the rationale for finalizing certain timeframes for the unified appeals processes for certain applicable integrated plans in that final rule was to provide consistency with existing timeframes in MA appeals procedures. In order to ensure that D–SNPs using the integrated appeals procedures operate consistently with other MA plans and provide protection of shorter timeframes for decisions regarding coverage of Part B drugs, we are finalizing here regulation text to require applicable integrated plans to use the same Part B organization determination and appeals timeframes finalized in this rule. Specifically, we are finalizing here the following amendments to the noted regulations:

- In § 422.629(a), text to require applicable integrated plans to use the Part B drug rules;
- In § 422.631(a), text to specify the applicability of Part B drug rules to integrated organization determinations; and
- In § 422.633(f), text to specify the applicability of Part B drug reconsideration timelines to the integrated reconsideration process.

We note that § 422.634(d) requires that when an applicable integrated plan completely reverses its integrated organization determination involving a Part B drug, the applicable integrated plan authorize or furnish the Part B drug within 72 hours. Because the 72-hour timeframe established in § 422.634(d) applies to all integrated reconsiderations involving benefit, including Part B drugs, that were not furnished while an appeal was pending, we do not believe that any amendment or revision is appropriate to make it consistent with the amendment finalized here at § 422.618(a)(3). Therefore, we are not amending § 422.634(d).

Based on the comments we received on the proposal that requests for Part B drugs be processed under the same adjudication timeframes as used in the Part D drug program and for the reasons provided in the proposed rule and our responses to comments, we are finalizing without substantive modification the following proposed changes to the regulatory provisions at Part 422, Subpart M:

- Add adjudication timeframes at §§ 422.568, 422.572(a), and 422.590(c) and (e)(2) for, respectively, standard organization determinations, expedited organization determinations, standard reconsiderations, and expedited reconsiderations related to coverage of Part B drugs.
- Specify in §§ 422.568(b)(2), 422.572(a), and 422.590(c) and (e)(2) that the rules related to extending the adjudication timeframe for requests for medical services and items (at §§ 422.568(b)(1)(i) and 422.572(b), and at redesignated § 422.590(f), respectively) do not apply to the timeframes for resolving standard and expedited organization determinations and reconsiderations for Part B drugs.
- Make conforming changes that reference the applicable proposed timeframes and deadlines for determinations regarding Part B drugs and update cross-references in §§ 422.570(d)(1), 422.584(d)(1), and 422.618(a).
- Add a reference to an ''item'' to regulation text to clarify that the scope covers services and items at

§§ 422.568(b), (d), and (e); 422.572(a) and (b), 422.590(a), (e), and (f); and 422.619(a) and (b).

- Add references to determinations regarding Part B drugs to §§ 422.568(d) and (e)(4), 422.584(d), 422. 618(a) and (b), and 422.619(a), (b) and (c).

- Redesignate existing regulatory paragraphs at § 422.568(b)(1) and (2) to § 422.568(b)(1)(i) and (ii), at § 422.590(c)–(f) to § 422.590(d)–(f), and at § 422.619(c)(2) to § 422.619(c)(3), without substantive change.

We are finalizing § 422.572(b)(1) with a slight modification to clarify that the rule for extending the timeframe for an MA plan to make its decision only applies if an extension to the timeframe is otherwise permitted; this clarification is necessary because we are finalizing, at § 422.572(a)(2), regulation text to prohibit the extension of the 24 hour timeframe for an MA plan to decide an expedited organization determination regarding coverage of a Part B drug. In addition, we are amending §§ 422.629, 422.631(a) and 422.633(f) to adopt the same timeframes for decisions related to coverage of Part B drugs made by integrated applicable plans.

Finally, as we previously noted, CMS will incorporate the shorter adjudication timeframes for Part B drug requests into the deadlines specified in the Part C IRE's contract per § 422.592(b).

F. Pharmacy Price Concessions in the Negotiated Price (§ 423.100)

In the proposed rule, we sought comment on a potential policy approach for requiring that all pharmacy price concessions be applied to drug prices at the point of sale under Part D. We received over 4,000 comments on this potential policy approach. We thank the commenters for their detailed responses. We will carefully review all input received from stakeholders on this issue as we continue our efforts to meaningfully address rising prescription drug costs for seniors.

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 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. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3 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.

In our November 30, 2018 (83 FR 62152) rule, we solicited public comment on our proposed information collection requirements, burden, and assumptions. As discussed in section III.B.4. of this final rule, we received comments related to our EOB burden estimates and revised our estimates as a result of those comments. We have also revised our business operations specialist-related cost estimates based on internal review (see sections III.A and III.B.5.).

A. Wage Data

To derive average costs we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2017 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/2017/may/oes_nat.htm*). In this regard, Table 2 presents the mean hourly wage, the upward adjustment to wages to account for the cost of benefits and overhead (calculated at 100 percent of salary), and the resulting adjusted hourly wage.

TABLE 2—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr.)	Benefits and overhead ($/hr.)	Adjusted hourly wage ($/hr.)
Business Operation Specialist	13–1199	$36.42	$36.42	$72.84
Pharmacist	29–1051	58.52	58.52	117.04
Software Developers and Programmers	15–1130	49.27	49.27	98.54

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

As previously mentioned, we have corrected the occupation code for business operations specialists from 13–0000 to 13–1199. The correction adds $1.88/hr. (mean) to our proposed business operations specialist-specific cost estimates and $3.76/hr. (adjusted). The cost under section III.B.5. of this final rule is affected by this change.

We are not making any changes to our Pharmacist (BLS occupation code 29–1051 at $117.04/hr.) or Software Developers and Programmers (BLS occupation code 15–1130 at $98.54/hr.) respondent types.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding the Provision of Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi)(C))

As described in section II.A. of this rule, the new paragraph at § 423.120(b)(2)(vi)(C) implements the authority granted to CMS by section 1860D–4(b)(3)(G) of the Act to establish exceptions that permit a Part D sponsor to exclude from its formulary (or to otherwise limit access to such a drug, including through prior authorization or utilization management) a particular Part D drug that is otherwise required to be included in the formulary. For the exception that addresses the use of prior authorization and step therapy for protected class drugs, the burden consists of the time and effort for Part D sponsors to submit their formularies to CMS under the active (or currently approved) annual submission process. The aforementioned provisions are active under OMB control number 0938–0763 (CMS–R–262) and will not impose any new or revised information collection requirements or burden.

Consequently, the provisions are not subject to the PRA.

We received no comments on our proposed information collection requirements, burden estimates, and assumptions associated with these exceptions and are finalizing them for the PA and ST exception without modification. We are not finalizing the proposed pricing threshold exception, or the proposed collection of information requirements associated with that exception.

2. ICRs Regarding the Prohibition Against Gag Clauses in Pharmacy Contracts (§ 423.120(a)(8)(iii))

This final rule codifies a ban on contract provisions that prohibit network pharmacies from informing Part D enrollees about instances where the pharmacy has a cash price for a prescribed drug that is lower than the out-of-pocket cost that would be charged to the enrollee. Since the codification will not change any existing practice and the provisions do not have any information collection implications, the provisions are not subject to the PRA. We received no comments on this assumption. As a result, we are finalizing this provision as proposed.

3. ICRs Regarding E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160)

We proposed that each Part D plan sponsor adopt one or more Real Time Benefit Tools (RTBTs) that are capable of integrating with at least one e-prescribing (eRx) and electronic medical record (EMR) system(s) (the latter of which will hereinafter be referred to as an electronic health record or EHR for consistency with current Departmental terminology) for use in Part D eRx transactions beginning on or before January 1, 2020. As discussed earlier in this preamble, we understand that some PBMs and a few prescription drug plans have already begun to use RTBT tools capable of meeting the specifications listed in our preamble discussion, which includes providing beneficiary-specific drug coverage and out-of-pocket cost information at the point-of-prescribing.

After giving a high-level description of the impact of this provision (83 FR 62185 through 621877), we solicited comment on the burden for implementing this provision since we had advanced the provision with unclear costs and impacts (83 FR 62185 through 62187).

While we received a few comments relative to the collection of information requirements as initially proposed, the input was not sufficient to help us reliably quantify the burden associated with the RTBT provisions. Consequently, we continue to maintain our inability to reliably score the RTBT burden as it pertains to the PRA. In this regard we are in the process of publishing stand-alone 60- and 30-day **Federal Register** notices that will be subject to the regular non-rule PRA process. Because of the uncertainty, the purpose would be to revisit the burden issues, solicit public comment, quantify the burden, and obtain OMB approval. The RTBT requirements and burden will be submitted to OMB for approval under control number 0938–0763 (CMS–R–262). Subject to renewal, it was last approved on November 28, 2018, and remains active.

A summary of the public comments and our responses are as follows:

Comment: Some commenters stated that a growing number of plans are already using RTBT due to the savings gained from enrollees switching to cheaper drugs as a result of information provided by the RTBT.

Response: We are pleased to see that the industry is moving in this direction and appreciate the feedback confirming that our understanding was correct.

Comment: Commenters provided various estimates of the prevalence of RTBT. The range was 70 percent to 90 percent of current plans are using RTBT or could easily transition to the technology with relative ease.

Response: We thank commenters for their responses, but point out that the range in estimate makes it difficult to estimate the total plan burden for RTBT use. Additionally, prior to publication of the proposed rule, one stakeholder suggested that only 30 percent were using RTBT. This range, 30 percent to 90 percent, which includes conversations prior to publication of the NPRM as well as comments on the NPRM received during the public comment period is one part of our justification for why no impact is provided.

Comment: Several commenters and without dissenting commenters commented that existing third party software was sufficient to meet the needs of RTBT.

Response: We thank these commenters for pointing this out. Based on this comment, we are dropping our estimate of software burden since we do not expect plans to develop their own software.

We are not quantitatively scoring this provision for the following reasons: (i) As just indicated the estimates of how many plans are using RTBT is 30 percent to 90 percent, implying that between 10 percent to 70 percent will need to implement RTBT. (ii) Based on the previously presented comments, we are not assuming any plans will develop their own software. (iii–iv) Based on internal CMS data there are 1.4 billion PDEs per year. Based on conversations with industry, for large volume, the cost of transactions for RTBT would be $0.01 per transaction. (iii) However, we have no basis to ascertain how many of the 1.4 billion PDE will have RTBT applied to them. (iv) Similarly, we have no way of estimating the volume of transactions for each type of drug. Consequently, we have no reliable way of quantifying impact.

4. ICRs Regarding Part D Explanation of Benefits (§ 423.128)

The requirements and burden related to the explanation of benefits (EOB) will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021. It was last approved on November 28, 2018, and remains active.

In accordance with § 423.128(e)(5) of this rule, sponsors will be required to include the cumulative percentage change in the negotiated price since the first day of the current benefit year for each prescription drug claim in the EOB. Sponsors will also be required to include information about drugs that are therapeutic alternatives with lower cost-sharing. The intent is to provide enrollees with greater transparency with respect to drug prices, leading to lower costs. Since plans use formularies, they already have the negotiated drug price and the lower cost alternatives in an existing information system. The cost of this provision consists of: Programming systems to calculate and connect information to the Part D EOB production, and the cost of paper, toner, and postage.

In the proposed rule, we assumed it would take 4 hours per contract at $98.54/hr. for a software programmer to link alternative prices to the EOB Model. However, commenters pointed out that there might be numerous systems to update. As a result, we are revising our 4 hour estimate to 160 hours. The change now estimates it will take two software programmers 8 hours (16 hours total) to revise 10 systems at the same hourly wage.

In the proposed rule we considered separate work for each contract. Upon internal review we now believe it is more appropriate to estimate burden by each parent organization since it is typically more efficient for major system

changes to be performed once at the parent organizational level with the contracts of that parent organization sharing the updated system.

Based on bid information and trends we expect 295 Part D Sponsors and PDP parent organizations for 2020. In aggregate, our revised one-time burden estimate for updating systems is 47,200 hours (160 hr per response × 295 responses) at a cost of $4,651,088 (47,200 hr × $98.54/hr) or $15,766 per respondent ($4,651,088/295 sponsors and organizations). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 15,733 hours (47,200 hr/3 years) at a cost of $1,550,363 ($4,651,088/3 years). We are annualizing the one-time labor estimate since we do not anticipate any additional burden after the 3-year approval period expires.

As discussed, commenters pointed out that there would be an added ongoing burden since EOBs would contain additional information about alternatives possibly requiring more printed pages per EOB. Based on internal bid information and projection we expect 47.6 million Part D enrollees in 2020. For our estimates of paper, toner, and postage we are adopting the same estimates that we used on April 16, 2018 (83 FR 16440) for our CY 2019 MA (Part C)/Prescription Drug Benefit (Part D) final rule (CMS–4182–F, RIN 0938–AT08) found on page 16695. However, we are revising the postage rate to the updated 2019 bulk mailing rates. Although our regulations allow electronic submission of Part D EOBs upon request, informal communication from stakeholders indicates small usage. We are therefore assuming mailings to all enrollees. Since we do not require first class postage for Part D EOBs, we are assuming that Part D sponsors will use the least expensive option, namely, the use of bulk mailing rates. We also assume that the added information about alternatives is not started on a separate page as that could be costly; accordingly we assume the current Part D EOB on average ends mid-page and that adding 1–2 pages would on average add 1.5 pages of print requiring at most 1 page of paper (since the other half page of print would go on an already printed page). Furthermore, we assume that the Part D EOB is double-sided. In some cases the extra 1.5 pages may fit on the last printed page and on its other side not necessitating more paper. Bulk mailing rates vary by vendor; an informal survey on the web suggests $0.19 for 2019 rates for 50 pounds (envelope weight is normally considered negligible when citing these rates). Other assumptions are possible but the main drivers of our added cost are paper and toner as opposed to postage. The following breaks down those costs:

- Paper costs $0.005 per sheet ($2.50 for a ream of paper with 500 sheets).
- Toner costs $0.005 per sheet ($50 for a toner cartridge lasting 10,000 sheets).
- Postage costs are $0.000038 per page since—

++ A sheet of paper weights 0.16 ounces (5 pounds/500 sheets × 16 ounces/pound).

++ Commercial bulk postage rates for 2019 are $0.19 for 200 pieces (50 pounds).

++ There are 16 ounces in one pound.

++ Postage cost per page is therefore $0.000038 ([$0.19 × 0.16 ounces per page]/[50 pounds × 16 ounces/pound]).

Thus, the total cost per page is $0.010038 ($0.005 for paper + $0.005 for toner + $0.000038 for postage). Finally, we note that Part D EOBs are sent out once per month to each enrollee summarizing drug transactions for the previous month. Thus we estimate an annual cost of $5,733,706 (47.6 million enrollees × 12 months × 1 page × $0.010038 per page). We believe that after appropriate programming (as discussed previously) the 47.6 million mailings will be performed automatically and will not require extra staff time.

Combining the estimates for system updates and mailing we obtain an annual estimated cost of $7,284,069 ($1,550,363 for updating systems + $5,733,706 for paper, printing, and mailing)

A summary of the public comments and our response follow:

Comment: Commenters disagreed with our burden analysis. They pointed out that multiple systems would have to be updated and disagreed with our estimates regarding template creation. Finally, one sponsor provided a $4.5 million estimate for set-up costs and a $6 million dollar estimate for mailing.

Response: We thank the commenters for this insight. Based on these comments, we revised our estimated time for sponsors to update their systems. Also, we note that our revised estimate assumes Part D sponsors will update their systems to obtain information for the template. Finally, our estimates for initial costs are $4.7 million for system updates $5.7 million for mailing costs. Our estimates, which were independently developed, are very close to the proposed impacts provided by the commenter.

5. ICRs Regarding Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, and 422.619)

The requirements and burden related to the establishment and use of a P&T Committee will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021. It was last approved on November 28, 2018, and remains active.

This rule provides protections to help ensure that beneficiaries maintain access to medically necessary Part B drugs while permitting MA plans to implement step therapy protocols that support stronger price negotiation and cost and utilization controls. In order to implement a step therapy program for one or more Part B drugs, this rule requires that an MA plan establish and use a P&T Committee to review and approve step therapy programs used in connection with Part B drugs. The P&T Committee requirements are similar to the requirements applicable to Part D plans under § 423.120(b). This rule allows MA–PD plans to use the Part D P&T Committee to satisfy the new requirements related to MA plans and Part B drugs. For MA plans that do not cover Part D benefits already, they may use the Part D P&T Committee of an MA–P&D plan under the same contract. Under § 422.4(c), every MA contract must have at least one plan offering Part D. Because of the small amount of work needed annually, we believe it is reasonable to assume that no new committees will be formed and that the added work will be performed by the existing P&T Committees.

The finalized § 422.136(b)(4) and (9) requires that the P&T Committee ''clearly articulate and document processes,'' We estimate it would take 1 hour at $72.84/hr. for a P&T Committee business specialist to perform certain tasks and review and retain documentation and information. This 1 hour estimate reflects half of the Part D P&T Committee burden (or 2 hours) that is currently approved by OMB under control number 0938–0964 (CMS–10141). We are estimating 1 hour since the MA P&T committee work for Part B step therapy programs is significantly less than the Part D P&T committee work; more specifically; per Section 30.1 of Chapter 6 of the Prescription Drug Benefit Manual,[16] the Part D P&T committee work has seven tasks, two of which, namely, formulary management

[16] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.*

and formulary exceptions, do not apply to the mandatory MA P&T committee work. The MA P&T committee work, under finalized § 422.136, is limited to review and approval of step therapy programs for Part B drugs (and not other types of utilization management programs). We lack quantitative data on the amount of work attributed to each of the seven tasks of the Part D P&T committee work. Therefore, we assumed a 50 percent reduction in the amount of work since two of the seven Part D P&T committee tasks are not required under Part B. In aggregate, we estimate an annual burden of 634 hours (1 hr. × [697 plans − 63 Prescription Drug plans which do not offer Part B]) at a cost of $46,181 (634 hr. × $72.84/hr.).

We received no comments on our proposed requirements and burden analysis and are finalizing this provision without modification.

We are also finalizing, without modification, our proposed beneficiary protection measure related to shorter adjudication timeframes for organization determinations and reconsiderations for requests for Part B drugs. Under this final rule, the adjudication timeframes applicable to requests for Part B drugs will, as proposed, be shorter than the timeframes that apply to requests for other covered medical items and services. At the time of the proposed rule's publication date (November 30, 2018) we did not finalize the necessary revisions to our Notice of Denial of Medical Coverage form and instructions (approved by OMB under control number 0938–0892; CMS–10003). Therefore, we did not set out such burden or solicit comment. Since that time, however, we have published a stand-alone 60-day **Federal Register** notice (April 10, 2019; 84 FR 14383) that sets out the revised form and form instructions. In compliance with the standard PRA process, we will also be publishing a stand-alone 30-day **Federal Register** notice (when ready). Please note that the revised form and instructions have no impact on this rule's burden estimates. Instead, the revision would include the Part B drug adjudication timeframes within the form and update the CFR citations within the instructions.

C. Summary of Information Collection Requirements and Burden

TABLE 3—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulatory reference	Provision brief title	Control No. (CMS ID No.)	Respondents	Total responses	Hours per respondent	Total hours	Labor cost ($/hr)	Total annual cost ($)
§ 423.128	Part D Explanation of Benefits (Updating Systems).	0938–0964 (CMS–10141)	295	295	160	15,733	$98.54	$1,550,363
§ 423.128	Part D Explanation of Benefits (Extra mailings) *.	0938–0964 (CMS–10141)	295	571,200,000	n/a	n/a	n/a	*5,733,706
§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, and 422.619.	Part B Step Therapy (use of PT Committee).	0938–0964 (CMS–10141)	634	634	1	634	72.84	46,181
Total			634	571,200,929	Varies	16,367	Varies	7,330,250

*Non-labor requirements and costs.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule supports Medicare health and drug plans' negotiation for lower drug prices and reduce out-of-pocket costs for Part C and D enrollees. Although satisfaction with the MA and Part D programs remains high, these proposals are responsive to input we received from stakeholders while administering the programs, as well as through our requests for comment.

HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 16, 2018, 83 FR 22692) sought to find out more information about lowering drug pricing using these four strategies: Improved competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs. We proposed a number of provisions that implement these four strategies in an attempt to lower out-of-pocket costs with a particular focus on strengthening negotiation for Part D plans and increasing competition in the market for prescription drugs. We proposed to offer more tools to MA and Part D plans that negotiate with drug companies on behalf of beneficiaries, so these plans are equipped with similar negotiation capabilities as group health plans and issuers have in the commercial market. We sought to drive robust competition among health plans and pharmacies, so consumers can shop based on quality and value. These provisions align with the Administration's focus on the interests and needs of beneficiaries, providers, MA plans, and Part D sponsors.

B. Overall Impact

We examined the impact of this final 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 Social Security Act (the Act), section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (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).

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This final rule affects MA plans and Part D sponsors (NAICS category 524114) with a minimum threshold for small business size of $38.5 million (*http://www.sba.gov/content/small-business-size-standards*). This final rule additionally affects hospitals (NAICS subsector 622) and a variety of provider categories, including physicians, specialists, and laboratories (subsector 621).

To clarify the flow of payments between these entities and the federal government, note that MA organizations submit bids (that is, proposed plan designs and projections of the revenue

needed to provide those benefits, divided into three categories—basic benefits, supplemental benefits, and Part D drug benefits) in June 2019 for operation in contract year 2020. These bids project payments to hospitals, providers, and staff as well as the cost of administration and profits. These bids in turn determine the payments from the Medicare Trust Fund to the MA organizations that pay providers and other stakeholders for their provision of covered benefits to enrollees. Consequently, our analysis will focus on MA organizations.

There are various types of Medicare health plans, including MA plans, Part D sponsors, demonstrations, section 1876 cost plans, prescription drug plans (PDPs), and Program of All-Inclusive Care for the Elderly (PACE) plans. Forty-three percent of all Medicare health plan organizations are not-for-profit, and 31 percent of all MA plans and Part D sponsors are not-for-profit. (These figures were determined by examining records from the most recent year for which we have complete data, 2016.)

There are varieties of ways to assess whether MA organizations meet the $38.5 million threshold for small businesses. The assessment can be done by examining net worth, net income, cash flow from operations, and projected claims as indicated in their bids. Using projected monetary requirements and projected enrollment for 2018 from submitted bids, 32 percent of the MA organizations fell below the $38.5 million threshold for small businesses. Additionally, an analysis of 2016 data—the most recent year for which we have actual data on MA organization net worth—shows that 32 percent of all MA organizations fall below the minimum threshold for small businesses.

If a final rule may have a significant impact on a substantial number of small entities, the final rule must discuss steps taken, including alternatives, to minimize burden on small entities. While a significant number (more than 5 percent) of not-for-profit organizations and small businesses are affected by this final rule, the impact is not significant. To assess impact, we use the data in Table 11C, which show that the raw (not discounted) net effect of this final rule over 10 years is $73.19 million. Comparing this number to the total monetary amounts projected to be needed just for 2020, based on plan submitted bids, we find that the impact of this final rule is significantly below the 3 to 5 percent threshold for significant impact. Had we compared the 2020 impact of the final rule to projected 2020 monetary need, the impact will be still less.

Consequently, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities, and we have met the requirements of the RFA. In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any final rule under title XVIII, title XIX, or Part B of Title XI of the Act that may have significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of UMRA 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 2019, that threshold is approximately $154 million. This final rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $150 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this final rule does not impose any substantial 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 750 MA contracts (which also includes PDPs), 50 State Medicaid Agencies, and 200 Medicaid Managed Care Organizations (1,000 reviewers total). 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.

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 rule is $107.38 per hour, including an upward adjustment to wages to account for overhead and benefits. (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 7.6 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is therefore, $816 (7.6 hours * $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $816,000 ($816 * 1000 reviewers).

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent entity or assuming (major) pharmacy benefit managers (PBMs) will read this rule. 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. However, we believe it is likely that reviewing will be performed by contract. 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.

As for PBMs, it is reasonable that only the major PBMs will review this rule. There are 30–50 major PBMs, and this will increase the estimate by 0.3 to 0.5 percent. Reviewing the source of comments on the proposed rule, we find about 300 distinct organizations commenting including health plans, universities and colleges, congressional-related entities, patient-centered associations, medical associations, pharmaceutical companies and manufacturers. Considering the wide source of comments and the wide use of drugs it is very reasonable that the total number of associations reading this is comparable to the number of health plans. This would double our estimate. Using these alternate considerations, we can safely say that the cost of reviewing is between half a million (50 percent * $816,000) and two million (2 * $816,000). Thus, we consider the $1 million a reasonable midpoint figure to estimate review cost.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget (OMB).

We received no comments on our estimates of impact on small businesses and other items mentioned in the overall impact section.

C. Anticipated Effects

1. Providing Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi))

In this rule, we are finalizing an exception to the protected class policy to allow Part D sponsors to apply PA and ST requirements for protected class

Part D drugs, except antiretrovirals, only for new starts to confirm intended use is for a protected class indication, and to ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. We also are finalizing a technical change to permit exclusion of interchangeable biological products.

Since under this exception, these utilization management tools (that is, PA and ST for new starts only, except for antiretrovirals) are already permitted today under similar circumstances for the protected classes for new treatment regimens, we do not anticipate any material impacts from the use of these tools for the five classes where it will be allowed. For antiretroviral drugs, we do not believe that utilization management would generate returns for plan sponsors' increased administrative burden, as these drug have narrower indications, clinical criteria, and range of products that curtail inappropriate use. As a result, we estimate no material impact from this provision as well.

Formally recognizing Part D sponsors' utilization management flexibility provides them with negotiating power. Additionally, utilization management will promote substitution when appropriate and reduce wasteful or inappropriate prescriptions. For example, if an antipsychotic drug is prescribed to a beneficiary and the beneficiary does not have a protected class indication that requires such a drug, these additional tools will allow Part D sponsors to better manage utilization of that drug. We did not assume any interactions with Part D sponsors' ability to use indication-based coverage, as no experience on that coverage is currently available.

At this time, we do not anticipate any adverse effects upon enrollee access to drugs in the protected classes. The reasons for this are two-fold. First, we did not propose to change or remove any of the protected classes identified in section 1860D–4(3)(G)(iv) of the Act. Second, in considering whether exceptions to the added protections afforded by the protected class policy are appropriate, we took into account the many other enrollee protections in the Part D program, which are mature and have proven workable. These protections include: Formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the expedited exception, coverage determination, and appeals processes.

Comment: Commenters generally agreed with our assessment of the impact of this provision. One commenter questioned why the impact analysis in this final rule sees more generic opportunity in the protected classes than MedPAC.

Response: While MedPAC has cited that the overall level of generic use in the antidepressant, antipsychotic, and anticonvulsant categories was similar to the overall generic use within Part D, our analysis of the drug level data using internal CMS files, on which MedPAC has not specifically commented, indicated that there was significant brand usage with the potential to shift to generic drugs under new utilization management practices. Comparing class-level generic use against overall generic use can also be misleading, as the availability of generics differs widely from class to class and over time.

Comment: Several commenters suggested that the estimated savings from these proposals were too limited to justify modifications to the protected classes policy.

Response: We disagree. While we are not finalizing modifications to the existing policy (but codifying existing policy), we continue to believe that it is possible that certain Part D sponsors may be able to use additional flexibility to improve their negotiating position and/or the effectiveness of their utilization management actions, thereby producing savings that we will not be able to quantify until after the policy takes effect. Additionally, we believe it is incumbent upon us to be a good steward of taxpayer dollars, no matter how modest the savings.

Comment: Some commenters encouraged us to consider manufacturer rebates across other Federal programs, including Medicaid, the VA and the 340B Drug Pricing Program (340B) before implementing our exceptions.

Response: While we appreciate the commenters' concerns, we are unable to quantify savings to the Part D program taking other Federal programs into account. Additionally, specific to 340B, with the exception of claims split-billed through AIDS Drug Assistance Programs (ADAPs), CMS does not collect information on which claims were processed under 340B.

Comment: A number of commenters expressed concern that PA and ST policies can lead to patients' not filling their prescriptions or underutilizing medications, which leads to non-adherence. Commenters expressed concern that non-adherence, in turn, can lead to interruptions in therapy across the six classes, and in the case of HIV, would endanger public health because it is a communicable disease which can rapidly mutate and become resistant to therapy.

Response: CMS acknowledges that PA and ST could potentially cause the issues cited when they are not implemented properly. However, we believe that based upon our more than 12 years of experience with the Part D program, including our existing policy, which allows for PA and ST for new starts of protected class Part D drugs (except antiretrovirals), and the unique protections we have in place, which are more robust than in other comparable programs, demonstrate that such concerns have been mitigated in Part D. For example, in the categories and classes of drugs not covered by the protected class policy, that is, all other Part D drug categories and classes, where wide use of PA and ST have been allowed since the beginning of the Part D program, subject to our other formulary requirements, we have no evidence to suggest that Part D enrollees routinely experience interruptions in therapy as a result of PA and ST requirements. Moreover, CMS is advancing improvements in price transparency, interoperability, and e-prescribing improvements, such as a real-time benefit tool (RTBTs) and Part D electronic prior authorization as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271), that could help mitigate the kinds of administrative burdens sometimes associated with PA and ST that commenters claim could lead to underutilization. As such, we did not account for any decreases in utilization in our estimate.

2. Prohibition Against Gag Clauses in Pharmacy Contracts (§ 423.120(a)(8)(iii))

This provision proposed to codify existing practice and therefore is expected to produce neither savings nor cost.

3. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160)

This provision proposed that each Part D plan sponsor adopt one or more Real Time Benefit Tool (RTBT) tools that are capable of integrating with at least one e-prescribing (eRx) and electronic health record (EHR) systems (the latter of which will hereinafter be referred to as an electronic health record or EHR for consistency with current Departmental terminology) for use in Part D E-Prescribing (eRx) transactions beginning on or before January 1, 2020. As discussed earlier in this preamble, we understand that some PBMs and a few prescription drug plans have already begun to use RTBT tools capable of meeting the specifications listed in

our preamble discussion, which includes providing beneficiary-specific drug coverage and out-of-pocket cost information at the point-of-prescribing. CMS sought to accelerate the use of such real time solutions in the Part D program so as to realize their potential to improve adherence, lower prescription drug costs, and minimize beneficiary out-of-pocket cost sharing. These tools have the capability to inform prescribers when lower-cost alternative therapies are available under the beneficiary's prescription drug benefit. We are interested in fostering the use of these real-time solutions in the Part D program, given their potential to lower prescription drug spending and minimize beneficiary out-of-pocket costs. Not only can program spending and beneficiary out-of-pocket costs be reduced, but (as discussed above) evidence suggests that reducing medication cost also yields benefits in patients' medication adherence.

We first give a high-level description of impact. The major savings of this provision will be use of RTBT to encourage prescribing of lower tier cost sharing drugs. This will result in a dollar savings to the Medicare Trust Fund. However, because of both lack of data and complexity of data, we are qualitatively scoring this provision and are therefore scoring this provision as a qualitative savings. In the NPRM we solicited comments from stakeholders on certain data. In response to our solicitation, the following assumptions and complications were pointed out:

- Current usage: Commenters confirmed our belief that some plans are already using RTBT. Commenter estimates ranged from 70 percent to 90 percent. Informal conversations with plans prior to publication of the NPRM provided an estimate of 30 percent. This combined wide range, 30 percent to 90 percent, shows both that RTBT is being adopted, that there is uncertainty on the extent of adoption.
- Cost if this Provision is Finalized:

Software costs: Commenters seem to reject the idea that any plans would create their own RTBT software. They believe that the existing opportunities from intermediaries was sufficient to satisfy new regulatory requirements. As a result of these comments, we are withdrawing in the Final Rule the estimates made in the NPRM on software costs.

Developing substitution logic. Many commenters cautioned that development of the logic to determine which formulary alternatives should be presented to a prescriber in a given situation will impose new burdens on plans. While IT programming can be leveraged across plans variable formularies require that each plan develop its own individual logic about which alternative drugs are available for use in RTBT scenarios. Plans must decide how many potential formulary substitutions should be presented to prescribers and must ensure that the prescriber is not overly burdened with choices.

Lower tier cost sharing substitution: CMS believes the primary source of RTBT savings to arise from the ability of providers to prescribe lower tier cost sharing drugs. While there are also savings from substitutions of generics for brands, many of these substitutions already are currently already being done by pharmacy benefit administrators. The commenters generally agreed with this assessment.

- Implementation date and Standardization:

We received numerous comments relating to the proposed January 1, 2020 implementation date. Although several commenters stated that the 2020 deadline was achievable, the majority of comments expressed concern. Most commenters, believe that it would be prudent to delay the implementation date until an industry standard was available with some commenters characterizing the proposed time frame as overly aggressive or unrealistic given the level of effort required to implement RTBT.

We understand that implementing RTBT requires time and resources for those plans that have not yet begun to implement a real time solution As a result, we are delaying the implementation date until January 1, 2021. However, given the potential benefits of RTBT, we strongly encourage plans to start implementing this requirement prior to January 1, 2021.

- Cost to providers: Some commenters were concerned about the cost of implementing multiple RTBT systems within EHRs. However, other commenters made it clear that plans who have implemented RTBT make the technology available to prescribers at no cost. Some commenters cautioned that RTBT may add time to a medical office visit but did not specify the potential cost impact of the additional time involved. Others commenters stated that while RTBT may add time to a medical office visit, it may provide enhanced benefits in terms of patient adherence to medication therapies which may save time in the long run. These divergent views left us unable to gain a definitive picture whether providers are negatively affected by the finalized provision. As a result, we lack data with which to reliably estimate and include provider costs in our analysis of the impact of this proposal.

CMS further notes that most plans are already making sure that prescribers are not bearing the cost of implementing RTBT tools. Indeed RTBT systems are being implemented by some plans because of the resulting cost savings.

- Savings vs Cost: Nearly all commenters were very enthusiastic about the concept of the proposed provision. They largely believed that any implementation costs incurred would be offset by costs savings. One commenter who has been using RTBT for about a year and noted that when presented with a lower cost, clinically appropriate alternatives, enrollees are receiving a lower cost medication 45 percent of the time, and saving an average of $130 per fill in out of pocket costs compared to the drug originally requested. CMS is unable to confirm these savings but these reported results suggest that RTBT can be instrumental in reducing drug costs. We recognize that it may take plans time to develop an RTBT infrastructure such as developing formulary alternatives and relationships with RTBT vendors.

We are finalizing the proposal for each Part D plan to support an RTBT of its choosing, effective January 1, 2021. We are removing the proposed requirement that covered health care providers get explicit beneficiary consent prior to using the RTBT.

We point out that any savings arising from this provision if finalized would be classified as a transfer since there is (at least as a primary impact) no reduction in consumption of goods (prescription drugs) but rather a transfer of expense from one drug to another. However, this transfer (between manufacturers of drugs) would result in reduced dollar spending by Part D Sponsors and enrollees and would result in reduced spending by the Medicare Trust Fund.

4. Part D Explanation of Benefits (§ 423.128)

In section III. of this final rule, we have detailed the cost to Part D sponsors to update their EOB templates. Additionally, CMS Central Office staff will have to develop the model language to be used by the Part D sponsors.

Significant effort goes into developing a model, including developing instructions and obtaining clearance. Therefore, we estimate that it would take two GS–13-Step 5 employees a month, each working a half a day, or 160 hours (2 employees * 4 hours a day * 5 days a week * 4 weeks) to develop the templates. It would additionally take a supervisory GS–15 staff, 5 hours to give approval.

Wages for 2018 for CMS staff may be obtained from the OPM website at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB_h.pdf.* We estimate a total burden of $17,583 (160 hours * $52.66/hr for GS–13, Step 5 staff * 2 ((for an upward adjustment to wages to account for overhead and benefits)).) + 5 hours * $73.20/hr for GS–15, Step 5 staff * 2 (for an upward adjustment to wages to account for overhead and benefits)).

As estimated in the Collection of Information Section of this Final Rule, the Part D EOB incurs a first year cost of $4.65 million for updating systems and ongoing costs in all years, including the first, of $5.73 million for additional mailings. Thus the total first year cost is $10.40 million (4.65+5.73+0.18 (the $17,583 cost for CMS staff to create a template)) and cost in subsequent years is $5.73 million.

5. Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, 422.619, 422.629, 422.633 and 422.634)

Step therapy is a type of utilization management (for example, prior authorization) for drugs that begin medication for a medical condition with the most preferred drug therapy and progress to other therapies only if necessary, promoting more cost effective therapies, potentially better clinical decisions, and lower costs for treatment. The lower costs of treatment primarily benefit MA enrollees and plans and are transferred to the government as savings.

A further source of savings is negotiations. If an MA plan offers all Part B drugs, then it typically will purchase drugs at market price. If the MA plan is allowed to use step therapy, then when there is more than one drug that has the same effect on a medical condition but the drugs differ significantly in price, drug manufacturers in their negotiations with MA plans, have an incentive to lower the cost of their drug so that their drug is selected by the MA plan as the first drug in the plan's step therapy protocol.

However, it is difficult to numerically estimate the savings from increased negotiations because, unlike other impact events, negotiations vary. Furthermore, we do not have access to negotiation data as this is proprietary information between MA plans and manufacturers and is not submitted in the MA bid. For these two reasons (lack of data and volatility) we are leaving the negotiation of increased savings as a qualitative, rather than a quantitative event. We believe that the potential savings from negotiations is significant, but have no way of quantifying the effect.

We note that although we are not estimating the savings from front-end negotiations, we do estimate the savings from back-end negotiations, more specifically, from the rebates manufacturers give plans with favorable drug management practices. Such rebates also occur on the Part D side and we have the data to estimate their effect. This is done in this section of this final rule when discussing the impact on the Medicare Trust Fund and beneficiary cost sharing due to step therapy.

Although CMS believes that step therapy can promote more cost effective therapies, potentially better clinical decisions, and lower costs for treatment for the reasons earlier discussed, we acknowledge that there are various studies suggesting that step therapy may be costly either economically or health-wise. There are two primary reasons for this.[17]

- Discontinuation: Several studies show that there is the potential for enrollees to become discouraged when step therapy is used. This is called discontinuation. Discontinuation means a portion of members with a claim rejection at the point of service go on to not have claims in that class of medications. In other words, an unwanted effect of step therapy is ''giving up'' and not seeking medical treatment. There are several studies of discontinuation.[18] Consequently, when discussing step therapy, it is important to address possible unwanted side effects such as discontinuation.
- Effects of delay: The idea of step therapy is that if the initial drug ''fails first'' then a provider will prescribe the drug they had originally wanted to prescribe. However, when the initially given drug does not work, this creates a delay in the patient receiving the necessary drug and consequently the delay may cause both a worsening of conditions and increased medical costs. Several studies on Part B drugs show this. For example, a study comparing spending in Georgia's Medicaid program found that while there were savings in the cost of medications when step therapy was used, the program spent more money on outpatient services because less-effective medications often led to higher health costs later.[19] Similar studies have been done on— legislation to protect people from certain harms of step therapy.[20] However, the MA program has many beneficiary protections and a robust appeals process to ensure that beneficiaries have access to the medications and health services they need. For example, we expect providers and enrollees who are concerned about the adverse effects of delay or that a drug on the initial step may not be the best or proper course of treatment, to seek pre-service organization determinations that permit use of the ultimate Part B drug and to appeal any denials by the MA plan. Since plan appeal rates are monitored by CMS, this creates a strong incentive for plans to use step therapy wisely and not exacerbating illness.

Summary: Step therapy can result in both savings and costs. While at the time of initiation of the step therapy there is initial savings arising from reduced drug costs, this savings may end up costing in the long run because of worsening conditions arising from the delay in receiving the proper drug resulting in increased medical costs. However, we believe the MA beneficiary protections and appeals process coupled with periodic CMS review and monitoring of MA plans is robust enough to ameliorate or eliminate the possible adverse effects of step therapy.

In addition to the complications in estimating the health savings from step therapy, some step therapy savings arise from negotiations, which are difficult to quantify. We can however, estimate the effect on the Medicare Trust Fund and on enrollee cost sharing.

The estimate of the impact on the Medicare Trust Fund includes the—(1) backend negotiations, rebates from manufacturers to plans; (2) use of less

[17] Article 1: Patrick P Gleason, PharmD, FCCP, BCPS, ''Assessing Step Therapy Programs: A step in the right direction,'' Journal of Managed Care Pharmacy, 13(3), 2007. Article 2: Adams AS, Zhang F, LeCates RF, et al. Prior authorization for antidepressants in Medicaid: Effects among disabled dual enrollees. Arch Intern Med. 2009; 169(8):750–756. Article 3: Zhang Y, Adams AS, Ross-Degnan D, Zhang F, Soumerai SB. Effects of prior authorization on medication discontinuation among Medicaid beneficiaries with bipolar disorder. Psychiatr Serv. 2009; 60(4):520–527.

[18] S. Shoemaker, R. Subramanian, D. Mauch, (Abt Associates). ''Effect of 6 Managed Care Pharmacy Tools: A Review of the Literature,'' Journal of Managed Care Pharmacy, Supplement, July 2010, Vol 16(6a), page s7.

[19] Retrospective assessment of Medicaid step therapy prior authorization antipsychotic medications. Clin Ther. 2008; 30(8):1524–39; discussion 1506–7. doi: 10.1016/j.clinthera.2008.08.009.

[20] Iowa passed a rule restricting the use of Step Therapy in Medicaid after patients encountered medical complications such as stomach ulcers and increased pain in cases where past efforts to find more cost-effective drugs or to try lower priced drugs were not considered by the plans. See *https://www.thegazette.com/subject/news/health/iowa-bill-would-allow-exemptions-from-fail-first-insurance-drug-practices-20170318.* In the absence of safeguards, such as requiring consideration of what works for patients, a grandfathering policy on existing therapies is advisable.

expensive biological products approved under section 351(k) of the Public Health Service Act (for example, biosimilars); and, (3) the choice of less expensive drugs with therapeutically equivalent effect. However, we do not discuss other quantitative effects of step therapy. The articles cited previously lay out many pros and cons of step therapy as well as the need for more studies to ascertain the true impact of step therapy.

CMS acknowledges that step therapy is a widely accepted tool for utilization management. Sixty percent of commercial insurers were using step therapy in 2010; in 2014, 75 percent of large employers offered enrollees plans with step therapy. Furthermore, the concerns expressed in this RIA section are not unique to Federal insurance programs such as Medicare Parts C and D. Eighteen states have enacted laws on the use of step therapy.[21] These laws vary widely and typically provide protections to beneficiaries against the misuse of step therapy.

TABLE 4—ESTIMATED SAVINGS TO MEDICARE TRUST FUND AND BENEFICARIES FROM STEP THERAPY

Year	Enrollment (thousands)	Part B Rx allowed pmpm with growth by medical inflation	Number of months per year	Adjustment for plans for proposed step therapy (%)	Assumed rebate percentage	Backing out of Part B premium (%)	Savings to medicare trust funds	Cost sharing percentage	Adjustment for enrollees for proposed step therapy (%)	Savings to beneficiaries
	(A)	(B)	(C)	(D)	(E)	(F)	(G) ($ millions)	(H)	(I)	(J) ($ millions)
							(G) = (A) * (B) * (C) * (D) * (E) * (F)			(J) = (A) * (B) * (C) * (H) * (I)
2020	23,181	$58.72	12	1.6	66	86	$145	13	0.2	$5
2021	24,062	60.21	12	1.6	66	86	154	13	0.2	5
2022	24,972	61.73	12	1.6	66	86	164	13	0.2	5
2023	25,858	63.30	12	1.6	66	86	174	13	0.2	6
2024	26,708	64.90	12	1.6	66	86	185	13	0.2	6
2025	27,549	66.55	12	1.6	66	86	195	13	0.2	6
2026	28,375	68.23	12	1.6	67	85	207	13	0.2	7
2027	29,161	69.96	12	1.6	67	85	218	13	0.2	7
2028	29,913	71.74	12	1.6	67	85	229	13	0.2	7
2029	30,590	73.55	12	1.6	67	85	240	13	0.2	8

The provision at § 422.136 will allow MA plans to use this utilization management tool for Part B drugs subject to some limits in the regulation. MA plans may explore the most effective ways to use step therapy to achieve savings while also ensuring access to medically necessary treatment options.

In the remainder of this section we estimate the impact on the Medicare Trust Fund and enrollee cost sharing, and explain the calculations which are summarized in Table 4.

We obtained projected MA enrollment from the 2018 Medicare Trust Fund report. This is presented in Column (A) of Table 4.

- 2016 is the most recent year for which we have Part B drug spending and utilization from the CMS data systems. Column (B) presents the average amount that MA enrollees pay per month on Part B drugs. This amount is trended (from 2016) to reflect medical inflation (5.2 percent a year) with ordinary inflation (2.6 percent) carved out. The inflation factors are obtained from the Medicare Trust Fund report. The product of MA enrollment and average Part B spending per month provides the aggregate MA Part B spending per month.
- The Part B spending per month is multiplied by 12 (Column (C)) to obtain the aggregate spending on Part B drugs annually.
- We estimate that, because of this step therapy provision, plans will save 1.6 percent (Column (D)) on the aggregate annual cost of Part B drugs. There are several points about this 1.6 percent. First, it represents the effect of the proposed provision (proposed § 422.136) in this final rule. As discussed earlier in this rule's preamble, an HPMS memo was issued by CMS in August 2018 rescinding an earlier memo prohibiting step therapy.[22] However, because this memo was published in late 2018, we do not have enough data to analyze the impact to 2019 claims at this point, so our estimate of 1.6 percent is based on prior experience. The 1.6 percent savings is independent, and not impacted, by the provisions in the August 2018 HPMS memo; rather, the 1.6 percent savings represents the estimated effects of the finalized provision versus a baseline (zero percent savings) which does not include the proposed provision nor the effects of the HPMS memo.

This finalized proposal surpasses the HPMS memo for periods beginning January 1, 2020 and it is the effects of this provision that the 1.6 percent captures. The 1.6 percent represents three factors contributing to savings from Step Therapy:

- Drugs for which there will be a less expensive biological product approved under section 351(k) of the Public Health Service Act in 2020, such as Remicade or Herceptin.
- Pairs of drugs which are clinically comparable but differ significantly in price. For example, Avastin®, Eylea®, and Lucentis® for the treatment of macular degeneration.
- Drugs for which the manufacturer gives a rebate to MA plans with favorable management patterns. This happens in drugs with sufficient competition, particularly in the treatment of rheumatoid arthritis. Using our experience on manufacturers providing rebates on Part D drugs, we are able to estimate the savings effects of similar rebates on Part B drugs. As mentioned previously, this corresponds to a savings in step-therapy from back-end negotiations.
- The multiplication of enrollment, average Part B cost per member per month, number of months per year and 1.6 percent represents the total dollar savings from this provision.
- We use this total dollar savings to estimate separately savings to the Medicare Trust Fund and savings to enrollees in cost sharing.
- To obtain savings to the Medicare Trust Fund we multiply the aggregate savings from step therapy by the average rebate percentage and the average backing out of part B premium representing the expected percentage reduction to Part B premium arising from savings. These percentages are found in Columns (E) and (F). The numbers in these columns are obtained by trending our experience with plan

[21] *https://www.aad.org/advocacy/state-policy/step-therapy-legislation.*

[22] Available online at: *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.*

submitted bids over the next 10 years. Column (G), the product of all previous columns, represents the dollar savings to the Medicare Trust Fund.

• To obtain savings to beneficiaries, we used the 2019 projected bid data submitted by MA plans to CMS in June 2018. These data show that on average 13 cents of every dollar paying for Part B drugs goes to cost sharing. We obtained this number by dividing the cost sharing for Part B drugs by the total cost of Part B drugs. This percentage is found in Column (H).

• We next have to adjust the savings due to step therapy. Recall that Column (D) indicates that step therapy will save 1.6 percent, the 1.6 percent arising from three factors listed previously. Of those three factors, enrollees do not benefit from manufacturer rebates. To illustrate this, consider a $20 drug for which the beneficiary pays a 20 percent copay ($4). At the end of the year, manufacturers and pharmacists give a rebate to plans that have used their products. Let us suppose (for purposes of illustration) that the rebate is $3. Theoretically the enrollee should get 60 cents of this $3 (20 percent copay * $3). However, the enrollee does not get a portion of the rebate. We estimate that 1.6 percent savings has a 1.4 percent component from manufacturer rebates and a 0.2 percent rebate from the other factors listed previously. It follows that for the enrollee, the savings from step therapy are 0.2 percent, not 1.6 percent. This is listed in Column (I).

• To obtain aggregate annual beneficiary savings we multiply MA enrollment (Column (A)), average cost of prescription drugs per month (Column (B)), number of months per year (Column (C)) and the 0.2 percent, the savings to enrollees from this step therapy provision (Column (I)). This gives the total dollar savings, of which enrollees pay 13 percent (Column (H)). The result is presented in Column (J).

The results of our calculations are summarized for 2020–2029 in Columns (G) and (J) of Table 4. The savings to enrollees are between $5 and $8 million; the savings to the Medicare Trust Fund are between $145 and $240 million.

These projected dollar savings to the Medicare Trust Fund are classified as transfers because the money on brand drugs would instead be spent on generic drugs. While brand drugs are more expensive, the primary driver of this expense is the research and development (R&D) that went into them, and for drugs that are already on the market R&D has already been done and would not change. In other words, although this regulatory provision would reduce the return on drug development because enrollees who are expected to purchase the brand and thus pay for the initial R&D would instead purchase generics, this reduced return would be experienced after the initial R&D has been completed; consequently, any immediate reduction in R&D services would not impact the availability of new drugs until later. There would also be no reduction in production of drugs, since generic manufacturers rather than brand manufacturers would produce the drugs consumed by enrollees. However, the cost to the enrollee and the Medicare Trust Fund would be significantly less because the enrollee and Medicare Trust Fund would no longer pay for the initial R&D. In conclusion, this provision would not reduce activities of production but rather transfers the performance of those services from brand manufacturers to generic manufacturers; however, as a consequence, the enrollees and Medicare Trust Fund would experience reduced dollars spent.

The allowance of step therapy for Part B drugs in MA could result in a higher appeal rate. We estimate the aggregate increase in cost in 2016 due to expected increased appeals as $0.8 million. Details are presented in Table 5. The following narrative explains this table.

TABLE 5—ESTIMATED INCREASE IN APPEALS ALL LEVELS DUE TO STEP THERAPY

	Total number of appeals in 2016	Estimated number of appeals involving step therapy (1)	Hours per appeal (2)	Hourly wages of physicians (3)	Total cost (1) × (2) × (3)
Reconsiderations	328,857	3913	0.8	$203.26	$636,350
IRE	58,023	690	0.8	203.26	112,277
Administrative Law Judge (ALJ)	3,481	41	0.8	203.26	6,737
Estimated Cost for 2016					755,363

Data for appeals are reported by MA plans. It typically takes 2 years for CMS to validate these data. Hence the latest year for which we have complete data is 2016. Appeals can happen at various levels. The first level is reconsiderations where an appeal is made for a plan to reconsider a decision. If this is denied, the case goes on to the IRE (a CMS contractor) to be reviewed. If this is also denied, the case can be appealed to an administrative law judge (ALJ) if the amount in controversy is met.

For 2016, there were 328,857 and 58,023 reconsiderations and IRE cases respectively in the MA program. We estimate that in general 6 percent of cases reaching the IRE go on to an ALJ.

Based on data pulled from the Medicare Appeals System for part D appeals, 1.19 percent of plan level appeals involving step therapy were denied. We use this as a proxy for the percent of cases involving part B drugs subject to step therapy that we expect to be appealed since we have no other basis. We believe it is reasonable to consider Part D appeals data related to cases that involve drugs subject to step therapy in developing these estimates. We also use the 1.19 percent as a proxy for the percent of reconsiderations and ALJ cases that involve step therapy. We acknowledge that percentages might be different at different appeal levels but the 1.19 percent is the only proportion we have.

Having derived the expected number of appeals involving step therapy we note that section 1852(g)(2) of the Act requires a reconsideration by a MA plan to deny coverage on the basis of medical necessity to be reviewed by a physician with the appropriate expertise; CMS has adopted two MA regulations (§§ 422.566(d) and 422.590(g)(2)) that implement this requirement for denials based on medical necessity determinations. We believe it is reasonable to assume that a decision to

deny coverage for a drug subject to step therapy will typically involve a medical determination whether the drug would be ineffective or cause adverse effects for the enrollee. A decision on a drug subject to step therapy is also likely to involve evaluation of a healthcare provider's assessment of medical necessity for the Part B drug; for example, the health care provider may indicate that the lower or earlier steps in the step therapy protocol are not clinically appropriate for that enrollee (such as in cases of allergy or a prior unsuccessful use of the preferred drug). Therefore, this estimate accounts for physician review of reconsiderations. Based on the BLS website at *https://www.bls.gov/oes/current/oes_nat.htm,* the mean hourly wage of physicians is $203.26. Our contractor experience with appeals suggests that the average time to process an appeal is 48 minutes, or, 0.8 hour.

Multiplying the number of appeals * 0.8 hour per appeal * $203.26 cost per hour we arrive at total cost for each appeal level. Adding these together we obtain the $0.8 million estimate, based on 2016 data.

Factors that enter into appeal rates include enrollment rates and changes in plan benefit packages. Appeal rates change from year to year. One major factor in appeal rates is enrollment. If enrollment increases by 10 or 20 percent then it is very reasonable that the number of appeals will approximately increase by that amount.

Thus to obtain estimates of cost for 2018 we will multiply the $0.8 million by the ratio of enrollment in 2018 to 2016. Similarly to obtain estimates for 2020 to 2024 we multiply by ratios of enrollment.

The ratio of 2018 to 2016 is 1.1585 based on enrollment figures from the CMS website. Projected enrollment for 2020 through 2029 may be obtained from Table IV.C1 in the 2018 Trustee report. Using these numbers we obtain the estimated cost of increased appeals for 2020 through 2029, presented in Table 6, as $1.0–$1.3 million.

TABLE 6—EXPECTED INCREASE IN APPEAL COSTS DUE TO STEP THERAPY

Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Cost of appeals (in millions)	1.0	1.0	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3

We received no comments on impact estimates of the proposed rule.

D. Expected Benefits

Any relevant expected benefits for enrollees, stakeholders, and the government have been fully discussed in section II. of this final rule.

E. Alternatives Considered

1. Providing Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi))

Previous proposals to address the protected classes were aimed at changing both the protected classes and exceptions to the requirement that formularies include all drugs in the protected class. However, we remain concerned that previous criteria, as established either by statute under the MIPPA authority, or by CMS under the Patient Protection and Affordable Care Act authority, did not strike the appropriate balance among enrollee access, quality assurance, cost-containment, and patient welfare that we were striving to achieve. Consequently, we elected not to propose any changes to the drug categories or classes that are the protected classes. As a result, the critical policy decision was how broadly or narrowly to establish exceptions to the requirement that all protected class drugs be included on the formulary. Overly broad exceptions might inappropriately limit the products within the protected classes, thereby creating access issues for Part D enrollees. Only narrow exceptions afford enrollee protections such as adequate access and improved quality assurance while also providing an incentive for manufacturers to aggressively rebate their products for formulary placement in an operationally feasible manner for Part D sponsors.

2. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160)

We proposed to require that each Part D plan select a real time benefit tool (RTBT) of its choosing by January 1, 2020. We had considered delaying regulatory action around real time requirements until the industry has developed a real time standard that could be used by all Part D plans. However, we believe that the benefits that would come with a real time standard in the form of cost transparency are substantial and should not be further delayed. We also considered requiring that plans use the optional fields in the NCPDP Formulary and Benefit standards (F&B) to provide much of the cost data that we believe would be important for prescribers to know. However, by definition, the F&B standards are batch standards so that the information provided is, by definition, not contemporaneous and are not specific to each beneficiary. For these reasons we opted in favor of proposing RTBT rather than proposing to require that plans use enhanced F&B standards.

3. Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, 422.619, 422.629, 422.633 and 422.634)

We finalized proposed requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs. We finalized our proposal to confirm authority for MA plans to implement appropriate utilization management and prior authorization tools for managing Part B drugs and proposed parameters on using step therapy to ensure it is implemented in a manner to reduce costs for both enrollees and the Medicare program. Our finalized policy includes specific parameters for how step therapy may be implemented for Part B drugs, including requiring review and approval from a P&T Committee that meets specific standards and permitting step therapy only for new administrations of the drug (subject to at least a 365 day lookback period). We also finalized our proposal to require new appeal timeframes and deadlines for MA plans to adjudicate and respond to requests concerning Part B drug coverage. An additional alternative considered during development of the proposed regulation was allowing step therapy for ongoing prescriptions or administrations of Part B drugs for enrollees who are actively receiving the affected medication at the time the step therapy program is adopted as well as for new administrations of a Part B drug. However, allowing MA plans to implement step therapy on ongoing prescriptions and administrations of Part B drugs would require the development of a transition process for affected enrollees and might result in negative health outcomes as on-going treatment would be disrupted. We lack a basis to quantify the impact of these expected negative health outcomes.

Furthermore, the estimated costs of developing a transition process, including providing enrollees with appropriate notice regarding their transition process and providing a temporary supply of affected drugs likely outweighs any savings. Moreover, we recognized the health significance of many Part B drug regimens (for example, cancer treatments) and are working to ensure enrollees will not encounter unnecessary barriers to medically necessary drugs or have disruptions in care. Therefore, under the finalized regulations at § 422.136(a)(1), step therapy programs are not permitted to disrupt enrollees' ongoing Part B drug therapies as our finalized regulations require that step therapy only be applied to new prescriptions or administrations of Part B drugs for enrollees who are not actively receiving the affected medication. More specifically, MA plans must have a look back period of 365 days instead of the proposed 108 days, to determine if the enrollee is actively taking a Part B drug and, thus, not subject to step therapy for that Part B drug. Further, when an enrollee elects a new plan, the plan would still be required to determine whether the enrollee has taken the Part B drug (that would otherwise be subject to step therapy) within the past 365 days. If the enrollee is actively taking the Part B drug, such enrollee would be exempted from the plan's step therapy requirement concerning that drug.

F. Accounting Statement and Table

The following table summarizes costs, savings, and transfers by provision.

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 7, we have prepared an accounting statement showing the savings and transfers associated with the provisions of this final rule for contract years 2020 through 2029. Table 7 is based on Table 8 which lists savings, costs, and transfers by provision.

TABLE 7—ACCOUNTING STATEMENT—CLASSIFICATIONS OF ESTIMATED SAVINGS, COSTS, AND TRANSFERS NEGATIVE NUMBERS INDICATE SAVINGS

From calendar years 2020 to 2029 [$ in millions]	Savings			Whom is spending or transferring
	Discount Rate		Period Covered	
	7%	3%		
Net Annualized Monetized Cost	7.46	7.38	CYs 2020–2029	MA Organizations, Part D Sponsors, Contractors for the Federal Government.
Annualized Monetized Savings			CYs 2020–2029	
Annualized Monetized Cost.	7.46	7.38	CYs 2020–2029	MA Organizations, Part D Sponsors, Beneficiaries.
Annualized Transfers	(191.23)	(194.63)	CYs 2020–2029	Federal government, MA organizations and Part D Sponsors, Beneficiaries.

The following Table 8 summarizes savings, costs, and transfers by provision and formed a basis for the accounting table. For reasons of space, Table 8 is broken into Table 8A (2020 through 2023), Table 8B (2024 through 2027) and Table 8C (2028 through 2029). In these tables savings are indicated as negative numbers in columns marked savings while costs are indicated as positive numbers in columns marked costs. Transfers result in reduced dollar spending by enrollees and the government and are indicated by negative numbers. All numbers are in millions. The row ''aggregate total by year'' gives the total of costs and savings for that year but does not include transfers. Table 8 forms the basis for Table 7 and for the calculation to the infinite horizon discounted to 2016, mentioned in the conclusion.

TABLE 8A—AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR

	2020 Savings	2020 Cost	2020 Transfers	2021 Savings	2021 Cost	2021 Transfers	2022 Savings	2022 Cost	2022 Transfers	2023 Savings	2023 Cost	2023 Transfers
Total Savings												
Total Costs		11.40			6.73			6.73			6.83	
Aggregate Total		11.40			6.73			6.73			6.83	
Total Transfers			(150.00)			(159.00)			(169.00)			(180.00)
Protected Classes, Government												
Protected Classes, Enrollees												
Gag Clauses												
E-Prescribing												
Part D EOB		10.40			5.73			5.73			5.73	
Step Therapy, Government			(145.00)			(154.00)			(164.00)			(174.00)
Step Therapy, Enrollees			(5.00)			(5.00)			(5.00)			(6.00)
Step Therapy Appeals		1.00			1.00			1.00			1.10	

TABLE 8B—AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR

	2024 Savings	2024 Cost	2024 Transfers	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers
Total Savings												
Total Costs		6.83			6.83			6.93			6.93	

TABLE 8B—AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR—Continued

	2024 Savings	2024 Cost	2024 Transfers	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers
Aggregate Total		6.83			6.83			6.93			6.93	
Total Transfers			(191.00)			(201.00)			(214.00)			(225.00)
Protected Classes, Government												
Protected Classes, Enrollees												
Gag Clauses												
E-Prescribing												
Part D EOB		5.73			5.73			5.73			5.73	
Step Therapy, Government			(185.00)			(195.00)			(207.00)			(218.00)
Step Therapy, Enrollees			(6.00)			(6.00)			(7.00)			(7.00)
Step Therapy Appeals		1.10			1.10			1.20			1.20	

TABLE 8C—AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLION BY PROVISION AND YEAR

	2028 Savings	2028 Cost	2028 Transfers	2029 Savings	2029 Cost	2029 Transfers	Raw 10 year totals
Total Savings							
Total Costs		6.93			7.03		73.19
Aggregate Total		6.93			7.03		73.19
Total Transfers			(236.00)			(248.00)	(1,973.00)
Protected Classes, Government							
Protected Classes, Enrollees							
Gag Clauses							
E-Prescribing							
Part D EOB		5.73			5.73		61.99
Step Therapy, Government			(229.00)			(240.00)	(1,911.00)
Step Therapy, Enrollees			(7.00)			(8.00)	(62.00)
Step Therapy Appeals		1.20			1.30		11.20

G. Conclusion

As indicated in the ''Aggregate Total'' row of Table 8, we estimate that this final rule generates for each year in 2021 through 2029, net costs of approximately $7 million, with a first year cost of approximately $11.4 million. These annual costs primarily reflect mailing and programming costs arising from descriptions of alternatives in the Part D EOB as well as increased appeals arising from the Step Therapy provision. This final rule has no provisions which save.

Although other impacts in this rule are classified as transfers as discussed in each provision, the aggregate effect of these transfers reduce dollar spending by MA enrollees and the Medicare Trust Fund:

- Enrollees: Enrollees are estimated to reduce their spending on cost sharing by $62 million over 10 years from reduced cost sharing from Step Therapy.
- Government: The Medicare Trust Fund in aggregate reduces their dollar spending by $1.91 billion over 10 years from the Step Therapy provisions.

H. Reducing Regulation and Controlling Regulatory Costs

In line with Executive Order 13771, in Table 9, we estimate present and annualized values of costs and cost savings over an infinite time horizon. Costs are indicated by positive numbers. Based on these costs, this Final Rule would be considered a regulatory action under Executive Order 13771. As shown, this final rule generates level annual costs of $5.9 million over an infinite horizon in 2016 dollars discounted at 7 percent.

TABLE 9—E.O. 13771 SUMMARY TABLE

[In 2016 dollars over a perpetual time horizon]

Item	Primary (7%)	Primary (3%)
Present Value of Costs	84.4	217.2
Present Value of Cost Savings	0.0	0.0
Present Value of Net Costs	84.4	217.2
Annualized Cost	5.9	6.5
Annualized Cost Savings	0.0	0.0
Annualized Net Costs	5.9	6.5

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, and 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 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 422.2 is amended by adding a definition for ''Step therapy'' in alphabetical order to read as follows:

§ 422.2 Definitions.

* * * * *

Step therapy means a utilization management policy for coverage of drugs that begins medication for a medical condition with the most preferred or cost effective drug therapy and progresses to other drug therapies if medically necessary.

■ 3. Section 422.136 is added to subpart C to read as follows:

§ 422.136 Medicare Advantage (MA) and step therapy for Part B drugs.

(a) *General.* If an MA plan implements a step therapy program to control the utilization of Part B-covered drugs, the MA organization must—

(1) Apply step therapy only to new administrations of Part B drugs, using at least a 365 day lookback period;

(2) Establish policies and procedures to educate and inform health care providers and enrollees concerning its step therapy policies.

(3) Prior to implementation of a step therapy program, ensure that the step therapy program has been reviewed and approved by the MA organization's pharmacy and therapeutic (P&T) committee.

(b) *Step therapy and pharmacy and therapeutic committee requirements.* An MA plan must establish a P&T committee prior to implementing any step therapy program. An MA plan must use a P&T committee to review and approve step therapy programs used in connection with Part B drugs. To meet this requirement, a MA–PD plan may utilize an existing Part D P&T committee established for purposes of administration of the Part D benefit under part 423 of this chapter and an MA plan may utilize an existing Part D P&T committee established by an MA–PD plan operated under the same contract as the MA plan. The P&T committee must—

(1) Include a majority of members who are practicing physicians or practicing pharmacists.

(2) Include at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to—

(i) The MA organization and MA plan; and

(ii) Pharmaceutical manufacturers.

(3) Include at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(4) Clearly articulate and document processes to determine that the requirements under paragraphs (b)(1) through (3) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(5) Base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(6) Consider whether the inclusion of a particular Part B drug in a step therapy program has any therapeutic advantages in terms of safety and efficacy.

(7) Review policies that guide exceptions and other step therapy processes.

(8) Evaluate and analyze treatment protocols and procedures related to the plan's step therapy policies at least annually consistent with written policy guidelines and other CMS instructions.

(9) Document in writing its decisions regarding the development and revision of step therapy activities and make this documentation available to CMS upon request.

(10) Review and approve all step therapy criteria applied to each covered Part B drug.

(11) Meet other requirements consistent with written policy guidelines and other CMS instructions.

(c) *Off-label drug requirement.* An MA plan may include a drug supported only by an off-label indication in step therapy protocols only if the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices.

(d) *Non-covered drugs.* A step therapy program must not include as a component of a step therapy protocol or other condition or requirement any drugs not covered by the applicable MA plan as a Part B drug or, in the case of an MA–PD plan, a Part D drug.

■ 4. Section 422.568 is amended by revising paragraphs (b), (d), (e) introductory text, and (e)(4)(i) to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

* * * * *

(b) *Timeframes*—(1) *Requests for service or item.* Except as provided in paragraph (b)(1)(i) of this section, when a party has made a request for a service or an item, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination.

(i) *Extensions; requests for service or item.* The MA organization may extend the timeframe by up to 14 calendar days if—

(A) The enrollee requests the extension;

(B) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(C) The extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest.

(ii) *Notice of extension.* When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(2) *Requests for a Part B drug.* An MA organization must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. This 72-hour period may not be extended under the provisions in paragraph (b)(1)(i) of this section.

* * * * *

(d) *Written notice for MA organization denials.* The MA organization must give the enrollee a written notice if—

(1) An MA organization decides to deny a service or an item, Part B drug, or payment in whole or in part, or reduce or prematurely discontinue the level of care for a previously authorized ongoing course of treatment.

(2) An enrollee requests an MA organization to provide an explanation of a practitioner's denial of an item, service or Part B drug, in whole or in part.

(e) *Form and content of the MA organization notice.* The notice of any denial under paragraph (d) of this section must—

* * * * *

(4)(i) For service, item, and Part B drug denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

* * * * *

■ 5. Section 422.570 is amended by revising paragraph (d)(1) to read as follows:

§ 422.570 Expediting certain organization determinations.

* * * * *

(d) * * *

(1) Automatically transfer a request to the standard timeframe and make the determination within the 72-hour or 14-

day timeframe, as applicable, established in § 422.568 for a standard determination. The timeframe begins when the MA organization receives the request for expedited determination.

* * * * *

■ 6. Section 422.572 is amended by revising paragraphs (a), the heading to paragraph (b), and (b)(1) to read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframes*—(1) *Requests for service or item.* Except as provided in paragraph (b) of this section, an MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(2) *Requests for a Part B drug.* An MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician or prescriber involved, as appropriate) of its decision as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. This 24-hour period may not be extended under the provisions in paragraph (b) of this section.

(b) *Extensions; requests for service or item.* (1) When timeframe may be extended. The MA organization may extend the 72-hour deadline for expedited organization determinations for requests for services or items by up to 14 calendar days if—

(i) The enrollee requests the extension;

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent, or other nonroutine circumstances and is in the enrollee's interest.

* * * * *

■ 7. Section 422.584 is amended by revising paragraph (d)(1) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(d) * * *

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30 calendar day or 7 calendar day, as applicable, timeframe established in § 422.590(a) and (c). The timeframe begins the day the MA organization receives the request for expedited reconsideration.

* * * * *

■ 8. Section 422.590 is revised to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Requests for service or item.* (1) Except as provided in paragraph (f) of this section, if the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration.

(2) If the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(b) *Standard reconsideration: Requests for payment.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with § 422.618(a)(1)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

(2) If the MA organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(c) *Standard reconsideration: Requests for a Part B drug.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)(3)) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard reconsideration. This 7 calendar-day period may not be extended under the provisions in paragraph (f) of this section.

(2) If the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted with CMS no later than 7 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding the information to the independent entity.

(d) *Effect of failure to meet timeframe for standard reconsideration.* If the MA organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a), (b), or (c) of this section, this failure constitutes an affirmation of its adverse organization determination, and the MA organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2), (b)(2), and (c)(2) of this section.

(e) *Expedited reconsideration*—(1) *Timeframe for services or items.* Except as provided in paragraph (f) of this section, an MA organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Timeframe for Part B drugs.* An MA organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician or other prescriber involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request. This 72-hour period may not be extended under the provisions in paragraph (f) of this section.

(3) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of a completely favorable expedited reconsideration orally, it

must mail written confirmation to the enrollee within 3 calendar days.

(4) *How the MA organization must request information from noncontract providers.* If the MA organization must receive medical information from noncontract providers, the MA organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the MA organization in meeting the required timeframe. Regardless of whether the MA organization must request information from noncontract providers, the MA organization is responsible for meeting the timeframe and notice requirements.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the MA organization affirms, in whole or in part, its adverse expedited organization determination, the MA organization must submit a written explanation and the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(f) *Extensions; requests for service or item.* (1) As described in paragraphs (f)(1)(i) through (iii) of this section, the MA organization may extend the standard or expedited reconsideration deadline for services by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent or other non-routine circumstances and is in the enrollee's interest.

(2) When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(g) *Failure to meet timeframe for expedited reconsideration.* If the MA organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (e)(1) or (2) of this section, as applicable, this failure constitutes an adverse reconsidered determination, and the MA organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (e)(1) or (2) of this section.

(h) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in making the organization determination must conduct the reconsideration.

(2) When the issue is the MA organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

■ 9. Section 422.618 is amended by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

§ 422.618 How an MA organization must effectuate standard reconsidered determinations or decisions.

(a) *Reversals by the MA organization*—(1) *Requests for service.* If, on reconsideration of a request for service, the MA organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(f)).

(2) *Requests for payment.* If, on reconsideration of a request for payment, the MA organization completely reverses its organization determination, the organization must pay for the service no later than 60 calendar days after the date the MA organization receives the request for reconsideration.

(3) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days after the date the MA organization receives the request for reconsideration.

(b) * * *

(3) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the Part B drug under dispute within 72 hours from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

* * * * *

■ 10. Section 422.619 is amended by—

■ a. Revising paragraphs (a) and (b);

■ b. Redesignating paragraph (c)(2) as paragraph (c)(3); and

■ c. Adding a new paragraph (c)(2).

The revisions and addition read as follows:

§ 422.619 How an MA organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the MA organization*—(1) *Requests for service or item.* If, on reconsideration of an expedited request for service, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the service or item under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(f)).

(2) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the MA organization receives the request for reconsideration.

(b) *Reversals by the independent outside entity*—(1) *Requests for service or item.* If the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the

organization has effectuated the decision.

(2) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The MA organization must inform the outside entity that the organization has effectuated the decision.

(c) * * *

(2) *Reversals of decisions related to Part B drugs.* If the independent outside entity's determination is reversed in whole or in part by an ALJ/attorney adjudicator or at a higher level of appeal, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The MA organization must inform the outside entity that the organization has effectuated the decision.

* * * * *

■ 11. Effective January 1, 2021, § 422.629 is amended by revising paragraph (a) to read as follows:

§ 422.629 General requirements for applicable integrated plans.

(a) *Scope.* The provisions in this section and in §§ 422.630 through 422.634 set forth requirements for unified appeals and grievance processes with which applicable integrated plans must comply. Beginning January 1, 2021, these provisions apply to an applicable integrated plan in lieu of §§ 422.564, 422.566(c) and (d), and 422.568 through 422.590, and 422.618(a) and §§ 438.404 through 438.424 of this chapter; provisions governing Part B drugs in §§ 422.568(b)(2), 422.570(d)(2), 422.572(a)(2), 422.584(d)(1), 422.590(c), and 422.590(e)(2) apply to an applicable integrated plan.

* * * * *

■ 12. Effective January 1, 2021, § 422.631 is amended by revising paragraph (a) to read as follows:

§ 422.631 Integrated organization determinations.

(a) *General rule.* An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits. Timeframes and notice requirements for integrated organization determinations for Part B drugs are governed by the provisions for Part B drugs in §§ 422.568(b)(2), 422.570(d)(2), and 422.572(a)(2).

* * * * *

■ 13. Effective January 1, 2021, § 422.633 is amended by revising paragraph (f) introductory text to read as follows:

§ 422.633 Integrated reconsideration.

* * * * *

(f) *Resolution and notification.* The applicable integrated plan must make integrated reconsidered determinations as expeditiously as the enrollee's health condition requires but no later than the timeframes established in this section. Integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2).

* * * * *

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 14. The authority citation for part 423 is revised to read as follows:

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

■ 15. Section 423.120 is amended—

■ a. In paragraph (a)(8)(i) by removing ''and'' from the end;

■ b. In paragraph (a)(8)(ii) by removing the ''.'' and adding in its place ''; and'';

■ c. Adding new paragraph (a)(8)(iii);

■ d. Revising paragraph (b)(2)(vi)(A);

■ e. Redesignating paragraph (b)(2)(vi)(C) as (b)(2)(vi)(D); and

■ f. Adding new paragraphs (b)(2)(vi)(C).

The additions and revisions read as follows:

§ 423.120 Access to covered Part D drugs.

(a) * * *

(8) * * *

(iii) May not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D plan enrollee of the availability at that pharmacy of a prescribed medication at a cash price that is below the amount that the enrollee would be charged to obtain the same medication through the enrollee's Part D plan.

* * * * *

(b) * * *

(2) * * *

(vi) * * *

(A) Drug or biological products that are rated as either of the following:

(*1*) Therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' also known as the Orange Book).

(*2*) Interchangeable (under the Food and Drug Administration's most recent publication of the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations).

* * * * *

(C) Subject to CMS review and approval, for enrollees that are not on existing therapy on the protected class Part D drug, and except for antiretroviral medications, prior authorization and step therapy requirements to confirm intended use is for a protected class indication, to ensure clinically appropriate use, to promote utilization of preferred formulary alternatives, or a combination thereof.

* * * * *

■ 16. Effective January 1, 2021, § 423.128 is amended by—

■ a. Redesignating paragraphs (e)(5) and (6) as paragraphs (e)(6) and (7); and

■ b. Adding a new paragraph (e)(5).

The addition reads as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(e) * * *

(5) For each prescription drug claim, must include the cumulative percentage increase (if any) in the negotiated price since the first claim of the current benefit year and therapeutic alternatives with lower cost-sharing, when available as determined by the plan, from the applicable approved plan formulary.

* * * * *

■ 17. Effective January 1, 2021, § 423.160 is amended by adding paragraph (b)(7) to read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(7) *Real time benefit tools.* No later than January 1, 2021, implement one or more electronic real-time benefit tools (RTBT) that are capable of integrating with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR) to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under

the Part D plan. Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug.

* * * * *

Dated: April 25, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: May 8, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–10521 Filed 5–16–19; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 84 Thursday,
No. 100 May 23, 2019

Part III

Department of Commerce

Bureau of Industry and Security

15 CFR Part 774

Implementation of Certain New Controls on Emerging Technologies Agreed at Wassenaar Arrangement 2018 Plenary; Final Rule

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No. 181129999–8999–01]

RIN 0694–AH69

Implementation of Certain New Controls on Emerging Technologies Agreed at Wassenaar Arrangement 2018 Plenary

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security maintains, as part of its Export Administration Regulations, the Commerce Control List (CCL), which identifies certain items subject to Department of Commerce's jurisdiction. This final rule revises the CCL to implement certain changes made to the Wassenaar Arrangement List of Dual-Use Goods and Technologies maintained and agreed to by governments participating in the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies (Wassenaar Arrangement, or WA) at the December 2018 WA Plenary meeting. The Wassenaar Arrangement advocates implementation of effective export controls on strategic items with the objective of improving regional and international security and stability. This rule harmonizes the CCL with only the agreements on recently developed or developing technologies not previously controlled that are essential to the national security of the United States and warrant early implementation. The remaining agreements will be implemented in a separate rule.

DATES: This rule is effective May 23, 2019.

FOR FURTHER INFORMATION CONTACT: For general questions, contact Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce at 202–482–2440 or by email: *Sharron.Cook@bis.doc.gov.*

For technical questions contact:

Category 3 (Electronics): Brian Baker at 202–482–5534.

Category 5 (Information Security): Aaron Amundson or Anita Zinzuvadia 202–482–0707.

Category 6 (Acoustic projector/transducer): Michael Tu 202–482–6462.

Category 9x515 (Satellites): Michael Tu 202–482–6462.

SUPPLEMENTARY INFORMATION:

Background

The Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies (Wassenaar or WA) (*http://www.wassenaar.org/*) is a group of 42 like-minded states committed to promoting responsibility and transparency in the global arms trade, and preventing destabilizing accumulations of arms. As a Participating State, the United States has committed to controlling for export all items on the WA control lists. The control lists, which include the Wassenaar Arrangement Munitions List and the Wassenaar Arrangement List of Dual-Use Goods and Technologies, were first established in 1996 and have been revised annually thereafter. Proposals for changes to the WA control lists are reviewed by Participating States at expert group and annual plenary meetings. Participating States are charged with implementing the agreed list changes as soon as possible after approval. The United States' implementation of WA list changes ensures U.S. companies have a level playing field with their competitors in other WA Participating States.

This rule adds to the EAR's Commerce Control List (CCL) five recently developed or developing technologies that are essential to the national security of the United States: discrete microwave transistors (a major component of wideband semiconductors), continuity of operation software, post-quantum cryptography, underwater transducers designed to operate as hydrophones, and air-launch platforms.

Revisions to the Commerce Control List Related to WA 2018 Plenary Agreements

Revises (4) ECCNs: 3A001, 5A002, 6A001 and 9A004.

Added ECCNs: 3D005.

3A001 Electronic Items

ECCN 3A001 is amended by adding paragraph b.3.f to control discrete microwave transistors ''rated for operation with a peak saturated power output greater than 5 W (37.0 dBm) at all frequencies exceeding 8.5 GHz up to and including 31.8 GHz''. While older devices specified limited frequency ranges, new microwave transistors cover wider frequency bands at higher power levels, opening up new possibilities for radar and other transmitting applications.

Note 1 that appears after paragraph b.3.f is revised, so that it does not apply to new paragraph b.3.f, meaning that the control status of a transistor in b.3.f is not determined by the lowest peak saturated power output control threshold.

Discrete microwave transistors are used in microwave semiconductors and are applicable for both civilian use, such as mobile phone base stations and weather radars, and military use, such as fire control radars, decoys and jammers. Discrete microwave transistors are also increasingly used in wideband semiconductors, which have less power output and are more energy-efficient than the narrowband semiconductors. These features permit wideband semiconductors to operate at much higher voltages, frequencies and temperatures than conventional semiconductors. The wideband semiconductor is mainly used for military applications, such as electronic counter-measures for decoys, jammers and military radars, because it has a fractional bandwidth greater than 100%, and can enable a wide range of military radars, seekers, decoys and jammers. However, there are also instances of wideband semiconductors being used in civilian applications, such as to make green and blue light emitting diodes (LEDs) and lasers, which are used in DVD players (the Blu-ray and HD DVD formats). Wideband semiconductors will likely be a technology used in new electrical grid and alternative energy devices, in which such semiconductors will reduce energy loss and enable longer performance life in solar and wind energy power converters and eliminate bulky grid substation transformers. In addition, these robust and efficient power components are expected to be used in high energy vehicles, including electric trains and plug-in electric vehicles. It has been predicted that wideband semiconductors will facilitate simpler and higher efficiency charging for hybrid and all-electric vehicles.

These discrete microwave transistors are subject to National Security (NS Column 1), Regional Stability (RS Column 1) and Anti-terrorism (AT Column 1) license requirements, except those being exported or reexported for use in civil telecommunications applications, as indicated on the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR. List-based license exceptions (Limited Value Shipment (LVS) and Group B Shipments (GBS) and Strategic Trade Authorization (STA), see part 740 of the EAR), are available for those discrete microwave transistors that are being exported or reexported for use in civil telecommunications applications that meet the criteria of the license

exception and where none of the license exception restrictions of § 740.2 apply. Transaction-based license exceptions may be available depending on the transaction meeting the license exception criteria; see part 740 of the EAR.

3D005 Continuity of Operation Software

ECCN 3D005 is added to the CCL in order to control software that ensures continuity of operation when electronics are exposed to Electromagnetic Pulse (EMP) or Electrostatic Discharge (ESD). The software is controlled for national security and anti-terrorism reasons and a license is required worldwide, except for Canada, under national security (NS Column 1) and Anti-terrorism (AT Column 1) license requirements as indicated on the Commerce Country Chart, Supplement no. 1 to part 738 of the EAR. No list-based license exceptions are applicable; however, License Exception Strategic Trade Authorization (STA) is available for countries listed in Country Group A:5, see Supplement No. 1 to part 740 of the EAR.

Research and development activities related to integrated circuit software that provides electromagnetic pulse (EMP) protective function to electronic devices is currently underway, and it is predicted that these products will be in the commercial marketplace in a few years. Because continuity of operation software would also be beneficial to military applications, it is being added to the CCL in this final rule.

Category 5—Part 2—''Information Security''

ECCN 5A002 is amended in order to add a control on certain types of post-quantum cryptographic algorithms. This rule adds paragraph 2.c of the Technical Notes that follow paragraph 5A002.a.4 to include a new paragraph addressing certain post-quantum asymmetric algorithms. This rule also revises paragraphs 5A002.a, a.4, paragraph 2 of the Technical Notes that follow paragraph 5A002.a.4, paragraph a.1.a.1.b in Note 2 to 5A002.a, and paragraph (4)(a) of Related Controls to 5A002, to replace the term 'in excess of 56 bits of symmetric key length, or equivalent' with 'described security algorithm'. These changes are being made for technical accuracy since methods for establishing equivalence between modern classical and post-quantum cryptography (PQC) are not settled. In addition, this rule revises the Nota Bene to Note 3 (the Cryptography Note) to specify that items that include post-quantum asymmetric algorithms described by paragraph 2.c of the Technical Notes are subject to the classification or self-classification reporting requirements for mass market items.

The WA cryptography controls reflect the development and application of modern cryptography. Currently, the WA includes controls over the most commonly-used forms of cryptography in the contemporary world: symmetric algorithms based on key length; and asymmetric algorithms based on factorization of integers or on the computation of discrete logarithms (over various groups). These controls are defined in the Technical Note 2 to 5A002.a of the CCL.

The WA introduced specific parameters for the export control of cryptography in 1998, along with a general Category 5—Part 2 exclusion for 'mass market' encryption products (Cryptography Note, Note 3), in recognition of the increasing use of cryptography in the public domain. While the structure of Category 5—Part 2 of the WA has evolved significantly since 1998, the algorithms addressed have remained unchanged.

These algorithms continue to provide adequate protection for encrypted data, based on the threat posed by attack by a non-quantum computer. However, if and when large scale quantum computers are built, they will likely undermine the security of current cryptographic systems.

One goal of PQC is to develop and deploy quantum-resistant algorithms well in advance of a potential attack from a quantum computer. As the threat of quantum computers grows nearer, cryptography researchers are developing algorithms and working towards standardizing algorithms that resist attack from existing known quantum algorithms (such as Shor's Algorithm). PQC is currently in use in commercial products, but those algorithms are not covered by any WA controls. Because such algorithms are becoming increasingly common, this control is being added to ensure that there is consistent treatment and a level playing field between modern classical and post-quantum cryptography.

5A002.a is subject to national security (NS Column 1), anti-terrorism (AT Column 1) and encryption items (EI) license requirements, as indicated on the Commerce Country Chart in Supplement no. 1 to part 738 of the EAR. Because this new control is added to 5A002.a with corresponding applicability to EI-controlled ECCNs 5D002.a.1, 5D002.c.1 and 5E002.a, BIS has determined that no changes to License Exception ENC are required to accommodate this change. Items with post-quantum algorithms described by the technical note are treated the same under License Exception ENC as products using classical algorithms.

6A001 Acoustic Systems, Equipment and ''Components''

ECCN 6A001 is amended by moving the Note previously located below Item paragraph a.2.g.4 to below the introductory Item paragraph a.2 for better readability. This Note informs the public that Item paragraph a.2 ''applies to receiving equipment, whether or not related in normal application to separate active equipment, and ''specially designed'' components therefor''. This rule also adds a Technical Note 2 after paragraph a.2.a to alert the public that underwater acoustic transducers designed to operate as passive receivers are hydrophones. This rule revises paragraph a.2.a.6 to add the parameter ''and having a 'hydrophone sensitivity' better than −230 dB below 4 kHz'', to remove any transducers or hydrophones that are not of strategic concern.

An underwater transducer that is designed to operate as a hydrophone, designed for operation below 1000 m and having a useful sensitivity below 4 kHz, must be controlled because of its utility in Anti-Submarine Warfare (ASW). These amendments will bridge the control gap that previously treated underwater acoustic transducers and receivers separately. Newer underwater acoustic devices can more readily operate in both transmit and receive mode. The new control structure resulting from these amendments allows each aspect of these multifunction devices to be evaluated.

This rule also corrects a License Exception LVS paragraph for 6A001.a.1.b.1 by reversing the frequency band range for the equipment from ''30 kHz to 2 kHz'' to read ''2 kHz to 30 kHz''. All items in ECCN 6A001 are subject to national security (NS Column 2) and anti-terrorism (AT Column 1) license requirements as indicated in the Commerce Country Chart in Supplement no. 1 to part 738 of the EAR. License Exception Low Value Shipment (LVS) may be available depending on the operating frequency. License Exception Strategic Trade Authorization (STA) and transaction-based license exceptions may also be available depending on the circumstances of the transaction and the destination; see part 740 of the EAR.

9A004 Space Launch Vehicles and ''Spacecraft'', ''Spacecraft Buses'', ''Spacecraft Payloads'', ''Spacecraft'' On-Board Systems or Equipment, and Terrestrial Equipment

ECCN 9A004 is amended by revising the Heading to add air-launch platforms. This rule adds new Item paragraph 9A004.g, which controls ''aircraft'' ''specially designed'' or modified to be air-launch platforms for space launch vehicles (SLV). The license requirements table is revised to add 9A004.g to the NS and AT license requirements paragraphs.

Several commercial entities are building space-bound craft that will utilize an air-launch rather than traditional ground launch. This new Item paragraph expands existing space-launch controls to include this developing technology. Originally, military aircraft were used for air-launched rockets to carry satellites specifically for military applications. Now, air-launch platforms allow the use of specialized commercial aircraft instead of rockets or military aircraft to facilitate the transport and launch of commercial satellites. The increase in commercial space activities has commercial satellite owners and space tourism companies moving toward air-launch platforms to support their endeavours.

Items specified in 9A004.g require a license for national security (NS Column 1) and anti-terrorism reasons (AT Column 1) as indicated on the Commerce Country Chart in Supplement no. 1 to part 738 of the EAR. There are no list-based license exceptions, but transaction-based license exceptions may be available; see part 740 of the EAR.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801 to 4852) that provides the legal basis for BIS's principal authorities. As set forth in Section 4826 of ECRA, all delegations, rules, regulations, orders, determinations, licenses, or other forms of administrative action that have been made, issued, conducted, or allowed to become effective under the Export Administration Act of 1979 (50 U.S.C. 4601 *et seq.*) and as continued in effect pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), shall continue in effect according to their terms until modified, superseded, set aside, or revoked under the authority of the ECRA.

Saving Clause

Shipments of items removed from license exception eligibility or eligibility for export, reexport or transfer (in-country) without a license as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on May 23, 2019, pursuant to actual orders for exports, reexports and transfers (in-country) to a foreign destination, may proceed to that destination under the previous license exception eligibility or without a license so long as they have been exported, reexported or transferred (in-country) before July 22, 2019. Any such items not actually exported, reexported or transferred (in-country) before midnight, on July 22, 2019, require a license in accordance with this final rule.

Executive Order Requirements

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This rule has been designated a ''significant regulatory action'' under Executive Order 12866. The Wassenaar Arrangement (WA) has been established in order to contribute to regional and international security and stability, by promoting transparency and greater responsibility in transfers of conventional arms and dual-use goods and technologies, thus preventing destabilizing accumulations. The aim is also to prevent the acquisition of these items by terrorists. There are presently 42 Participating States, including the United States, that seek through their national policies to ensure that transfers of these items do not contribute to the development or enhancement of military capabilities that undermine these goals, and to ensure that these items are not diverted to support such military capabilities that undermine these goals. Implementation of the WA agreements in a timely manner enhances the national security of the United States and global international trade.

This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

This rule is not subject to the requirements of Executive Order 13771 (82 FR 9339, February 3, 2017) because it is issued with respect to a national security function of the United States.

Paperwork Reduction Act Requirements

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number.

This rule involves the following OMB approved collections of information subject to the PRA: 0694–0088, ''Multi-Purpose Application'', and carries a burden hour estimate of 29.6 minutes for a manual or electronic submission; 0694–0106, ''Reporting and Recordkeeping Requirements under the Wassenaar Arrangement'', which carries a burden hour estimate of 21 minutes for a manual or electronic submission; 0694–0137 ''License Exceptions and Exclusions'', which carries a burden hour estimate average of 1.5 hours per submission (Note: submissions for License Exceptions are rarely required); 0694–0096 ''Five Year Records Retention Period'', which carries a burden hour estimate of less than 1 minute; and 0607–0152 ''Automated Export System (AES) Program, which carries a burden hour estimate of 3 minutes per electronic submission. Specific license application submission estimates are discussed further in the preamble of this rule where the revision is explained. BIS estimates that revisions that are editorial, moving the location of control text on the Commerce Control List, or clarifications will result in no change in license application submissions.

Any comments regarding these collections of information, including suggestions for reducing the burden, may be sent to OMB Desk Officer, New Executive Office Building, Washington, DC 20503; and to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285.

Administrative Procedure Act and Regulatory Flexibility Act Requirements

Pursuant to § 4821 of the ECRA, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects in 15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

Accordingly, part 774 of the Export Administration Regulations (15 CFR parts 730 through 774) is amended as follows:

PART 774—[AMENDED]

■ 1. The authority citation for part 774 continues to read as follows:

Authority: Pub. L. 115–232, Title XVII, Subtitle B. 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824a; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2018, 83 FR 39871 (August 13, 2018).

■ 2. In supplement no. 1 to part 774, Category 3, ECCN 3A001 is revised to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

3A001 Electronic Items as Follows (see List of Items Controlled).

Reason for Control: NS, RS, MT, NP, AT

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
NS applies to "Monolithic Microwave Integrated Circuit" ("MMIC") amplifiers in 3A001.b.2 and discrete microwave transistors in 3A001.b.3, except those 3A001.b.2 and b.3 items being exported or reexported for use in civil telecommunications applications.	NS Column 1
NS applies to entire entry.	NS Column 2
RS applies "Monolithic Microwave Integrated Circuit" ("MMIC") amplifiers in 3A001.b.2 and discrete microwave transistors in 3A001.b.3, except those 3A001.b.2 and b.3 items being exported or reexported for use in civil telecommunications applications.	RS Column 1
MT applies to 3A001.a.1.a when usable in "missiles"; and to 3A001.a.5.a when "designed or modified" for military use, hermetically sealed and rated for operation in the temperature range from below −54°C to above +125°C.	MT Column 1
NP applies to pulse discharge capacitors in 3A001.e.2 and superconducting solenoidal electromagnets in 3A001.e.3 that meet or exceed the technical parameters in 3A201.a and 3A201.b, respectively.	NP Column 1
AT applies to entire entry.	AT Column 1

License Requirements Note: *See § 744.17 of the EAR for additional license requirements for microprocessors having a processing speed of 5 GFLOPS or more and an arithmetic logic unit with an access width of 32 bit or more, including those incorporating ''information security'' functionality, and associated ''software'' and ''technology'' for the ''production'' or ''development'' of such microprocessors.*

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A for MT or NP; N/A for ''Monolithic Microwave Integrated Circuit'' (''MMIC'') amplifiers in 3A001.b.2 and discrete microwave transistors in 3A001.b.3, except those that are being exported or reexported for use in civil telecommunications applications

Yes for:

$1500: 3A001.c

$3000: 3A001.b.1, b.2 (exported or reexported for use in civil telecommunications applications), b.3 (exported or reexported for use in civil telecommunications applications), b.9, .d, .e, .f, and .g.

$5000: 3A001.a (except a.1.a and a.5.a when controlled for MT), b.4 to b.7, and b.12.

GBS: Yes for 3A001.a.1.b, a.2 to a.14 (except .a.5.a when controlled for MT), b.2 (exported or reexported for use in civil telecommunications applications), b.8 (except for vacuum electronic device amplifiers exceeding 18 GHz), b.9, b.10, .g, .h, and .i.

CIV: Yes for 3A001.a.3, a.7, and a.11.

Special Conditions for STA

STA: License Exception STA may not be used to ship any item in 3A001.b.2 or b.3, except those that are being exported or reexported for use in civil telecommunications applications, to any of the destinations listed in Country Group A:5 or A:6 (See Supplement No.1 to part 740 of the EAR).

List of Items Controlled

Related Controls: (1) See Category XV of the USML for certain ''space-qualified'' electronics and Category XI of the USML for certain ASICs, 'transmit/receive modules,' or 'transmit modules' ''subject to the ITAR'' (see 22 CFR parts 120 through 130). (2) See also 3A101, 3A201, 3A611, 3A991, and 9A515.

Related Definitions: 'Microcircuit' means a device in which a number of passive or active elements are considered as indivisibly associated on or within a continuous structure to perform the function of a circuit. For the purposes of integrated circuits in 3A001.a.1, 5×10^3 Gy (Si) = 5×10^5 Rads (Si); 5×10^6 Gy (Si)/s = 5×10^8 Rads (Si)/s.

Items:

a. General purpose integrated circuits, as follows:

Note 1: *The control status of wafers (finished or unfinished), in which the function has been determined, is to be evaluated against the parameters of 3A001.a.*

Note 2: *Integrated circuits include the following types:*

—''Monolithic integrated circuits'';

—''Hybrid integrated circuits'';

—''Multichip integrated circuits'';

—''Film type integrated circuits'', including silicon-on-sapphire integrated circuits;

—''Optical integrated circuits'';

—''Three dimensional integrated circuits'';

—''Monolithic Microwave Integrated Circuits'' (''MMICs'').

a.1. Integrated circuits designed or rated as radiation hardened to withstand any of the following:

a.1.a. A total dose of 5×10^3 Gy (Si), or higher;

a.1.b. A dose rate upset of 5×10^6 Gy (Si)/s, or higher; *or*

a.1.c. A fluence (integrated flux) of neutrons (1 MeV equivalent) of 5×10^{13} n/cm^2 or higher on silicon, or its equivalent for other materials;

Note: *3A001.a.1.c does not apply to Metal Insulator Semiconductors (MIS).*

a.2. ''Microprocessor microcircuits'', ''microcomputer microcircuits'', microcontroller microcircuits, storage integrated circuits manufactured from a compound semiconductor, analog-to-digital converters, integrated circuits that contain analog-to-digital converters and store or process the digitized data, digital-to-analog converters, electro-optical or ''optical integrated circuits'' designed for ''signal processing'', field programmable logic devices, custom integrated circuits for which either the function is unknown or the control status of the equipment in which the integrated circuit will be used in unknown, Fast Fourier Transform (FFT) processors, Static Random-Access Memories (SRAMs), or 'non-volatile memories,' having any of the following:

Technical Note: *'Non-volatile memories' are memories with data retention over a period of time after a power shutdown.*

a.2.a. Rated for operation at an ambient temperature above 398 K (+125 °C);

a.2.b. Rated for operation at an ambient temperature below 218 K (−55 °C); *or*

a.2.c. Rated for operation over the entire ambient temperature range from 218 K (−55 °C) to 398 K (125 °C);

Note: *3A001.a.2 does not apply to integrated circuits for civil automobile or railway train applications.*

a.3. ''Microprocessor microcircuits'', ''microcomputer microcircuits'' and microcontroller microcircuits, manufactured from a compound semiconductor and operating at a clock frequency exceeding 40 MHz;

Note: *3A001.a.3 includes digital signal processors, digital array processors and digital coprocessors.*

a.4. [Reserved]

a.5. Analog-to-Digital Converter (ADC) and Digital-to-Analog Converter (DAC) integrated circuits, as follows:

a.5.a. ADCs having any of the following:

a.5.a.1. A resolution of 8 bit or more, but less than 10 bit, with a ''sample rate'' greater than 1.3 Giga Samples Per Second (GSPS);

a.5.a.2. A resolution of 10 bit or more, but less than 12 bit, with a ''sample rate'' rate greater than 600 Mega Samples Per Second (MSPS);

a.5.a.3. A resolution of 12 bit or more, but less than 14 bit, with a ''sample rate'' rate greater than 400 MSPS;

a.5.a.4. A resolution of 14 bit or more, but less than 16 bit, with a ''sample rate'' rate greater than 250 MSPS; *or*

a.5.a.5. A resolution of 16 bit or more with a ''sample rate'' rate greater than 65 MSPS;

N.B.: For integrated circuits that contain analog-to-digital converters and store or process the digitized data see 3A001.a.14.

Technical Notes:

1. A resolution of n bit corresponds to a quantization of 2^n levels.

2. The resolution of the ADC is the number of bits of the digital output that represents the measured analog input. Effective Number of Bits (ENOB) is not used to determine the resolution of the ADC.

3. For ''multiple channel ADCs'', the ''sample rate'' is not aggregated and the ''sample rate'' is the maximum rate of any single channel.

4. For ''interleaved ADCs'' or for ''multiple channel ADCs'' that are specified to have an interleaved mode of operation, the ''sample rates'' are aggregated and the ''sample rate'' is the maximum combined total rate of all of the interleaved channels.

a.5.b. Digital-to-Analog Converters (DAC) having any of the following:

a.5.b.1. A resolution of 10 bit or more with an 'adjusted update rate' of greater than 3,500 MSPS; *or*

a.5.b.2. A resolution of 12-bit or more with an 'adjusted update rate' of greater than 1,250 MSPS and having any of the following:

a.5.b.2.a. A settling time less than 9 ns to arrive at or within 0.024% of full scale from a full scale step; *or*

a.5.b.2.b. A 'Spurious Free Dynamic Range' (SFDR) greater than 68 dBc (carrier) when synthesizing a full scale analog signal of 100 MHz or the highest full scale analog signal frequency specified below 100 MHz.

Technical Notes:

1. 'Spurious Free Dynamic Range' (SFDR) is defined as the ratio of the RMS value of the carrier frequency (maximum signal component) at the input of the DAC to the RMS value of the next largest noise or harmonic distortion component at its output.

2. SFDR is determined directly from the specification table or from the characterization plots of SFDR versus frequency.

3. A signal is defined to be full scale when its amplitude is greater than −3 dBfs (full scale).

4. 'Adjusted update rate' for DACs is:

a. For conventional (non-interpolating) DACs, the 'adjusted update rate' is the rate at which the digital signal is converted to an analog signal and the output analog values are changed by the DAC. For DACs where the interpolation mode may be bypassed (interpolation factor of one), the DAC should be considered as a conventional (non-interpolating) DAC.

b. For interpolating DACs (oversampling DACs), the 'adjusted update rate' is defined as the DAC update rate divided by the smallest interpolating factor. For interpolating DACs, the 'adjusted update rate' may be referred to by different terms including:

- *Input data rate*
- *input word rate*
- *input sample rate*
- *maximum total input bus rate*
- *maximum DAC clock rate for DAC clock input.*

a.6. Electro-optical and ''optical integrated circuits'', designed for ''signal processing'' and having all of the following:

a.6.a. One or more than one internal ''laser'' diode;

a.6.b. One or more than one internal light detecting element; *and*

a.6.c. Optical waveguides;

a.7. 'Field programmable logic devices' having any of the following:

a.7.a. A maximum number of single-ended digital input/outputs of greater than 700; *or*

a.7.b. An 'aggregate one-way peak serial transceiver data rate' of 500 Gb/s or greater;

Note: *3A001.a.7 includes:*

—Complex Programmable Logic Devices (CPLDs)

—Field Programmable Gate Arrays (FPGAs)

—Field Programmable Logic Arrays (FPLAs)

—Field Programmable Interconnects (FPICs)

N.B.: For integrated circuits having field programmable logic devices that are combined with an analog-to-digital converter, see 3A001.a.14.

Technical Notes:

1. Maximum number of digital input/outputs in 3A001.a.7.a is also referred to as maximum user input/outputs or maximum available input/outputs, whether the integrated circuit is packaged or bare die.

2. 'Aggregate one-way peak serial transceiver data rate' is the product of the peak serial one-way transceiver data rate times the number of transceivers on the FPGA.

a.8. [Reserved]

a.9. Neural network integrated circuits;

a.10. Custom integrated circuits for which the function is unknown, or the control status of the equipment in which the integrated circuits will be used is unknown to the manufacturer, having any of the following:

a.10.a. More than 1,500 terminals;

a.10.b. A typical ''basic gate propagation delay time'' of less than 0.02 ns; *or*

a.10.c. An operating frequency exceeding 3 GHz;

a.11. Digital integrated circuits, other than those described in 3A001.a.3 to 3A001.a.10 and 3A001.a.12, based upon any compound semiconductor and having any of the following:

a.11.a. An equivalent gate count of more than 3,000 (2 input gates); *or*

a.11.b. A toggle frequency exceeding 1.2 GHz;

a.12. Fast Fourier Transform (FFT) processors having a rated execution time for an N-point complex FFT of less than ($N \log_2 N$)/20,480 ms, where N is the number of points;

Technical Note: *When N is equal to 1,024 points, the formula in 3A001.a.12 gives an execution time of 500* μ*s.*

a.13. Direct Digital Synthesizer (DDS) integrated circuits having any of the following:

a.13.a. A Digital-to-Analog Converter (DAC) clock frequency of 3.5 GHz or more and a DAC resolution of 10 bit or more, but less than 12 bit; *or*

a.13.b. A DAC clock frequency of 1.25 GHz or more and a DAC resolution of 12 bit or more;

Technical Note: *The DAC clock frequency may be specified as the master clock frequency or the input clock frequency.*

a.14. Integrated circuits that perform or are programmable to perform all of the following:

a.14.a. Analog-to-digital conversions meeting any of the following:

a.14.a.1. A resolution of 8 bit or more, but less than 10 bit, with a ''sample rate'' greater than 1.3 Giga Samples Per Second (GSPS);

a.14.a.2. A resolution of 10 bit or more, but less than 12 bit, with a ''sample rate'' greater than 1.0 GSPS;

a.14.a.3. A resolution of 12 bit or more, but less than 14 bit, with a ''sample rate'' greater than 1.0 GSPS;

a.14.a.4. A resolution of 14 bit or more, but less than 16 bit, with a ''sample rate'' greater than 400 Mega Samples Per Second (MSPS); *or*

a.14.a.5. A resolution of 16 bit or more with a ''sample rate'' greater than 180 MSPS; *and*

a.14.b. Any of the following:

a.14.b.1. Storage of digitized data; *or*

a.14.b.2. Processing of digitized data;

N.B. 1: For analog-to-digital converter integrated circuits, see 3A001.a.5.a.

N.B. 2: For field programmable logic devices, see 3A001.a.7.

Technical Notes:

1. A resolution of n bit corresponds to a quantization of 2^n levels.

2. The resolution of the ADC is the number of bits of the digital output of the ADC that represents the measured analog input. Effective Number of Bits (ENOB) is not used to determine the resolution of the ADC.

3. For integrated circuits with non-interleaving ''multiple channel ADCs'', the ''sample rate'' is not aggregated and the ''sample rate'' is the maximum rate of any single channel.

4. For integrated circuits with ''interleaved ADCs'' or with ''multiple channel ADCs'' that are specified to have an interleaved mode of operation, the ''sample rates'' are aggregated and the ''sample rate'' is the maximum combined total rate of all of the interleaved channels.

b. Microwave or millimeter wave items, as follows:

Technical Notes:

1. For purposes of 3A001.b, the parameter peak saturated power output may also be referred to on product data sheets as output power, saturated power output, maximum power output, peak power output, or peak envelope power output.

2. For purposes of 3A001.b.1, 'vacuum electronic devices' are electronic devices based on the interaction of an electron beam with an electromagnetic wave propagating in a vacuum circuit or interacting with radio-frequency vacuum cavity resonators. 'Vacuum electronic devices' include klystrons, traveling-wave tubes, and their derivatives.

b.1. 'Vacuum electronic devices' and cathodes, as follows:

Note 1: *3A001.b.1 does not control 'vacuum electronic devices' designed or rated for operation in any frequency band and having all of the following:*

a. Does not exceed 31.8 GHz; and

b. Is ''allocated by the ITU'' for radio-communications services, but not for radio-determination.

Note 2: *3A001.b.1 does not control non-''space-qualified'' 'vacuum electronic devices' having all the following:*

a. An average output power equal to or less than 50 W; and

b. Designed or rated for operation in any frequency band and having all of the following:

1. Exceeds 31.8 GHz but does not exceed 43.5 GHz; and

2. Is ''allocated by the ITU'' for radio-communications services, but not for radio-determination.

b.1.a. Traveling-wave 'vacuum electronic devices,' pulsed or continuous wave, as follows:

b.1.a.1. Devices operating at frequencies exceeding 31.8 GHz;

b.1.a.2. Devices having a cathode heater with a turn on time to rated RF power of less than 3 seconds;

b.1.a.3. Coupled cavity devices, or derivatives thereof, with a ''fractional bandwidth'' of more than 7% or a peak power exceeding 2.5 kW;

b.1.a.4. Devices based on helix, folded waveguide, or serpentine waveguide circuits, or derivatives thereof, having any of the following:

b.1.a.4.a. An ''instantaneous bandwidth'' of more than one octave, and average power (expressed in kW) times frequency (expressed in GHz) of more than 0.5;

b.1.a.4.b. An ''instantaneous bandwidth'' of one octave or less, and average power (expressed in kW) times frequency (expressed in GHz) of more than 1;

b.1.a.4.c. Being ''space-qualified''; *or*

b.1.a.4.d. Having a gridded electron gun;

b.1.a.5. Devices with a ''fractional bandwidth'' greater than or equal to 10%, with any of the following:

b.1.a.5.a. An annular electron beam;

b.1.a.5.b. A non-axisymmetric electron beam; *or*

b.1.a.5.c. Multiple electron beams;

b.1.b. Crossed-field amplifier 'vacuum electronic devices' with a gain of more than 17 dB;

b.1.c. Thermionic cathodes, designed for 'vacuum electronic devices,' producing an emission current density at rated operating conditions exceeding 5 A/cm^2 or a pulsed (non-continuous) current density at rated operating conditions exceeding 10 A/cm^2;

b.1.d. 'Vacuum electronic devices' with the capability to operate in a 'dual mode.'

Technical Note: *'Dual mode' means the 'vacuum electronic device' beam current can be intentionally changed between continuous-wave and pulsed mode operation by use of a grid and produces a peak pulse output power greater than the continuous-wave output power.*

b.2. ''Monolithic Microwave Integrated Circuit'' (''MMIC'') amplifiers that are any of the following:

N.B.: For ''MMIC'' amplifiers that have an integrated phase shifter see 3A001.b.12.

b.2.a. Rated for operation at frequencies exceeding 2.7 GHz up to and including 6.8 GHz with a ''fractional bandwidth'' greater than 15%, and having any of the following:

b.2.a.1. A peak saturated power output greater than 75 W (48.75 dBm) at any frequency exceeding 2.7 GHz up to and including 2.9 GHz;

b.2.a.2. A peak saturated power output greater than 55 W (47.4 dBm) at any frequency exceeding 2.9 GHz up to and including 3.2 GHz;

b.2.a.3. A peak saturated power output greater than 40 W (46 dBm) at any frequency exceeding 3.2 GHz up to and including 3.7 GHz; *or*

b.2.a.4. A peak saturated power output greater than 20 W (43 dBm) at any frequency exceeding 3.7 GHz up to and including 6.8 GHz;

b.2.b. Rated for operation at frequencies exceeding 6.8 GHz up to and including 16 GHz with a ''fractional bandwidth'' greater than 10%, and having any of the following:

b.2.b.1. A peak saturated power output greater than 10 W (40 dBm) at any frequency exceeding 6.8 GHz up to and including 8.5 GHz; *or*

b.2.b.2. A peak saturated power output greater than 5 W (37 dBm) at any frequency exceeding 8.5 GHz up to and including 16 GHz;

b.2.c. Rated for operation with a peak saturated power output greater than 3 W (34.77 dBm) at any frequency exceeding 16 GHz up to and including 31.8 GHz, and with a ''fractional bandwidth'' of greater than 10%;

b.2.d. Rated for operation with a peak saturated power output greater than 0.1n W (−70 dBm) at any frequency exceeding 31.8 GHz up to and including 37 GHz;

b.2.e. Rated for operation with a peak saturated power output greater than 1 W (30 dBm) at any frequency exceeding 37 GHz up to and including 43.5 GHz, and with a ''fractional bandwidth'' of greater than 10%;

b.2.f. Rated for operation with a peak saturated power output greater than 31.62 mW (15 dBm) at any frequency exceeding 43.5 GHz up to and including 75 GHz, and with a ''fractional bandwidth'' of greater than 10%;

b.2.g. Rated for operation with a peak saturated power output greater than 10 mW (10 dBm) at any frequency exceeding 75 GHz up to and including 90 GHz, and with a ''fractional bandwidth'' of greater than 5%; *or*

b.2.h. Rated for operation with a peak saturated power output greater than 0.1 nW (−70 dBm) at any frequency exceeding 90 GHz;

Note 1: *[Reserved]*

Note 2: *The control status of the ''MMIC'' whose rated operating frequency includes frequencies listed in more than one frequency range, as defined by 3A001.b.2.a through 3A001.b.2.h, is determined by the lowest peak saturated power output control threshold.*

Note 3: *Notes 1 and 2 following the Category 3 heading for product group A. Systems, Equipment, and Components mean that 3A001.b.2 does not control ''MMICs'' if they are ''specially designed'' for other applications, e.g., telecommunications, radar, automobiles.*

b.3. Discrete microwave transistors that are any of the following:

b.3.a. Rated for operation at frequencies exceeding 2.7 GHz up to and including 6.8 GHz and having any of the following:

b.3.a.1. A peak saturated power output greater than 400 W (56 dBm) at any

frequency exceeding 2.7 GHz up to and including 2.9 GHz;

b.3.a.2. A peak saturated power output greater than 205 W (53.12 dBm) at any frequency exceeding 2.9 GHz up to and including 3.2 GHz;

b.3.a.3. A peak saturated power output greater than 115 W (50.61 dBm) at any frequency exceeding 3.2 GHz up to and including 3.7 GHz; *or*

b.3.a.4. A peak saturated power output greater than 60 W (47.78 dBm) at any frequency exceeding 3.7 GHz up to and including 6.8 GHz;

b.3.b. Rated for operation at frequencies exceeding 6.8 GHz up to and including 31.8 GHz and having any of the following:

b.3.b.1. A peak saturated power output greater than 50 W (47 dBm) at any frequency exceeding 6.8 GHz up to and including 8.5 GHz;

b.3.b.2. A peak saturated power output greater than 15 W (41.76 dBm) at any frequency exceeding 8.5 GHz up to and including 12 GHz;

b.3.b.3. A peak saturated power output greater than 40 W (46 dBm) at any frequency exceeding 12 GHz up to and including 16 GHz; *or*

b.3.b.4. A peak saturated power output greater than 7 W (38.45 dBm) at any frequency exceeding 16 GHz up to and including 31.8 GHz;

b.3.c. Rated for operation with a peak saturated power output greater than 0.5 W (27 dBm) at any frequency exceeding 31.8 GHz up to and including 37 GHz;

b.3.d. Rated for operation with a peak saturated power output greater than 1 W (30 dBm) at any frequency exceeding 37 GHz up to and including 43.5 GHz;

b.3.e. Rated for operation with a peak saturated power output greater than 0.1 nW (−70 dBm) at any frequency exceeding 43.5 GHz; or

b.3.f. Other than those specified by 3A001.b.3.a to 3A001.b.3.e and rated for operation with a peak saturated power output greater than 5 W (37.0 dBm) at all frequencies exceeding 8.5 GHz up to and including 31.8 GHz;

Note 1: *The control status of a transistor in 3A001.b.3.a through 3A001.b.3.e, whose rated operating frequency includes frequencies listed in more than one frequency range, as defined by 3A001.b.3.a through 3A001.b.3.e, is determined by the lowest peak saturated power output control threshold.*

Note 2: *3A001.b.3 includes bare dice, dice mounted on carriers, or dice mounted in packages. Some discrete transistors may also be referred to as power amplifiers, but the status of these discrete transistors is determined by 3A001.b.3.*

b.4. Microwave solid state amplifiers and microwave assemblies/modules containing microwave solid state amplifiers, that are any of the following:

b.4.a. Rated for operation at frequencies exceeding 2.7 GHz up to and including 6.8 GHz with a ''fractional bandwidth'' greater than 15%, and having any of the following:

b.4.a.1. A peak saturated power output greater than 500 W (57 dBm) at any frequency exceeding 2.7 GHz up to and including 2.9 GHz;

b.4.a.2. A peak saturated power output greater than 270 W (54.3 dBm) at any frequency exceeding 2.9 GHz up to and including 3.2 GHz;

b.4.a.3. A peak saturated power output greater than 200 W (53 dBm) at any frequency exceeding 3.2 GHz up to and including 3.7 GHz; *or*

b.4.a.4. A peak saturated power output greater than 90 W (49.54 dBm) at any frequency exceeding 3.7 GHz up to and including 6.8 GHz;

b.4.b. Rated for operation at frequencies exceeding 6.8 GHz up to and including 31.8 GHz with a ''fractional bandwidth'' greater than 10%, and having any of the following:

b.4.b.1. A peak saturated power output greater than 70 W (48.54 dBm) at any frequency exceeding 6.8 GHz up to and including 8.5 GHz;

b.4.b.2. A peak saturated power output greater than 50 W (47 dBm) at any frequency exceeding 8.5 GHz up to and including 12 GHz;

b.4.b.3. A peak saturated power output greater than 30 W (44.77 dBm) at any frequency exceeding 12 GHz up to and including 16 GHz; *or*

b.4.b.4. A peak saturated power output greater than 20 W (43 dBm) at any frequency exceeding 16 GHz up to and including 31.8 GHz;

b.4.c. Rated for operation with a peak saturated power output greater than 0.5 W (27 dBm) at any frequency exceeding 31.8 GHz up to and including 37 GHz;

b.4.d. Rated for operation with a peak saturated power output greater than 2 W (33 dBm) at any frequency exceeding 37 GHz up to and including 43.5 GHz, and with a ''fractional bandwidth'' of greater than 10%;

b.4.e. Rated for operation at frequencies exceeding 43.5 GHz and having any of the following:

b.4.e.1. A peak saturated power output greater than 0.2 W (23 dBm) at any frequency exceeding 43.5 GHz up to and including 75 GHz, and with a ''fractional bandwidth'' of greater than 10%;

b.4.e.2. A peak saturated power output greater than 20 mW (13 dBm) at any frequency exceeding 75 GHz up to and including 90 GHz, and with a ''fractional bandwidth'' of greater than 5%; *or*

b.4.e.3. A peak saturated power output greater than 0.1 nW (−70 dBm) at any frequency exceeding 90 GHz; *or*

b.4.f. [Reserved]

N.B.:

1. For ''MMIC'' amplifiers see 3A001.b.2.

2. For 'transmit/receive modules' and 'transmit modules' see 3A001.b.12.

3. For converters and harmonic mixers, designed to extend the operating or frequency range of signal analyzers, signal generators, network analyzers or microwave test receivers, see 3A001.b.7.

Note 1: *[Reserved]*

Note 2: *The control status of an item whose rated operating frequency includes frequencies listed in more than one frequency range, as defined by 3A001.b.4.a through 3A001.b.4.e, is determined by the lowest peak saturated power output control threshold.*

b.5. Electronically or magnetically tunable band-pass or band-stop filters, having more than 5 tunable resonators capable of tuning across a 1.5:1 frequency band (f_{max}/f_{min}) in less than 10 μs and having any of the following:

b.5.a. A band-pass bandwidth of more than 0.5% of center frequency; *or*

b.5.b. A band-stop bandwidth of less than 0.5% of center frequency;

b.6. [Reserved]

b.7. Converters and harmonic mixers, that are any of the following:

b.7.a. Designed to extend the frequency range of ''signal analyzers'' beyond 90 GHz;

b.7.b. Designed to extend the operating range of signal generators as follows:

b.7.b.1. Beyond 90 GHz;

b.7.b.2. To an output power greater than 100 mW (20 dBm) anywhere within the frequency range exceeding 43.5 GHz but not exceeding 90 GHz;

b.7.c. Designed to extend the operating range of network analyzers as follows:

b.7.c.1. Beyond 110 GHz;

b.7.c.2. To an output power greater than 31.62 mW (15 dBm) anywhere within the frequency range exceeding 43.5 GHz but not exceeding 90 GHz;

b.7.c.3. To an output power greater than 1 mW (0 dBm) anywhere within the frequency range exceeding 90 GHz but not exceeding 110 GHz; *or*

b.7.d. Designed to extend the frequency range of microwave test receivers beyond 110 GHz;

b.8. Microwave power amplifiers containing 'vacuum electronic devices' controlled by 3A001.b.1 and having all of the following:

b.8.a. Operating frequencies above 3 GHz;

b.8.b. An average output power to mass ratio exceeding 80 W/kg; *and*

b.8.c. A volume of less than 400 cm^3;

Note: *3A001.b.8 does not control equipment designed or rated for operation in any frequency band which is ''allocated by the ITU'' for radio-communications services, but not for radio-determination.*

b.9. Microwave Power Modules (MPM) consisting of, at least, a traveling-wave 'vacuum electronic device,' a ''Monolithic Microwave Integrated Circuit'' (''MMIC'') and an integrated electronic power conditioner and having all of the following:

b.9.a. A 'turn-on time' from off to fully operational in less than 10 seconds;

b.9.b. A volume less than the maximum rated power in Watts multiplied by 10 cm^3/W; *and*

b.9.c. An ''instantaneous bandwidth'' greater than 1 octave ($f_{max.} > 2f_{min,}$) and having any of the following:

b.9.c.1. For frequencies equal to or less than 18 GHz, an RF output power greater than 100 W; *or*

b.9.c.2. A frequency greater than 18 GHz;

Technical Notes:

1. To calculate the volume in 3A001.b.9.b, the following example is provided: for a maximum rated power of 20 W, the volume would be: 20 W × 10 cm^3/W = 200 cm^3.

2. The 'turn-on time' in 3A001.b.9.a refers to the time from fully-off to fully operational, i.e., it includes the warm-up time of the MPM.

b.10. Oscillators or oscillator assemblies, specified to operate with a single sideband

(SSB) phase noise, in dBc/Hz, less (better) than $-(126 + 20\log_{10}F - 20\log_{10}f)$ anywhere within the range of 10 Hz ≤F ≤10 kHz;

Technical Note: *In 3A001.b.10, F is the offset from the operating frequency in Hz and f is the operating frequency in MHz.*

b.11. 'Frequency synthesizer' ''electronic assemblies'' having a ''frequency switching time'' as specified by any of the following:

b.11.a. Less than 143 ps;

b.11.b. Less than 100 μs for any frequency change exceeding 2.2 GHz within the synthesized frequency range exceeding 4.8 GHz but not exceeding 31.8 GHz;

b.11.c. [Reserved]

b.11.d. Less than 500 μs for any frequency change exceeding 550 MHz within the synthesized frequency range exceeding 31.8 GHz but not exceeding 37 GHz; *or*

b.11.e. Less than 100 μs for any frequency change exceeding 2.2 GHz within the synthesized frequency range exceeding 37 GHz but not exceeding 90 GHz; *or*

b.11.f. [Reserved]

b.11.g. Less than 1 ms within the synthesized frequency range exceeding 90 GHz;

Technical Note: *A 'frequency synthesizer' is any kind of frequency source, regardless of the actual technique used, providing a multiplicity of simultaneous or alternative output frequencies, from one or more outputs, controlled by, derived from or disciplined by a lesser number of standard (or master) frequencies.*

N.B.: *For general purpose ''signal analyzers'', signal generators, network analyzers and microwave test receivers, see 3A002.c, 3A002.d, 3A002.e and 3A002.f, respectively.*

b.12. 'Transmit/receive modules,' 'transmit/receive MMICs,' 'transmit modules,' and 'transmit MMICs,' rated for operation at frequencies above 2.7 GHz and having all of the following:

b.12.a. A peak saturated power output (in watts), P_{sat}, greater than 505.62 divided by the maximum operating frequency (in GHz) squared [P_{sat}>505.62 W*GHz^2/f_{GHz}^2] for any channel;

b.12.b. A ''fractional bandwidth'' of 5% or greater for any channel;

b.12.c. Any planar side with length d (in cm) equal to or less than 15 divided by the lowest operating frequency in GHz [d ≤ 15cm*GHz*N/f_{GHz}] where N is the number of transmit or transmit/receive channels; *and*

b.12.d. An electronically variable phase shifter per channel.

Technical Notes:

1. A 'transmit/receive module' is a multifunction ''electronic assembly'' that provides bi-directional amplitude and phase control for transmission and reception of signals.

2. A 'transmit module' is an ''electronic assembly'' that provides amplitude and phase control for transmission of signals.

3. A 'transmit/receive MMIC' is a multifunction ''MMIC'' that provides bi-directional amplitude and phase control for transmission and reception of signals.

4. A 'transmit MMIC' is a ''MMIC'' that provides amplitude and phase control for transmission of signals.

*5. 2.7 GHz should be used as the lowest operating frequency (f_{GHz}) in the formula in 3A001.b.12.c for transmit/receive or transmit modules that have a rated operation range extending downward to 2.7 GHz and below [d≤15cm*GHz*N/2.7 GHz].*

6. 3A001.b.12 applies to 'transmit/receive modules' or 'transmit modules' with or without a heat sink. The value of d in 3A001.b.12.c does not include any portion of the 'transmit/receive module' or 'transmit module' that functions as a heat sink.

7. 'Transmit/receive modules' or 'transmit modules,' 'transmit/receive MMICs' or 'transmit MMICs' may or may not have N integrated radiating antenna elements where N is the number of transmit or transmit/receive channels.

c. Acoustic wave devices as follows and ''specially designed'' ''components'' therefor:

c.1. Surface acoustic wave and surface skimming (shallow bulk) acoustic wave devices, having any of the following:

c.1.a. A carrier frequency exceeding 6 GHz;

c.1.b. A carrier frequency exceeding 1 GHz, but not exceeding 6 GHz and having any of the following:

c.1.b.1. A 'frequency side-lobe rejection' exceeding 65 dB;

c.1.b.2. A product of the maximum delay time and the bandwidth (time in μs and bandwidth in MHz) of more than 100;

c.1.b.3. A bandwidth greater than 250 MHz; *or*

c.1.b.4. A dispersive delay of more than 10 μs; *or*

c.1.c. A carrier frequency of 1 GHz or less and having any of the following:

c.1.c.1. A product of the maximum delay time and the bandwidth (time in μs and bandwidth in MHz) of more than 100;

c.1.c.2. A dispersive delay of more than 10 μs; *or*

c.1.c.3. A 'frequency side-lobe rejection' exceeding 65 dB and a bandwidth greater than 100 MHz;

Technical Note: *'Frequency side-lobe rejection' is the maximum rejection value specified in data sheet.*

c.2. Bulk (volume) acoustic wave devices that permit the direct processing of signals at frequencies exceeding 6 GHz;

c.3. Acoustic-optic ''signal processing'' devices employing interaction between acoustic waves (bulk wave or surface wave) and light waves that permit the direct processing of signals or images, including spectral analysis, correlation or convolution;

Note: *3A001.c does not control acoustic wave devices that are limited to a single band pass, low pass, high pass or notch filtering, or resonating function.*

d. Electronic devices and circuits containing ''components'', manufactured from ''superconductive'' materials, ''specially designed'' for operation at temperatures below the ''critical temperature'' of at least one of the ''superconductive'' constituents and having any of the following:

d.1. Current switching for digital circuits using ''superconductive'' gates with a product of delay time per gate (in seconds) and power dissipation per gate (in watts) of less than 10^{-14} J; *or*

d.2. Frequency selection at all frequencies using resonant circuits with Q-values exceeding 10,000;

e. High energy devices as follows:

e.1. 'Cells' as follows:

e.1.a. 'Primary cells' having any of the following at 20 °C:

e.1.a.1. 'Energy density' exceeding 550 Wh/kg and a 'continuous power density' exceeding 50 W/kg; *or*

e.1.a.2. 'Energy density' exceeding 50 Wh/kg and a 'continuous power density' exceeding 350 W/kg;

e.1.b. 'Secondary cells' having an 'energy density' exceeding 350 Wh/kg at 293 K (20 °C);

Technical Notes:

1. For the purpose of 3A001.e.1, 'energy density' (Wh/kg) is calculated from the nominal voltage multiplied by the nominal capacity in ampere-hours (Ah) divided by the mass in kilograms. If the nominal capacity is not stated, energy density is calculated from the nominal voltage squared then multiplied by the discharge duration in hours divided by the discharge load in Ohms and the mass in kilograms.

2. For the purpose of 3A001.e.1, a 'cell' is defined as an electrochemical device, which has positive and negative electrodes, an electrolyte, and is a source of electrical energy. It is the basic building block of a battery.

3. For the purpose of 3A001.e.1.a, a 'primary cell' is a 'cell' that is not designed to be charged by any other source.

4. For the purpose of 3A001.e.1.b, a 'secondary cell' is a 'cell' that is designed to be charged by an external electrical source.

5. For the purpose of 3A001.e.1.a, 'continuous power density' (W/kg) is calculated from the nominal voltage multiplied by the specified maximum continuous discharge current in ampere (A) divided by the mass in kilograms. 'Continuous power density' is also referred to as specific power.

Note: *3A001.e does not control batteries, including single-cell batteries.*

e.2. High energy storage capacitors as follows:

e.2.a. Capacitors with a repetition rate of less than 10 Hz (single shot capacitors) and having all of the following:

e.2.a.1. A voltage rating equal to or more than 5 kV;

e.2.a.2. An energy density equal to or more than 250 J/kg; *and*

e.2.a.3. A total energy equal to or more than 25 kJ;

e.2.b. Capacitors with a repetition rate of 10 Hz or more (repetition rated capacitors) and having all of the following:

e.2.b.1. A voltage rating equal to or more than 5 kV;

e.2.b.2. An energy density equal to or more than 50 J/kg;

e.2.b.3. A total energy equal to or more than 100 J; *and*

e.2.b.4. A charge/discharge cycle life equal to or more than 10,000;

e.3. ''Superconductive'' electromagnets and solenoids, ''specially designed'' to be fully charged or discharged in less than one second and having all of the following:

Note: *3A001.e.3 does not control ''superconductive'' electromagnets or solenoids ''specially designed'' for Magnetic Resonance Imaging (MRI) medical equipment.*

e.3.a. Energy delivered during the discharge exceeding 10 kJ in the first second;

e.3.b. Inner diameter of the current carrying windings of more than 250 mm; *and*

e.3.c. Rated for a magnetic induction of more than 8 T or ''overall current density'' in the winding of more than 300 A/mm²;

e.4. Solar cells, cell-interconnect-coverglass (CIC) assemblies, solar panels, and solar arrays, which are ''space-qualified'', having a minimum average efficiency exceeding 20% at an operating temperature of 301 K (28 °C) under simulated 'AM0' illumination with an irradiance of 1,367 Watts per square meter (W/m²);

Technical Note: *'AM0,' or 'Air Mass Zero,' refers to the spectral irradiance of sun light in the earth's outer atmosphere when the distance between the earth and sun is one astronomical unit (AU).*

f. Rotary input type absolute position encoders having an ''accuracy'' equal to or less (better) than ± 1.0 second of arc and ''specially designed'' encoder rings, discs or scales therefor;

g. Solid-state pulsed power switching thyristor devices and 'thyristor modules,' using either electrically, optically, or electron radiation controlled switch methods and having any of the following:

g.1. A maximum turn-on current rate of rise (di/dt) greater than 30,000 A/µs and off-state voltage greater than 1,100 V; *or*

g.2. A maximum turn-on current rate of rise (di/dt) greater than 2,000 A/µs and having all of the following:

g.2.a. An off-state peak voltage equal to or greater than 3,000 V; *and*

g.2.b. A peak (surge) current equal to or greater than 3,000 A;

Note 1: *3A001.g includes:*

—Silicon Controlled Rectifiers (SCRs)

—Electrical Triggering Thyristors (ETTs)

—Light Triggering Thyristors (LTTs)

—Integrated Gate Commutated Thyristors (IGCTs)

—Gate Turn-off Thyristors (GTOs)

—MOS Controlled Thyristors (MCTs)

—Solidtrons

Note 2: *3A001.g does not control thyristor devices and 'thyristor modules' incorporated into equipment designed for civil railway or ''civil aircraft'' applications.*

Technical Note: *For the purposes of 3A001.g, a 'thyristor module' contains one or more thyristor devices.*

h. Solid-state power semiconductor switches, diodes, or 'modules,' having all of the following:

h.1. Rated for a maximum operating junction temperature greater than 488 K (215 °C);

h.2. Repetitive peak off-state voltage (blocking voltage) exceeding 300 V; *and*

h.3. Continuous current greater than 1 A.

Technical Note: *For the purposes of 3A001.h, 'modules' contain one or more solid-state power semiconductor switches or diodes.*

Note 1: *Repetitive peak off-state voltage in 3A001.h includes drain to source voltage, collector to emitter voltage, repetitive peak reverse voltage and peak repetitive off-state blocking voltage.*

Note 2: *3A001.h includes:*

—Junction Field Effect Transistors (JFETs)

—Vertical Junction Field Effect Transistors (VJFETs)

—Metal Oxide Semiconductor Field Effect Transistors (MOSFETs)

—Double Diffused Metal Oxide Semiconductor Field Effect Transistor (DMOSFET)

—Insulated Gate Bipolar Transistor (IGBT)

—High Electron Mobility Transistors (HEMTs)

—Bipolar Junction Transistors (BJTs)

—Thyristors and Silicon Controlled Rectifiers (SCRs)

—Gate Turn-Off Thyristors (GTOs)

—Emitter Turn-Off Thyristors (ETOs)

—PiN Diodes

—Schottky Diodes

Note 3: *3A001.h does not apply to switches, diodes, or 'modules', incorporated into equipment designed for civil automobile, civil railway, or ''civil aircraft'' applications.*

i. Intensity, amplitude, or phase electro-optic modulators, designed for analog signals and having any of the following:

i.1. A maximum operating frequency of more than 10 GHz but less than 20 GHz, an optical insertion loss equal to or less than 3 dB and having any of the following:

i.1.a. A 'half-wave voltage' ('Vπ') less than 2.7 V when measured at a frequency of 1 GHz or below; *or*

i.1.b. A 'Vπ' of less than 4 V when measured at a frequency of more than 1 GHz; *or*

i.2. A maximum operating frequency equal to or greater than 20 GHz, an optical insertion loss equal to or less than 3 dB and having any of the following:

i.2.a. A 'Vπ' less than 3.3 V when measured at a frequency of 1 GHz or below; *or*

i.2.b. A 'Vπ' less than 5 V when measured at a frequency of more than 1 GHz.

Note: *3A001.i includes electro-optic modulators having optical input and output connectors* (*e.g., fiber-optic pigtails*).

Technical Note: *For the purposes of 3A001.i, a 'half-wave voltage' ('Vπ') is the applied voltage necessary to make a phase change of 180 degrees in the wavelength of light propagating through the optical modulator.*

■ 3. In supplement no. 1 to part 774, Category 3, add ECCN 3D005, after ECCN 3D004, to read as follows:

3D005 ''Software'' ''specially designed'' to restore normal operation of a microcomputer, ''microprocessor microcircuit'' or ''microcomputer microcircuit'' within 1 ms after an Electromagnetic Pulse (EMP) or Electrostatic Discharge (ESD) disruption, without loss of continuation of operation.

License Requirements

Reason for Control: NS, AT

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
NS applies to entire entry.	NS Column 1
AT applies to entire entry.	AT Column 1

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

CIV: N/A
TSR: N/A

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit ''software'' to any of the destinations listed in Country Group A:6 (See Supplement No.1 to part 740 of the EAR).

List of Items Controlled

Related Controls: N/A
Related Definitions: N/A
Items:

The list of items controlled is contained in the ECCN heading.

■ 4. In supplement no. 1 to part 774, Category 5 Part 2, the N.B. to Note 3 (Cryptography Note) at the beginning of the Category is revised to read as follows:

Category 5—Telecommunications and ''Information Security''

* * * * *

Part 2—''Information Security''

* * * * *

N.B. to Note 3 (Cryptography Note): You must submit a classification request or self-classification report to BIS for mass market encryption commodities and software eligible for the Cryptography Note employing a key length greater than 64 bits for the symmetric algorithm (or, for commodities and software not implementing any symmetric algorithms, employing a key length greater than 768 bits for asymmetric algorithms described by Technical note 2.b to 5A002.a or greater than 128 bits for elliptic curve algorithms, or any asymmetric algorithm described by Technical Note 2.c to 5A002.a) in accordance with the requirements of § 740.17(b) of the EAR in order to be released from the ''EI'' and ''NS'' controls of ECCN 5A002 or 5D002.

* * * * *

■ 5. In supplement no. 1 to part 774, Category 5 Part 2, ECCN 5A002 is revised to read as follows:

5A002 ''Information security'' systems, equipment and ''components,'' as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, AT, EI

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
NS applies to entire entry.	NS Column 1
AT applies to entire entry.	AT Column 1
EI applies to entire entry.	Refer to § 742.15 of the EAR

License Requirements Note: *See § 744.17 of the EAR for additional license requirements for microprocessors having a processing speed of 5 GFLOPS or more and an arithmetic logic unit with an access width of 32 bit or more, including those*

incorporating ''information security'' functionality, and associated ''software'' and ''technology'' for the ''production'' or ''development'' of such microprocessors.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: Yes: $500 for ''components''.
N/A for systems and equipment.
GBS: N/A
CIV: N/A
ENC: Yes for certain EI controlled commodities, see § 740.17 of the EAR for eligibility.

List of Items Controlled

Related Controls: (1) ECCN 5A002.a controls ''components'' providing the means or functions necessary for ''information security.'' All such ''components'' are presumptively ''specially designed'' and controlled by 5A002.a. (2) See USML Categories XI (including XI(b)) and XIII(b) (including XIII(b)(2)) for controls on systems, equipment, and components described in 5A002.d or .e that are subject to the ITAR. (3) For Global Navigation Satellite Systems (GNSS) receiving equipment containing or employing decryption see 7A005, and for related decryption ''software'' and ''technology'' see 7D005 and 7E001. (4) Noting that items may be controlled elsewhere on the CCL, examples of items not controlled by ECCN 5A002.a.4 include the following: (a) An automobile where the only 'cryptography for data confidentiality' having a 'described security algorithm' is performed by a Category 5—Part 2 Note 3 eligible mobile telephone that is built into the car. In this case, secure phone communications support a non-primary function of the automobile but the mobile telephone (equipment), as a standalone item, is not controlled by ECCN 5A002 because it is excluded by the Cryptography Note (Note 3) (See ECCN 5A992.c). (b) An exercise bike with an embedded Category 5—Part 2 Note 3 eligible web browser, where the only controlled cryptography is performed by the web browser. In this case, secure web browsing supports a non-primary function of the exercise bike but the web browser (''software''), as a standalone item, is not controlled by ECCN 5D002 because it is excluded by the Cryptography Note (Note 3) (See ECCN 5D992.c). (5) After classification or self-classification in accordance with § 740.17(b) of the EAR, mass market encryption commodities that meet eligibility requirements are released from ''EI'' and ''NS'' controls. These commodities are designated 5A992.c.
Related Definitions: N/A
Items:

a. Designed or modified to use 'cryptography for data confidentiality' having a 'described security algorithm', where that cryptographic capability is usable, has been activated, or can be activated by means of ''cryptographic activation'' not employing a secure mechanism, as follows:

a.1. Items having ''information security'' as a primary function;

a.2. Digital communication or networking systems, equipment or components, not specified in paragraph 5A002.a.1;

a.3. Computers, other items having information storage or processing as a primary function, and components therefor, not specified in paragraphs 5A002.a.1 or .a.2;

N.B.: For operating systems see also 5D002.a.1 and .c.1.

a.4. Items, not specified in paragraphs 5A002.a.1 to a.3, where the 'cryptography for data confidentiality' having a 'described security algorithm' meets all of the following:

a.4.a. It supports a non-primary function of the item; *and*

a.4.b. It is performed by incorporated equipment or ''software'' that would, as a standalone item, be specified by ECCNs 5A002, 5A003, 5A004, 5B002 or 5D002.

N.B. to paragraph a.4: *See Related Control Paragraph (4) of this ECCN 5A002 for examples of items not controlled by 5A002.a.4.*

Technical Notes:

1. For the purposes of 5A002.a, 'cryptography for data confidentiality' means ''cryptography'' that employs digital techniques and performs any cryptographic function other than any of the following:

1.a. ''Authentication;''

1.b. Digital signature;

1.c. Data integrity;

1.d. Non-repudiation;

1.e. Digital rights management, including the execution of copy-protected ''software;''

1.f. Encryption or decryption in support of entertainment, mass commercial broadcasts or medical records management; or

1.g. Key management in support of any function described in paragraphs 1.a to 1.f of this Technical Note paragraph 1.

2. For the purposes of 5A002.a, 'described security algorithm' means any of the following:

2.a. A ''symmetric algorithm'' employing a key length in excess of 56 bits, not including parity bits; or

2.b. An ''asymmetric algorithm'' where the security of the algorithm is based on any of the following:

2.b.1. Factorization of integers in excess of 512 bits (e.g., RSA);

2.b.2. Computation of discrete logarithms in a multiplicative group of a finite field of size greater than 512 bits (e.g., Diffie-Hellman over Z/pZ); or

2.b.3. Discrete logarithms in a group other than mentioned in paragraph 2.b.2 of this Technical Note in excess of 112 bits (e.g., Diffie-Hellman over an elliptic curve); or

2.c. An ''asymmetric algorithm'' where the security of the algorithm is based on any of the following:

2.c.1. Shortest vector or closest vector problems associated with lattices (e.g., NewHope, Frodo, NTRUEncrypt, Kyber, Titanium);

2.c.2. Finding isogenies between Supersingular elliptic curves (e.g., Supersingular Isogeny Key Encapsulation); or

2.c.3. Decoding random codes (e.g., McEliece, Niederreiter).

Technical Note: *An algorithm described by Technical Note 2.c. may be referred to as being post-quantum, quantum-safe or quantum-resistant.*

Note 1: *Details of items must be accessible and provided upon request, in order to establish any of the following:*

a. Whether the item meets the criteria of 5A002.a.1 to a.4; or

b. Whether the cryptographic capability for data confidentiality specified by 5A002.a is usable without ''cryptographic activation.''

Note 2: *5A002.a does not control any of the following items, or specially designed ''information security'' components therefor:*

a. Smart cards and smart card 'readers/writers' as follows:

a.1. A smart card or an electronically readable personal document (e.g., token coin, e-passport) that meets any of the following:

a.1.a. The cryptographic capability meets all of the following:

a.1.a.1. It is restricted for use in any of the following:

a.1.a.1.a. Equipment or systems, not described by 5A002.a.1 to a.4;

a.1.a.1.b. Equipment or systems, not using 'cryptography for data confidentiality' having a 'described security algorithm'; or

a.1.a.1.c. Equipment or systems, excluded from 5A002.a by entries b. to f. of this Note; and

a.1.a.2. It cannot be reprogrammed for any other use; or

a.1.b. Having all of the following:

a.1.b.1. It is specially designed and limited to allow protection of 'personal data' stored within;

a.1.b.2. Has been, or can only be, personalized for public or commercial transactions or individual identification; and

a.1.b.3. Where the cryptographic capability is not user-accessible;

Technical Note to paragraph a.1.b of Note 2: *'Personal data' includes any data specific to a particular person or entity, such as the amount of money stored and data necessary* for ''*authentication.*''

a.2. 'Readers/writers' specially designed or modified, and limited, for items specified by paragraph a.1 of this Note;

Technical Note to paragraph a.2 of Note 2: *'Readers/writers' include equipment that communicates with smart cards or electronically readable documents through a network.*

b. Cryptographic equipment specially designed and limited for banking use or 'money transactions';

Technical Note to paragraph b. of Note 2: *'Money transactions' in 5A002 Note 2 paragraph b. includes the collection and settlement of fares or credit functions.*

c. Portable or mobile radiotelephones for civil use (e.g., for use with commercial civil cellular radio communication systems) that are not capable of transmitting encrypted data directly to another radiotelephone or equipment (other than Radio Access Network (RAN) equipment), nor of passing encrypted data through RAN equipment (e.g., Radio Network Controller (RNC) or Base Station Controller (BSC));

d. Cordless telephone equipment not capable of end-to-end encryption where the maximum effective range of unboosted cordless operation (i.e., a single, unrelayed hop between terminal and home base station) is less than 400 meters according to the manufacturer's specifications;

e. Portable or mobile radiotelephones and similar client wireless devices for civil use, that implement only published or

commercial cryptographic standards (except for anti-piracy functions, which may be non-published) and also meet the provisions of paragraphs a.2 to a.4 of the Cryptography Note (Note 3 in Category 5—Part 2), that have been customized for a specific civil industry application with features that do not affect the cryptographic functionality of these original non-customized devices;

f. Items, where the ''information security'' functionality is limited to wireless ''personal area network'' functionality, meeting all of the following:

f.1. Implement only published or commercial cryptographic standards; and

f.2. The cryptographic capability is limited to a nominal operating range not exceeding 30 meters according to the manufacturer's specifications, or not exceeding 100 meters according to the manufacturer's specifications for equipment that cannot interconnect with more than seven devices;

g. Mobile telecommunications Radio Access Network (RAN) equipment designed for civil use, which also meet the provisions of paragraphs a.2 to a.4 of the Cryptography Note (Note 3 in Category 5—Part 2), having an RF output power limited to 0.1W (20 dBm) or less, and supporting 16 or fewer concurrent users;

h. Routers, switches or relays, where the ''information security'' functionality is limited to the tasks of ''Operations, Administration or Maintenance'' (''OAM'') implementing only published or commercial cryptographic standards; or

i. General purpose computing equipment or servers, where the ''information security'' functionality meets all of the following:

i.1. Uses only published or commercial cryptographic standards; and

i.2. Is any of the following:

i.2.a. Integral to a CPU that meets the provisions of Note 3 in Category 5—Part 2;

i.2.b. Integral to an operating system that is not specified by 5D002; or

i.2.c. Limited to ''OAM'' of the equipment.

b. Designed or modified for converting, by means of ''cryptographic activation'', an item not specified by Category 5—Part 2 into an item specified by 5A002.a or 5D002.c.1, and not released by the Cryptography Note (Note 3 in Category 5—Part 2), or for enabling, by means of ''cryptographic activation'', additional functionality specified by 5A002.a of an item already specified by Category 5—Part 2;

c. Designed or modified to use or perform ''quantum cryptography;''

Technical Note: ''*Quantum cryptography*'' *is also known as Quantum Key Distribution (QKD).*

d. Designed or modified to use cryptographic techniques to generate channelizing codes, scrambling codes or network identification codes, for systems using ultra-wideband modulation techniques and having any of the following:

d.1. A bandwidth exceeding 500 MHz; *or*

d.2. A ''fractional bandwidth'' of 20% or more;

e. Designed or modified to use cryptographic techniques to generate the spreading code for ''spread spectrum'' systems, not specified by 5A002.d, including the hopping code for ''frequency hopping'' systems.

■ 6. In supplement no. 1 to part 774, Category 6, ECCN 6A001 is revised to read as follows:

6A001 Acoustic systems, equipment and ''components,'' as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, AT

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
NS applies to entire entry.	NS Column 2
AT applies to entire entry.	AT Column 1

Reporting Requirements

See § 743.1 of the EAR for reporting requirements for exports under License Exceptions, and Validated End-User authorizations.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: $3000; N/A for 6A001.a.1.b.1 object detection and location systems having a transmitting frequency below 5 kHz or a sound pressure level exceeding 210 dB (reference 1 μPa at 1 m) for equipment with an operating frequency in the band from 2 kHz to 30 kHz inclusive; 6A001.a.1.e, 6A001.a.2.a.1, a.2.a.2, 6A001.a.2.a.3, a.2.a.5, a.2.a.6, 6A001.a.2.b; processing equipment controlled by 6A001.a.2.c, and ''specially designed'' for real-time application with towed acoustic hydrophone arrays; a.2.e.1, a.2.e.2; and bottom or bay cable systems controlled by 6A001.a.2.f and having processing equipment ''specially designed'' for real-time application with bottom or bay cable systems.

GBS: Yes for 6A001.a.1.b.4.

CIV: Yes for 6A001.a.1.b.4.

Special Conditions for STA

STA: License Exception STA may not be used to ship commodities in 6A001.a.1.b, 6A001.a.1.e or 6A001.a.2 (except .a.2.a.4) to any of the destinations listed in Country Group A:6 (See Supplement No.1 to part 740 of the EAR).

List of Items Controlled

Related Controls: See also 6A991.

Related Definitions: N/A

Items:

a. Marine acoustic systems, equipment and ''specially designed'' ''components'' therefor, as follows:

a.1. Active (transmitting or transmitting-and-receiving) systems, equipment and ''specially designed'' ''components'' therefor, as follows:

Note: 6A001.a.1 does not control equipment as follows:

a. Depth sounders operating vertically below the apparatus, not including a scanning function exceeding ± 20°, and limited to measuring the depth of water, the distance of submerged or buried objects or fish finding;

b. Acoustic beacons, as follows:

1. Acoustic emergency beacons;

2. Pingers ''specially designed'' for relocating or returning to an underwater position.

a.1.a. Acoustic seabed survey equipment as follows:

a.1.a.1. Surface vessel survey equipment designed for sea bed topographic mapping and having all of the following:

a.1.a.1.a. Designed to take measurements at an angle exceeding 20° from the vertical;

a.1.a.1.b. Designed to measure seabed topography at seabed depths exceeding 600 m;

a.1.a.1.c.'Sounding resolution' less than 2; and

a.1.a.1.d. 'Enhancement' of the depth ''accuracy'' through compensation for all the following:

a.1.a.1.d.1. Motion of the acoustic sensor;

a.1.a.1.d.2. In-water propagation from sensor to the seabed and back; and

a.1.a.1.d.3. Sound speed at the sensor;

Technical Notes:

1. 'Sounding resolution' is the swath width (degrees) divided by the maximum number of soundings per swath.

2. 'Enhancement' includes the ability to compensate by external means.

a.1.a.2. Underwater survey equipment designed for seabed topographic mapping and having any of the following:

Technical Note: The acoustic sensor pressure rating determines the depth rating of the equipment specified by 6A001.a.1.a.2.

a.1.a.2.a. Having all of the following:

a.1.a.2.a.1. Designed or modified to operate at depths exceeding 300 m; and

a.1.a.2.a.2. 'Sounding rate' greater than 3,800 m/s; *or*

Technical Note: 'Sounding rate' is the product of the maximum speed (m/s) at which the sensor can operate and the maximum number of soundings per swath assuming 100% coverage. For systems that produce soundings in two directions (3D sonars), the maximum of the 'sounding rate' in either direction should be used.

a.1.a.2.b. Survey equipment, not specified by 6A001.a.1.a.2.a, having all of the following:

a.1.a.2.b.1. Designed or modified to operate at depths exceeding 100 m;

a.1.a.2.b.2. Designed to take measurements at an angle exceeding 20°from the vertical;

a.1.a.2.b.3. Having any of the following:

a.1.a.2.b.3.a. Operating frequency below 350 kHz; *or*

a.1.a.2.b.3.b. Designed to measure seabed topography at a range exceeding 200 m from the acoustic sensor; *and*

a.1.a.2.b.4. 'Enhancement' of the depth ''accuracy'' through compensation of all of the following:

a.1.a.2.b.4.a. Motion of the acoustic sensor;

a.1.a.2.b.4.b. In-water propagation from sensor to the seabed and back; *and*

a.1.a.2.b.4.c. Sound speed at the sensor.

a.1.a.3. Side Scan Sonar (SSS) or Synthetic Aperture Sonar (SAS), designed for seabed imaging and having all of the following, and ''specially designed'' transmitting and receiving acoustic arrays therefor:

a.1.a.3.a. Designed or modified to operate at depths exceeding 500 m; and

a.1.a.3.b. An 'area coverage rate' of greater than 570 m^2/s while operating at the

maximum range that it can operate with an 'along track resolution' of less than 15 cm; *and*

a.1.a.3.c. An 'across track resolution' of less than 15 cm;

Technical Notes:

1. 'Area coverage rate' (m^2/s) is twice the product of the sonar range (m) and the maximum speed (m/s) at which the sensor can operate at that range.

2. 'Along track resolution' (cm), for SSS only, is the product of azimuth (horizontal) beamwidth (degrees) and sonar range (m) and 0.873.

3. 'Across track resolution' (cm) is 75 divided by the signal bandwidth (kHz).

a.1.b Systems or transmitting and receiving arrays, designed for object detection or location, having any of the following:

a.1.b.1. A transmitting frequency below 10 kHz;

a.1.b.2. Sound pressure level exceeding 224dB (reference 1 μPa at 1 m) for equipment with an operating frequency in the band from 10 kHz to 24 kHz inclusive;

a.1.b.3. Sound pressure level exceeding 235 dB (reference 1 μPa at 1 m) for equipment with an operating frequency in the band between 24 kHz and 30 kHz;

a.1.b.4. Forming beams of less than 1° on any axis and having an operating frequency of less than 100 kHz;

a.1.b.5. Designed to operate with an unambiguous display range exceeding 5,120 m; *or*

a.1.b.6. Designed to withstand pressure during normal operation at depths exceeding 1,000 m and having transducers with any of the following:

a.1.b.6.a. Dynamic compensation for pressure; *or*

a.1.b.6.b. Incorporating other than lead zirconate titanate as the transduction element;

a.1.c. Acoustic projectors, including transducers, incorporating piezoelectric, magnetostrictive, electrostrictive, electrodynamic or hydraulic elements operating individually or in a designed combination and having any of the following:

Notes:

1. The control status of acoustic projectors, including transducers, ''specially designed'' for other equipment is determined by the control status of the other equipment.

2. 6A001.a.1.c does not control electronic sources that direct the sound vertically only, or mechanical (e.g., air gun or vapor-shock gun) or chemical (e.g., explosive) sources.

3. Piezoelectric elements specified in 6A001.a.1.c include those made from lead-magnesium-niobate/lead-titanate ($Pb(Mg_{1/3}Nb_{2/3})O_3-PbTiO_3$, or PMN–PT) single crystals grown from solid solution or lead-indium-niobate/lead-magnesium niobate/lead-titanate ($Pb(In_{1/2}Nb_{1/2})O_3$–$Pb(Mg_{1/3}Nb_{2/3})O_3$–$PbTiO_3$, or PIN–PMN–PT) single crystals grown from solid solution.

a.1.c.1. Operating at frequencies below 10 kHz and having any of the following:

a.1.c.1.a. Not designed for continuous operation at 100% duty cycle and having a radiated 'free-field Source Level (SLRMS)' exceeding (10log(f) + 169.77)dB (reference 1 μPa at 1 m) where f is the frequency in Hertz of maximum Transmitting Voltage Response (TVR) below 10 kHz; *or*

a.1.c.1.b. Designed for continuous operation at 100% duty cycle and having a continuously radiated 'free-field Source Level (SLRMS)' at 100% duty cycle exceeding (10log(f) + 159.77)dB (reference 1 μPa at 1 m) where f is the frequency in Hertz of maximum Transmitting Voltage Response (TVR) below 10 kHz; *or*

Technical Note: *The 'free-field Source Level (SL_{RMS})' is defined along the maximum response axis and in the far field of the acoustic projector. It can be obtained from the Transmitting Voltage Response using the following equation: $SL_{RMS} = (TVR + 20log V_{RMS})$ dB (ref 1μPa at 1 m), where SL_{RMS} is the source level, TVR is the Transmitting Voltage Response and V_{RMS} is the Driving Voltage of the Projector.*

a.1.c.2. [Reserved]

N.B. *See 6A001.a.1.c.1 for items previously specified in 6A001.a.1.c.2.*

a.1.c.3. Side-lobe suppression exceeding 22 dB;

a.1.d. Acoustic systems and equipment, designed to determine the position of surface vessels or underwater vehicles and having all of the following, and ''specially designed'' ''components'' therefor:

a.1.d.1. Detection range exceeding 1,000 m; *and*

a.1.d.2. Determined position error of less than 10 m rms (root mean square) when measured at a range of 1,000 m;

Note: *6A001.a.1.d includes:*

a. Equipment using coherent ''signal processing'' between two or more beacons and the hydrophone unit carried by the surface vessel or underwater vehicle;

b. Equipment capable of automatically correcting speed-of-sound propagation errors for calculation of a point.

a.1.e. Active individual sonars, ''specially designed'' or modified to detect, locate and automatically classify swimmers or divers, having all of the following, and ''specially designed'' transmitting and receiving acoustic arrays therefor:

a.1.e.1. Detection range exceeding 530 m;

a.1.e.2. Determined position error of less than 15 m rms (root mean square) when measured at a range of 530 m; *and*

a.1.e.3. Transmitted pulse signal bandwidth exceeding 3 kHz;

N.B.*: For diver detection systems ''specially designed'' or modified for military use, see the U.S. Munitions List in the International Traffic in Arms Regulations (ITAR) (22 CFR part 121).*

Note: *For 6A001.a.1.e, where multiple detection ranges are specified for various environments, the greatest detection range is used.*

a.2. Passive systems, equipment and ''specially designed'' ''components'' therefor, as follows:

Note: 6A001.a.2 also applies to receiving equipment, whether or not related in normal application to separate active equipment, and ''specially designed'' components therefor.

a.2.a. Hydrophones having any of the following:

Note: The control status of hydrophones ''specially designed'' for other equipment is determined by the control status of the other equipment.

Technical Notes:

1. Hydrophones consist of one or more sensing elements producing a single acoustic output channel. Those that contain multiple elements can be referred to as a hydrophone group.

2. *For the purposes of 6A001.a.2.a, underwater acoustic transducers designed to operate as passive receivers are hydrophones.*

a.2.a.1. Incorporating continuous flexible sensing elements;

a.2.a.2. Incorporating flexible assemblies of discrete sensing elements with either a diameter or length less than 20 mm and with a separation between elements of less than 20 mm;

a.2.a.3. Having any of the following sensing elements:

a.2.a.3.a. Optical fibers;

a.2.a.3.b. 'Piezoelectric polymer films' other than polyvinylidene-fluoride (PVDF) and its co-polymers {P(VDF − TrFE) and P(VDF–TFE)};

a.2.a.3.c. 'Flexible piezoelectric composites';

a.2.a.3.d. Lead-magnesium- niobate/lead-titanate (*i.e.,* $Pb(Mg_{1/3}Nb_{2/3})O_3-PbTiO_3$, or PMN–PT) piezoelectric single crystals grown from solid solution; *or*

a.2.a.3.e.Lead-indium-niobate/lead-magnesium niobate/lead-titanate (*i.e.,* $Pb(In_{1/2}Nb_{1/2})O_3$–$Pb(Mg_{1/3}Nb_{2/3})O_3$–$PbTiO_3$, or PIN–PMN–PT) piezoelectric single crystals grown from solid solution;

a.2.a.4. A 'hydrophone sensitivity' better than −180dB at any depth with no acceleration compensation;

a.2.a.5. Designed to operate at depths exceeding 35 m with acceleration compensation; *or*

a.2.a.6. Designed for operation at depths exceeding 1,000 m and having a 'hydrophone sensitivity' better than −230 dB below 4 kHz;

Technical Notes:

1. '*Piezoelectric polymer film*' *sensing elements consist of polarized polymer film that is stretched over and attached to a supporting frame or spool (mandrel).*

2. '*Flexible piezoelectric composite*' *sensing elements consist of piezoelectric ceramic particles or fibers combined with an electrically insulating, acoustically transparent rubber, polymer or epoxy compound, where the compound is an integral part of the sensing elements.*

3. '*Hydrophone sensitivity*' *is defined as twenty times the logarithm to the base 10 of the ratio of rms output voltage to a 1 V rms reference, when the hydrophone sensor, without a pre-amplifier, is placed in a plane wave acoustic field with an rms pressure of 1 μPa. For example, a hydrophone of −160 dB (reference 1 V per μPa) would yield an output voltage of 10^{-8} V in such a field, while one of −180 dB sensitivity would yield only 10^{-9} V output. Thus, −160 dB is better than −180 dB.*

a.2.b. Towed acoustic hydrophone arrays having any of the following:

Technical Note: *Hydrophones arrays consist of a number of hydrophones providing multiple acoustic output channels.*

a.2.b.1. Hydrophone group spacing of less than 12.5 m or 'able to be modified' to have hydrophone group spacing of less than 12.5 m;

a.2.b.2. Designed or 'able to be modified' to operate at depths exceeding 35m;

Technical Note: '*Able to be modified*' *in 6A001.a.2.b means having provisions to allow a change of the wiring or interconnections to alter hydrophone group spacing or operating depth limits. These provisions are: Spare wiring exceeding 10% of the number of wires, hydrophone group spacing adjustment blocks or internal depth limiting devices that are adjustable or that control more than one hydrophone group.*

a.2.b.3. Heading sensors controlled by 6A001.a.2.d;

a.2.b.4. Longitudinally reinforced array hoses;

a.2.b.5. An assembled array of less than 40 mm in diameter;

a.2.b.6. [Reserved];

a.2.b.7. Hydrophone characteristics controlled by 6A001.a.2.a; *or*

a.2.b.8. Accelerometer-based hydro-acoustic sensors specified by 6A001.a.2.g;

a.2.c. Processing equipment, ''specially designed'' for towed acoustic hydrophone arrays, having ''user-accessible programmability'' and time or frequency domain processing and correlation, including spectral analysis, digital filtering and beamforming using Fast Fourier or other transforms or processes;

a.2.d. Heading sensors having all of the following:

a.2.d.1. An ''accuracy'' of better than ± 0.5°; *and*

a.2.d.2. Designed to operate at depths exceeding 35 m or having an adjustable or removable depth sensing device in order to operate at depths exceeding 35 m;

N.B.: *For inertial heading systems, see 7A003.c.*

a.2.e. Bottom or bay-cable hydrophone arrays having any of the following:

a.2.e.1. Incorporating hydrophones controlled by 6A001.a.2.a;

a.2.e.2. Incorporating multiplexed hydrophone group signal modules having all of the following characteristics:

a.2.e.2.a. Designed to operate at depths exceeding 35 m or having an adjustable or removal depth sensing device in order to operate at depths exceeding 35 m; *and*

a.2.e.2.b. Capable of being operationally interchanged with towed acoustic hydrophone array modules; *or*

a.2.e.3. Incorporating accelerometer-based hydro-acoustic sensors specified by 6A001.a.2.g;

a.2.f. Processing equipment, ''specially designed'' for bottom or bay cable systems, having ''user-accessible programmability'' and time or frequency domain processing and correlation, including spectral analysis, digital filtering and beamforming using Fast Fourier or other transforms or processes;

a.2.g. Accelerometer-based hydro-acoustic sensors having all of the following:

a.2.g.1. Composed of three accelerometers arranged along three distinct axes;

a.2.g.2. Having an overall 'acceleration sensitivity' better than 48 dB (reference 1,000 mV rms per 1g);

a.2.g.3. Designed to operate at depths greater than 35 meters; *and*

a.2.g.4. Operating frequency below 20 kHz;

Note: *6A001.a.2.g does not apply to particle velocity sensors or geophones.*

Technical Notes:

1. *Accelerometer-based hydro-acoustic sensors are also known as vector sensors.*

2. *'Acceleration sensitivity' is defined as twenty times the logarithm to the base 10 of the ratio of rms output voltage to a 1 V rms reference, when the hydro-acoustic sensor, without a preamplifier, is placed in a plane wave acoustic field with an rms acceleration of 1 g* (*i.e., 9.81 m/s*^{2}).

b. Correlation-velocity and Doppler-velocity sonar log equipment designed to measure the horizontal speed of the equipment carrier relative to the sea bed, as follows:

b.1. Correlation-velocity sonar log equipment having any of the following characteristics:

b.1.a. Designed to operate at distances between the carrier and the sea bed exceeding 500 m; *or*

b.1.b. Having speed ''accuracy'' better than 1% of speed;

b.2. Doppler-velocity sonar log equipment having speed ''accuracy'' better than 1% of speed;

Note 1: *6A001.b does not apply to depth sounders limited to any of the following:*

a. Measuring the depth of water;

b. Measuring the distance of submerged or buried objects; or

c. Fish finding.

Note 2: *6A001.b does not apply to equipment ''specially designed'' for installation on surface vessels.*

c. [Reserved]

N.B.: *For diver deterrent acoustic systems, see 8A002.r.*

■ 7. In supplement no. 1 to part 774, Category 9, ECCN 9A004 is revised to read as follows:

9A004 Space launch vehicles and ''spacecraft,'' ''spacecraft buses'', ''spacecraft payloads'', ''spacecraft'' on-board systems or equipment, terrestrial equipment, and air-launch platforms, as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS and AT

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
NS applies to 9A004.g, .u, .v, .w and .x.	NS Column 1
AT applies to 9A004.g, .u, .v, .w, .x and .y.	AT Column 1

License Requirements Note: *9A004.b through .f are controlled under ECCN 9A515.*

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Related Controls: (1) See also 9A104, 9A515, and 9B515. (2) See ECCNs 9E001 (''development'') and 9E002 (''production'') for technology for items controlled by this entry. (3) See USML Categories IV for the space launch vehicles and XV for other spacecraft that are ''subject to the ITAR'' (see 22 CFR parts 120 through 130).

Related Definition: N/A

Items:

a. Space launch vehicles;

b. ''Spacecraft'';

c. ''Spacecraft buses'';

d. ''Spacecraft payloads'' incorporating items specified by 3A001.b.1.a.4, 3A002.g, 5A001.a.1, 5A001.b.3, 5A002.c, 5A002.e, 6A002.a.1, 6A002.a.2, 6A002.b, 6A002.d, 6A003.b, 6A004.c, 6A004.e, 6A008.d, 6A008.e, 6A008.k, 6A008.l or 9A010.c;

e. On-board systems or equipment, ''specially designed'' for ''spacecraft'' and having any of the following functions:

e.1. 'Command and telemetry data handling';

Note: *For the purpose of 9A004.e.1, 'command and telemetry data handling' includes bus data management, storage, and processing.*

e.2. 'Payload data handling'; *or*

Note: *For the purpose of 9A004.e.2, 'payload data handling' includes payload data management, storage, and processing.*

e.3. 'Attitude and orbit control';

Note: *For the purpose of 9A004.e.3, 'attitude and orbit control' includes sensing and actuation to determine and control the position and orientation of a ''spacecraft''.*

N.B.: *Equipment specially designed for military use is ''subject to the ITAR''. See 22 CFR parts 120 through 130.*

f. Terrestrial equipment ''specially designed'' for ''spacecraft'', as follows:

f.1. Telemetry and telecommand equipment ''specially designed'' for any of the following data processing functions:

f.1.a. Telemetry data processing of frame synchronization and error corrections, for monitoring of operational status (also known as health and safe status) of the ''spacecraft bus''; *or*

f.1.b. Command data processing for formatting command data being sent to the ''spacecraft'' to control the ''spacecraft bus'';

f.2. Simulators ''specially designed'' for 'verification of operational procedures' of ''spacecraft''.

Technical Note: *For the purposes of 9A004.f.2, 'verification of operational procedures' is any of the following:*

1. Command sequence confirmation;

2. Operational training;

3. Operational rehearsals; or

4. Operational analysis.

g. ''Aircraft'' ''specially designed'' or modified to be air-launch platforms for space launch vehicles.

h. through t. [RESERVED]

u. The James Webb Space Telescope (JWST) being developed, launched, and operated under the supervision of the U.S. National Aeronautics and Space Administration (NASA).

v. ''Parts,'' ''components,'' ''accessories'' and ''attachments'' that are ''specially designed'' for the James Webb Space Telescope and that are *not:*

v.1. Enumerated or controlled in the USML;

v.2. Microelectronic circuits;

v.3. Described in ECCNs 7A004 or 7A104; *or*

v.4. Described in an ECCN containing ''space-qualified'' as a control criterion (*See* ECCN 9A515.x.4).

w. The International Space Station being developed, launched, and operated under the supervision of the U.S. National Aeronautics and Space Administration.

x. ''Parts,'' ''components,'' ''accessories'' and ''attachments'' that are ''specially designed'' for the International Space Station.

y. Items that would otherwise be within the scope of ECCN 9A004.v or .x but that have been identified in an interagency-cleared commodity classification (CCATS) pursuant to § 748.3(e) as warranting control in 9A004.y.

Nazak Nikakhtar,

Assistant Secretary for Industry & Analysis, Performing the Non-exclusive Duties of the Under Secretary for Industry and Security.

[FR Doc. 2019–10778 Filed 5–22–19; 8:45 am]

BILLING CODE 3510–33–P

FEDERAL REGISTER

Vol. 84 Thursday,
No. 100 May 23, 2019

Part IV

Department of Energy

Federal Energy Regulatory Commission

18 CFR Part 35

Electric Storage Participation in Markets Operated by Regional Transmission Organizations and Independent System Operators; Final Rule

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket Nos. RM16–23–001; AD16–20–001; Order No. 841–A]

Electric Storage Participation in Markets Operated by Regional Transmission Organizations and Independent System Operators

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Order on rehearing and clarification.

SUMMARY: The Federal Energy Regulatory Commission addresses petitions for rehearing and clarification and generally affirms its determinations in Order No. 841, amending its regulations under the Federal Power Act to remove barriers to the participation of electric storage resources in the capacity, energy, and ancillary service markets operated by Regional Transmission Organizations and Independent System Operators.

DATES: This order on rehearing and clarification will become effective August 21, 2019.

FOR FURTHER INFORMATION CONTACT:

Kaitlin Johnson (Technical Information), Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8542, *kaitlin.johnson@ferc.gov*

Karin Herzfeld (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8459, *karin.herzfeld@ferc.gov*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

1. On February 15, 2018, the Federal Energy Regulatory Commission (Commission) issued Order No. 841, which established reforms to remove barriers to the participation of electric storage resources [1] in the Regional Transmission Organization and Independent System Operator markets (RTO/ISO markets).[2] The Commission found that existing RTO/ISO market rules are unjust and unreasonable in light of barriers that they present to the participation of electric storage resources in the RTO/ISO markets, thereby reducing competition and failing to ensure just and reasonable rates.[3] To help ensure that the RTO/ISO markets produce just and reasonable rates, pursuant to the Commission's legal authority under Federal Power Act (FPA) section 206,[4] the Commission in Order No. 841 modified § 35.28 of the Commission's regulations [5] to require each RTO/ISO to revise its tariff to establish market rules that, recognizing the physical and operational characteristics of electric storage resources, facilitate their participation in the RTO/ISO markets.[6]

2. More specifically, Order No. 841 required each RTO/ISO to revise its tariff to establish a participation model consisting of market rules that, recognizing the physical and

[1] *Electric Storage Participation in Markets Operated by Regional Transmission Organizations and Independent System Operators,* Order No. 841, 83 FR 9580, 162 FERC ¶ 61,127, at P 1 (2018). Order No. 841 defined an electric storage resource as a resource capable of receiving electric energy from the grid and storing it for later injection of electric energy back to the grid. *Id.* P 1 n.1.

[2] For purposes of Order No. 841, the Commission defined RTO/ISO markets as the capacity, energy, and ancillary services markets operated by the RTOs and ISOs. *Id.* P 1 n.2.

[3] *Id.* P 1.

[4] 16 U.S.C. 824e (2012).

[5] 18 CFR 35.28 (2018).

[6] Order No. 841, 162 FERC ¶ 61,127 at P 1.

operational characteristics of electric storage resources, facilitates their participation in the RTO/ISO markets.[7] For each RTO/ISO, the tariff provisions for the participation model for electric storage resources must (1) ensure that a resource using the participation model for electric storage resources is eligible to provide all capacity, energy, and ancillary services that it is technically capable of providing in the RTO/ISO markets; (2) ensure that a resource using the participation model for electric storage resources can be dispatched and can set the wholesale market clearing price as both a wholesale seller and wholesale buyer consistent with existing market rules that govern when a resource can set the wholesale price; (3) account for the physical and operational characteristics of electric storage resources through bidding parameters or other means; and (4) establish a minimum size requirement for participation in the RTO/ISO markets that does not exceed 100 kW.[8] Additionally, Order No. 841 directed each RTO/ISO to specify that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets must be at the wholesale locational marginal price (LMP).

3. The following petitioners filed timely requests for rehearing or rehearing and clarification of Order No. 841: AES Companies; American Municipal Power, Inc., American Public Power Association, and National Rural Electric Cooperative Association (collectively, AMP/APPA/NRECA); California Energy Storage Alliance; California Independent System Operator Corporation (CAISO); Edison Electric Institute (EEI); Midcontinent Independent System Operator, Inc. (MISO); National Association of Regulatory Utility Commissioners (NARUC); Transmission Access Policy Study Group (TAPS); and Xcel Energy Services Inc. (Xcel Energy Services).[9] Organization of MISO States; Pacific Gas and Electric Company; PJM Interconnection, L.L.C. (PJM); and Southwest Power Pool, Inc. (SPP) filed requests for clarification. For the reasons discussed below, we deny the requests for rehearing and deny in part and grant in part the requests for clarification.

4. Specifically, we grant SPP's request for clarification that Order No. 841 does not require an RTO/ISO to create and provide a capacity product that an RTO/ISO market does not otherwise offer. We also grant PJM's request for clarification that the final rule allows for flexibility in how RTOs/ISOs account for the physical and operational characteristics of electric storage resources, including State of Charge. We further grant EEI's request to clarify that the Commission will not dismiss as per se unreasonable any proposal to establish a non-facility-specific rate for wholesale distribution service to an electric storage resource for its charging. We also grant CAISO's request to clarify that an RTO/ISO could require verification from the host distribution utility that it is unable or unwilling to net wholesale demand from retail settlement before the RTO/ISO ceases to settle an electric storage resource's wholesale demand at the wholesale LMP. Finally, we grant clarification of the Commission's finding that applicable transmission charges should apply when an electric storage resource is charging to resell energy at a later time. We also modify § 35.28(g)(9)(i)(B) of the Commission's regulations to clarify that each RTO/ISO is required to allow resources using the participation model for electric storage resources to participate in the RTO/ISO markets as dispatchable resources, not that such resources are required to be dispatchable to use that participation model.

II. Discussion

A. Definition of Electric Storage Resource

1. Final Rule

5. In Order No. 841, the Commission revised § 35.28(b) of the Commission's regulations to define an electric storage resource as ''a resource capable of receiving electric energy from the grid and storing it for later injection of electric energy back to the grid.'' [10] The Commission stated that this definition is intended to cover electric storage resources capable of receiving electric energy from the grid and storing it for later injection of electric energy back to the grid, regardless of their storage medium (*e.g.,* batteries, flywheels, compressed air, and pumped-hydro). Additionally, the Commission stated that electric storage resources located on the interstate transmission system, on a distribution system, or behind the meter fall under this definition. The Commission stated that, by including all electric storage technologies, and by allowing resources that are interconnected to the transmission system, distribution system, or behind the meter to use the participation model for electric storage resources, the Commission was ensuring that the market rules will not be designed for any particular electric storage technology.[11]

6. The Commission observed that an electric storage resource that injects electric energy back to the grid for purposes of participating in an RTO/ISO market engages in a sale of electric energy at wholesale in interstate commerce.[12] As a result, the Commission found that such an electric storage resource must fulfill certain responsibilities set forth in the FPA and the Commission's rules and regulations.[13]

7. The Commission disagreed with commenters who asserted that the definition of an electric storage resource should be limited to those electric storage resources that are interconnected to the transmission system.[14] The Commission found that electric storage resources interconnected to the distribution system are already participating in the RTO/ISO markets [15] and that they should continue to be able to do so. The Commission stated that such a limitation also would be inconsistent with the participation of other types of resources because various types of traditional generation and demand-side resources that are not connected directly to the transmission

[7] *Id.* P 3. In Order No. 841, the Commission used the term ''participation model'' to refer to distinct tariff provisions that an RTO/ISO creates for a particular type of resource when that type of resource has unique physical and operational characteristics or other attributes that warrant distinctive treatment from other market participants. The Commission further explained that it was requiring a participation model for electric storage resources that will help facilitate the participation of electric storage resources in the RTO/ISO markets. *Id.*

[8] *Id.* P 4.

[9] Advanced Energy Economy, Energy Storage Association, and Monitoring Analytics, LLC acting in its capacity as the Independent Market Monitor for PJM filed answers to the requests for rehearing or clarification. Title 18 CFR 385.713(d)(1), Rule 713(d)(1) of the Commission's Rules of Practice and Procedure, prohibits an answer to a request for rehearing. Accordingly, we reject these answers.

[10] Order No. 841, 162 FERC ¶ 61,127 at P 29.

[11] *Id.*

[12] *Id.* P 30. The Commission also observed that injections of electric energy back to the grid do not necessarily trigger the Commission's jurisdiction. *Id.* n.49 (citing *Sun Edison LLC,* 129 FERC ¶ 61,146 (2009), *reh'g granted on other grounds,* 131 FERC ¶ 61,213 (2010) (the Commission's jurisdiction would arise only when a facility operating under a state net metering program produces more power than it consumes over the relevant netting period); *MidAmerican Energy Co.,* 94 FERC ¶ 61,340 (2001)).

[13] *Id.* P 30. The Commission provided the following examples of such responsibilities: Filing rates under FPA section 205 (potentially including obtaining market-based rate authority); submitting FPA sections 203 and 204 filings related to corporate mergers and other activities; and fulfilling FPA section 301 accounting obligations and FPA section 305(b) interlocking directorate obligations. *Id.* (citing 16 U.S.C. 824b, 824c, 824d, 825, 825d(b)).

[14] *Id.* P 31.

[15] *Id.* (citing *PJM Interconnection L.L.C.,* 149 FERC ¶ 61,185 (2014), *order on reh'g,* 151 FERC ¶ 61,231 (2015)).

system currently participate in the RTO/ISO markets.

8. The Commission also explained that, by ''capable of . . . later injection of electric energy back to the grid,'' it meant that the electric storage resource is both physically designed and configured to inject electric energy back onto the grid and, as relevant, is contractually permitted to do so (*e.g.,* per the interconnection agreement between an electric storage resource that is interconnected on a distribution system or behind-the-meter with the distribution utility to which it is interconnected).[16] Consequently, the Commission found that the definition of an electric storage resource excludes a resource that is either (1) physically incapable of injecting electric energy back onto the grid due to its design or configuration or (2) contractually barred from injecting electric energy back onto the grid. Further, the Commission explained that Order No. 841 requires each RTO/ISO to implement market rules applicable to electric storage resources, as defined therein, that voluntarily seek to participate in the RTO/ISO markets; Order No. 841 does not require electric storage resources to participate in those markets.[17]

9. The Commission stated that it has exclusive jurisdiction over the wholesale markets and the criteria for participation in those markets, including the wholesale market rules for participation of resources connected at or below distribution-level voltages.[18] The Commission also noted its understanding that numerous resources connected to the distribution system participate in the RTO/ISO markets today.[19] Under those circumstances, the Commission was not persuaded to grant commenters' request that the Commission allow states to decide whether electric storage resources in their state that are located behind a retail meter or on the distribution system are permitted to participate in the RTO/ISO markets through the electric storage resource participation model.

10. That said, the Commission emphasized the ongoing, vital role of the states with respect to the development and operation of electric storage resources.[20] The Commission noted that such state responsibilities include, among other things, retail services and matters related to the distribution system, including design, operations, power quality, reliability, and system costs. The Commission added that nothing in Order No. 841 was intended to affect or implicate the responsibilities of distribution utilities to maintain the safety and the reliability of the distribution system or their use of electric storage resources on their systems. Further, in Order No. 841, the Commission added § 35.28(g)(9)(ii) to the Commission's regulations to require that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets be at the wholesale LMP.[21]

2. Requests for Rehearing or Clarification

11. Petitioners raise several issues concerning the Commission's authority with respect to electric storage resources' participation in RTO/ISO markets. First, some petitioners contend that the Commission must, or should, provide relevant electric retail regulatory authorities (RERRA) with an electric storage resource opt-out similar to that afforded for demand response in Order No. 719. Second, petitioners raise concerns about the Commission's authority to require that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets be at the wholesale LMP.

12. Several petitioners[22] ask the Commission to grant rehearing or clarification of the Commission's denial of requests to ''allow states to decide whether electric storage resources in their state that are located behind a retail meter or on the distribution system are permitted to participate in the RTO/ISO markets through the electric storage resource participation model.''[23] Generally, these petitioners contend that the Commission's decision to decline to adopt an electric storage resource opt-out is a violation of FPA section 201, which expressly excludes from Commission jurisdiction retail electric service and facilities for the local distribution of electric energy.[24] Petitioners also cite to the Commission's demand response rule in Order No. 719 and the U.S. Supreme Court's decision in *EPSA* to support their proposition that the Commission must adopt an electric storage resource opt-out.[25]

a. Whether the Commission Is Required To Adopt an Opt-Out

13. AMP/APPA/NRECA ask the Commission to grant rehearing and declare that Order No. 841 is limited to RTO/ISO market rules, and nothing in Order No. 841 overrides state laws or tariff requirements that might prohibit or limit an electric storage resource interconnected with the distribution system or behind a retail meter from directly accessing the wholesale market.[26] They assert that the Commission does not have authority to disregard or override state and local restrictions on the participation of distribution-level and behind-the-meter electric storage resources in wholesale markets because FPA section 201(b) reserves to the states the regulation of retail service and specifically excludes local distribution facilities from the Commission's jurisdiction.[27] They further argue that the Commission lacks authority to compel entities exempt from the Commission's rate jurisdiction under FPA section 201(f), such as public power and cooperative utilities, to allow retail behind-the-meter electric storage resources to participate in wholesale markets.[28] They contend that, while certain distribution-connected resources may participate in wholesale markets, the Commission has indicated that ''the vast majority of small generator interconnections will be with state jurisdictional facilities'' and that such interconnections will be governed by state law.[29] Therefore, they argue that

[16] *Id.* P 33.

[17] *Id.* P 35.

[18] *Id.* (citing *FERC* v. *Elec. Power Supply Ass'n,* 136 S. Ct. 760 (2016) (*EPSA*); *Advanced Energy Economy,* 161 FERC ¶ 61,245, at PP 59–60 (2017) (*AEE*), *reh'g denied,* 163 FERC ¶ 61,030 (2018) (AEE Rehearing Order)).

[19] *Id.* (citing *Southern California Edison Co.,* Docket No. ER10–1356–000 (2010) (accepting Southern California Edison's Wholesale Distribution Access Tariff); *PJM Interconnection, L.L.C.,* Docket No. ER11–3148–000 (2011) (delegated letter order) (accepting Wholesale Market Participation Agreement among PJM, CleanLight Power, L.L.C. and Public Service Electric and Gas Company); PJM Manual 14C, section 1.3 (discussing requirements of Wholesale Market Participation Agreements)).

[20] *Id.* P 36.

[21] The substantive requirements of this determination are discussed further in section II.G. (Energy Used to Charge Electric Storage Resources).

[22] *See e.g.,* AMP/APPA/NRECA; EEI; NARUC; Organization of MISO States; TAPS; and Xcel Energy Services.

[23] Order No. 841, 162 FERC ¶ 61,127 at P 35 (referred to herein as the decision not to adopt an ''electric storage resource opt-out'').

[24] *See, e.g.,* AMP/APPA/NRECA Rehearing Request at 8 (citing 16 U.S.C. 824(b); NARUC Rehearing Request at 3 (citing 16 U.S.C. 824(b), 824o(i); *Cal. Indep. Sys. Operator Corp.* v. *FERC,* 372 F.3d 395, 398–99 (D.C. Cir. 2004)); Xcel Energy Services Rehearing Request at 8.

[25] *See Wholesale Competition in Regions with Organized Electric Markets,* Order No. 719, 125 FERC ¶ 61,071 (2008), *order on reh'g,* Order No. 719–A, 128 FERC ¶ 61,059, *order on reh'g,* Order No. 719–B, 129 FERC ¶ 61,252 (2009); *EPSA,* 136 S. Ct. 760.

[26] AMP/APPA/NRECA Rehearing Request at 8.

[27] *Id.* at 9 (citing 16 U.S.C. 824(b)(1); *EPSA,* 136 S. Ct. at 775).

[28] *Id.* at 9 n.25.

[29] *Id.* at 9 (citing S*tandardization of Small Generator Interconnection Agreements and Procedures,* Order No. 2006–A, 113 FERC ¶ 61,195,

the Commission has exceeded its authority if Order No. 841 indicates that an electric storage resource taking retail service from a distribution utility may disregard retail service terms and conditions that limit direct participation in the wholesale market.[30]

14. TAPS similarly asserts that states' exclusive jurisdiction to set the terms and conditions of retail service includes conditioning receipt of retail service on the customer's agreement as to whether and how to interconnect behind-the-meter resources and what the customer may do with such resources.[31] Xcel Energy Services contends that granting rehearing would not allow states to change the Commission's criteria for participating in wholesale markets, but would require electric storage resources connected at the distribution level or behind the meter to also ensure that their activities are in accordance with state legal requirements governing retail sales and use of the distribution system.[32]

15. Some petitioners argue that, while the Commission cites *EPSA* [33] for the proposition that it ''has exclusive jurisdiction over the wholesale markets and the criteria for participation in those markets,'' [34] *EPSA* does not support the Commission's decision not to adopt an electric storage resource opt-out.[35] AMP/APPA/NRECA assert that (1) *EPSA* concerned federal authority to regulate wholesale demand response compensation, not state authority over demand response resource participation,[36] (2) the Order No. 719 opt-out rules were not at issue in *EPSA* because the Supreme Court treated those rules as an established part of the regulatory framework for demand response,[37] and (3) the authority of states to veto retail customer participation in demand response aggregations was a reason for the Court's finding that the Commission did not improperly intrude on states' jurisdiction over retail sales.[38] NARUC argues that, while *EPSA* supports the assertion that the Commission may determine *how* resources participate in the RTO/ISO markets because the Commission has the authority to determine how prices are set, *EPSA* does not support the finding that states cannot determine *whether* resources can participate in the RTO/ISO markets.[39]

16. Xcel Energy Services claims that the Supreme Court permitted the Commission's demand response pricing changes in *EPSA* because, there, the Commission addressed only ''transactions occurring on the wholesale market,'' and ''every aspect of the regulatory plan happen[ed] exclusively on the wholesale market and govern[ed] exclusively that market's rules.'' [40] Xcel Energy Services argues that, unlike the indirect effects on retail sales that the Supreme Court permitted in *EPSA,* Order No. 841 directly affects retail sales because it allows distribution-connected and behind-the-meter electric storage resources to make wholesale sales *and purchases,* which fundamentally changes how retail sales occur and directly interferes with a state's ability to regulate retail sales.[41] For instance, Xcel Energy Services argues that, if a retail customer sells into the wholesale market and sells more than it purchases for the applicable billing period, then what had previously been a retail sale by the distribution company is now a wholesale sale within the Commission's jurisdiction.[42] Xcel Energy Services adds that, because Order No. 841 entitles an electric storage resource to purchase at wholesale from the RTO/ISO market, Order No. 841 removes what was previously a franchised retail sale by the distribution provider, which could preempt the distribution utility's state-granted franchise.[43] Xcel Energy Services also claims that, unlike Order No. 745, which was at issue in *EPSA,* Order No. 841 will require distribution utilities to establish extensive and expensive processes to assist the market participation of distribution-connected and behind-the-meter electric storage resources, including (1) processes that allow electric storage resources to use their wires to transmit energy to and from the electric transmission grid, and (2) processes to separately track retail and wholesale sales and purchases.[44] Xcel Energy Services further argues that Order No. 841 will require distribution providers to manage both state-regulated and Commission-jurisdictional interconnections, interfere with state regulation of distribution system reliability, permit resources to cycle in and out of state jurisdiction, and force states to accommodate the Commission's electric storage policy.[45]

17. Some petitioners further argue that the Commission's decision not to adopt an opt-out is inconsistent with other provisions of Order No. 841 that, according to petitioners, indicate that RERRAs and distribution utilities have the authority to limit the ability of electric storage resources to access the RTO/ISO markets.[46] Some of these petitioners point to the Commission's finding that ''[t]o the extent that the host distribution utility is unable . . . or unwilling to net out any energy purchases associated with . . . electric storage resources' wholesale charging activities from the host customer's retail bill, the RTO/ISO would be prevented from charging that resource wholesale rates for the charging energy for which it is already paying retail rates.'' [47] These petitioners also argue that, by finding that an electric storage resource is not eligible, by definition, for participation in the RTO/ISO markets if it is ''contractually barred from injecting electric energy back onto the grid,'' the Commission acknowledged that an electric storage resource could be barred from participation by a distribution interconnection agreement.[48] NARUC asserts that the Commission failed, however, to acknowledge that the states have jurisdiction over those agreements.[49]

18. NARUC also adds that PJM Manual 14C, which the Commission cited as support for the finding that

at P 105 (2005), *clarified,* Order No. 2006–B, 116 FERC ¶ 61,046 (2006), *corrected,* 71 FR 53,965 (Sept. 13, 2006)).

[30] *Id.* at 9.

[31] TAPS Rehearing Request at 7–8.

[32] Xcel Energy Services Rehearing Request at 6–7.

[33] 136 S. Ct. 760.

[34] Order No. 841, 162 FERC ¶ 61,127 at P 35.

[35] *See, e.g.,* AMP/APPA/NRECA, NARUC, and Xcel Energy Services.

[36] AMP/APPA/NRECA Rehearing Request at 10–11 (citing Order No. 841, 162 FERC ¶ 61,127 at P 35; *EPSA,* 136 S. Ct. at 773).

[37] *Id.* at 11 (citing *EPSA,* 136 S. Ct. at 771, 772, 779–80). They assert that the Court had no reason to address and did not address the scope of the Commission's authority to determine which demand response resources are eligible to participate in the wholesale market in the first place, nor did it suggest that the Commission may override retail service terms and conditions that might restrict or condition such eligibility. *Id.*

[38] *Id.* (citing *EPSA,* 136 S. Ct. at 779–80).

[39] NARUC Rehearing Request at 6 (citing *EPSA,* 136 S. Ct. at 771, 773, 780).

[40] Xcel Energy Services Rehearing Request at 7 (citing *EPSA,* 136 S. Ct. at 764, 777).

[41] *Id.* at 7.

[42] *Id.* at 8 (citing Order No. 841, 162 FERC ¶ 61,127 at P 289 (''The Commission has found that the sale of energy from the grid that is used to charge electric storage resources for later resale into the energy or ancillary service markets constitutes a sale for resale in interstate commerce.'')).

[43] *Id.* at 8–9 (citing Order No. 841, 162 FERC ¶ 61,127 at P 56).

[44] *Id.* at 9.

[45] *Id.* at 10–12.

[46] *See, e.g.,* AMP/APPA/NRECA, NARUC, Organization of MISO States, and TAPS.

[47] AMP/APPA/NRECA Rehearing Request at 6; TAPS Rehearing Request at 7 (citing Order No. 841, 162 FERC ¶ 61,127 at P 326).

[48] AMP/APPA/NRECA Rehearing Request at 6 (citing Order No. 841, 162 FERC ¶ 61,127 at P 33 (''per the interconnection agreement between an electric storage resource that is interconnected on a distribution system or behind-the-meter with a distribution utility to which it is interconnected'')); NARUC Rehearing Request at 8 (citing Order No. 841, 162 FERC ¶ 61,127 at P 33).

[49] NARUC Rehearing Request at 8.

distribution-level resources currently participate in the wholesale markets, indicates that the Commission does not determine *whether* distribution-level resources can participate in wholesale markets.[50] NARUC asserts that PJM's Manual 14C specifies that the only reason for a Wholesale Market Participation Agreement is to facilitate participation by distribution-level generators over which the Commission lacks jurisdiction.[51] According to NARUC, the Commission and PJM generally are not involved in the physical interconnection of distribution-level facilities using the Wholesale Market Participation Agreement; rather, it is a product of federal-state comity that should not be mistaken for an exercise of exclusive federal jurisdiction.[52]

19. AMP/APPA/NRECA, NARUC, and TAPS also point to the Commission's acknowledgment in Order No. 2006–A that the vast majority of distribution-level interconnections are subject to state, rather than Commission, jurisdiction.[53] TAPS asserts that, because the Commission has acknowledged that the vast majority of distribution-level interconnections are subject to RERRA jurisdiction, the language in Order No. 841 requiring an electric storage resource to be ''contractually permitted'' to inject electric energy back to the grid gives RERRAs a veto over wholesale sales by distribution-connected and behind-the-retail-meter electric storage resources.[54] TAPS adds that, while the Commission has reached into the distribution systems of public utilities in narrow circumstances where the purpose of the interconnection is for wholesale sales and the distribution facilities at issue are already subject to the public utility's open access transmission tariff (OATT), facilities behind the retail meter are plainly beyond the scope of facilities ''included in a public utility's Commission-filed OATT.'' [55] TAPS also states that, with respect to net metering, the Commission allows the RERRA to set the netting interval to determine whether a distributed resource makes a net sale of electricity subject to the Commission's jurisdiction.[56] TAPS asserts that, because electric storage resources that rely on energy purchases to charge always purchase more energy than they sell, if the RERRA sets a netting interval for such a resource that is longer than its charge/discharge cycle, there does not appear to be a net sale of electricity from that resource under the ''*MidAmerican* standard.'' [57]

20. Organization of MISO States argues that being ''contractually permitted'' to inject electric energy back onto the grid could be interpreted broadly to include the rules surrounding operation and interconnection to the distribution system or narrowly to address only technical interconnection rules.[58] Organization of MISO States asks the Commission to clarify that nothing in Order No. 841 is intended to impact existing rules related to interconnection or operation of resources connected to the distribution system and that each RTO/ISO may adopt tariff provisions that require compliance with applicable rules as confirmed by the distribution utility and RERRA before an asset can be authorized to participate in the RTO/ISO markets.[59]

21. MISO seeks clarification with respect to the Commission's statement that it did not intend Order No. 841 ''to affect or implicate the responsibilities of distribution utilities to maintain the safety and the reliability of the distribution system or their use of electric storage resources on their systems.'' MISO requests that the Commission clarify that each RTO/ISO may require a distribution-connected electric storage resource to comply with interconnection and/or operating requirements intended to address, to the reasonable satisfaction of the RTO/ISO, any potential material adverse reliability impacts on the distribution system raised by the relevant local distribution company. If the Commission declines to provide this clarification, MISO seeks rehearing on this issue.

Organization of MISO States similarly asks the Commission to clarify that an RTO/ISO may propose tariff provisions recognizing a unique regional situation that requires additional RERRA oversight of resources connected to the distribution system that participate in wholesale markets.

b. Whether the Commission Should Exercise Its Discretion and Adopt an Opt-Out

22. Several petitioners argue that, even if the Commission concludes that it is not required to adopt an electric storage resource opt-out, the Commission's decision not to adopt an opt-out is an unexplained departure from Order No. 719, in which the Commission reasoned that its demand response resource opt-out properly balanced the Commission's goal of removing barriers to the development of demand response resources in the organized wholesale markets with the interests and concerns of state and local regulatory authorities.[60] EEI contends that the Commission's sole reason for declining to pursue a path of cooperative federalism by adopting an opt-out is that distribution-connected resources already participate in the wholesale market, which lacks factual support as to penetration and impact.[61] AMP/APPA/NRECA and TAPS claim that the Commission's decision in Order No. 841 not to adopt an opt-out for

[50] *Id.* at 6.

[51] *Id.* at 6–7 (citing PJM Manual 14C, Generation and Transmission Interconnection Facility Construction, Revision 12, section 1.3 (''Generators planning to connect to the local distribution systems at locations that are not under FERC jurisdiction and wish to participate in PJM's market need to execute a PJM Wholesale Market Participation Agreement'')).

[52] *Id.* (citing PJM Manual 14C: Generation and Transmission Interconnection Facility Construction, Revision 12, section 1.3 (''Generators planning to connect to the local distribution systems at locations that *are not under FERC jurisdiction* and wish to participate in PJM's market need to execute a PJM Wholesale Market Participation Agreement''); PJM Manual 14A: New Service Request Process, Revision 20, 4.3 (''Developers interconnecting to *non-FERC jurisdictional facilities* who intend on participating in the PJM wholesale market will receive a three party agreement known as a [Wholesale Market Participation Agreement]. The [Wholesale Market Participation Agreement] is a non-Tariff agreement which must be filed with the FERC. *The [Wholesale Market Participation Agreement] is essentially an ISA without interconnection provisions.*'') (emphasis added)).

[53] AMP/APPA/NRECA Rehearing Request at 9; NARUC Rehearing Request at 3; TAPS Rehearing Request at 6 n.8 (citing Order No. 2006–A, 113 FERC ¶ 61,195 at P 105).

[54] TAPS Rehearing Request at 6 (quoting Order No. 2006–A, 113 FERC ¶ 61,195 at P 105 (''Order No. 2006 in no way affects rules adopted by the states for the interconnection of generators with state jurisdictional facilities. We expect that the vast majority of small generator interconnections will be with state jurisdictional facilities. The Commission encourages development of state interconnection programs, and interconnections with state jurisdictional facilities continue to be governed by state law.'')).

[55] *Id.* at 6 n.8 (quoting *Standardization of Generator Interconnection Agreements and Procedures,* Order No. 2003–A, 106 FERC ¶ 61,220, at PP 710, 730, *order on reh'g,* Order No. 2003–B, 109 FERC ¶ 61,287 (2004), *order on reh'g,* Order No. 2003–C, 111 FERC ¶ 61,401 (2005), *aff'd sub nom. Nat'l Ass'n of Regulatory Util. Comm'rs* v. *FERC,* 475 F.3d 1277 (D.C. Cir. 2007); *Standardization of Small Generator Interconnection Agreements and Procedures,* Order No. 2006, 111 FERC ¶ 61,220, at P 481, *order on reh'g,* Order No. 2006–A, 113 FERC ¶ 61,195 (2005), *order granting clarification,* Order No. 2006–B, 116 FERC ¶ 61,046 (2006)).

[56] TAPS Rehearing Request at 6 n.9 (citing *MidAmerican Energy Co.,* 94 FERC ¶ 61,340, at 62,263 (2001); Order No. 2003–A, 106 FERC ¶ 61,220 at P 747; *Sun Edison LLC,* 129 FERC ¶ 61,146, at P 19 (2009), *on reh'g,* 131 FERC ¶ 61,213 (2010)).

[57] *Id.* at 6 n.9.

[58] Organization of MISO States Rehearing Request at 5.

[59] *Id.* at 5–6.

[60] *See, e.g.,* AMP/APPA/NRECA, EEI, NARUC, TAPS, and Xcel Energy Services.

[61] EEI Rehearing Request at 7 (citing Order No. 841, 162 FERC ¶ 61,127 at P 35).

electric storage resources is arbitrary or inconsistent because an electric storage resource may still choose to participate in RTO/ISO markets as demand response, in which case it would be subject to the RERRA opt-out rules.[62]

23. AMP/APPA/NRECA, EEI, and TAPS argue that there is a more compelling argument for the Commission to adopt an opt-out in Order No. 841 than there was in Order No. 719 because electric storage resources inject power into the distribution system, thereby creating more significant operational, safety, and reliability concerns for retail customer interconnections and distribution systems than demand response resources.[63] EEI adds that, in some regions, the infrastructure, technology and resources are not in place to support large numbers of distribution-connected electric storage resources participating in the wholesale markets.[64] Organization of MISO States notes that, in *AEE,* the Commission cited the distinction between wholesale energy efficiency resources and demand response resources, finding that ''[energy efficiency resources] are not likely to present the same operational and day-to-day planning complexity.'' [65] Organization of MISO States argues that the potential moment-to-moment changes in utilization of electric storage resources are more in line with demand response than energy efficiency.[66]

24. TAPS asserts that the lack of an opt-out creates confusion that will undermine investment and create market uncertainty.[67] Therefore, TAPS argues that, instead of leaving RERRA policies to be implemented on a case-by-case basis, the Commission should provide a straightforward mechanism to enable RTOs/ISOs to implement RERRA decisions in a systematic and orderly way.[68] TAPS argues that the opt-out approach afforded for demand response in Order No. 719 has a proven record and can be implemented easily by RTOs/ISOs because they already use the mechanism for demand response resources. According to TAPS, this approach could help avoid the need to consider disruptive market re-runs or alternative enforcement mechanisms if an RTO/ISO accepts supply offers or demand bids from distribution-connected or behind-the-retail-meter electric storage resources that are barred from making such sales or purchases under state law.[69]

25. NARUC also expresses concern that the Commission's decision not to adopt an opt-out in Order No. 841 could inhibit state energy storage initiatives and posits that adopting an opt-out would provide clarity that would advance federal and state policymakers' shared interest in a resilient electric system with a diverse resource mix. If the Commission does not grant rehearing on the opt-out, NARUC asks the Commission to defer the determination of this jurisdictional issue to Docket No. RM18–9–000.[70]

26. If the Commission does not grant rehearing and provide an opt-out for electric storage resources, Xcel Energy Services requests that the Commission allow states, in conjunction with RTOs/ISOs, to determine the appropriate minimum capacity threshold at which electric storage resources connected to the distribution system or located behind a retail meter can participate in wholesale markets.[71]

c. Other Issues

27. SPP seeks clarification regarding whether it is the responsibility of the RTO/ISO to ensure that the necessary contractual arrangements are in place to permit an electric storage resource to inject energy onto the grid, or whether it is sufficient for an RTO/ISO to require an electric storage resource to attest that it has all the necessary contractual arrangements in place.[72] SPP states that it has taken the attestation approach in the area of demand response aggregation and seeks confirmation that such an approach would be sufficient for SPP to determine that a facility meets that particular qualification for an electric storage resource.[73]

28. SPP also seeks clarification that, while nothing in Order No. 841 requires an electric storage resource to participate in an RTO/ISO market, this does not supersede other reasons outside of the context of Order No. 841 that an electric storage resource might be required to comply with provisions of RTO/ISO tariffs applicable to all resources and loads.[74] SPP argues that these generally applicable requirements are critical as they give SPP awareness of the loads and resources that may exist within its markets and ensure that its tariff is administered in a manner that is not unduly discriminatory to any type of load or resource.[75]

29. Finally, AMP/APPA/NRECA claim that the assertion of jurisdiction over the purchase of charging energy as a wholesale sale presupposes that the electric storage resource may bypass the distribution utility and purchase directly from the wholesale market.[76] TAPS argues that the Commission does not have the authority to authorize retail customers to purchase energy from entities other than their distribution utility because the decision to allow a retail customer to purchase directly from suppliers other than its retail utility is a matter of state law or voluntary choice by the public-utility distribution company.[77]

3. Commission Determination

30. We deny rehearing. As a preliminary matter, we decline to defer the determination of whether to adopt an electric storage resource opt-out to

[62] AMP/APPA/NRECA Rehearing Request at 14 n.48 (citing Order No. 841, 162 FERC ¶ 61,127 at P 56; 18 CFR 35.28(g)(1)(iii)); TAPS Rehearing Request at 4 (citing Order No. 841, 162 FERC ¶ 61,127 at PP 32, 55–56) (arguing that the electric storage resource owner's choice of which construct to use to participate in the RTO/ISO markets should not strip away the RERRA's authority that the Commission has previously recognized).

[63] *See, e.g.,* EEI Rehearing Request at 5 (claiming that the charging and discharging activity of distribution-connected electric storage resources could raise complicated interactions between wholesale and retail market activity that the distribution utility and RERRA will need to address); TAPS Rehearing Request at 4 (claiming that the need for deference is especially high for behind-the-retail-meter electric storage resources that may involve retail customers using retail interconnections to make wholesale purchases and sales).

[64] EEI Rehearing Request at 5.

[65] Organization of MISO States Rehearing Request at 3 (citing Order No. 841, 162 FERC ¶ 61,127 at P 35; *AEE,* 161 FERC ¶ 61,245 at P 63).

[66] *Id.* at 3.

[67] TAPS Rehearing Request at 9.

[68] *Id.* at 10.

[69] *Id.* at 11.

[70] NARUC Rehearing Request at 9.

[71] Excel Energy Services Rehearing Request at 16.

[72] SPP Motion for Clarification at 2 (citing Order No. 841, 162 FERC ¶ 61,127 at P 33), 13.

[73] *Id.* at 2–3.

[74] *Id.* at 3 (citing Order No. 841, 162 FERC ¶ 61,127 at P 35). For example, SPP states that it requires all loads and resources within the SPP region to register with SPP and it has certain must-offer requirements that apply to all available registered resources. SPP also states that it requires behind-the-meter resources of 10 MW or greater to register. *Id.* at 3–4.

[75] *Id.* at 4.

[76] AMP/APPA/NRECA Rehearing Request at 10 (citing Order No. 841, 162 FERC ¶ 61,127 at P 294 (requiring that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets be at the wholesale LMP)).

[77] TAPS Rehearing Request at 8 n.11 (citing *New York* v. *FERC,* 535 U.S. 1, 12 n.9, 13, 20, 23 (2002) (quoting *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, FERC Stats. & Regs. ¶ 31,036, at 31,782–83, 31,969 (1996), (cross-referenced at 77 FERC ¶ 61,080), *order on reh'g,* Order No. 888–A, FERC Stats. & Regs. ¶ 31,048, (cross-referenced at 78 FERC ¶ 61,220), *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC,* 225 F.3d 667 (D.C. Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002)).

Docket No. RM18–9–000.[78] That proceeding is focused on issues relating to distributed energy resource aggregations, while Order No. 841 addresses the participation of non-aggregated electric storage resources in RTO/ISO markets. We find that the Commission had sufficient record evidence before it to determine whether to adopt an electric storage resource opt-out, regardless of its decision to gather more information with respect to its proposals to remove barriers to the participation of distributed energy resource aggregations in RTO/ISO markets in Docket No. RM18–9–000.[79]

31. We continue to find that the Commission's establishing the criteria for participation in the RTO/ISO markets of electric storage resources, including those resources located on the distribution system or behind the meter, is essential to the Commission's ability to fulfill its statutory responsibility to ensure that wholesale rates are just and reasonable.[80] Below, we outline the relevant precedent with respect to the Commission's authority over electric storage participation in RTO/ISO markets, and then we address arguments raised by petitioners and the dissent concerning the Commission's decision not to adopt an electric storage resource opt-out. Finally, we address arguments that the Commission does not have authority to require that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets be at the wholesale LMP.

a. Whether the Commission Must Adopt an Opt-Out

32. As discussed below, we find that the FPA and relevant precedent does not legally compel the Commission to adopt an opt-out with respect to participation in RTO/ISO markets by electric storage resources interconnected on a distribution system or located behind a retail meter. FPA section 201[81] authorizes the Commission to regulate the transmission of electric energy in interstate commerce and the wholesale sale of electric energy in interstate commerce, as well as all facilities used for such transmission or sale of electric energy. Section 201 also defines a public utility as ''any person who owns or operates facilities subject to the jurisdiction of the Commission.'' [82] FPA sections 205[83] and 206[84] provide the Commission with jurisdiction over all rates and charges made, demanded, or received by any public utility for or in connection with the transmission or sale of electric energy subject to the Commission's jurisdiction. Those sections also provide the Commission with jurisdiction over all rules, regulations, practices, or contracts affecting jurisdictional rates, charges, or classifications.

33. In *EPSA,* the U.S. Supreme Court interpreted those FPA sections to uphold the Commission's jurisdiction over the participation in RTO/ISO markets of demand response resources: A type of non-traditional resource that, by definition, is located behind a customer meter and generally is located on the distribution system.[85] The Court did not find the Commission's authority to be lessened by the location of demand response resources behind the retail customer meter.

34. First, the Court found that the Commission's regulation of demand response participation in wholesale markets met the ''affecting'' standard in FPA sections 205 and 206 ''with room to spare.'' [86] In making this finding, the Court approved a ''common-sense'' construction of the FPA's language, previously articulated by the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit), that ''limit[s] [the Commission]'s 'affecting' jurisdiction to rules or practices that directly affect the wholesale rate.'' [87] The Court then described, among other considerations, how RTOs/ISOs employ demand response bids in competitive auctions that balance wholesale supply and wholesale demand and thereby set wholesale prices. For these reasons, the Court found that ''[w]holesale demand response, in short, is all about reducing wholesale rates; so too, then, the rules and practices that determine how those programs operate.'' [88] The Court concluded that ''[c]ompensation for demand response thus directly affects wholesale prices. Indeed, it is hard to think of a practice that does so more.'' [89]

35. Second, the Court found that the Commission's regulation of demand response resources did not regulate retail sales in violation of FPA section 201(b).[90] In making that finding, the Court rejected EPSA's arguments that the Commission (1) effectively regulated the retail price by increasing effective retail rates and (2) forced retail customers to respond to wholesale price signals for the express purpose of overriding state policy. Rather, the Court held that the Commission's regulation did ''anything but increase retail prices'' and that, ''[i]n promoting demand response, [the Commission] did no more than follow the dictates of its regulatory mission to improve the competitiveness, efficiency, and reliability of the wholesale market.'' [91]

36. Finally, the Court stated that the ''finishing blow to both of EPSA's arguments comes from [the Commission]'s notable solicitude toward the States.'' [92] Describing and commenting on the opt-out for states that the Commission included in Order No. 745, the Court stated that

> the Rule allows any State regulator to prohibit its consumers from making demand response bids in the wholesale market. Although claiming the ability to negate such state decisions, the Commission chose not to do so in recognition of the linkage between wholesale and retail markets and the States' role in overseeing retail sales. The veto power thus granted to the States belies EPSA's view that FERC aimed to 'obliterate[ ]' their regulatory authority or 'override' their pricing policies. And that veto gives States the means to block whatever 'effective' increases in retail rates demand response programs might be thought to produce. Wholesale demand response as implemented in the Rule is a program of cooperative federalism, in which the States retain the last word. That feature of the Rule removes any conceivable doubt as to its compliance with 824(b)'s allocation of federal and state authority.[93]

37. Consistent with *EPSA,* the Commission found in *AEE* that, although the Commission in Order Nos. 719 and 745 granted RERRAs an opt-out

[78] *See* NARUC Rehearing Request at 9.

[79] *See* Order No. 841, 162 FERC ¶ 61,127 at P 5.

[80] *See id.* PP 1, 35.

[81] 16 U.S.C. 824.

[82] *Id.* 824(e).

[83] *Id.* 824d.

[84] *Id.* 824e.

[85] *See EPSA,* 136 S. Ct. 760; 18 CFR 35.28(b)(4) (defining demand response as ''a reduction in the consumption of electric energy by customers from their expected consumption in response to an increase in the price of electric energy or to incentive payments designed to induce lower consumption of electric energy'').

[86] *EPSA,* 136 S. Ct. at 774 (referring to the Commission's jurisdiction under FPA sections 205 and 206 to regulate practices affecting jurisdictional rates).

[87] *Id.* (citing *Cal. Indep. Sys. Operator Corp.* v. *FERC,* 372 F.3d 395, 403 (2004) (internal quotation marks omitted)).

[88] *Id.* at 774.

[89] *Id.* at 775.

[90] *Id.* at 784.

[91] *Id.* at 778–79.

[92] *Id.* at 779. Earlier in its decision, the Court described the Commission's action as follows: ''Pointing to the Commission's analysis in Order No. 719, [Order No. 745] explained that the FPA gives [the Commission] jurisdiction over such bids because they directly affect wholesale rates. Nonetheless, [Order No. 745] noted, [the Commission] would continue Order No. 719's policy of allowing any state regulatory body to prohibit consumers in its retail market from taking part in wholesale demand response programs.'' *Id.* at 772.

[93] *Id.* at 779–80 (internal citations omitted).

from allowing retail customers to participate as wholesale demand response, the Commission was not obligated to do so.[94] Like compensation for demand response, the Commission held that it has jurisdiction over the participation of energy efficiency resources in RTO/ISO markets as a practice directly affecting wholesale markets, rates, and prices.[95] The Commission found that, because it has exclusive jurisdiction to regulate the participation of energy efficiency resources in RTO/ISO markets, RERRAs may not bar, restrict, or otherwise condition the participation of energy efficiency resources in RTO/ISO markets unless the Commission expressly gives RERRAs such authority.[96] The Commission explained that, as part and parcel of the participation of energy efficiency resources in RTO/ISO markets, the terms of eligibility of energy efficiency resource participation in the RTO/ISO markets has a direct effect on wholesale rates and that the Commission may set the terms of transactions occurring in the RTO/ISO markets, including which resources are eligible to participate, to ensure the reasonableness of wholesale prices and the reliability of the interstate grid.[97] The Commission thus concluded that a provision directly restricting retail customers' participation in RTO/ISO markets, even if contained in the terms of retail service, nonetheless intrudes on the Commission's jurisdiction over those markets and prevents the Commission from carrying out its statutory authority to ensure that wholesale electricity markets produce just and reasonable rates.[98]

38. Several of these findings are relevant to the Commission's decision to apply Order No. 841 to electric storage resources, including those connected at distribution-level voltages or behind the meter, without adopting an electric storage resource opt-out.[99] The Commission has exclusive jurisdiction over the wholesale markets and the criteria for participation in those markets, including the wholesale market rules for participation of resources connected at distribution-level voltages or behind the meter.[100] As the Commission previously has found, the authority to determine which resources are eligible to participate in the RTO/ISO markets is a fundamental component of the regulation of the RTO/ISO markets.[101] By applying Order No. 841 to electric storage resources connected at distribution-level voltages or behind the meter, and by finding that the Commission is not required to adopt an electric storage resource opt-out, the Commission is not specifying any terms of sale at retail. Rather, the Commission is merely exercising its authority under the FPA to ''regulate what takes place in the wholesale market'' by ensuring that technically capable resources are eligible and able to participate in those markets.[102]

39. We disagree with assertions by petitioners and the dissent that, unless the Commission adopts an opt-out, the Commission's regulation of the RTO/ISO market participation of distribution-connected and behind-the-meter electric storage resources violates FPA section 201.[103] We find that the Supreme Court's jurisdictional findings in *EPSA* regarding wholesale demand response apply with at least as much force to participation in RTO/ISO markets by electric storage resources engaged in wholesale sales in interstate commerce, even where those resources are interconnected on a distribution system or located behind a retail meter. Order No. 841 directed changes to wholesale RTO/ISO markets to remove barriers to the participation of resources that directly engage in sales for resale under the FPA, an objective that is at the very core of the Commission's jurisdictional responsibilities. We acknowledge that the Commission's actions in Order No. 841 to improve wholesale markets will have impacts beyond those markets. However, as the Supreme Court stated in *EPSA,* ''[w]hen FERC regulates what takes place on the wholesale market, as part of carrying out its charge to improve how that market runs, then no matter the effect on retail rates, § 824(b) imposes no bar.'' [104]

40. Further, contrary to the petitioners' arguments, the Court's jurisdictional conclusion in *EPSA* did not rest upon the fact that states were granted an opt-out. As alluded to above, the Court described how its ''analysis of FERC's regulatory authority proceeds'' without referring to an opt-out, stating:

> First, the practices at issue in the Rule—market operators' payments for demand response commitments—directly affect wholesale rates. Second, in addressing those practices, the Commission has not regulated retail sales. Taken together, those conclusions establish that the Rule complies with the FPA's plain terms.[105]

When the Court then stated that it viewed the opt-out merely as the ''finishing blow'' to EPSA's already losing arguments that the Commission ''aimed to obliterate [states'] regulatory authority or override their pricing policies,'' [106] that statement was not a determinative part of its analysis.[107] Thus, we find that the Court's overall analysis of the Commission's jurisdiction with respect to participation by demand response resources in RTO/ISO markets makes clear that the Commission is not legally compelled to adopt an opt-out with respect to participation in RTO/ISO markets by electric storage resources interconnected on a distribution system or located behind a retail meter. Moreover, as the Commission noted in Order No. 841, there are already numerous distribution-connected resources participating in the RTO/ISO markets that are subject to the RTO/ISO tariffs.[108] For these reasons, contrary to petitioners' arguments, *EPSA* does not require the Commission

[94] *AEE,* 161 FERC ¶ 61,245 at P 62 (citing *EPSA,* 136 S. Ct. at 776).

[95] *Id.* P 60.

[96] *Id.* P 61.

[97] *Id.* (citing *EPSA,* 136 S. Ct. 760 at 784).

[98] AEE Rehearing Order, 163 FERC ¶ 61,030 at P 37 (citing *Oneok, Inc.* v. *Learjet, Inc.,* 135 S. Ct. 1591, 1600 (2015) (finding that the proper test for determining whether a state action is preempted is ''whether the challenged measures are 'aimed directly at interstate purchasers and wholesalers for resale' or not'') (*Oneok*) (quoting *N. Natural Gas Co.* v. *State Corp. Comm'n of Kan.,* 372 U.S. 84, 94 (1963)); *Nantahala Power & Light Co.* v. *Thornburg,* 476 U.S. 953, 970 (finding that ''a State may not exercise its undoubted jurisdiction over retail sales to prevent the wholesaler-as-seller from recovering the costs of paying the FERC-approved rate'')).

[99] *See* Order No. 841, 162 FERC ¶ 61,127 at P 35.

[100] *Id.* P 35 (citing *EPSA,* 136 S. Ct. 760).

[101] *See* AEE Rehearing Order, 163 FERC ¶ 61,030 at P 36.

[102] *See EPSA,* 136 S. Ct. at 776.

[103] *See, e.g.,* AMP/APPA/NRECA Rehearing Request at 8; NARUC Rehearing Request at 3; Xcel Energy Services Rehearing Request at 8; *Electric Storage Participation in Markets Operated by Regional Transmission Organizations and Independent System Operators,* Order No. 841–A, 167 FERC ¶ 61,154, at PP 5–12 (McNamee, Comm'r, *concurring in part and dissenting in part*) (Dissent).

[104] *EPSA,* 136 S. Ct. at 776.

[105] *Id.* at 773. Similarly, after concluding its discussion of the first of these two points, the Court stated, ''The above conclusion does not end our inquiry into the Commission's statutory authority; to uphold the Rule, we also must determine that it does not regulate retail electricity sales.'' *Id.* at 775.

[106] *Id.* at 779 (internal quotations omitted).

[107] In his dissent, Justice Scalia shared this understanding of the Court's analysis, stating, ''Moreover, the rule itself allows States to forbid their retail customers to participate in the existing demand response scheme. The majority accepts FERC's argument that this is merely a matter of grace, and claims that it puts the 'finishing blow' to respondents' argument that 16 U.S.C. 824(b)(1) prohibits the scheme.'' *Id.* at 789 (Scalia, J., dissenting).

[108] Order No. 841, 162 FERC ¶ 61,127 at P 35. Contrary to EEI's assertion that this statement lacks factual support, the Commission cited to wholesale market participation programs in both PJM and CAISO. As further evidence that numerous distribution-connected resources are participating in the RTO/ISO markets, we note the filing of Wholesale Market Participation Agreements and Wholesale Distribution Access Tariffs that allow such resources to participate in the RTO/ISO markets.

to adopt an electric storage resource opt-out.[109]

41. We also disagree with assertions that states can dictate whether resources are allowed to participate in the RTO/ISO markets through conditions on the receipt of retail service.[110] We acknowledge that states have the authority to include conditions in their own retail distributed energy resource or retail electric storage resource programs that prohibit any participating resources from also selling into the RTO/ISO markets. In that scenario, the owner of a resource has a choice between participating in the retail market or wholesale market. However, states may not take away that choice by broadly prohibiting all retail customers from participating in RTO/ISO markets. As explained above, the Commission has exclusive jurisdiction over the terms of eligibility for participation in the RTO/ISO markets.[111] Therefore, such conditions aimed *directly* at the RTO/ISO markets, even if contained in the terms of retail service, would intrude on the Commission's jurisdiction over the RTO/ISO markets.[112] Just as the Commission cannot issue ''a regulation compelling every consumer to buy a certain amount of electricity on the retail market'' [113] because such a regulation would specify terms of sale at retail, states cannot intrude on the Commission's jurisdiction by prohibiting all consumers from selling into the wholesale market.

42. We thus also disagree with petitioners' arguments that the requirement in Order No. 841 that an electric storage resource be ''contractually permitted'' to inject electric energy back to the grid gives RERRAs a ''veto'' over the participation in wholesale markets of electric storage resources that are interconnected to the distribution system or located behind a retail meter.[114] Rather, we clarify that the requirement to be contractually permitted to inject energy onto the grid is intended to ensure that the definition of electric storage resource does not encompass any resource that does not have the requisite permits, agreements, or other necessary documentation in place that would ensure its ability to inject electric energy back to the grid and therefore engage in a wholesale sale. As the Commission stated in Order No. 841, the Commission recognizes a vital role for the states with respect to ''retail services and matters related to the distribution system, including design, operations, power quality, reliability, and system costs.'' [115] We acknowledge that states have jurisdiction over the interconnections of certain resources to the distribution system and the requirements reasonably related to those interconnections, such as a requirement to upgrade the distribution system to facilitate the injection of electric energy back to the grid, a requirement to install certain technologies to mitigate a reliability or safety concern, or a charge for wholesale distribution service. We further understand that interconnection agreements may include technical requirements to safeguard against reliability or safety concerns, such as utility curtailment and anti-islanding provisions, or requirements to install equipment that forces resources to trip offline during extreme frequency, voltage, or fault current incidents. Indeed, such requirements could address the concerns raised by petitioners regarding the physical and operational impacts of electric storage resources on the distribution system. However, a broad prohibition on participating in the RTO/ISO markets is not reasonably related to the interconnection of a particular resource to the distribution system. We therefore disagree with assertions that state authority over certain interconnections necessitates that the Commission adopt an opt-out for electric storage resources connected to the distribution system or behind the meter.

43. We also are not persuaded by Xcel Energy Services' assertion that, unlike the ''indirect'' effects permitted in *EPSA,* Order No. 841 directly affects retail sales because it ''fundamentally changes how retail sales occur and directly interferes with a state's ability to regulate retail sales.'' [116] The Court in *EPSA* recognized that, because the wholesale and retail markets are not ''hermetically sealed,'' Commission regulation of the ''wholesale market ha[s] natural consequences at the retail level.'' [117] The Court concluded, however, that when the Commission ''regulates what takes place on the wholesale market, as part of carrying out its charge to improve how that market runs,'' the effects on the retail market have ''no legal consequence'' and FPA section 201 ''imposes no bar'' on the Commission's action.[118]

44. Like the Commission's regulation of demand response participation in the wholesale market, Order No. 841 ''addresses—and addresses only—transactions occurring on the wholesale market.'' [119] In addition, as with Order No. 745, the Commission's justifications for Order No. 841 ''are all about, and only about, improving the wholesale market.'' [120] And, just as the Court explained with respect to demand response, the Commission did not ''invent'' wholesale market participation of electric storage resources and the practice did not emerge as a ''Commission power grab.'' [121] Rather ''the impetus came from wholesale market operators'' that ''sought, and obtained, [the Commission's] approval to institute such programs.'' [122] Accordingly, Order No. 841 does not regulate retail sales and the effects that the order may have on retail sales are of ''no legal consequence.'' [123]

45. Contrary to Xcel Energy Services' contention that Order No. 841 requires distribution utilities to establish expensive processes to assist the market participation of distribution-connected and behind-the-meter electric storage resources, the Commission is not imposing any new requirements on distribution utilities to enable the participation of electric storage resources in RTO/ISO markets. To the extent that distribution utilities do incur costs associated with enabling such

[109] *See, e.g.,* AMP/APPA/NRECA Rehearing Request at 10–11; NARUC Rehearing Request at 5–6.

[110] *See* AMP/APPA/NRECA Rehearing Request at 9; TAPS Rehearing Request at 7–8.

[111] *See AEE,* 161 FERC ¶ 61,245 at P 61.

[112] *See* AEE Rehearing Order, 163 FERC ¶ 61,030 at P 37 (finding that a provision directly restricting retail customers' participation in RTO/ISO markets, even if contained in the terms of retail service, nonetheless intrudes on the Commission's jurisdiction over the wholesale markets). *See also Oneok,* 135 S. Ct. at 1600 (finding that the proper test for determining whether a state action is preempted is ''whether the challenged measures are 'aimed directly at interstate purchasers and wholesalers for resale' or not'') (quoting *N. Natural Gas Co.* v. *State Corp. Comm'n of Kan.,* 372 U.S. 84, 94 (1963)); *Nantahala Power & Light Co.* v. *Thornburg,* 476 U.S. 953, 970 (finding that ''a State may not exercise its undoubted jurisdiction over retail sales to prevent the wholesaler-as-seller from recovering the costs of paying the FERC-approved rate'').

[113] *EPSA,* 136 S. Ct. at 776.

[114] *See, e.g.,* AMP/APPA/NRECA Rehearing Request at 6; NARUC Rehearing Request at 7–8; TAPS Rehearing Request at 6.

[115] Order No. 841, 162 FERC ¶ 61,127 at P 36.

[116] *See* Xcel Energy Services Rehearing Request at 7.

[117] *EPSA,* 136 S. Ct. at 776.

[118] *Id.* (''When FERC sets a wholesale rate, when it changes wholesale market rules, when it allocates electricity as between wholesale purchasers—in short, when it takes virtually any action respecting wholesale transactions—it has some effect, in either the short or the long term, on retail rates. That is of no legal consequence.'').

[119] *Id.*

[120] *Id.* at 779.

[121] *Id.*

[122] *Id. See, e.g., Midwest Indep. Trans. Sys. Operator, Inc.,* 129 FERC ¶ 61,303 (2009); *New York Indep. Sys. Operator, Inc.,* 127 FERC ¶ 61,135 (2009); *California Indep. Sys. Operator Corp.,* 132 FERC ¶ 61,211 (2010).

[123] *EPSA,* 136 S. Ct. at 776.

participation, the Commission is also not changing the ability of distribution utilities to allocate any costs that they incur in operating and maintaining their respective power systems.[124] In any event, any additional costs imposed on distribution utilities could be outweighed by the overall benefits from increased competition due to greater participation of electric storage resources in RTO/ISO markets.

46. In response to Xcel Energy Services' argument that Order No. 841 interferes with state regulation of the reliability of the distribution system and MISO's request to clarify that each RTO/ISO may require a distribution-connected electric storage resource to comply with interconnection or operating requirements to address any potential material adverse reliability impacts on the distribution system, we reiterate that nothing in Order No. 841 preempts the states' right to regulate the safety and reliability of the distribution system and that all electric storage resources must comply with any applicable interconnection and operating requirements. As noted above, we understand that electric storage resources located on the distribution system are subject to various technical requirements that should help alleviate any concerns related to the safety and reliability of the distribution system due to RTO/ISO dispatch. As to Xcel Energy Services' concern that a distribution utility's retail sale to its customer could become a wholesale sale if that customer participates in the wholesale markets and sells more than it purchases for a billing period, we find that concern regarding a distribution utility's sale of energy to an electric storage resource to be outside the scope of this proceeding. The Commission's findings in Order No. 841 are limited to sales in RTO/ISO markets and do not address what retail customers may do with energy purchased at retail.[125]

47. The dissent suggests that today's order ''mandates'' that electric storage resources ''be permitted to use distribution facilities so that they may access the wholesale market.'' [126] That is incorrect. As explained above, Order No. 841 addressed only the rules governing electric storage resources' participation in the wholesale market.[127] Order No. 841 did not mandate that electric storage resources must have access to the distribution system. Instead, Order No. 841 concluded that states cannot directly prohibit electric storage resources from participating in the wholesale market because doing so would invade the Commission's ''exclusive jurisdiction over the wholesale markets and the criteria for participation in those markets.'' [128] In reaching that conclusion, the Commission recognized explicitly, as it must, that the states have authority to regulate the distribution system, ''including [its] design, operations, power quality, reliability, and system costs.'' [129]

48. The dissent also characterizes today's order as ''hav[ing] the effect of directing that [electric storage resources] have access to distribution facilities.'' [130] That too is incorrect. Although Order No. 841 provides that states may not prohibit electric storage resources from participating in wholesale markets,[131] that requirement does not amount to an effective right of access to the distribution system itself.[132] As noted, Order No. 841 does not modify states' authority to regulate the distribution system, including the terms of access, provided that they do not ''aim[ ] *directly* at the RTO/ISO markets.'' [133] Consistent with the FPA's cooperative federalist foundation, where electric storage resources interconnected with the distribution system are participating in RTO/ISO markets, it will be under circumstances that are consistent with states' authority to regulate the distribution system. Accordingly, Order No. 841 does not amount to regulation of the distribution system, effectively or otherwise.[134]

49. Some petitioners cite the Commission's interconnection policies generally to argue that the Commission must adopt an electric storage resource opt-out.[135] However, Order No. 841 did not reform or address any procedures pertaining to the interconnection of resources to transmission or distribution facilities. The Commission cited to certain RTO/ISO interconnection and market participation procedures, but merely to demonstrate that many distribution-connected resources are currently participating in those markets.[136] As the Commission found in Order No. 841, an electric storage resource that injects electric energy back into the grid for purposes of participating in an RTO/ISO market engages in a sale of electric energy at wholesale in interstate commerce [137] and the sale of charging energy to an electric storage resource that the resource then resells into an RTO/ISO market is also a sale for resale in interstate commerce.[138]

b. Whether the Commission Should Exercise Its Discretion and Adopt an Opt-Out

50. We also disagree that the Commission's decision not to exercise its discretion and adopt an opt-out in Order No. 841 is an unexplained departure from the demand response resource opt-out adopted in Order No. 719.[139] As the Commission explained in *AEE,* Order No. 719 expressly provided that it only applies to demand response resources;[140] therefore, the Commission's decision not to adopt an electric storage resource opt-out is not a change in policy.[141]

---

[124] *See* Order No. 841, 162 FERC ¶ 61,127 at P 274.

[125] Moreover, to the extent that Xcel Energy Services is concerned that retail customers could attempt to make purchases under a state-regulated retail tariff and then sell that energy into the Commission-jurisdictional wholesale market, nothing in Order No. 841 prevents states from prohibiting the resale of energy purchased under a retail tariff in the terms and conditions of retail service.

[126] Dissent at P 5.

[127] *See supra* P 44 (''[A]s with Order No. 745, the Commission's justifications for Order No. 841 'are all about, and only about, improving the wholesale market.' '' (quoting *EPSA,* 136 S. Ct. at 779)).

[128] *See supra* P 38; *supra* P 41 (explaining that ''conditions aimed *directly* at the RTO/ISO markets, even if contained in the terms of retail service, would intrude on the Commission's jurisdiction over the RTO/ISO markets'' (citing *Oneok,* 135 S. Ct. at 1600)).

[129] Order No. 841, 162 FERC ¶ 61,127 at P 36.

[130] Dissent at n.18.

[131] *See supra* PP 38, 41.

[132] To paraphrase the Court in *EPSA,* the word ''effect[ ] is doing quite a lot of work in that argument.'' *EPSA,* 136 S. Ct. at 777.

[133] *See supra* PP 38, 41.

[134] In addition, the D.C. Circuit has held that the Commission properly may exercise jurisdiction with respect to distribution facilities in certain circumstances. *See Nat'l Ass'n of Regulatory Util. Comm'rs* v. *FERC,* 475 F.3d 1277 at 1282. Like the orders in that case, Order No. 841 also ''leave[s] state law completely undisturbed'' and thus the Commission is not impermissibly ''commandeering'' the states, as the dissent argues. *Id.* at 1283.

[135] *See, e.g.,* AMP/APPA/NRECA Rehearing Request at 9; NARUC Rehearing Request at 3; TAPS Rehearing Request at 6 n.8 (citing the Commission's acknowledgment in Order No. 2006–A that the vast majority of distribution-level interconnections are subject to state jurisdiction); Xcel Energy Services Rehearing Request at 10 (arguing that Order No. 841 will convert distribution facilities into Commission-regulated transmission facilities for interconnection purposes).

[136] *See* Order No. 841, 162 FERC ¶ 61,127 at P 35 n.56.

[137] *Id.* P 26.

[138] *See id.* P 295.

[139] *See* EEI Rehearing Request at 7; NARUC Rehearing Request at 3; TAPS Rehearing Request at 3–4; Xcel Energy Services Rehearing Request at 13–15.

[140] *AEE,* 161 FERC ¶ 61,245 at P 65.

[141] Even if it were a policy change, the Commission ''need not demonstrate . . . that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better.'' *FCC* v. *Fox Television Stations,* 556 U.S. 502, 513 (2009).

51. Further, the resources that will use the electric storage resource participation model under Order No. 841 differ significantly from the demand response resources at issue in Order No. 719. Most notably, unlike demand response, electric storage resources are capable of engaging in sales for resale of electricity and those electric storage resources making sales in the RTO/ISO markets are public utilities subject to the Commission's jurisdiction.[142]

52. In addition, unlike in the case of demand response resources, RERRAs and distribution utilities do not have a longstanding history of managing and regulating programs for electric storage resources within their boundaries. Prior to the Commission's issuance of Order No. 719, many RERRAs supported the use of demand response resources in their boundaries, either requiring the distribution utilities that they regulate to establish demand response programs and compensate retail customers for their participation, or approving distribution utility-developed demand response programs. Such entities were concerned that, as a result of Order No. 719, the ''best'' demand response resources would choose to participate in the wholesale markets instead of retail programs, depriving load serving entities of important resources used to keep rates down for all consumers.[143] The Commission adopted the opt-out in Order No. 719 in part to help address that concern.[144] With respect to electric storage resources, fewer states have policies that involve electric storage resources, and those policies that exist were implemented fairly recently.[145] Accordingly, we find that the record in these proceedings does not indicate that a comparable opt-out is appropriate for energy storage resources.

53. We further reject AMP/APPA/NRECA's and TAPS's argument that, because an electric storage device may choose to participate in RTO/ISO markets as demand response and thus become subject to opt-out rules, the Commission's decision not to adopt an electric storage resource opt-out is arbitrary or inconsistent.[146] As the Commission stated in Order No. 841, participation by demand response resources in an RTO/ISO market does not involve a sale of electric energy at wholesale in interstate commerce.[147] Although electric storage resources participate in the RTO/ISO markets by injecting electric energy back to the grid, demand response participates in the RTO/ISO markets as a ''reduction in the consumption of electricity.'' [148] Therefore, when an electric storage device chooses to participate in the RTO/ISO markets as demand response, it is not participating as an ''electric storage resource'' or injecting electricity onto the grid and should not be subject to the market rules applicable to electric storage resources. Accordingly, because demand response and electric storage resources have differing ways of interacting with RTO/ISO markets and are subject to different market rules, it is not arbitrary or inconsistent for the Commission to take different policy approaches when integrating those resources into the RTO/ISO markets.

54. We also disagree with Organization of MISO States' argument that electric storage resources are more similar to demand response resources than energy efficiency resources due to the operational challenges that they present and therefore the Commission should adopt an opt-out here.[149] As discussed above, electric storage resources are capable of engaging in sales for resale of electricity, and those electric storage resources making sales in the RTO/ISO markets are public utilities subject to the Commission's jurisdiction. These characteristics distinguish electric storage resources making sales in the RTO/ISO markets from both demand response resources and energy efficiency resources.

55. In response to TAPS' concern about whether there is a net sale of electricity from an electric storage resource under the *MidAmerican* standard, we note that *MidAmerican* applies only to retail customers participating in retail net metering programs, which is consistent with the Commission's acknowledgement in Order No. 841 that injections of electric energy back to the grid do not necessarily trigger the Commission's jurisdiction.[150] If an electric storage resource were to participate in a retail net metering program and in the RTO/ISO markets—which the Commission did not prohibit in Order No. 841—Commission jurisdiction would arise only where the electric storage resource participates in the wholesale market by making a Commission-jurisdictional sale for resale. It would be the responsibility of the RTO/ISO to establish metering and accounting practices to measure which actions taken by that electric storage resource are wholesale actions in the RTO/ISO markets.[151]

56. We recognize, as did the Court in *EPSA,* that sales for resale of electricity necessarily have effects on the distribution system.[152] We have considered those effects in evaluating whether to exercise our discretion to grant an opt-out, but find that the benefits of allowing electric storage resources broader access to the wholesale market outweigh any policy considerations in favor of an opt-out. In particular, Order No. 841 found that the benefits of removing barriers to the participation of electric storage resources in RTO/ISO markets are significant and, in light of those benefits, we are not persuaded to adopt an opt-out that could limit that participation. In addition, as discussed in the preceding section, there are several ways that RERRAs may address any concerns about effects on the distribution system without broadly prohibiting the participation of distribution-connected and behind-the-meter resources in RTO/ISO markets.

c. Other Issues

57. Finally, we deny rehearing regarding the Commission's authority to require that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets be at the wholesale LMP. We find to be misplaced suggestions that Order No. 841 ''authorizes'' retail customers (in this case, electric storage resources) to purchase energy from entities other than their distribution utility or ''entitles'' electric storage resources to bypass the

[142] *See* Order No. 841, 162 FERC ¶ 61,127 at P 30 (observing that an electric storage resource that injects electric energy back to the grid for purposes of participating in an RTO/ISO market engages in a sale of electric energy at wholesale in interstate commerce and must fulfill certain responsibilities set forth in the FPA and the Commission's rules and regulations); *EnergyConnect, Inc.,* 130 FERC ¶ 61,031, at P 30 (2010) (finding that an entity only engaged in the provision of demand response services that makes no sales of electric energy for resale would not be a public utility required to have a rate on file with the Commission).

[143] *See* Order No. 719, 125 FERC ¶ 61,071 at P 141.

[144] *See id.* P 155 (explaining that ''[t]he Commission's intent was not to interfere with the operation of successful demand response programs'').

[145] For instance, among the many comments on the NOPR submitted by various state agencies and representatives, only California, Connecticut, Massachusetts and New York mentioned any specific state electric storage initiatives. *See* California Commission Comments (RM16–23–000) at 4–5, 10–13; Connecticut Commission Comments (RM16–23–000) at 4–5; Massachusetts Commission Comments (RM16–23–000) at 3, 6–8; New York Commission Comments (RM16–23–000) at 8.

[146] *See* AMP/APPA/NRECA Rehearing Request at 14 n.48; TAPS Rehearing Request at 4.

[147] *See EnergyConnect, Inc.,* 130 FERC ¶ 61,031 at P 30.

[148] 18 CFR 35.28(b)(4).

[149] *See* Organization of MISO States Rehearing Request at 3.

[150] *See* Order No. 841, 162 FERC ¶ 61,127 at P 30 n.49.

[151] *See id.* P 317.

[152] *See EPSA,* 136 S. Ct. 760 at 776.

distribution utility by purchasing from the RTO/ISO market.[153] The Commission is not preempting distribution utilities' franchised right to continue to make retail sales to their retail customers, as Xcel Energy Services suggests.

58. First, an electric storage resource purchasing charging energy directly from the RTO/ISO markets that it will resell back to those markets is not a retail customer making a purchase of retail energy but rather is a public utility engaging in a wholesale purchase and a wholesale sale.[154] Therefore, such a purchase of charging energy from the RTO/ISO markets does not infringe upon a distribution utility's right to sell at retail because that energy will be resold in the RTO/ISO markets.

59. Second, in Order No. 841, the Commission did not purport to *authorize* electric storage resources who are retail customers to bypass their distribution utilities and make purchases of energy directly from RTO/ISO markets. Order No. 841 does not require electric storage resources to participate in the RTO/ISO markets; it only directs RTOs/ISOs to adopt market rules that apply to electric storage resources that *voluntarily* seek to participate in the RTO/ISO markets. Furthermore, Order No. 841 only addresses sales for resale; for this reason, the Commission only addressed pricing issues related to the wholesale sales addressed therein and did not preclude other options for electric storage resources to obtain charging energy.[155]

60. To further eliminate the potential for confusion on this point, we clarify that, in declining requests to allow states to decide whether electric storage resources in their state that are located behind a retail meter or on the distribution system are permitted to ''participate'' in the RTO/ISO markets through the electric storage resource participation model, the Commission was referring to the ability of electric storage resources to *sell* into the RTO/ISO markets. Given this clarification, we also dismiss as moot the argument that there is inconsistency between the Commission's finding that an RTO/ISO is prevented from charging a resource wholesale rates if the host distribution utility is unable or unwilling to net out wholesale energy purchases and the Commission's decision to decline to adopt an opt-out.[156]

61. In response to SPP's request for clarification regarding whether it is sufficient for an RTO/ISO to require an electric storage resource to attest that it has all the necessary contractual arrangements in place to permit that resource to inject energy onto the grid,[157] we clarify that Order No. 841 did not specify how an RTO/ISO must determine whether a particular resource seeking to participate in its markets qualifies as an electric storage resource under the definition set forth therein. Therefore, we clarify for SPP that, on compliance, it may propose the attestation approach that it has taken for demand response. Based on the full record before it, the Commission will consider on compliance whether allowing a resource to attest that it meets the definition of electric storage resources, including the associated requirement that it be contractually permitted to inject energy onto the grid, is just and reasonable.

62. In response to Organization of MISO States' request for clarification that RTOs/ISOs may propose tariff provisions that require electric storage resources to comply with applicable RERRA and distribution utility rules, we note that any resources subject to a RERRA's jurisdiction must comply with that RERRA's rules assuming that such rules do not conflict with the requirements of Order No. 841 (*e.g.,* by placing a broad prohibition on participating in the RTO/ISO markets).[158] Similarly, in response to SPP's request for clarification regarding whether the requirements of Order No. 841 supersede RTO/ISO tariff provisions that apply to all resources, we clarify that the requirements of Order No. 841 do not absolve electric storage resources from complying with RTO/ISO tariff provisions of general applicability as long as those tariff provisions do not conflict with the requirements of Order No. 841.

B. Participation Model for Electric Storage Resources

1. Final Rule

63. In Order No. 841, the Commission added § 35.28(g)(9)(i) to the Commission's regulations to require each RTO/ISO to revise its tariff to include a participation model consisting of market rules that, recognizing the physical and operational characteristics of electric storage resources, facilitates their participation in the RTO/ISO markets.[159] In adopting this requirement, the Commission stated that it was not convinced by commenters who argued that separate participation models are necessary for different types of electric storage resources (*e.g.,* slower, faster, or aggregated).[160] Specifically, the Commission noted that it believed that the physical differences between electric storage resources can be represented by complying with the final rule's requirements for bidding parameters[161] and that a single participation model can be designed to be flexible enough to accommodate any type of electric storage resource. However, the Commission stated that, to the extent an RTO/ISO seeks to include in its tariff additional market rules that accommodate electric storage resources with specific physical and operational characteristics, the RTO/ISO may propose such revisions to its tariff through a separate FPA section 205 filing.[162]

2. Requests for Rehearing or Clarification

64. In their rehearing request, AES Companies argue that there are significant differences in operating characteristics, such as response speeds, among the technologies that fall under Order No. 841's definition of an electric storage resource. According to AES Companies, legacy RTO/ISO software is incapable of supporting a participation model that all such technologies can use, and the RTOs/ISOs cannot anticipate all yet-to-be-developed technologies. AES Companies therefore argue that, because multiple participation models are needed to remove the barriers to the participation of electric storage resources that the Commission identified in Order No. 841, the Commission's directive to each RTO/ISO to establish a single participation model for all electric storage resources is an impossible task, invariably excluding some resources. AES Companies add that the Commission's statement that an RTO/ISO may propose additional market

[153] *See* AMP/APPA/NRECA Rehearing Request at 10; TAPS Rehearing Request at 8 n.11; Xcel Energy Services Rehearing Request at 8.

[154] Because such a resource is making wholesale sales in interstate commerce, it is a public utility that must fulfill certain responsibilities set forth in the FPA and the Commission's rules and regulations. *See* Order No. 841, 162 FERC ¶ 61,127 at P 30.

[155] *Id.* P 299.

[156] *See* AMP/APPA/NRECA Rehearing Request at 6; TAPS Rehearing Request at 7 (citing Order No. 841, 162 FERC ¶ 61,127 at P 326).

[157] SPP Motion for Clarification at 2 (citing Order No. 841, 162 FERC ¶ 61,127 at P 33), 13.

[158] *See id.* at 5–6.

[159] Order No. 841, 162 FERC ¶ 61,127 at P 51.

[160] *Id.* P 54.

[161] In Order No. 841, the Commission added § 35.28(g)(9)(i)(C) to the Commission's regulations to require each RTO/ISO to have tariff provisions providing a participation model for electric storage resources that accounts for the physical and operational characteristics of electric storage resources through bidding parameters or other means. *Id.* P 191.

[162] *Id.* P 54 (referencing 16 U.S.C. 824d).

rules to accommodate electric storage resources with specific physical and operational characteristics through a separate FPA section 205 filing is insufficient to address these concerns.[163]

3. Commission Determination

65. We deny AES Companies' request for rehearing. While we agree with AES Companies that the various technologies that qualify as an electric storage resource under the definition that the Commission adopted in the final rule may have different operating characteristics and that new electric storage technologies will likely emerge, we continue to find that a single participation model can be designed to be flexible enough to accommodate any type of electric storage resource.[164] Specifically, Order No. 841's requirement that each RTO/ISO must establish tariff provisions providing a participation model for electric storage resources that accounts for the physical and operational characteristics of electric storage resources through bidding parameters or other means should allow for the representation of the physical and operational differences between different types of electric storage resources. For this reason, we remain unpersuaded that the Commission must require separate participation models for different types of electric storage resources to remove barriers to their participation in RTO/ISO markets.

C. Eligibility of Electric Storage Resources To Participate in the RTO/ISO Markets

1. Final Rule

66. Order No. 841 added § 35.28(g)(9)(i)(A) to the Commission's regulations to require each RTO/ISO to establish market rules so that a resource using the participation model for electric storage resources is eligible to provide all capacity, energy, and ancillary services that it is technically capable of providing, including services that the RTOs/ISOs do not procure through an organized market.[165] While noting that there is significant variation in how each RTO/ISO approaches resource adequacy, the Commission found that it is important for electric storage resources that can provide value in those resource adequacy constructs to be eligible to participate.[166] The Commission further stated that, if an RTO/ISO does not have existing tariff provisions that enable electric storage resources to provide capacity, it must propose such rules on compliance.

2. Requests for Rehearing or Clarification

67. SPP seeks clarification that Order No. 841 does not require an RTO/ISO to create and provide a capacity product that an RTO/ISO market does not otherwise offer, noting that SPP does not currently operate a forward capacity market or offer capacity as a biddable product on its system.[167]

3. Commission Determination

68. We grant SPP's request for clarification. Order No. 841 does not require an RTO/ISO that does not have a capacity product in its markets to create such a product to comply with the final rule. However, to the extent that an RTO/ISO has a resource adequacy construct, the RTO/ISO must demonstrate on compliance that the existing market rules governing its resource adequacy construct provide a means for electric storage resources to participate in that construct if electric storage resources are technically capable of doing so.[168]

D. Participation in the RTO/ISO Markets as Supply and Demand

1. Eligibility To Participate as a Wholesale Seller and Wholesale Buyer

a. Final Rule

69. In Order No. 841, the Commission added § 35.28(g)(9)(i)(B) to the Commission's regulations to require each RTO/ISO to revise its tariff to ensure that a resource using the participation model for electric storage resources can be dispatched as supply and demand and can set the wholesale market clearing price as both a wholesale seller and wholesale buyer, consistent with rules that govern the conditions under which a resource can set the wholesale price.[169] The Commission found that, for a resource using the participation model for electric storage resources to be able to set prices in the RTO/ISO markets as either a wholesale seller or a wholesale buyer, it must be available to the RTO/ISO as a dispatchable resource. Moreover, the Commission required that resources using the participation model for electric storage resources must be allowed to participate in the RTO/ISO markets as price takers, consistent with the existing rules for self-scheduled resources.

70. Additionally, the Commission required in Order No. 841 that RTOs/ISOs must accept wholesale bids from resources using the participation model for electric storage resources to buy energy.[170] The Commission further stated that allowing electric storage resources to participate in the RTO/ISO markets as dispatchable load will allow these resources to set the market clearing price under certain circumstances, thus better reflecting the value of the marginal resource and ensuring that electric storage resources are dispatched in accordance with the highest value service that they are capable of providing during a set market interval.[171]

b. Requests for Rehearing or Clarification

71. AES Companies seek rehearing of what they construe as Order No. 841's requirement that all resources using an RTO's/ISO's participation model for electric storage resources be dispatchable, citing to the Commission's determinations in Order No. 841 that (1) to set prices in the RTO/ISO markets as either a wholesale seller or a wholesale buyer, a resource using the participation model for electric storage resources must be available to the RTO/ISO as a dispatchable resource and (2) an electric storage resource participation model must ensure that a resource using it can be dispatched.[172] AES Companies argue that these requirements codify the existing unjust, unreasonable, unduly discriminatory and preferential *status quo* that prevents resources that provide services automatically from participating in RTO/ISO markets without risking the physical damage to their equipment that can occur if they are subject to RTO/ISO dispatch. AES Companies argue that, contrary to Order No. 841's statement that a participation model for electric storage resources must recognize the physical and operational characteristics of electric storage resources, predicating participation on dispatchability fails to recognize the physical and operational characteristics of these electric storage resources.[173]

72. In addition, AES Companies argue that Order No. 841 unreasonably limits its application of the term ''dispatch'' to an activity performed exclusively by RTO/ISO software. According to AES

[163] AES Companies Rehearing Request at 11–13.

[164] Order No. 841, 162 FERC ¶ 61,127 at P 54.

[165] *Id.* P 76.

[166] *Id.* P 100.

[167] SPP Motion for Clarification at 4–5.

[168] Order No. 841, 162 FERC ¶ 61,127 at P 76. *See also id.* P 100.

[169] *See id.* P 142.

[170] *See id.*

[171] *See id.* P 143.

[172] AES Companies Rehearing Request at 7 (citing Order No. 841, 162 FERC ¶ 61,127 at PP 142, 4).

[173] *Id.* at 8–11.

Companies, the term ''dispatch'' should instead be ''inclusive of scheduling an electric storage resource to operate autonomously, and ordered outside of the RTO/ISO software by the Reliability Coordinator.'' [174]

73. SPP seeks clarification that Order No. 841 will not require an RTO/ISO that does not currently offer a real-time dispatchable load service, such as SPP, to create a new service to dispatch an electric storage resource as load or negative generation. To the extent that Order No. 841 requires the development of such a new service, SPP asks whether the Commission will provide each RTO/ISO with flexibility to develop such service consistent with its existing market design constructs, with a full opportunity to evaluate the potential system impacts, and with flexibility to propose its own timeline for developing and implementing such a service.[175]

c. Commission Determination

74. In their rehearing request, AES Companies argue that Order No. 841 requires a resource seeking to participate in RTO/ISO markets under the electric storage resource participation model to be available to the RTO/ISO as a dispatchable resource. We disagree with this characterization of Order No. 841's requirements and thus, deny AES Companies' request for rehearing. However, we find it is necessary to modify § 35.28(g)(9)(i)(B) of the Commission's regulations to clarify that, to the extent electric storage resources are dispatchable, the RTO/ISO is required to allow them to participate as dispatchable resources and to set the clearing price in the RTO/ISO markets as part of the participation model. We clarify that not all electric storage resources that seek to use the electric storage resource participation model need to be dispatchable to use that participation model.

75. Order No. 841 added § 35.28(g)(9)(i)(B) to the Commission's regulations to require each RTO/ISO to revise its tariff to provide a participation model for electric storage resources that ensures that a resource using the participation model can be dispatched and can set the wholesale market clearing price.[176]

76. We clarify here that this requirement was not intended to require that a resource using the participation model for electric storage resources be dispatchable. Rather, by stating that this was to be ''consistent with rules that govern the conditions under which a resource can set the wholesale price,'' Order No. 841 requires each RTO/ISO to revise its tariff to include a participation model for electric storage resources enabling the RTO/ISO to dispatch a resource using that model to the extent that the resource has indicated to the RTO/ISO, whether through its offers to sell or bids to buy or some other mechanism, that it desires to be dispatchable. Our clarification is consistent with Order No. 841's findings that (1) resources using the participation model for electric storage resources must be allowed to participate in the RTO/ISO markets as price takers, consistent with the existing market rules for self-scheduled resources [177] and (2) to ensure consistent treatment in the RTO/ISO markets, electric storage resources must maintain the same ability to self-schedule their resource as other market participants.[178]

77. To remove the ambiguity, we revise § 35.28(g)(9)(i)(B) of the Commission's regulations to require each RTO/ISO to revise its tariff to provide a participation model for electric storage resources that *enables* a resource using the participation model for electric storage resources *to* be dispatched and *ensures that such a dispatchable resource* can set the wholesale market clearing price.

78. This modification clarifies that each RTO/ISO is required to allow resources using the participation model for electric storage resources to participate in the RTO/ISO markets as dispatchable resources, not that such resources must be dispatchable to use that participation model. We reiterate, however, that the Commission will continue to require that resources using the participation model for electric storage resources can only set prices in the RTO/ISO markets as either a wholesale seller or a wholesale buyer if they are available to the RTO/ISO as a dispatchable resource.[179]

79. AES Companies request that the Commission expand our use of the term dispatch beyond those ''activities performed by RTO/ISO software.'' However, as clarified above, Order No. 841 only required that each RTO/ISO must be capable of dispatching resources using the participation model for electric storage resources and allow such dispatchable resources to set prices in the RTO/ISO markets. Given this clarification, we do not find it necessary to expand our use of the term dispatch beyond RTO/ISO activities, as requested by AES Companies.

80. We deny SPP's request for clarification that it need not revise its market rules to allow for dispatchable load. In Order No. 841, the Commission required each RTO/ISO to create a participation model for electric storage resources that ensures that a resource using that model can be dispatched as a wholesale buyer.[180] Additionally, the Commission required that RTOs/ISOs accept wholesale bids from resources using the participation model for electric storage resources to buy energy.[181] As the Commission stated in Order No. 841, allowing electric storage resources to participate in the RTO/ISO markets as dispatchable load will allow these resources to set the market clearing price under certain circumstances, thus better reflecting the value of the marginal resource and ensuring that electric storage resources are dispatched in accordance with the highest value service that they are capable of providing during a set market interval.[182]

81. We clarify for SPP that Order No. 841 provides flexibility for each RTO/ISO to develop a participation model for electric storage resources consistent with its existing market design constructs, as SPP requests. Order No. 841 did not, however, provide each RTO/ISO with flexibility to propose its own timeline for developing and implementing any aspect of the participation model for electric storage resources, including the requirement that RTOs/ISOs must ensure a resource using the participation model for electric storage resources can be dispatched as a wholesale buyer.

2. Participation as Price Takers

a. Final Rule

82. In the final rule, the Commission required that resources using the participation model for electric storage resources must be allowed to participate in the RTO/ISO markets as price takers, consistent with the existing rules for self-scheduled resources.[183] The Commission rejected assertions that an RTO/ISO must decide whether to allow electric storage resources to be price takers, finding that, to ensure consistent

[174] *Id.* at 9.

[175] SPP Motion for Clarification at 5–6.

[176] 18 CFR 35.28(g)(9)(i)(B); Order No. 841, 162 FERC ¶ 61,127 at P 142.

[177] *See* Order No. 841, 162 FERC ¶ 61,127 at P 142.

[178] *See id.* P 144.

[179] *See id.* P 142.

[180] *See id.;* 18 CFR 35.28 (g)(9)(i)(B).

[181] Order No. 841, 162 FERC ¶ 61,127 at P 142. *See also id.* P 150 (''This final rule requires an electric storage resource to be eligible to participate in the RTO/ISO markets as a wholesale buyer and for each RTO/ISO to be able to dispatch them as such. Such a mechanism would entail participation in the energy markets, not the provision of a new service . . . .'').

[182] *See id.* P 143.

[183] *Id.* P 142.

treatment in the RTO/ISO markets, electric storage resources must maintain the same ability to self-schedule their resource as other market participants.[184] Additionally, to ensure that electric storage resources are treated consistently with the ability of self-scheduled load resources and traditional generation resources to participate in the RTO/ISO markets, the Commission determined that the ability of electric storage resources to participate as price takers should not be limited to their participation as load.[185]

b. Requests for Rehearing or Clarification

83. MISO requests clarification that, in complying with the directive to allow electric storage resources to be price takers as self-scheduled resources,[186] MISO may also consider treating an electric storage resource as a self-scheduled price-taker if the electric storage resource uses its State of Charge to lock its energy output to a very narrow range. MISO explains that, in real time, an electric storage resource could use its State of Charge to lock its MW amount around its day-ahead position, and that locking energy output to a very narrow range may result in capacity that cleared in the capacity market not being fully available to the day-ahead market, counter to the day-ahead must-offer obligation.[187]

c. Commission Determination

84. We deny MISO's request for clarification. We reiterate that RTOs/ISOs must provide electric storage resources with the same ability to self-schedule as other market participants.[188] We therefore find that, to the extent that a resource using the participation model for electric storage resources has not elected to be a self-scheduled price taker, it would be unreasonable for an RTO/ISO to designate that resource as a self-scheduled price taker solely based on the State of Charge parameters that the resource has submitted. We find that the RTO/ISO must provide resources using the electric storage resource participation model with the opportunity to determine whether to self-schedule, consistent with the RTO's/ISO's existing rules for self-scheduled resources.

85. However, in response to MISO's concern that, if a resource using the participation model for electric storage resources restricts its energy output to a very narrow range through its State of Charge, any of its capacity that cleared in the capacity market may not be fully available to the day-ahead market, we agree that a resource using the participation model for electric storage resources may not use a bidding parameter, such as State of Charge, to circumvent its obligations in the RTO/ISO markets, including any day-ahead must-offer obligation for capacity resources.

E. Physical and Operational Characteristics of Electric Storage Resources

1. Requirement To Incorporate Bidding Parameters as Part of the Electric Storage Resource Participation Model

a. Final Rule

86. In the final rule, the Commission added § 35.28(g)(9)(i)(C) to the Commission's regulations to require each RTO/ISO to have tariff provisions providing a participation model for electric storage resources that accounts for the physical and operational characteristics of electric storage resources through bidding parameters or other means.[189] Specifically, the Commission required that each RTO's/ISO's participation model for electric storage resources must account for 13 different physical and operational characteristics, as defined in the final rule.[190] In adopting this requirement, the Commission noted that it was persuaded by commenters' arguments that there may be other means of accounting for the physical and operational characteristics of electric storage resources than bidding parameters and that greater regional flexibility than the Commission proposed in the Notice of Proposed Rulemaking (NOPR) is appropriate.[191] In particular, the Commission stated that different RTOs/ISOs may be able to more effectively account for the physical and operational characteristics of electric storage resources through different mechanisms given their unique market designs.

b. Requests for Rehearing or Clarification

87. MISO requests clarification on whether it may require electric storage resources to submit their State of Charge forecasts at the beginning of a particular market interval. MISO contends that such a requirement will allow it to derive the charging or discharging status of a resource for every interval, eliminating the need for MISO to introduce a binary variable to determine the charging or discharging mode of a resource in its co-optimization process and in turn avoiding potential adverse impacts on its market clearing and commitment processes.[192]

88. MISO also requests clarification that, if an electric storage resource does not provide minimum charge and discharge limits and can be moved smoothly between negative and positive, MISO may require the resource to submit a single hourly ramp rate for the day-ahead market and for its Look Ahead Commitment process. According to MISO, it has currently adopted this practice with respect to other resources. MISO argues that such a requirement would allow it to avoid the nonlinearity caused by a megawatt dependent ramp curve and additional integer variables. MISO also asks the Commission to clarify that it may apply its current practice of allowing three ramp rates and ramp rate curves for regulating, up, and down movement to electric storage resources.[193]

89. PJM seeks clarification that the final rule allows for flexibility in how RTOs/ISOs account for the physical and operational characteristics of electric storage resources, including State of Charge.[194] Specifically, PJM argues that there are different approaches to

[184] *Id.* P 144.

[185] *Id.* P 148.

[186] MISO Request for Rehearing at 7 (citing Order No. 841, 162 FERC ¶ 61,127 at P 142).

[187] MISO states that such a limitation would be consistent with the principle articulated in Order No. 841 that an [electric storage resource] ''must not de-rate its capacity below any capacity obligations it has assumed, such as any applicable must-offer requirement.'' *Id.* at 7–8 (citing Order No. 841, 162 FERC ¶ 61,127 at P 99).

[188] *See* Order No. 841, 162 FERC ¶ 61,127 at P 144.

[189] *Id.* P 191.

[190] *Id.* P 236. Those physical and operating characteristics are as follows: (1) State of Charge, (2) Maximum State of Charge, (3) Minimum State of Charge, (4) Maximum Charge Limit, (5) Maximum Discharge Limit, (6) Minimum Charge Time, (7) Maximum Charge Time, (8) Minimum Run Time, (9) Maximum Run Time, (10) Minimum Discharge Limit, (11) Minimum Charge Limit, (12) Discharge Ramp Rate, and (13) Charge Ramp Rate. Relevant to the discussion of MISO's request for clarification below, the final rule defined State of Charge as ''the amount of energy stored in proportion to the limit on the amount of energy that can be stored, typically expressed as a percentage. It represents the forecasted starting State of Charge for the market interval being offered into.'' Minimum Charge Limit is the ''minimum [megawatt] level that a resource using the participation model for electric storage resources can receive from the grid'' and Minimum Discharge Limit is the ''minimum [megawatt] output level that a resource using the participation model for electric storage resources can inject onto the grid.'' Discharge Ramp Rate and Charge Ramp Rate are the speed at which a resource using the participation model for electric storage resources can move from zero output to its Maximum Discharge Limit and Maximum Charge Limit, respectively. *Id.*

[191] *Id.* P 190; NOPR (Docket Nos. RM16–23–000; AD16–20–000), 81 FR 86522.

[192] MISO Request for Rehearing at 6.

[193] *Id.* at 6–7.

[194] PJM Motion for Clarification at 1 (citing Order No. 841, 162 FERC ¶ 61,127 at PP 189–194, 211–216, 220–224).

implementing Order No. 841's requirement that an electric storage resource participation model account for electric storage resources' physical and operational characteristics, which involve different degrees of modeling and operational changes and challenges.[195]

c. Commission Determination

90. In response to MISO's request for clarification, we clarify that, on compliance, MISO may propose to require a resource using the electric storage resource participation model to submit its forecasted State of Charge at the beginning of any market interval in which it intends to participate. With that said, we make no findings on the proposal that MISO outlines in its request for clarification. Order No. 841 provided flexibility to the RTOs/ISOs on how to account for the physical and operational characteristics of electric storage resources.[196] We will not prejudge any particular approach to implementing Order No. 841's requirement that each RTO/ISO establish a participation model for electric storage resources that accounts for the physical and operational characteristics of electric storage resources through bidding parameters or other means; rather, we will evaluate MISO's proposal on compliance with the full record before us.

91. Similarly, in response to MISO's clarification request regarding ramp rates, we clarify that MISO may propose for an electric storage resource that does not provide minimum charge and discharge limits and can be moved smoothly between negative and positive to submit a single hourly ramp rate for the day-ahead market and for its Look Ahead Commitment process. However, we also make no findings on the merits of the proposal that MISO outlines in its request for clarification.

92. Order No. 841 also states that, to the extent that an RTO/ISO proposes to comply with the final rule using its existing bidding parameters or other market mechanisms, it must demonstrate in its compliance filing how its existing market rules account for these characteristics of electric storage resources.[197] We therefore clarify that MISO may propose to apply its current practice of allowing three ramp rates and ramp rate curves for regulating, up, and down movement to resources using the electric storage resource participation model, but that it must demonstrate in its compliance filing how this practice accounts for Discharge Ramp Rate and Charge Ramp Rate. The Commission will determine on compliance whether MISO's proposal complies with the requirements of Order No. 841.

93. We also grant PJM's request for clarification. The Order No. 841 requirement that each RTO/ISO establish tariff provisions providing a participation model for electric storage resources that accounts for the physical and operational characteristics of electric storage resources through bidding parameters or other means, allows for regional flexibility.[198] Specifically, in Order No. 841, the Commission noted that it was persuaded by commenters' arguments that there may be other means of accounting for the physical and operational characteristics of electric storage resources than bidding parameters and that greater regional flexibility than the Commission proposed in the NOPR was appropriate. In particular, the Commission stated that different RTOs/ISOs may be able to more effectively account for the physical and operational characteristics of electric storage resources through different mechanisms given their unique market designs.[199] That said, we make no findings on the proposed approaches that PJM outlines in its request for clarification. We will not prejudge any particular approach to implementing the final rule's requirement that each RTO/ISO establish a participation model for electric storage resources that accounts for the physical and operational characteristics of electric storage resources through bidding parameters or other means; rather, we will evaluate PJM's proposal on compliance with a full record before us.

F. Minimum Size Requirement

1. Final Rule

94. In Order No. 841, the Commission added § 35.28(g)(9)(i)(D) to the Commission's regulations to require each RTO/ISO to revise its tariff to include a participation model for electric storage resources that establishes a minimum size requirement for participation in the RTO/ISO markets that does not exceed 100 kW.[200] The Commission stated that this minimum size requirement includes all minimum capacity requirements, minimum offer to sell requirements, and minimum bid to buy requirements for resources participating in these markets under the participation model for electric storage resources. In support of the requirement, the Commission found that requiring the RTOs/ISOs to establish a minimum size requirement not to exceed 100 kW for the participation model for electric storage resources balances the benefits of increased competition with the potential need to update RTO/ISO market clearing software to effectively model and dispatch smaller resources.[201]

95. The Commission further found that the record shows that all RTOs/ISOs are already accommodating the participation of smaller resources in their markets.[202] For example, the Commission stated that the record shows that all RTOs/ISOs already have the modeling and dispatch software capabilities to accommodate the participation of resources that are as small as 100 kW. Specifically, the Commission noted that both PJM and SPP have a minimum size requirement of 100 kW for all resources, and all of the RTOs/ISOs have at least one participation model that allows resources as small as 100 kW to participate in their markets.[203]

96. Moreover, in response to concerns about potential impacts on the distribution systems and related costs, the Commission noted that there are resources located on the distribution system that are already participating in the RTO/ISO markets.[204] The Commission stated that establishing a standard minimum size requirement for resources using the participation model for electric storage resources may potentially result in more resources on the distribution systems participating in the RTO/ISO markets. However, the Commission stated that it does not change the responsibilities of the RTOs/ISOs or the distribution utilities, and it does not change the ability of distribution utilities to allocate any costs that they incur in operating and maintaining their respective power systems.

97. With respect to concerns about the need to upgrade RTO/ISO software to manage the potentially large number of resources using the participation model for electric storage resources under the proposed minimum size requirement, the Commission found that it was

[195] *Id.* at 2–3.

[196] *See* Order No. 841, 162 FERC ¶ 61,127 at P 191.

[197] *Id.* P 229.

[198] *See id.* P 191.

[199] *Id.* P 190.

[200] *Id.* P 270.

[201] *Id.* P 271.

[202] *Id.* P 272.

[203] *Id.* (citing CAISO Data Request Response at 10–11; ISO–NE Data Request Response at 13–14; MISO Data Request Response at 10; NYISO Data Request Response at 9; PJM Data Request Response at 10; SPP Data Request Response at 5).

[204] *Id.* P 274.

providing the RTOs/ISOs with adequate time to develop the requisite tariff language and update their modeling and dispatch software to comply with Order No. 841.[205] The Commission was also not concerned about the potential availability of software solutions as multiple RTOs/ISOs already provide a minimum size requirement of 100 kW for all resources and have not expressed similar concerns regarding the minimum size requirement. However, the Commission recognized that there are currently fewer 100 kW resources than there may be in the future and stated that it will consider future requests to increase the minimum size requirement to the extent an RTO/ISO can show that it is experiencing difficulty calculating efficient market results and there is not a viable software solution for improving such calculations.

2. Requests for Rehearing or Clarification

98. In its rehearing request, EEI states that the Commission should allow the RTOs/ISOs, in conjunction with the electric distribution utilities, to establish a minimum size requirement for electric storage resources that would be manageable for their markets while maintaining reliability on both the bulk electric power system and the relevant distribution systems.[206] EEI argues that the Commission has provided insufficient support for its proposed minimum size requirement, stating that the evidence that the Commission cites is inadequate given the concerns expressed in the record that the 100 kW minimum size requirement may be too small due to software, settlement, and other infrastructure limitations. For example, EEI contends that the Commission does not provide evidence in the form of numbers of 100 kW resources directly participating in the RTO/ISO markets or the number of tariff provisions that permit participation at such size.[207]

99. EEI argues that the number of electric storage resources that could potentially seek to participate in the wholesale market at the proposed threshold could become so voluminous that they (1) exceed the ability of RTOs/ISOs to manage this volume of resources, (2) exceed the ability of distribution utilities to address various reliability, operational, and interconnection matters given that smaller resources are far more likely to interconnect to the distribution system, and (3) impose implementation costs significantly greater than corresponding benefits, particularly in regions where resources of the 100 kW size have other compensation options such as net energy metering. EEI argues that allowing the RTOs/ISOs to make an after-the-fact showing of difficulties in calculating efficient market outcomes does not adequately account for these concerns or address the software and other costs on both the transmission and distribution system of complying with the final rule.[208]

100. MISO requests clarification or, in the alternative, rehearing that it may phase in the implementation of the minimum size requirement. Specifically, MISO seeks clarification that it may cap the number of very small electric storage resources that can participate in its markets at the number of such resources that its initial software and system changes can handle in the first year of implementation. According to MISO, it will increase the number of small electric storage resources that it will allow in its market as it improves its software's capability to manage them. MISO argues that this phased approach is a reasonable precaution to proactively address the potential for large numbers of small electric storage resources, rather than waiting to react to adverse impacts of future high volumes of small electric storage resources.[209]

101. MISO also requests clarification or, in the alternative, rehearing, that the 100 kW limit applies to the Maximum Charge Limit or Maximum Discharge Limit and not to the Minimum Charge Limit or Minimum Discharge Limit. MISO contends that small electric storage resources can offer a smaller Minimum Charge Limit or Minimum Discharge Limit, such as 0.0001 MW. MISO adds that, if the offered minimum limit is too small, an RTO/ISO can round it to zero and assume that the resource can smoothly move between the negative Maximum Charge Limit and positive Maximum Discharge Limit. MISO argues that this rounding can avoid unnecessarily limiting the range for clearing energy or reserve products.[210]

3. Commission Determination

102. We deny EEI's request for clarification and rehearing. We continue to find that requiring each RTO/ISO to establish a minimum size requirement not to exceed 100 kW for the participation model for electric storage resources balances the benefits of increased competition with the potential need to update RTO/ISO market clearing software to effectively model and dispatch smaller resources.[211] We disagree with EEI that the Commission lacked sufficient evidence to support a minimum size requirement of 100 kW. As the Commission stated in Order No. 841, both PJM and SPP have a minimum size requirement of 100 kW for all resources, and all of the RTOs/ISOs have at least one participation model that allows resources as small as 100 kW to participate in their markets.[212] We continue to find this evidence sufficient to demonstrate that all RTOs/ISOs already have the modeling and dispatch software capabilities to accommodate the participation of resources that are as small as 100 kW.

103. EEI argues that the implementation costs of the minimum size requirement will outweigh any benefits and RTOs/ISOs and distribution utilities may not be able to manage the volume of smaller resources to participate in RTO/ISO markets and interconnect to the distribution system. We disagree. As stated in the final rule, we acknowledge that the 100 kW minimum size requirement is a balance between the benefits of increased competition fostered by the opportunity for smaller resources to participate in the RTO/ISO markets using the electric storage resource participation model and the potential need to update RTO/ISO market clearing software to effectively model and dispatch these smaller resources.[213] Based on the record before us, we find that the benefits of increased competition will outweigh implementation costs, especially given that all RTOs/ISOs are already accommodating the participation of smaller resources in their markets, as demonstrated in the final rule.[214]

104. With respect to EEI's and MISO's concerns about the volume of smaller resources that may seek to participate in RTO/ISO markets and interconnect to the distribution system, in the final rule,

[205] *Id.* P 275.

[206] EEI Rehearing Request at 9–10.

[207] *Id.* at 8–9.

[208] *Id.* at 9 (citing Order No. 841, 162 FERC ¶ 61,127 at P 275).

[209] MISO Rehearing Request at 4–5.

[210] *Id.* at 4 (citing Order No. 841, 162 FERC ¶ 61,127 at P 236).

[211] *See* Order No. 841, 162 FERC ¶ 61,127 at P 271.

[212] *Id.* P 272 (citing CAISO Data Request Response at 10–11; ISO–NE Data Request Response at 13–14; MISO Data Request Response at 10; NYISO Data Request Response at 9; PJM Data Request Response at 10; SPP Data Request Response at 5).

[213] *See id.* P 271.

[214] *See id.* P 272 (citing CAISO Data Request Response at 10–11; ISO–NE Data Request Response at 13–14; MISO Data Request Response at 10; NYISO Data Request Response at 9; PJM Data Request Response at 10; SPP Data Request Response at 5).

the Commission recognized that there are currently fewer 100 kW resources than there may be in the future. While we recognize that EEI argues for greater flexibility for each RTO/ISO to establish its own minimum size requirement as an initial matter, for the reasons discussed above,[215] we continue to find that it is reasonable to establish a minimum size requirement not to exceed 100 kW for the participation model for electric storage resources.

105. For these reasons, we also deny MISO's request for clarification or, in the alternative, rehearing that it may phase in the implementation of the minimum size requirement. We continue to believe that, given the record showing that all RTOs/ISOs are already accommodating the participation of smaller resources in their markets [216] and the Commission's willingness to consider requests to increase the minimum size requirement in the future, we are providing the RTOs/ISOs with adequate time to develop the requisite tariff language and update their modeling and dispatch software to comply with Order No. 841.[217] MISO's arguments on rehearing do not convince us otherwise. As the Commission stated in the final rule, upon implementation, if an RTO/ISO, including MISO, finds that it is experiencing difficulty calculating efficient market results and there is not a viable software solution for improving such calculations, it may file with the Commission demonstrating such and proposing to increase the minimum size requirement for its electric storage resource participation model.[218] Further, as stated in the final rule, a minimum size requirement that does not exceed 100 kW does not change the responsibilities of the RTOs/ISOs or the distribution utilities, and it does not change the ability of distribution utilities to allocate any costs that they incur in operating and maintaining their respective power systems.[219]

106. Finally, in response to MISO's request for clarification that the 100 kW limit does not apply to the Minimum Charge Limit or Minimum Discharge Limit, we clarify that the minimum size requirement does not prohibit an RTO/ISO from establishing a minimum size limit that is lower than 100 kW on any minimum capacity requirements, minimum offer to sell requirements, or minimum bid to buy requirements. Therefore, it is possible that the quantities for the Minimum Charge Limit and Minimum Discharge Limit may be smaller than 100 kW for resources using the participation model for electric storage resources. However, we do not specify how the minimum size requirement may affect the quantities submitted for some of the physical and operational characteristics of electric storage resources, and will not prejudge how the RTOs/ISOs may propose any such relationships between the minimum size requirement and the physical and operational characteristics of resources using the participation model for electric storage resources.

G. Energy Used To Charge Electric Storage Resources (Charging Energy)

1. Price for Charging Energy

a. Final Rule

107. In Order No. 841, the Commission added § 35.28(g)(9)(ii) to the Commission's regulations to require that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets be at the wholesale LMP.[220] The Commission stated that this requirement will apply regardless of whether the electric storage resource is using the participation model for electric storage resources or another participation model to participate in the RTO/ISO markets, as long as the resource meets the definition of an electric storage resource set forth in Order No. 841. The Commission noted that it found that the sale of energy from the grid that is used to charge electric storage resources for later resale into the energy or ancillary service markets constitutes a sale for resale in interstate commerce.[221] The Commission stated that, as such, the just and reasonable rate for that wholesale sale of energy used to charge that electric storage resource is the RTO/ISO market's wholesale LMP, regardless of whether the electric storage resource uses the participation model for electric storage resources.[222]

108. In addition, the Commission disagreed with some commenters' contention that transmission charges that apply to load should not apply to electric storage resources.[223] The Commission stated that, when an electric storage resource is charging to resell energy at a later time, then its behavior is similar to other load-serving entities and applicable transmission charges should apply. However, in response to the concern that transmission charges should not apply when an electric storage resource is dispatched by an RTO/ISO, the Commission found that electric storage resources that are dispatched to consume electricity to provide a service in the RTO/ISO markets (such as frequency regulation or a downward ramping service) should not pay the same transmission charges as load during the provision of that service.[224] The Commission found that this would be consistent with the treatment afforded traditional generation resources that provide ancillary services because they are not charged for their impacts on the transmission system when they reduce their output to provide a service such as frequency regulation down. Therefore, the Commission found that electric storage resources should not be charged transmission charges when they are dispatched by an RTO/ISO to provide a service because (1) their physical impacts on the bulk power system are comparable to traditional generators providing the same service and (2) assessing transmission charges when they are dispatched to provide a service would create a disincentive for them to provide the service.

109. With respect to concerns about electric storage resources' use of the distribution system, the Commission noted that, in *PJM Interconnection LLC,* the Commission permitted a distribution utility to assess a wholesale distribution charge to an electric storage resource participating in the PJM markets.[225] Consistent with this precedent, the Commission found that it may be appropriate, on a case-by-case basis, for distribution utilities to assess a charge on electric storage resources similar to those assessed to the market participant in that proceeding.

[215] *See supra* P 103.

[216] *See* Order No. 841, 162 FERC ¶ 61,127 at P 272 (citing CAISO Data Request Response at 10–11; ISO–NE Data Request Response at 13–14; MISO Data Request Response at 10; NYISO Data Request Response at 9; PJM Data Request Response at 10; SPP Data Request Response at 5).

[217] *See id.* P 275. The Commission provided RTOs/ISOs with 270 days after the publication of the final rule in the **Federal Register** to file the tariff changes (*i.e.,* December 3, 2018) and a further 365 days from that date to implement the tariff provisions.

[218] *See id.*

[219] *Id.* P 274.

[220] *Id.* P 294.

[221] *Id.* (citing *Norton Energy Storage,* 95 FERC at 62,701–02).

[222] *Id.*

[223] *Id.* P 297.

[224] *Id.* P 298.

[225] *Id.* P 301 (citing *PJM Interconnection L.L.C.,* 149 FERC ¶ 61,185 at P 12 (wholesale distribution charge that ComEd will assess to Energy Vault is a weighted average carrying charge that is applied on a case-by-case basis, depending on the distribution facilities expected to be used in providing wholesale distribution service), *order on reh'g,* 151 FERC ¶ 61,231 at PP 16–18).

b. Requests for Rehearing or Clarification

110. Pacific Gas and Electric requests that the Commission clarify that nothing in Order No. 841 is intended to suggest that the state no longer has jurisdiction to determine how power flowing from the distribution grid, through the customer meter, and then into the electric storage resource located behind the customer meter is to be split between retail consumption and wholesale charging for later discharge into the wholesale markets.[226] Pacific Gas and Electric argues that the final rule implies that the state has the authority to determine whether the power flowing through the customer meter, or some fraction of it, is appropriately categorized as wholesale charging or whether all of it must be determined to be retail usage.[227] Pacific Gas and Electric asserts that, if the Commission were to conclude that the state no longer has this authority, then a retail customer could use its behind-the-retail-meter electric storage resource as a means to completely bypass retail rates for its on-site electricity consumption by claiming that the electricity is for later discharge into the wholesale markets, whether or not that discharge actually occurs.[228]

111. Both California Energy Storage Alliance and CAISO contend that the final rule presents conflicting positions on whether transmission charges should apply to wholesale charging energy purchased for later resale.[229] Specifically, they note that, in paragraph 298 of Order No. 841, the Commission found that ''electric storage resources should not be charged transmission charges when they are dispatched by an RTO/ISO to provide a service. . . .'' [230] They point out that, in contrast, in paragraph 297 of the final rule, the Commission stated that ''[w]hen an electric storage resource is charging to resell energy at a later time, then its behavior is similar to other load-serving entities, and we find that applicable transmission charges should apply.'' [231]

112. According to California Energy Storage Alliance, transmission charges should not apply to wholesale charging energy that an electric storage resource later resells. In support of its position, California Energy Storage Alliance argues that applying transmission charges in CAISO would result in an unreasonable ''double-application'' of those charges: Once to the electric storage resource purchasing its charging energy at wholesale and once to the load that the energy is used to serve or the export transaction that it is needed to support. California Energy Storage Alliance further contends that this double-billing would be unduly and financially burdensome for electric storage resources.[232]

113. CAISO argues that requiring an RTO/ISO to assess transmission charges on an electric storage resource's charging demand could blunt electric storage resources' market effectiveness and financial viability and inappropriately shifts transmission costs into energy markets, which is inconsistent with Commission precedent.[233] According to CAISO, unlike load-serving entities with firm load and little to no ability to curb or curtail demand, electric storage resources can charge during periods of excess generation and low prices, thereby shifting demand to combat over-generation, providing ramping flexibility, addressing negative prices, and mitigating potential reliability issues in systems like CAISO that operate with a high degree of supply and demand variability. CAISO argues that requiring RTOs/ISOs to assess transmission charges on electric storage devices will force such resources to include those costs in their market bids, thus affecting energy market prices.[234]

114. With respect to Commission precedent on this issue, CAISO claims that requiring electric storage resources to pay transmission charges would contravene prior Commission precedent, such as CAISO's Commission-accepted non-generator resource model, which treats non-generator resource demand as negative generation and does not require it to pay transmission charges.[235] CAISO maintains that, since the acceptance of the non-generator resource model, the Commission has noted in other proceedings that the negative generation model is a best practice that ''may allow transmission providers to better account for the transitions of electric storage resources between generation and load and may better enable the use of existing generator interconnection procedures and agreements due to their treatment as negative generation instead of load.'' [236]

115. For these reasons, CAISO asks the Commission to clarify that RTOs/ISOs may, but are not required to, impose transmission charges on electric storage resources when they are charging pursuant to RTO/ISO dispatch. Alternatively, CAISO asks the Commission to clarify that each RTO/ISO may determine (1) what types of charging activities would not cause an electric storage resource to incur transmission charges, (2) that those services are not limited to ancillary services, and (3) that charging pursuant to economic dispatch may qualify as such a service.[237] According to CAISO, charging an electric storage resource when it is economic to do so as instructed by the RTO/ISO to help balance the system is a critically important ''service'' that electric storage resources provide the grid.[238]

116. Finally, CAISO seeks clarification that electric storage resources participating as transmission resources under the Commission's Policy Statement should not incur transmission charges for their charging demand.[239] CAISO notes that it may soon approve a proposal to allow electric storage resources to provide reliability/transmission services in its transmission planning process and that these resources would then be eligible to recover some of their costs through regulated transmission rates and the remainder through participation in the wholesale markets. CAISO explains that whether these resources will incur transmission charges for charging will significantly affect their projected costs

[226] Pacific Gas and Electric Rehearing Request at 2.

[227] *Id.* (citing Order No. 841, 162 FERC ¶ 61,127 at P 325 (To the extent that the host distribution utility is unable—due to a lack of the necessary metering infrastructure and accounting practices—or unwilling to net out any energy purchases associated with a resource using the participation model for electric storage resources' wholesale charging activities from the host customer's retail bill, the RTO/ISO would be prevented from charging that resource using the participation model for electric storage resources electric wholesale rates for the charging energy for which it is already paying retail rates.)).

[228] *Id.* at 2–3.

[229] California Energy Storage Alliance Rehearing Request at 2; CAISO Rehearing Request at 11.

[230] California Energy Storage Alliance Rehearing Request at 2 (citing Order No. 841, 162 FERC ¶ 61,127 at P 298); CAISO Rehearing Request at 11 (citing Order No. 841, 162 FERC ¶ 61,127 at P 298).

[231] California Energy Storage Alliance Rehearing Request at 2 (citing Order No. 841, 162 FERC ¶ 61,127 at 297); CAISO Rehearing Request at 11 (citing Order No. 841, 162 FERC ¶ 61,127 at P 297).

[232] California Energy Storage Alliance Rehearing Request at 2–3.

[233] CAISO Rehearing Request at 5–6, 11–13 (citing *Cal. Indep. Sys. Operator Corp.,* 132 FERC ¶ 61,211 (2010); *Reform of Generator Interconnection Procedures and Agreements,* 157 FERC ¶ 61,212, at PP 226–230 (2017)).

[234] *Id.* at 5–6, 11–13.

[235] *Id.* at 12 (citing *Cal. Indep. Sys. Operator Corp.,* 132 FERC ¶ 61,211 (2010)).

[236] *Id.* (citing *Reform of Generator Interconnection Procedures and Agreements,* 157 FERC ¶ 61,212 at PP 226–230).

[237] *Id.* at 5.

[238] *Id.* at 5, 11.

[239] *Id.* at 12–13 (referencing *Utilization of Electric Storage Resources for Multiple Services When Receiving Cost-Based Rate Recovery,* 158 FERC ¶ 61,051 (2017)).

in competitive solicitations, as well as how the resource intends to recover those costs.[240]

117. EEI seeks clarification and Xcel Energy Services seeks rehearing of the Commission's finding in Order No. 841 that it may be appropriate, on a case-by-case basis, for distribution utilities to assess a charge on electric storage resources similar to those assessed to the market participant in *PJM Interconnection LLC.* They explain that, in *PJM Interconnection LLC,* the Commission permitted the distribution utility to establish a wholesale distribution rate that was based on the carrying charges associated with the distribution facilities that would be used to provide wholesale distribution service to a particular electric storage resource. According to EEI and Xcel Energy Services, a customer-specific methodology for assessing wholesale distribution charges may no longer be appropriate when there are a large number of distribution-connected electric storage resources participating in the wholesale markets.[241] EEI further argues that it would be unduly burdensome to require a distribution utility to establish a separate, facility-specific rate for each individual electric storage resource's use of the distribution system,[242] while Xcel Energy Services contends that establishing such rates would involve significant regulatory development and filing costs and could even be unworkable given that the distribution system is periodically reconfigured based on system conditions.[243]

118. Therefore, EEI seeks clarification on what the Commission meant by ''case-by-case basis,'' stating that the Commission should not dismiss as per se unreasonable a proposal to establish a non-facility-specific rate for wholesale distribution service to charging load.[244] Similarly, Xcel Energy Services asks the Commission to grant rehearing of its decision to permit wholesale distribution charges on only a ''case-by-case basis'' and permit more generic wholesale distribution rates or tariffs.[245]

c. Commission Determination

119. We deny Pacific Gas and Electric's request to clarify that states have jurisdiction to determine how power flowing from the distribution grid into the electric storage resource located behind the customer meter is split between retail consumption and wholesale charging for later discharge into the wholesale markets. In the final rule, the Commission noted that it found that the sale of energy from the grid that is used to charge electric storage resources for later resale into the energy or ancillary service markets constitutes a sale for resale in interstate commerce; as such, the just and reasonable rate for that wholesale sale of energy used to charge that electric storage resource is the RTO/ISO market's wholesale LMP.[246] However, we reiterate that the Commission's finding regarding charging energy did not address payment of the retail rate for energy. Thus, Order No. 841 does not authorize electric storage resources to bypass retail rates for its on-site electricity consumption, as Pacific Gas & Electric suggests.[247]

120. In response to CAISO's arguments, we acknowledge that the participation of electric storage resources in RTO/ISO markets may convey a range of benefits, particularly under certain system conditions, but we cannot conclude based on the record before us that an electric storage resource charging when it is economic to do so necessarily constitutes the provision of a service in the RTO/ISO markets, though it may provide a service in some specific circumstances. Thus, we decline to grant clarification that charging pursuant to economic dispatch always qualifies as a service. However, we clarify that services do not need to be limited to ancillary services; they could include any service defined in an RTO/ISO tariff. To the extent that an RTO/ISO seeks to create a new service that would involve charging pursuant to economic dispatch under certain system conditions, the RTO/ISO may propose such revisions to its tariff through a separate FPA section 205 filing.[248]

121. We also grant clarification of the Commission's finding in paragraph 297 that applicable transmission charges should apply when an electric storage resource is charging to resell energy at a later time. In response to the concerns of CAISO and California Energy Storage Alliance, we clarify that, in paragraph 297 of the final rule, the Commission's use of the phrase ''applicable transmission charges'' was intended to convey that an RTO/ISO may propose to apply its existing rate structure for transmission charges to an electric storage resource that is charging at wholesale but is not being dispatched by the RTO/ISO to provide a service in the RTO/ISO markets. Thus, each RTO/ISO may on compliance propose that any electric storage resource that is charging at wholesale but is not being dispatched by the RTO/ISO to provide a service should be assessed charges consistent with how the RTO/ISO assesses transmission charges to wholesale load under its existing rate structure. We further clarify that, if an RTO/ISO proposes not to apply transmission charges to an electric storage resource that is charging at wholesale but is not being dispatched by the RTO/ISO to provide a service, then the RTO/ISO must demonstrate that exempting such a resource from these charges is reasonable given its existing rate structure for transmission charges.

122. We find that CAISO's request for clarification that electric storage resources participating as transmission resources, as described in the Commission's Policy Statement,[249] should not incur transmission charges for charging demand is premature because CAISO has not yet filed a proposal to allow electric storage resources to provide transmission or reliability services under the Policy Statement. We find that it is appropriate to address CAISO's concerns related to resources that might seek to recover their costs through both regulated transmission rates and the wholesale markets in the context of a specific proposal involving resources that provide multiple services and seek to recover their costs through both cost-based and market-based rates concurrently. We therefore deny clarification that such resources should not incur transmission charges for charging demand and decline to address CAISO's concerns here.

123. In response to concerns regarding the Commission's finding that it may be appropriate, on a case-by-case basis, for distribution utilities to assess a charge on electric storage resources similar to those assessed to the market participant in *PJM Interconnection L.L.C.,*[250] we grant EEI's requested clarification. Specifically, we clarify that the Commission will not dismiss as per se unreasonable any proposal to establish a non-facility-specific rate for wholesale distribution service to an electric storage resource for its charging. Rather, the Commission will consider any proposal

[240] *Id.* at 13.

[241] EEI Rehearing Request at 12; Xcel Energy Services Rehearing Request at 27–28.

[242] EEI Rehearing Request at 12.

[243] Xcel Energy Services Rehearing Request at 29.

[244] EEI Rehearing Request at 11–12.

[245] Xcel Energy Services Rehearing Request at 28, 30.

[246] Order No. 841, 162 FERC ¶ 61,127 at P 294.

[247] *See id.* PP 323–324.

[248] *See* 16 U.S.C. 824d.

[249] *See Utilization of Electric Storage Resources for Multiple Services When Receiving Cost-Based Rate Recovery,* 158 FERC ¶ 61,051.

[250] *See* Order No. 841, 162 FERC ¶ 61,127 at P 301 (citing *PJM Interconnection L.L.C.,* 149 FERC ¶ 61,185 at P 12, *order on reh'g,* 151 FERC ¶ 61,231 at PP 16–18).

to establish a rate for providing wholesale distribution service to an electric storage resource for its charging (whether a facility-specific rate, a wholesale distribution service rate that applies to all or some subset of electric storage resources, a generally applicable wholesale distribution service tariff, or any other rate mechanism) on a case-by-case basis in light of the record evidence. Accordingly, we find that Xcel Energy Services' request for rehearing of this issue is moot.

2. Metering and Accounting Practices for Charging Energy

a. Final Rule

124. To help implement the new requirement in § 35.28(g)(9)(ii) of the Commission's regulations, in Order No. 841, the Commission required each RTO/ISO to implement metering and accounting practices as needed to address the complexities of implementing the requirement that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets be at the wholesale LMP.[251] To this end, the Commission required each RTO/ISO to directly meter electric storage resources, so all the energy entering and exiting the resources is measured by that meter. However, the Commission recognized that some electric storage resources (such as those located on a distribution system or behind a customer meter) may be subject to other metering requirements that could be used in lieu of a direct metering requirement by an RTO/ISO. Therefore, the Commission stated that it will consider, in the individual RTO/ISO compliance filings, alternative proposals that may not entail direct metering but nonetheless address the complexities of implementing the requirement that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets be at the wholesale LMP.

125. The Commission was not persuaded by commenters who argued that developing metering practices that distinguish between wholesale and retail activity is impractically complex.[252] The Commission noted that CAISO provided two examples of how it has achieved market rules that accurately account for wholesale and retail activities by using direct metering. Additionally, the Commission stated that retail metering infrastructure, which is subject to state jurisdiction, may be able to work in concert with the RTO/ISO requirements to lower the overall metering costs for electric storage resources. Therefore, the Commission provided each RTO/ISO with the flexibility to propose in its compliance filing other reasonable metering solutions that may help reduce costs for developers.

126. The Commission further found that developing new accounting practices for electric storage resources in response to this requirement will be complex, but nonetheless found that they are feasible to develop.[253] The Commission recognized that it may be beneficial for each RTO/ISO to coordinate accounting requirements in cooperation with the distribution utilities and RERRAs in its footprint to help identify workable accounting solutions for distribution-interconnected or behind-the-meter electric storage resources to participate in the RTO/ISO markets. The Commission also found that metering and accounting rules may need to differ based on whether the resource is located on the transmission system, the distribution system, or behind the meter.

127. As a related matter, the Commission found that electric storage resources should not be required to pay both the wholesale and retail price for the same charging energy because doing so would create market inefficiencies due to the double payment.[254] Therefore, the Commission required each RTO/ISO to prevent electric storage resources from paying twice for the same charging energy. The Commission stated that, to the extent that the host distribution utility is unwilling or unable—due to a lack of the necessary metering infrastructure and accounting practices—to net out any energy purchases associated with an electric storage resource's wholesale charging activities from the host customer's retail bill, the RTO/ISO would be prevented from charging that resource electric wholesale rates for the same charging energy that it is already paying for through retail rates.

128. Finally, the Commission stated that it was not persuaded by commenters' suggestion that electric storage resources must choose to participate in either wholesale or retail markets due to the complexity of the metering and accounting practices.[255] The Commission found that it is possible for electric storage resources that are selling retail services also to be technically capable of providing wholesale services, and it would adversely affect competition in the RTO/ISO markets if these technically capable resources were excluded from participation.

b. Requests for Rehearing or Clarification

129. Several petitioners request rehearing or clarification with respect to Order No. 841's requirements related to metering and accounting practices. First, CAISO requests that the Commission clarify or, in the alternative, grant rehearing that the RTO/ISO does not need to be the entity that directly meters electric storage resources. CAISO explains that it is a common and useful practice in RTOs/ISOs for third parties, such as a scheduling coordinator, to perform the metering, validation, estimation, and editing to submit settlement quality meter data to the RTO/ISO, which the RTO/ISO then ensures is accurate. CAISO argues that a requirement for the RTO/ISO to be the sole entity directly metering electric storage resources is inconsistent with previous precedent, inconsistent with RTOs'/ISOs' current just and reasonable metering practices, and unnecessarily restrictive for electric storage resources and RTOs/ISOs.[256]

130. With respect to Order No. 841's requirement that, to the extent that the host distribution utility is unable or unwilling to net out any energy purchases associated with an electric storage resource's wholesale charging activities from the host customer's retail bill, the RTO/ISO may not charge that resource for the charging energy for which it is already paying retail rates, CAISO states that it is unclear what constitutes a utility that is unwilling or unable to net out wholesale charging energy from an electric storage resource's total demand. Therefore, CAISO asks the Commission to clarify or, in the alternative, grant rehearing that an RTO/ISO could require verification from the host distribution utility that it is unable or unwilling to

[251] *Id.* P 322.

[252] *Id.* P 323.

[253] *Id.* P 324.

[254] *Id.* P 326. Paragraph 326 of the preamble of Order No. 841 used the term ''resources using the participation model for electric storage resources'' with respect to the requirements set forth therein (*e.g.,* ''we require each RTO/ISO to prevent resources using the participation model for electric storage resources from paying twice for the same charging energy''). However, § 35.28(g)(9)(ii) of the Commission's regulations (as modified by Order No. 841), which these requirements are intended to implement, specifies that it applies to electric storage resources. Thus, the Commission used the incorrect term in paragraph 326 of Order No. 841. In this order, we use the correct term throughout.

[255] *Id.* P 325.

[256] CAISO Rehearing Request at 6–8 (citing *Cal. Indep. Sys. Operator Corp.,* Docket No. ER17–949–000 (Mar. 31, 2017) (delegated order)).

net wholesale demand from retail settlement before the RTO/ISO ceases to settle an electric storage resources' wholesale demand at the wholesale LMP. CAISO contends that this clarification is especially critical for electric storage resources that are located on the distribution system or behind the meter and participating in the CAISO market because they may be providing services to other entities.[257]

131. Relatedly, CAISO asks the Commission to clarify or, in the alternative, grant rehearing that, when an RTO/ISO cannot verify that the host distribution utility is unable or unwilling to net wholesale demand from retail settlement, the RTO/ISO can either (1) require the electric storage resource to use a participation model designed for retail customer participation (such as demand response) or (2) continue settling the electric storage resource's charging demand at the wholesale LMP. According to CAISO, this clarification is necessary because prohibiting certain electric storage resources from having their demand settled at the wholesale LMP (1) will require new participation models, modeling, and software upgrades; (2) could materially affect how that resource bids, potentially distorting the market; and (3) could negatively affect the host utility distribution company's settlement charges, in the form of unaccounted for energy, for example.[258]

132. Both TAPS and Xcel Energy Services request rehearing of the Commission's decision in Order No. 841 to decline to require electric storage resources located on the distribution system or behind the meter to participate exclusively either in the wholesale markets or at retail.[259] Xcel Energy Services contends that it is difficult to see how an RTO/ISO can differentiate between the wholesale and retail activities of an electric storage resource located on the distribution system or behind the meter without compelling entities that are not Commission jurisdictional, such as loads and distribution utilities, to provide information on their sales to and purchases from such a resource.[260]

133. TAPS states that, to ensure that an electric storage resource that is located on the distribution system or behind the meter does not ''improperly evade the distribution utility's retail service'' through its participation in the RTO/ISO markets, the Commission must ensure that any energy that such resources purchase from the RTO/ISO markets is resold.[261] TAPS further argues that allowing an electric storage resource located on the distribution system or behind the meter to participate both in the wholesale markets and at retail could provide its owner with the opportunity to simultaneously purchase energy at retail and sell energy to the wholesale market at a higher price, thus shifting costs to other retail customers without ever changing the physical State of Charge of its electric storage resource.[262]

134. According to TAPS, normal revenue-quality metering is inadequate to address these concerns because it requires knowledge of two separate energy level balances (one for wholesale energy and one for retail energy) rather than simply the total energy balance. TAPS contends that maintaining and auditing a system to track this information would be complicated and expensive.[263] TAPS adds that the market rules in CAISO that the Commission claimed accurately account for wholesale and retail activities do not address the issues that TAPS has identified.[264]

135. Similarly, Xcel Energy Services argues that the Commission's reliance on CAISO's market rules to support its decision not to preclude electric storage resources located on the distribution system or behind the meter from participating both in the wholesale markets and at retail was misplaced. Specifically, Xcel Energy Services contends that CAISO's market rules do not provide for tracking retail purchases, retail sales, wholesale purchases, and wholesale sales all at the same time, and thus they do not allow an RTO/ISO to distinguish between the wholesale and retail activities of electric storage resources located on the distribution system or behind the meter that seek to participate in its markets. Xcel Energy Services states that, instead, CAISO's market rules only account for resources that are selling exclusively at wholesale or at retail at a given point in time (as opposed to providing services at wholesale and at retail during the same time period). According to Xcel Energy Services, CAISO's market rules also fail to account for multiple resources and retail loads behind a single meter. Xcel Energy Services adds that, even if CAISO's market rules were sufficient, they do not support a finding that other RTOs/ISOs, whose member utilities all have their own requirements for metering, billing systems, and other supporting software and Information Technology (IT) platforms, could necessarily adopt them.[265]

136. Finally, TAPS also argues that the Commission's decision on TAPS's proposal to require distribution-connected electric storage resources to choose between wholesale and retail participation was premature given that the issues that TAPS raised are within the scope of the distributed energy resource aggregation-related issues which the Commission determined in Order No. 841 that it did not have sufficient information to act upon. Therefore, TAPS argues that the Commission should have deferred its decision until after the technical conference in Docket No. RM18–9–000.[266]

137. EEI asks the Commission to clarify that it is the responsibility of the electric storage resource located on the distribution system or behind the meter to pay for any metering or other costs associated with distinguishing between its wholesale and retail activities; if they are not given that responsibility, then EEI argues that the entire load can and should be treated as retail load. EEI contends that this clarification reflects the statement in Order No. 841 that the finding regarding charging energy does not address payment of the retail rate for energy or charging a device off of co-located generation resources.[267]

c. Commission Determination

138. As an initial matter, we clarify, in response to CAISO, that the RTO/ISO itself does not need to be the entity that directly meters electric storage resources. We also grant CAISO's request to clarify that an RTO/ISO could require verification from the host distribution utility that it is unable or unwilling to net wholesale demand from retail settlement before the RTO/ISO ceases to settle an electric storage resource's wholesale demand at the wholesale LMP. While Order No. 841 stated that each RTO/ISO must prevent electric storage resources from paying twice for the same charging energy,[268] it did not specify how each RTO/ISO must implement this requirement. Therefore, we clarify that the Commission will consider on compliance each RTO's/

[257] *Id.* at 9–11.

[258] *Id.* at 10–11.

[259] TAPS Rehearing Request at 12; Xcel Energy Services Rehearing Request at 17, 20.

[260] Xcel Energy Services Rehearing Request at 20.

[261] TAPS Rehearing Request at 13.

[262] *Id.* at 14.

[263] *Id.* at 14–15.

[264] *Id.* at 15 (citing Order No. 841, 162 FERC ¶ 61,127 at P 318).

[265] Xcel Energy Services Rehearing Request at 17–20.

[266] TAPS Rehearing Request at 16–17.

[267] EEI Request for Rehearing and Clarification at 12 (citing Order No. 841, 162 FERC ¶ 61,127 at P 299).

[268] Order No. 841, 162 FERC ¶ 61,127 at P 326.

ISO's proposal to identify whether a distribution utility is unable or unwilling to net out from a host customer's retail bill the wholesale energy purchases associated with charging an electric storage resource that is participating in the RTO/ISO market from the host customer's retail bill.

139. However, we deny CAISO's request for clarification or, in the alternative, rehearing that when an RTO/ISO cannot verify the host distribution utility's inability or unwillingness to net out wholesale charging energy, the RTO/ISO can require the electric storage resource to use a participation model designed for retail customer participation. In Order No. 841, the Commission stated that each RTO/ISO must prevent electric storage resources from paying twice for the same charging energy.[269] While the Commission provided flexibility with respect to how each RTO/ISO implements that requirement, we find it inappropriate for an RTO/ISO to meet that requirement by requiring an electric storage resource to use a participation model designed for retail customer participation. Consistent with Order No. 841, we reiterate that, to the extent that the host distribution utility is unable or unwilling to net out any energy purchases associated with a resource using the participation model for electric storage resources' wholesale charging activities from the host customer's retail bill, the RTO/ISO must determine how it will prevent an electric storage resource participating in its markets from being charged wholesale rates for charging energy for which it already is paying retail rates.[270]

140. We deny TAPS' and Xcel Energy Services' requests for rehearing regarding the Commission's decision to decline to require electric storage resources to choose to participate exclusively in either wholesale or retail markets due to the complexity of the metering and accounting practices. While we agree with TAPS and Xcel Energy Services that appropriate metering and accounting practices will be necessary to distinguish between wholesale and retail activity, we disagree that these practices would be prohibitively complex or costly to develop and implement given the flexibility provided to the RTOs/ISOs to propose reasonable approaches.[271] As the Commission stated in Order No. 841, retail metering infrastructure also may be able to work in concert with the RTO/ISO requirements to lower the overall metering costs.[272]

141. Further, TAPS and Xcel Energy Services argue that CAISO's metering and accounting practices are insufficient to allow for the implementation of Order No. 841's requirement that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets be at the wholesale LMP. Therefore, TAPS and Xcel Energy Services argue that the Commission's reliance on these practices as evidence that establishing such metering and accounting practices is possible is misplaced. We disagree. The Commission relied on CAISO's metering and accounting practices to demonstrate that direct metering for behind-the-meter resources can remove barriers to their participation in RTO/ISO markets, not necessarily as an example of metering and accounting that would comply with the requirements of the final rule. Moreover, in Order No. 841, the Commission chose not to prescribe particular metering and accounting practices that each RTO/ISO must adopt, instead providing flexibility for each RTO/ISO to develop practices that reflect its unique market rules and its member utilities' requirements for metering, billing systems, and other supporting software and IT platforms.

142. TAPS also argues that the Commission's decision not to require electric storage resources to choose to participate exclusively in either wholesale or retail markets will allow resources using the participation model for electric storage resources to evade the distribution utility's retail service or simultaneously buy electricity at the retail rate and sell it at the wholesale LMP. While we acknowledge these concerns, we believe that each RTO/ISO can address these issues by developing its metering and accounting requirements in cooperation with the distribution utilities and RERRAs in its footprint, as the Commission recognized in Order No. 841.[273] In addition, we note that, when the Commission stated in Order No. 841 that the sale of electric energy from the RTO/ISO markets to an electric storage resource that the resource then resells back to those markets be at the wholesale LMP, it was referring to the sale of energy from the grid that is used to charge electric storage resources for later resale into the energy or ancillary service markets.[274] To the extent that TAPS has concerns that a particular RTO's/ISO's proposed metering and accounting practices do not address these issues, TAPS may raise these concerns in response to the RTO's/ISO's compliance filing.

143. Finally, we disagree with TAPS' contention that the Commission should have deferred action on this issue until after the technical conference in Docket No. RM18–9–000. The technical conference in Docket No. RM18–9–000 focused on issues relating to distributed energy resource aggregations, while Order No. 841 addresses the participation of non-aggregated electric storage resources in RTO/ISO markets. We find that the Commission had sufficient record evidence before it to determine whether to require electric storage resources to choose to participate exclusively in either wholesale or retail markets, regardless of its decision to gather more information with respect to its proposals to remove barriers to the participation of distributed energy resource aggregations in RTO/ISO markets in Docket No. RM18–9–000.[275]

144. In response to EEI, we decline to clarify whether an electric storage resource located on the distribution system or behind the meter is responsible for paying for any metering or other costs associated with distinguishing between its wholesale and retail activities. While EEI contends that its requested clarification relates to the Commission's statement in Order No. 841 that its finding regarding charging energy does not address payment of the retail rate for energy or charging a device off of co-located generation resources, Order No. 841 did not establish any requirement with respect to which entity should bear the costs of metering. Therefore, we find that this issue is outside the scope of this proceeding.

III. Compliance Requirements

A. Final Rule

145. In the final rule, the Commission required each RTO/ISO to file the tariff changes needed to implement the requirements of Order No. 841 within 270 days of the publication date of Order No. 841 in the **Federal Register**.[276] The Commission also allowed each RTO/ISO a further 365 days from that date to implement the tariff provisions. The Commission found that, given the modifications and clarifications to the NOPR made in Order No. 841, particularly the omission of the reforms relevant to distributed energy resource aggregations, and the

[269] *Id.*

[270] *Id.*

[271] *See id.* PP 323–324.

[272] *Id.* P 323.

[273] *Id.* P 324.

[274] *Id.* P 294.

[275] *Id.* P 5.

[276] *Id.* P 348.

record in this proceeding in support of the reforms that the Commission finalized therein, the implementation schedule was reasonable.[277]

146. Additionally, the Commission noted that many of the RTOs/ISOs already have rules in place to enable the participation of electric storage resources in their markets.[278] The Commission further stated that the additional time that it provided for the RTOs/ISOs to make their compliance filings, along with the ability of the RTOs/ISOs to use existing tariff provisions to demonstrate compliance with aspects of the final rule, would mean that the RTOs/ISOs can meet the deadlines established therein. Finally, the Commission noted that it was allowing regional flexibility to the extent possible throughout the final rule, which it believed would assist the RTOs/ISOs in meeting the compliance and implementation deadlines.

B. Requests for Rehearing or Clarification

147. MISO, AMP/APPA/NRECA, and EEI raise issues relating to the relationship between the implementation of Order No. 841 and the Commission's decision therein to defer consideration of its proposals with respect to the participation of distributed energy resource aggregations in RTO/ISO markets. Both AMP/APPA/NRECA and EEI assert that, because some electric storage resources may be distributed energy resources, and a single electric storage resource may constitute a distributed energy resource aggregation, many of the issues raised at the technical conference in Docket No. RM18–9–000 are applicable to electric storage resources located on the distribution system or behind the meter.[279] They contend that it is unclear how the Commission can reasonably adopt final rules governing the participation of electric storage resources located on the distribution system or behind the meter in RTO/ISO markets while finding that additional information is needed prior to allowing distributed energy resource aggregations, which can include electric storage resources, to participate in those same markets.[280]

148. MISO asks the Commission to grant rehearing of the compliance date and extend Order No. 841's implementation timetable by at least six months with respect to matters that affect the potential participation of electric storage resources as distributed energy resources in RTO/ISO markets.[281] Moreover, MISO contends that it wishes to avoid devoting significant effort and expense to develop software and system adjustments to address the participation of distribution-connected electric storage resources, which may be significantly impacted by a final rule in Docket No. RM18–9–000.[282] According to MISO, the cost and time needed to ''ensure the synergy of [electric storage resource] and [distributed energy resource]-related software changes are likely to be significant.'' [283] Therefore, MISO ask the Commission to further adjust the implementation timeframe for Order No. 841 if necessitated by any electric storage-resource related requirements in a final rule in Docket No. RM18–9–000.[284]

149. To ensure consistency, AMP/APPA/NRECA ask the Commission to clarify that the wholesale market participation by electric storage resources located on a distribution system or behind a retail meter will be subject to any final rule in Docket No. RM18–9–000.[285] Likewise, EEI asks the Commission to clarify that rules on the participation in the RTO/ISO markets of electric storage resources located on the distribution system or behind the meter should be informed by the discussion in Docket No. RM18–9–000.[286] Both AMP/APPA/NRECA and EEI also ask the Commission to determine that the RTO/ISO tariff revisions related to electric storage resources located on a distribution system or behind a retail meter made in compliance with Order No. 841 will not become effective until the effective date of the RTO/ISO tariff revisions related to distributed energy resource aggregations made in compliance with any final rule in Docket No. RM18–9–000.[287]

150. Xcel Energy Services contends that the Commission offered no evidence in Order No. 841 explaining why it chose a period of 270 days for each RTO/ISO to submit a compliance filing and a further 365 days to implement the tariff revisions proposed therein.[288] Xcel Energy Services argues that Order No. 841's inflexible compliance schedule appears inconsistent with other provisions in in Order No. 841 that acknowledge that each RTO/ISO will have to revise its tariff in a manner that recognizes the unique physical and operational characteristics of their markets and the effects of integrating electric storage resources.[289] Xcel Energy Services adds that, while the Commission acknowledged that the tariff revisions could require significant work on the part of the RTOs/ISOs, it did not explain what that significant work would encompass, the expected timeframe for completion, or why a longer time period may not be necessary to comply.[290] Xcel Energy Services also contends that implementing Order No. 841 will require IT systems that tie together transmission and distribution systems, along with wholesale and retail markets and metering. Thus, Xcel Energy Services asks the Commission to grant rehearing to permit RTO/ISOs to propose their own implementation schedules that more appropriately reflect the unique characteristics of their systems.[291]

151. Xcel Energy Services also asks the Commission to grant rehearing to require RTOs/ISOs to collaborate with distribution utilities to develop a cost recovery mechanism for distribution utility upgrades and improvements required to implement Order No. 841.[292] Xcel Energy Services argues that, for distribution utilities, Order No. 841's implementation costs are disproportionate to the benefits they will receive, given that the beneficiaries of Order No. 841 are the RTO/ISO markets and their market participants.[293] Xcel Energy Services argues that, under FPA section 205, the costs that the distribution utilities incur must be commensurate with the benefits that they receive.[294] Xcel Energy Services argues that Order No. 841 will burden distribution utilities and their ratepayers because they will need to harden the underlying distribution system to support bidirectional power flows and pay for substantial metering upgrades for electric storage resources.[295] Xcel Energy Services adds that IT improvements to allow electric storage resources to engage in retail and wholesale transactions and to

[277] *Id.* P 349.

[278] *Id.* P 350.

[279] APPA/NRECA Rehearing Request at 16; EEI Rehearing Request at 10.

[280] APPA/NRECA Rehearing Request at 16; EEI Rehearing Request at 11.

[281] MISO Rehearing Request at 13.

[282] *Id.* at 9–10.

[283] *Id.* at 11.

[284] *Id.* at 11, 13.

[285] AMP/APPA/NRECA Rehearing Request at 17.

[286] EEI Rehearing Request at 11.

[287] AMP/APPA/NRECA Rehearing Request at 17; EEI Rehearing Request at 11.

[288] Xcel Energy Services Rehearing Request at 21.

[289] *Id.* at 21.

[290] *Id.* at 22 (citing Order No. 841, 162 FERC ¶ 61,127 at P 343).

[291] *Id.* at 22.

[292] *Id.* at 24–25.

[293] *Id.* at 22–23.

[294] *Id.* at 23 (citing *Ill. Commerce Comm'n* v. *FERC,* 576 F.3d 470, 477 (7th Cir. 2009); *El Paso Elec. Co.* v. *FERC,* 832 F.3d 495, 506 (5th Cir. 2016) (explaining that the Commission ''need only roughly correlate costs to benefits'')).

[295] *Id.* at 23–24.

communicate with the RTO/ISO and distribution utility will be costly and will be of comparatively little benefit to distribution ratepayers and their utility.[296]

152. AES Companies ask the Commission to clarify that Order No. 841's compliance timeframe aligns with the Commission's compliance directive in Docket No. EL17–8–000.[297] AES Companies explain that, on February 1, 2017, the Commission issued an order [298] in Docket No. EL17–8–000 granting in part and denying in part a complaint filed by Indianapolis Power & Light Company, a member of AES Companies.[299] AES Companies explain that the Commission found in the February 1 Order that MISO's tariff ''unreasonably restricts competition by preventing electric storage resources from providing all the services that they are technically capable of providing, which could lead to unjust and unreasonable rates.'' [300] AES Companies note that the Commission required MISO to submit a compliance filing proposing tariff revisions, within 60 days of the date of that order.[301] AES Companies therefore ask the Commission to clarify the scope and timing of MISO's existing compliance obligation resulting from the February 1 Order, given that Order No. 841's requirements are similar to the compliance directive that the Commission issued in the February 1 Order.[302]

153. If the Commission determines that Order No. 841's requirements supersede the tariff changes that the Commission directed in the February 1 Order, such that MISO need not comply with the directives of the February 1 Order until the implementation date for Order No. 841's requirements, AES Companies argue that the Commission should direct MISO to examine and asses any modifications to its business practice manuals or software that could accommodate existing, presently-interconnected electric storage resources. AES Companies further ask the Commission to direct MISO to submit quarterly informational filings describing these efforts.[303]

C. Commission Determination

154. We deny the rehearing requests that seek to change the compliance deadlines established in Order No. 841. We continue to find that the timeline for compliance and implementation is reasonable.[304] Moreover, in establishing Order No. 841's compliance and implementation schedule, the Commission indicated that it was already ''[t]aking into account that the Commission is not implementing the distributed energy resource aggregation reforms [proposed in the NOPR] at this time. . . .'' [305] Also, because we find that Order No. 841's compliance timeframe is reasonable, we will not allow the individual RTOs/ISOs to propose their own timeframes.

155. We also decline to adjust the compliance timeframe to consider matters that affect distributed energy resources. In Order No. 841, the Commission found that more information was needed with respect to certain proposed reforms related to distributed energy resource aggregations and decided to continue to explore those proposed reforms in a separate proceeding in Docket No. RM18–9–000.[306] While Order No. 841 addresses the participation model for non-aggregated electric storage resources participating directly in the RTO/ISO markets, the proceeding in Docket No. RM18–9–000 involves issues related to RTO/ISO market rules for distributed energy resources participating through aggregations. Thus, no topic addressed in Docket No. RM18–9–000 limits the ability of the RTOs/ISOs to move forward with implementation of Order No. 841, and we do not find that it is necessary to delay the implementation of the reforms for electric storage resources located on the distribution system or behind the meter in Order No. 841 pending the outcome of the proceeding on distributed energy resource aggregations in Docket No. RM18–9–000.

156. Additionally, we deny Xcel Energy Services' request for rehearing regarding a cost recovery mechanism for distribution utility upgrades and improvements required to implement Order No. 841. The requirements of Order No. 841 apply to the RTOs/ISOs, not distribution utilities, and therefore this request is outside the scope of this proceeding. As stated in Order No. 841, we are not changing the responsibilities of the distribution utilities or their ability to allocate any costs that they incur in operating and maintaining their respective power systems.[307]

157. We find that AES Companies' concerns regarding the February 1 Order are moot. Since AES Companies requested rehearing in this docket, the Commission has issued orders [308] addressing these rehearing requests and MISO's compliance obligations in that separate proceeding. Any concerns AES Companies may have regarding MISO's compliance obligations in that separate proceeding are appropriately addressed in that proceeding and accordingly the Commission will not consider them here.

IV. Document Availability

158. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

159. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number of this document, excluding the last three digits, in the docket number field.

160. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

List of Subjects in 18 CFR Part 35

Electric power rates, Electric utilities.

Issued: May 16, 2019.

Kimberly D. Bose,

Secretary.

In consideration of the foregoing, the Commission amends part 35, chapter I, title 18 of the *Code of Federal Regulations* as follows:

[296] *Id.* at 24.

[297] AES Companies Rehearing Request at 1–2.

[298] *Indianapolis Power & Light Co.* v. *Midcontinent Indep. Sys. Operator, Inc.,* 158 FERC ¶ 61,107 (2017) (February 1 Order).

[299] AES Companies Rehearing Request at 2.

[300] *Id.* (citing February 1 Order, 158 FERC ¶ 61,107 at P 69).

[301] *Id.* at 2–3 (citing February 1 Order, 158 FERC ¶ 61,107 at P 72).

[302] *Id.* at 4–5.

[303] *Id.* at 5–6.

[304] Order No. 841, 162 FERC ¶ 61,127 at P 349.

[305] *Id.* P 348. *See also id.* P 349 (noting that some commenters provided feedback on the NOPR indicating that acting on only the electric storage components would expedite compliance and implementation).

[306] *Id.* P 5.

[307] *Id.* P 274.

[308] *Indianapolis Power & Light Co.* v. *Midcontinent Indep. Sys. Operator, Inc.,* 162 FERC ¶ 61,266 (2018); *Midcontinent Indep. Sys. Operator, Inc.,* 164 FERC ¶ 61,109 (2018).

PART 35—FILING OF RATE SCHEDULES AND TARIFFS

■ 1. The authority citation for part 35 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

■ 2. In § 35.28, paragraph (g)(9)(i)(B) is revised as follows:

§ 35.28 Non-discriminatory open access transmission tariff.

* * * * *

(g) * * *

(9) * * *

(i) * * *

(B) Enables a resource using the participation model for electric storage resources to be dispatched and ensures that such a dispatchable resource can set the wholesale market clearing price as both a wholesale seller and wholesale buyer consistent with rules that govern the conditions under which a resource can set the wholesale price;

* * * * *

[FR Doc. 2019–10742 Filed 5–22–19; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL REGISTER

Vol. 84 Thursday,
No. 100 May 23, 2019

Part V

Department of Homeland Security

8 CFR Parts 103 and 214
Adjusting Program Fees for the Student and Exchange Visitor Program; Final Rule

DEPARTMENT OF HOMELAND SECURITY

8 CFR Parts 103 and 214

[DHS No. ICEB–2017–0003]

RIN 1653–AA74

Adjusting Program Fees for the Student and Exchange Visitor Program

AGENCY: U.S. Immigration and Customs Enforcement (ICE), Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This rule adjusts the Student and Exchange Visitor Program (SEVP) school certification petition fees and the application fees for nonimmigrants seeking to become academic (F visa) or vocational (M visa) students, or exchange visitors (J visa). The rule sets the following fees: $3,000 for a school certification petition; $655 for each school site visit; $1,250 to submit a school recertification petition; and $675 to submit an appeal or motion following a denial or withdrawal of a school petition. The rule also sets new fees for filing the Form I–901 at $350 for each F or M nonimmigrant student applicant and a $220 for most J exchange visitor applicants; however, the existing $35 fee for each J nonimmigrant exchange visitor seeking admission as an au pair, camp counselor, or summer work/travel program participant will remain the same. All fee payments addressed in this final rule must be made in the amounts established by this rule beginning June 24, 2019.

DATES: This final rule is effective June 24, 2019.

FOR FURTHER INFORMATION CONTACT: Sharon Snyder, Unit Chief, Student and Exchange Visitor Program; U.S. Immigration and Customs Enforcement, Department of Homeland Security; 500 12th Street SW, Washington, DC 20536; 703–603–3400, *sevp@ice.dhs.gov.* This is not a toll-free number. Program information can be found at *http://www.ice.gov/sevis/.*

SUPPLEMENTARY INFORMATION:

Table of Contents

Table of Abbreviations and Acronyms

ABC Activity Based Cost/Costing
CFO Chief Financial Officer
CTCEU Counterterrorism and Criminal Exploitation Unit
DHS Department of Homeland Security
DOS Department of State
DSO Designated School Official
EBSVERA Enhanced Border Security and Visa Entry Reform Act of 2002, Pub. L. 107–173; May 14, 2002
FASAB Federal Accounting Standards Advisory Board
FISMA Federal Information Security Management Act
Form I–17 Petition for Approval of School for Attendance by Nonimmigrant Student
Form I–901 Fee Remittance for Certain F, J and M Nonimmigrants
Form I–290B Notice of Appeal or Motion
HSPD–2 Homeland Security Presidential Directive–2
ICE U.S. Immigration and Customs Enforcement
IEFA Immigration Examinations Fee Account
IIRIRA Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as amended
INA Immigration and Nationality Act of 1952, as amended
MD Management Directive
NEPA National Environmental Policy Act of 1969
NPRM Notice of Proposed Rulemaking
OMB Office of Management and Budget
PDSO Principal Designated School Official
RFA Regulatory Flexibility Act
SEVIS Student and Exchange Visitor Information System
SEVP Student and Exchange Visitor Program
SFFAS FASAB Statement of Federal Financial Accounting Standard
UMRA Unfunded Mandates Reform Act of 1995
USCIS U.S. Citizenship and Immigration Services

I. Executive Summary

A. Purpose of Regulatory Action

The Department of Homeland Security (DHS) is adjusting its fee schedule for nonimmigrant students and exchange visitors as well as for petitioning and certified schools. These fees are associated with SEVP and the Student and Exchange Visitor Information System (SEVIS). They were last adjusted in 2008. *See* 73 FR 55683 (Sept. 26, 2008).

SEVP, an ICE component, is funded entirely by fees charged to individual applicants and organizational petitioners. Fees collected from individuals and organizations are deposited into the Immigration Examinations Fee Account (IEFA) and used to fund the operational costs associated with SEVP and its management of SEVIS. *See* Immigration and Nationality Act (INA) section 286(m), as amended, 8 U.S.C. 1356(m), and Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as amended, (IIRIRA) section 641(e), (g), 8 U.S.C. 1372(e), (g).

In accordance with the requirements and principles of the Chief Financial Officers Act of 1990, 31 U.S.C. 901–903 (CFO Act), and the Office of Management and Budget (OMB) Circular A–25, SEVP reviews its associated fees that are deposited into the IEFA biennially and, if necessary, proposes adjustments to ensure recovery of costs necessary to meet national security, customer service, and adjudicative processing goals. SEVP completed a biennial fee review for

fiscal year (FY) 2016 and FY 2017 in 2017. The projected results indicated that fee levels were insufficient to recover the full cost of current and planned program activities. Section 286(m) of the INA, 8 U.S.C. 1356(m), provides that DHS may set fees for adjudication and naturalization services at a level that would ensure recovery of the full costs of providing such services, including the costs of providing similar services without charge to asylum applicants and certain other immigrants. Additionally, section 641 of IIRIRA, 8 U.S.C. 1372, authorizes DHS to periodically revise fees that cover the cost of carrying out SEVP and maintenance of SEVIS. Pursuant to these laws, DHS is implementing the adjustments contained in this rule.

SEVP has calculated the totality of its operating costs to set fees that fully recover such costs. Following its biennial fee review, SEVP anticipated that if it continued to operate at previous fee levels, it would experience a revenue shortfall. At previous fee levels, SEVP's expenditures exceeded revenues, without any service upgrades. The deficit had been covered by surplus revenue that was previously accumulated from 2009 to 2015. As a consequence of multiple factors, including inflation, costs associated with SEVIS enhancement, complying with a two-year recertification cycle of schools, increased demand for program and investigatory services, and increased litigation related to administrative enforcement and regulatory actions, the surplus is expected to be exhausted in FY 2019 even without any further service upgrades. The projected shortfall poses a risk of degrading operations and services funded by fee revenue. The fee increases in this final rule will allow SEVP to cover the current deficit between revenue and expenditures plus make necessary service upgrades. The fee levels thus eliminate the risk of degrading operations, while also ensuring full cost recovery by providing fees for each specific benefit that will more adequately recover the cost associated with administering the benefit.

B. Summary of Major Provisions of the Final Rule

This rule adjusts, institutes, and clarifies the application of fees pertaining to services SEVP provides to reflect existing and projected operating costs, program requirements, and continued planned program improvements, in the following manner:

- Increases the two types of individual nonimmigrant student and exchange visitor application fees, specifically the F and M fee for Form I–901, ''Fee Remittance for Certain F, J and M Nonimmigrants,'' to $350 and the Form I–901 Full J fee to $220;
- Increases the SEVP school certification petition fee for initial certification to $3,000;
- Imposes a fee of $1,250 when a school files a petition for recertification of its existing SEVP certification;
- Imposes a $675 fee to accompany the filing of a Form I–290B, Notice of Appeal or Motion, when a school appeals or files a motion to reconsider or reopen a denial or withdrawal of its SEVP certification; and
- Maintains the $655 fee for a site visit at its current level, but clarifies that, with the effective date of the rule, SEVP is exercising its current regulatory authority to charge the site visit fee when a certified school changes its physical location or adds a new physical location or campus on its Form I–17, Petition for Approval of School for Attendance by Nonimmigrant Student.

In making these changes, the rule allows SEVP to fully fund activities included in this cost model and institute critical near-term program and system enhancements in a more equitable manner through a fairer balance of the recovery of SEVP operational costs between beneficiary classes. A summary of the current and future fee structures is provided in Table 1 below.

C. Costs and Benefits

With this final rule, SEVP will adjust fees to the amounts listed in Table 1:

Table 1: Current and Final Fee Amounts

Fee Type	Current Fee	Final Fee	Incremental Fee Adjustment
I-901 F/M	$200	$350	$150
I-901 J-Full	$180	$220	$40
I-901 J-Partial	$35	$35	$0
I-17 Initial Certification	$1,700	$3,000	$1,300
I-17 Recertification	$0	$1,250	$1,250
Site Visit – initial	$655	$655	$0
Site Visit – new location	$0	$655	$655
Appeal Fee	$0	$675	$675

SEVP expects to have a total annual increase in fees of $75.2 million in FY 2019 transferred from individuals and entities for the services they receive. Table 2 shows the summary of the total annual number of payments, incremental fee amounts, and total fees projected for FY 2019. This increase in fees will allow SEVP to not only maintain its current level of service but also enhance SEVP's capability to support national security and counter immigration fraud through the continued development and implementation of critical system and programmatic enhancements. Enhancements to SEVIS, including the establishment of a student portal, will assist designated school officials (DSOs) in their regulatory obligation to provide accurate and timely information and will also rebalance this reporting requirement by providing students an automated means to update their information. Increased numbers of adjudication personnel will assist in reducing the processing times for initial petitions, updates, and recertifications, while enhanced vetting protocols will ensure that only those nonimmigrant students who are eligible to enter and remain in the country do so.

Table 2: Annual Final Incremental Fee Amounts, FY 2019

	Projected Number of Payments	Final Incremental Fee Amounts	Annual Incremental Fees Transfer to Government
I-901 F and M	418,393	$150	$62,758,950
I-901 J-Full	157,550	$40	$6,302,000
I-17 Initial Certification	426	$1,300	$553,800
I-17 Recertification	4,373	$1,250	$5,466,250
Site Visits – initial	426	$0	$0
Site Visits – new location	174	$655	$113,970
Appeals	54	$675	$36,450
Total			$75,231,420

II. Background

A. The 2018 NPRM and Purpose of the Rule

On July 17, 2018, DHS published a Notice of Proposed Rulemaking (NPRM) to amend the fees charged by SEVP. 83 FR 33762. This final rule implements those proposed changes by amending DHS regulations governing the fees charged by SEVP to F and/or M nonimmigrant students, schools that enroll such students, and fees charged to J nonimmigrant exchange visitors.

SEVP helps ensure the integrity of the U.S. immigration system by collecting, maintaining, and analyzing information so only legitimate nonimmigrant students and exchange visitors gain admission into the United States under these programs, and by ensuring that the institutions accepting them are certified and follow the rules that govern them. The information collected by SEVP and compliance investigations conducted on students and educational institutions support other law enforcement activities within ICE.

The rule adjusts the SEVP school certification fee and implements a recertification fee, increases student and exchange visitor application fees (Form I–901 fees), and imposes a fee for a Form I–290B filed with SEVP, to reflect existing program operating costs, program requirements, and planned program enhancements. DHS maintains the fee for an initial school site visit at the current level, but clarifies that, with the effective date of the rule, DHS will exercise its current regulatory authority to charge the site visit fee not only when a certified school changes its physical location, but also when it adds a new physical location or campus. The rule sets the fee for an initial school certification petition at $3,000 and the fee for each site visit at $655. It sets a $1,250 fee for a school recertification petition and a $675 fee to submit an appeal or motion following a denial or withdrawal of a school certification. Further, it sets the fee for each F or M student at $350. The rule sets the fee for certain J exchange visitors at $220 and maintains the fee for exchange visitors seeking admission as au pairs, camp counselors, and summer work/travel program participants at $35. All fee payments addressed in this final rule must be made in the amounts established by this rule beginning June 24, 2019.

These fee adjustments are driven by two factors: The need to comply with statutory and regulatory requirements that SEVP review its fee structure biennially to ensure that the cost of the services that are provided by SEVP are captured by fees assessed on those receiving the services, and the need to enhance SEVP's capability to achieve current programmatic goals to support national security and counter immigration fraud through the development and implementation of critical system and programmatic enhancements. Enhancements to SEVIS, including the establishment and further expansion of a student portal, will assist designated school officials (DSOs) in their regulatory obligation to provide accurate and timely information and will also rebalance this reporting requirement by providing students an automated means to update their information. ICE continues to examine programmatic goals and refine its cost projection model. Future fee reviews may capture additional includable costs, such as additional enforcement costs generated by SEVP information or compliance investigations.

The rule ensures the full recovery of SEVP operational costs in a manner that fairly allocates costs between beneficiary classes and facilitates the development of activities designed to achieve defined program goals. These include new initiatives critical to improving homeland security through enhanced vetting of SEVIS users, increased adjudication personnel, and SEVIS modernization.

B. Authority To Collect Fees

The Secretary is specifically authorized to collect fees for SEVP from prospective F and M nonimmigrant students and J nonimmigrant exchange visitors, subject to certain limits for certain J–1 nonimmigrants. 8 U.S.C. 1372(e)(1). The Secretary is authorized to periodically revise those fees, with certain exceptions, to take into account changes in the overall cost of carrying out the program. IIRIRA section 641(e)(4)(A), (g)(2), 8 U.S.C. 1372(e)(4)(A), (g)(2). Similarly, section 286(m) of the INA authorizes the Secretary to collect fees for adjudication and naturalization services at a level that would ensure recovery of the full costs of providing such services, including the costs of providing similar services without charge to asylum applicants and certain other immigrants. Additionally, pursuant to INA section 286(m), the level that is set may include recovery of any additional costs associated with the administration of the fees themselves. Under this authority, user fees are employed not only for the benefit of the payer of the fee and any collateral benefit resulting to the public, but also to provide a benefit to certain others.[1]

[1] DHS has interpreted section 286(m), including its authorization for DHS to collect ''full costs'' for providing ''adjudication . . . services,'' as granting DHS broad discretion to charge fees at a level that will ensure recovery of *all* direct and indirect costs associated with providing pertinent immigration adjudication services. This interpretation is also consistent with the SEVP-specific fee authority referenced above, which authorizes DHS to set fees

All fees collected under these authorities are deposited as offsetting receipts into the IEFA and remain available to the Secretary until expended for authorized purposes. *See* IIRIRA section 641(e)(4)(B), 8 U.S.C. 1372(e)(4)(B); INA section 286(m), 8 U.S.C. 1356(m). DHS is implementing the fee schedule contained in this rule in accordance with the above-referenced authorities.

As a general matter, in developing fees and fee rules, DHS looks to a range of governmental accounting provisions, including OMB Circular A–25, User Charges (revised). *See* 58 FR 38142 (July 15, 1993). Section 6 of OMB Circular A–25 defines ''full cost'' to include all direct and indirect cost to any part of the federal government for providing a good, resource, or service. For the purposes of this rulemaking, DHS considers ''full cost'' to mean the cost of all activities related to individual and organizational compliance issues within the jurisdiction of SEVP that DHS included in the cost model. These activities include the cost of investigating the compliance of schools participating in SEVP and exchange visitor programs, as well as investigations in which F, M, or J nonimmigrants are identified as potential threats to national security or where it is suspected that an immigration violation or fraud may be occurring. DHS also considers OMB Circular A–11, Preparation, Submission and Execution of the Budget, section 51.13 (June 29, 2018), which states that budget requests should reflect the results of the biennial review of existing user charges and of the potential for establishing user charges, under OMB Circular A–25. This final rule adjusts fees in order to recover the cost of services provided by SEVP.

In addition, DHS considers the Federal Accounting Standards Advisory Board (FASAB) Statement of Federal Financial Accounting Standards (SFFAS) No 4: Managerial Cost Accounting Concepts and Standards for the Federal Government, July 31, 1995, updated June 2018, which provides federal government standards regarding managerial cost accounting and full cost recovery. SFFAS No. 4 defines ''full cost'' to include ''direct and indirect costs that contribute to the output, regardless of funding sources.'' [2] FASAB identifies various classifications of costs to be included and recommends various methods of cost assignment to identify full cost. Activity-based costing (ABC) is highlighted as a costing methodology useful to determine full cost within an agency. The Chief Financial Officers Act of 1990, 31 U.S.C. 901–903, requires each agency's Chief Financial Officer (CFO) to ''review, on a biennial basis, the fees, royalties, rents and other charges imposed by the agency for services and things of value it provides, and make recommendations on revising those charges to reflect cost incurred by it in providing those services and things of value.'' 31 U.S.C. 902(a)(8). This final rule reflects consideration of these federal sector financial and accounting standards.

III. Adjustment of SEVP Fees

A. Basis for Fee Schedule

As discussed in the NPRM, the new fees are based on estimates of funding needed to maintain and enhance SEVP's capability to achieve programmatic goals associated with its statutory mandate, including supporting national security and countering immigration fraud through the continued development and implementation of critical system and programmatic enhancements. This rule establishes the following fee structure detailed in Table 3.

Table 3: Fee Structure

Fee Type	Responsible Party
I-901 Fee	Student or exchange visitor issued an initial Form I-20 or DS-2019 seeking an F, M, or J visa
I-17 School Certification Fee	Institutions petitioning for SEVP certification to enroll international students
Site Visit Fee	Institutions applying for initial certification or certified schools changing locations or adding a campus/location
I-17 School Recertification Fee	Certified institutions seeking recertification every two years
Appeal or Motion Fee	Institutions that have had certification or recertification denied by SEVP, including denied I-17 updates, or that have had certification withdrawn, and which are filing an appeal or motion regarding the SEVP decision

The current fee structure includes the Form I–901 fee, I–17 school certification fee, and the site visit fee. By introducing fees for other services, this final rule allows SEVP to fully fund activities included in the cost model and institute critical near-term program and system enhancements in a more equitable manner. The new fee structure also includes the addition of a recertification fee and a fee for filing an appeal or motion.

With this rule, SEVP imposes a fee for filing an appeal using Form I–290B that is similar to the current fee for appeals

at a level that funds the full cost of conducting the program. *See* IIRIRA section 641(e), 8 U.S.C. 1372(e). The longstanding interpretation of DHS is that the ''including'' clause in section 286(m) does not constrain DHS's fee authority under the statute. The ''including''' clause offers only a non-exhaustive list of some of the costs that DHS may consider part of the full costs of providing adjudication and naturalization services. *See* 8 U.S.C. 1356(m); 81 FR 26903, 26906 n.10 (May 4, 2016).

[2] *See* FASAB, Statement of Federal Financial Accounting Standards 4: Managerial Cost Accounting Standards and Concepts 26 (June 2018), *http://files.fasab.gov/pdffiles/handbook_sffas_4.pdf* (last visited Oct. 26, 2018).

filed with U.S. Citizenship and Immigration Services (USCIS) using Form I–290B. *See* 8 CFR 103.7(b)(1)(i)(S) (listing the fee for appealing a decision over which the Board of Immigration Appeals does not have appellate jurisdiction). DHS also eliminates regulations that currently state there is no fee required for an appeal by a school, to maintain consistency and to more fairly balance allocation of the recovery of SEVP operational costs between beneficiary classes. Under this final rule, SEVP charges the fee for all appeals and motions.

This rule ensures the recovery of SEVP operational costs in a manner that fairly allocates costs between beneficiary classes and facilitates the development of activities designed to achieve defined program goals. For example, the rule continues funding for critical SEVIS modernization efforts and incorporates the added cost of increased analytical support for investigative operations into the Form I–901 fee. The fee schedule will provide the necessary revenue for SEVP to fund approximately 20 additional SEVP adjudication personnel, including approximately 15 new frontline adjudicators. The additional adjudicators are intended to cover site visits which are authorized under a 2016 final rule,[3] augment out -of -cycle review teams, and reduce times for recertifications, updates, and initial applications.

B. SEVP Baseline Costs and Fees

SEVP fees are paid by individuals and organizations. DHS certifies schools that enroll F and M students; recertifies schools with active certifications; conducts site visits; administers, maintains, and develops SEVIS; collects fees from prospective F and M nonimmigrant students and J nonimmigrant exchange visitors, as well as from schools; adjudicates motions and appeals in regard to certification petitions; undertakes investigatory initiatives; and provides overall guidance to schools about program enrollment and compliance, as well as the use of SEVIS. These activities are funded solely through the collection of fees.

The Form I–901 fee, collected from students and exchange visitors, currently underwrites the operation of SEVP; the cost of administering, maintaining, and developing SEVIS; the cost of school recertification; and all activities related to individual and organizational compliance issues within the jurisdiction of SEVP. These activities include the cost of investigating the compliance of schools participating in SEVP and exchange visitor programs, as well as investigations in which F, M, or J nonimmigrants are identified as potential threats to national security or where it is suspected that an immigration violation or fraud may be occurring.

The certification fee is paid by schools that petition for the authority to issue Certificates of Eligibility (COE), commonly referred to as Forms I–20, to prospective nonimmigrant students for the purpose of their applying for F or M visas and admission to the United States in those statuses. These monies fund the base internal cost for SEVP to process and adjudicate the initial school certification petition (Form I–17). The recertification fee paid by schools to remain certified partially funds the cost of adjudicating the recertification petition.

If SEVP finds that a petitioning or certified school does not meet regulatory standards, it will deny the affected school's Form I–17 or withdraw its SEVP certification. 8 CFR 214.4. When SEVP sends a school a notice of denial or withdrawal, the notice also includes reasons for the unfavorable decision(s), an explanation of the school's rights, and the applicable appeal and motion filing information and deadlines. In many cases, a school may file an appeal or motion to reopen and/or reconsider unfavorable decisions issued by SEVP by filing the Form I–290B pursuant to the process set forth in 8 CFR 103.3(a) or 103.5(a).[4] A school may initiate a motion to reopen or reconsider to request that the original deciding body review the unfavorable decision, including an appeals decision, pursuant to requirements in 8 CFR 103.5(a). A school may also initiate an appeal in order to request review of the unfavorable Notice of Denial, Automatic Withdrawal, or Withdrawal on Notice by an authority independent of the original deciding body. Currently, DHS uses Form I–901 funds to offset the costs of SEVP appeals and motions. As noted in the proposed rule, DHS believes that the introduction of an appeal fee will result in a more equitable distribution of costs. Although DHS declined to introduce such a fee in 2008, DHS believes that given the costs of the appeal process and the increase in the I–901 fee, it is appropriate to establish an appeal fee at this time. With this rule, DHS removes the SEVP-related exceptions to the payment of the Form I–290B fee and adds regulatory text at 8 CFR 103.7(b)(1)(ii)(O) providing for the fee of $675 when the Form I–290B is filed with SEVP. This fee applies when schools or institutions file an appeal or motion with regard to a denied petition for initial certification or recertification or a withdrawal of certification.

With these regulatory changes for the Form I–290B filing fee, DHS more fairly balances allocation of the recovery of SEVP operational costs among beneficiary classes. To date, the cost of adjudicating appeals and motions has never been placed directly upon the beneficiaries of those adjudications—the schools seeking to obtain or maintain SEVP certification. The fee for filing the Form I–290B with SEVP is set at a level that requires those who file the Form I–290B to pay for at least a portion of the operating expenses for DHS to adjudicate the Form I–290B, while preventing the fee from becoming cost-prohibitive.

The site visit fee is currently paid by schools that petition for certification to issue Forms I–20 or by a certified school when it physically moves to a new location. DHS established this fee in the 2008 Fee Rule and with that rule codified SEVP's authority to charge the fee when a school changes its physical location or adds a new physical location or campus. *See* 8 CFR 103.7(b)(3)(ii)(B), 8 CFR 214.3(h)(3)(i), (ii). Specifically, the 2008 Fee Rule imposed a site visit fee of $655 for each location listed on the Form I–17, and required the Form I–17 to include ''any physical location in which a nonimmigrant can attend classes through the school (*i.e.,* campus, extension campuses, satellite campuses, etc.).'' *See* 73 FR 55683, 55698–55699 (amending 8 CFR 103.7(b)(3)(ii)(B) and 214.3(a)(1), respectively). The 2008 Fee Rule also imposed a continuing duty on schools to update school locations as changes arise, *i.e.,* even after initial certification, a school must update SEVIS within 21 days of a change to a range of information types, including school location and campus location. *See* 73 FR 55683, 55700 (amending 8 CFR 214.3(g)(2), (h)(3)). Consistent with the aforementioned regulatory amendments, the preamble to the 2008 Fee Rule made clear that these provisions require the imposition of a site visit fee for each location listed on the initial SEVP certification, as well as each location added as part of an initial event, such as a SEVIS update requesting approval of a changed or new location or campus. 73 FR 55683, 55691.

SEVP will begin collecting the fee when a certified school adds a new physical location or campus following

[3] *See* 81 FR 13039 (Mar. 11, 2016).

[4] Form I–290B is managed by USCIS and not ICE. USCIS has agreed to the use of the form by ICE for SEVP appeals and the use has been approved by OMB under control number 1615–0095.

the effective date of this final rule. The site visit fee applies when a certified school updates its Form I–17 in SEVIS to indicate, pursuant to 8 CFR 214.3(h)(3)(ii), it is changing its physical location or adding a new physical location or campus. This revenue assists in recovering the costs DHS incurs for site visits of these locations, including collecting evidence on school eligibility for certification, reviewing the facilities, and interviewing personnel nominated on the petition to become DSOs, including the person nominated to be the Principal Designated School Official (PDSO).

C. Methodology

SEVP captured and allocated cost using an ABC approach to define full cost with regards to current SEVP activities and planned enhancements, outline the sources of SEVP cost, and define the fees. The ABC approach also provides detailed information on the cost and activities allocated to each fee.

1. ABC Approach

SEVP used CostPerform ABC modeling software, Version 9.3 (0147), to determine the full cost associated with updating and maintaining SEVIS to collect and maintain information on F, M, and J nonimmigrants; certifying schools; overseeing school compliance; recertifying schools; adjudicating appeals; investigating suspected violations of immigration law and other potential threats to national security by F, M, or J nonimmigrants; providing outreach and education to users; and performing regulatory and policy analysis. SEVP also used the model to identify management and overhead costs associated with the program.

ABC is a business management methodology that links inputs (cost) and outputs (products and services) by quantifying how work is performed in an organization (activities). The ABC methodology allows fee-funded organizations to trace service costs and to calculate an appropriate fee for the service, based on the cost of activities associated with the services for which the fee is levied.

Using the ABC methodology, SEVP identified and defined the activities needed to support SEVP functions to include current and future initiatives. SEVP captured the full cost of operations for current activities and planned enhancements and apportioned that full cost to the appropriate program activities. The full cost of each activity is then assigned to the appropriate fee category based on the nature of the activity, as described further below. By tracking costs to the various fee categories, SEVP was able to use forecasted payments to determine the appropriate fee amount for each fee type. SEVP examined historical data and performed statistical payment analysis to forecast payments in future years.

SEVP used an independent contractor and commercially available ABC software to compute the fees. The structure of the software was tailored to SEVP needs for continual and real-time fee review and cost management.

2. Full Cost

In building the ABC model, it was critical for SEVP to identify the sources and cost for all elements of the program, including all activities related to individual and organizational compliance issues within the jurisdiction of SEVP. These activities include the cost of investigating the compliance of schools participating in SEVP and exchange visitor programs, as well as investigations in which F, M, or J nonimmigrants are identified as potential threats to national security or where it is suspected that an immigration violation or fraud may be occurring. Consistent with instructive legislative and regulatory guidance, SEVP fees recoup the full cost of providing SEVP's overall resources and services.[5] The amended fees are calculated to recoup the cost of current SEVP operations, including planned enhancements detailed in the NPRM.

To the extent applicable, SEVP used the cost accounting concepts and standards recommended in the FASAB Handbook, Version 15, ''Statement of Financial Accounting Standards Number 4, Managerial Cost Accounting Concepts and Standards for the Federal Government'' (2016). FASAB Standard Number 4 sets the following five standards as fundamental elements of managerial cost accounting: (1) Accumulate and report cost of activities on a regular basis for management information purposes, (2) establish responsibility segments and match the cost of each segment with its outputs, (3) determine the full cost of government goods and services,[6] (4) recognize the costs of goods and services provided among federal entities, and (5) use appropriate costing methodologies to accumulate and assign costs to outputs.

SEVP calculates projected fees using the full cost of SEVP current activities and planned enhancements, as defined by a regularly updated spend plan. The projected spend plans for FY 2019 and FY 2020 were used in calculation of SEVP's new fee structure. Tables 4 through 7 detail the full cost of SEVP operations, consistent with the spend plan, from various perspectives: By program category, by cost initiative, by fee type, and by activity.

As with the previous fee adjustment in 2008, the goal of ICE compliance efforts is to achieve full compliance with F, M, and J nonimmigrant regulations by institutions participating in these programs and to prevent any abuse of SEVP for criminal purposes. Through consistent and expanded enforcement of SEVP requirements, the integrity of the F, M, and J nonimmigrant student and exchange visitor programs within the United States is better maintained. ICE continues to examine programmatic goals and refine its cost projection models. Future fee reviews may capture additional includable costs, such as additional enforcement costs for activities resulting from SEVP information or related compliance investigations.

[5] These include but are not limited to: Direct and indirect personnel cost, including salaries and fringe benefits, such as medical insurance and retirement; retirement cost, including all (funded or unfunded) accrued cost not covered by employee contributions, as specified in OMB Circular A–11; overhead, consulting, and other indirect cost, including material and supply cost, utilities, insurance, travel, as well as rents or imputed rents on land, buildings, and equipment; management and supervisory cost; and cost of enforcement, collection, research, establishment of standards, and regulation.

[6] Full cost includes the costs associated with resources that directly or indirectly contribute to the output and supporting services within the entity and from other entities.

3. Cost Basis for SEVP Fees Based on Current Services

The FY 2019 and FY 2020 budgets provide the cost basis for the fees. These budgets reflect the required revenue to sustain current initiatives. The revenue is also assessed to ensure a sufficient level of continued funding for program enhancements as discussed above, such as enhanced vetting and investigative analysis to support enforcement operations, SEVIS modernization, and increased numbers of adjudication personnel. Finally, the past budgets provide the cost basis for adjusting annualized cost-of-living increases.

Determining the projected cost for continuation of current efforts involved routine budget projection processes. The budget establishes the current services of the program and projects the mandatory and cost-of-living adjustments necessary to maintain current services. The budget adjusts the services provided by SEVP to include enhancements that reflect program policy decisions. Table 4 reflects the FY 2017 final budget, the FY 2018 approved budget, and the FY 2019 and FY 2020 planned budget requests.

BILLING CODE 9111–28–P

Table 4: Student and Exchange Visitor Program Summary of Requirements by Organization and Program Category (Dollars in thousands)

SEVP Expenses	2017 Spend Plan	2018 Spend Plan	2019 Spend Plan	2020 Spend Plan
SEVP Payroll				
Full-Time Equivalent Personnel	134	175	221	221
Executive Office	$1,735	$1,744	$2,048	$2,084
Fee Management Section	$1,350	$1,597	$1,775	$1,806
Field Representative Unit	$6,480	$6,958	$7,641	$7,776
Policy Section	$1,178	$969	$1,283	$1,325
Systems Management Unit	$1,258	$1,299	$1,391	$1,416
SEVP Response Center Section	$652	$652	$931	$941
School Certification Unit	$2,993	$2,966	$3,291	$3,349
SEVP Analysis and Operations Section	$1,070	$1,226	$1,402	$1,388
New Required Positions	-	$296	$2,357	$5,610
Office of the Principal Legal Advisor	$328	$517	$642	$659
SEVP Outside Positions	$1,444	$1,776	$2,544	$2,629
Total SEVP Payroll	**$18,488**	**$20,000**	**$25,305**	**$28,983**
Program Expenses				
Advisory and Assistance Services	$58,630	$58,108	$52,755	$50,977
SEVIS (Modernization and O&M)*	$8,237	$18,722	$22,240	$21,912
Interagency Agreements with other agencies	$8,046	$9,815	$8,360	$8,583
Travel	$1,474	$1,500	$1,100	$1,100
Service-wide Costs	$3,222	$4,015	$2,400	$2,400
Total Program Expenses	**$79,609**	**$92,160**	**$86,855**	**$84,972**
CTCEU / Domestic Operations				
Personnel Costs	$43,299	$42,285	$43,251	$43,251
Contract Costs	$9,767	$19,605	$20,166	$20,166
GE Costs	$4,585	$2,843	$1,316	$1,316
Relevant Direct Costs	$9,549	$9,717	$9,717	$9,717
Total CTCEU/ Domestic Operations Expenses	**$67,200**	**$74,450**	**$74,450**	**$74,450**
Total, SEVP	**$165,297**	**$186,610**	**$186,610**	**$188,405**

*includes costs for the SEVIS Modernization and SEVIS Operations and Maintenance

D. Summary of the Full Cost Information

The total cost projection for FY 2019 is $186,610,000 and for FY 2020 is $188,405,000. Table 4 sets out the projected current services for SEVP and supporting Counterterrorism and Criminal Exploitation Unit (CTCEU) and HSI Domestic Operations personnel in FY 2019 ($74.45 million) and FY 2020 ($74.45 million). These costs are direct extensions of the FY 2018 costs that are supported by the current fees. Table 5 summarizes the enhancements and other costs, which include investigative analysis, SEVIS Modernization, increased numbers of adjudication personnel, and annualized inflation.

Table 5: FY 2018, FY 2019 and FY 2020 SEVP Cost by Initiative

Program Cost by Initiative	FY 2018 Budgeted Cost (thousands)	FY 2019 Budgeted Cost (thousands)	FY 2020 Budgeted Cost (thousands)
Program Base:			
SEVP (Current operational costs)	$95,097	$94,497	$95,106
CTCEU / Domestic Operations (Current operational costs)	$70,200	$70,200	$70,200
Subtotal	**$165,297**	**$164,697**	**$165,306**
Enhancements and Other Costs:			
Investigative Analysis Support	$4,250	$4,250	$4,250
SEVIS Modernization	$13,150	$13,750	$13,141
Increased Personnel	$1,100	$1,100	$3,500
Annualized Inflation	$2,813	$2,813	$2,208
Subtotal	**$21,313**	**$21,913**	**$23,099**
TOTAL:	**$186,610**	**$186,610**	**$188,405**

1. Fee Allocation

The purpose of the ABC methodology is to trace costs to organizational elements, as well as identify all cost components associated with the services offered. For fee-based organizations such as SEVP, this allows the assignment of cost to one or more fees. SEVP defined five fee categories: The Form I–901 fee, certification fee, recertification fee, fee for filing an appeal or motion, and site visit fee.

Recently SEVP has only collected fees from students and exchange visitors—the Form I–901 fee—and from schools applying for certification, to include a separate site visit fee. In this analysis, SEVP considered the creation of additional fee categories for all the distinct services it provides in deciding how to apportion fees. For example, SEVP considered charging a separate Form I–901 fee to F, M, and J dependents. SEVP also examined various tiered fee structures and considered assigning some specific costs to separate fees. The ABC fee model allowed SEVP to evaluate these scenarios for services provided directly by SEVP. DHS opted for an updated fee structure that segments program cost to the appropriate fee—F and M nonimmigrant students, J nonimmigrant exchange visitors, or schools.

The adjusted Form I–901 fee recovers the systems cost for SEVIS, including the remainder of certification, recertification, site visits, as well as appeals and motions costs that are not covered by the respective new fees. The Form I–901 fee is apportioned between three categories—full fee of $350 for F and M students, reduced fee of $220 for most J participants, and the further reduced fee of $35 for certain J program participants. Federal Government-sponsored J program participants are fee-exempt by law, so their costs will be funded by other fee payers. 8 U.S.C. 1372(e)(3).

The adjusted school certification fee recovers a portion of the costs necessary to process initial school certifications. The new recertification fee recovers a portion of the cost to process school recertifications and a portion of SEVP administrative costs. The adjusted site visit fee recovers the full cost of performing the site visit upon initial school certification and when a school changes its physical location or adds a new physical location or campus. The new fee for filing an appeal or motion recovers a portion of the cost to process an appeal or motion. The remainder of these costs are covered by the adjusted Form I–901 fee as detailed in the preceding paragraph.

2. SEVP FY 2019 and FY 2020 Cost Model Results

Table 6 shows the summary of SEVP FY 2019 and FY 2020 cost by source of cost.

Table 6: Total SEVP FY 2019 and FY 2020 Cost by Fee Category

SEVP ABC Model Output Category	FY 2019 Budgeted Cost (thousands)	FY 2020 Budgeted Cost (thousands)
I-901 Fee	$156,989	$157,365
I-17 Certification Fee	$1,910	$1,993
I-17 Recertification Fee	$25,369	$26,458
Site Visit Fee	$386	$390
Appeal or Motion Fee	$1,956	$2,199
Total:	**$186,610**	**$188,405**

Table 7 shows a more detailed cost breakdown. The numbers are shown in thousands, rather than millions, of dollars due to the level of detail. There are two levels for the costs: Process and activity. Costs are allocated from payroll, contracts, and other expenses to activities through activity surveys and volume based cost allocations. The full cost of operations from the spend plans is distributed to the activities that best describe the work being performed. Table 7 details these costs from an activity perspective. To simplify the presentation, the numbers are rounded to the nearest thousand. These numbers are not rounded in the cost model.

[7] SEVP Automated Management System

Table 7: Detailed Cost Breakdown (FY 19 + FY 20, Dollars in Thousands)

Process	Activity	I-901	I-17 Certification	I-17 Re-certification	I-17 Site Visit	Appeal or Motion
Certify Schools	A-01: Certify schools (initial certification)		$3,115			
	A-02: Recertify schools			$4,614		
	A-03: Notify students if school is withdrawn			$129		
	A-04: Withdraw schools from SEVIS			$1,102		
	A-05: Process appeals/ motions					$3,420
	A-06: Process petition updates			$3,036		
	A-07: Monitor school compliance			$3,761		
	A-08: Monitor school risk			$3,446		
Secure Compliance with Regulations and Laws	A-28: Conduct Student and Exchange Visitor (I-901) investigations	$93,921		$16,574		
	A-29: Conduct school and sponsor investigations	$34,238		$6,042		
	A-30: Operate CTCEU programs	$4,130		$729		
	A-31: Provide CTCEU liaison support	$417		$74		
	A-41: Perform I-515 operations duties	$1,471				
	A-43: PDSO/DSO background checks	$1,038		$54		
Formulate Policy	A-16: Analyze and develop policy	$3,170		$600		
	A-17: Develop and review rules and regulations	$2,476		$469		
	A-18: Implement policy	$1,501		$284		
	A-19: Develop future policy strategy	$816		$154		
Provide Stakeholder Communications	A-11: Develop and deliver SEVP communications	$9,040	$118	$1,224	$24	$130
	A-12: Respond to stakeholders' policy and technical inquiries (including Tier III Help Desk)	$8,218				
	A-13: Provide Field Representative support	$13,731		$2,598		
	A-14: Prepare and attend conferences/ workshops related to the SEVIS community	$3,404	$62	$644	$13	$68
	A-15: Develop and conduct strategic communications	$2,699	$49	$511		

Process	Activity	I-901	I-17 Certification	I-17 Re-certification	I-17 Site Visit	Appeal or Motion
Provide Systems Program Management Support	A-20: Modify and enhance functionality of SEVP mission systems (e.g. SEVIS, SEVPAMS[7])	$24,816				
	A-21: Operate and maintain SEVP mission systems (e.g. SEVIS, SEVPAMS)	$28,491				
	A-22: Provide Tier I and Tier II Help Desk support	$12,814				
	A-23: Conduct systems program management	$5,291				
	A-24: Analyze and disseminate program data	$3,510	$46	$475	$9	$50
	A-25: Operate and maintain SEVP inter-office systems	$1,735	$32	$328		
Support SEVP Operations	A-26: Maintain SEVP systems security	$2,867	$37	$388		
	A-27: Maintain SEVP physical security	$223	$4	$42	$1	$4
	A-32: Provide Executive Leadership for SEVP	$2,539	$33	$344	$7	$36
	A-33: Provide SEVP administrative support	$1,599	$21	$217	$4	$23
	A-34: Develop strategic plan	$1,612	$29	$305	$6	$32
	A-35: Manage financial resources	$7,300	$95	$988	$20	$105
	A-36: Manage procurement	$1,886	$25	$256	$5	$27
	A-37: Manage personnel resources	$2,065	$27	$280	$6	$30
	A-38: Manage SEVP records	$3,274	$60	$619	$12	$66
	A-39: Manage facility resources	$1,782	$23	$241	$5	$25
	A-40: Manage I-901 payment system	$7,766				
	A-42: Manage I-901 J program	$15,966				
	A-44: Site Visits				$638	
Train SEVP staff, other staff, and DSOs	A-09: Develop and deliver SEVIS training	$5,936	$78	$803	$16	$85
	A-10: Develop and deliver internal training	$2,613	$48	$494	$10	$52
	Total	**$314,355**	**$3,902**	**$51,827**	**$775**	**$4,155**

3. Fee Calculations

The cost model provides detailed cost information by activity and a summary cost for each, giving the aggregate fee cost by category. Next, SEVP projected the total number of fee payments of each type for FY 2019 and FY 2020 and determined the fee-recoverable budget. SEVP selected a forecasting approach to determine the total number of expected fee payments for each fee.

a. Form I–901 Fee

To calculate fee amounts for the Form I–901 fee, SEVP estimated the number of fee payments expected in FY 2019 and FY 2020 for each of the three fee payment types: The reduced fee for J participants (excluding the additional cost for initial certification and recertification of SEVP-certified schools); the full fee for J participants (excluding the additional cost for initial certification and recertification of SEVP-certified schools); and the full fee for F and M nonimmigrant students (including additional costs for certification, recertification, and appeals). The total fee category budget is taken directly from the FY 2019 and FY 2020 SEVP ABC model, reflected in Table 8 and Table 9.

Table 8: I-901 F/M Fee-Recoverable Budget

Fiscal Year	I-901 F/M Payments Expected	Fee-Recoverable Budget
2019	418,393	$117,365,448
2020	407,933	$118,132,152
Total	826,326	**$235,497,600**

Table 9: I-901 J Fee-Recoverable Budget

Fiscal Year	I-901 J Payments Expected	Fee-Recoverable Budget
2019	316,495	$39,624,171
2020	312,556	$39,233,218
Total	629,052	$78,857,390

Form I–901 fees are calculated by dividing the fee-recoverable budget by the anticipated number of payments. This results in a fee-recoverable amount of $290 for all F and M payments and $130 for both the J Full and J Partial fees. Model results indicate a required fee of $290 before addition of additional costs of other fee types, discussed throughout the remainder of the document. Additional costs of subsidization of other SEVP fees results in a F/M fee of $350.

For reasons discussed below related to the $35 J-Partial fee, DHS must increase the J-Full fee by a proportional amount to cover the cost of operating the J program. This results in a J-Full fee of $220.Calculations for each of the three fee payment types vary because each fee type is treated differently in federal statutes and regulations. Section 641 of IIRIRA exempts Federal Government-sponsored J–1 nonimmigrant exchange visitors from the fee payment. Prior to this final rule, all F and M nonimmigrant students were required to pay $200, and nonexempt J nonimmigrant exchange visitors were required to pay $180. 8 CFR 103.7(b)(1)(ii)(H), 214.13(a). Congress modified the statute in December of 2000 to establish a reduced fee of $35 for au pairs, camp counselors, or participants in a summer work travel program, demonstrating strong congressional intent that the fee remain at that level. Act of Dec. 21, 2000, Public Law 106–553, app. B, sec. 110, 114 Stat. 2762, 2762A–51, 2762A–68. IIRIRA also provided for revising the fee once the program to collect information was expanded to include information collection on all F, M, and J nonimmigrants. As a result, the Form I–901 fee was revised in 2008 under the provisions of IIRIRA to take into account the actual cost of carrying out the program. *See* 73 FR 55683. The Form I–901 fee is now being revised a second time, through this rule, due to an increase in the actual cost of carrying out the program.

SEVP determined the number of expected Form I–901 fee payments in FY 2019 and FY 2020. SEVP calculated the Form I–901 fee over a 2-year period to account for potential fluctuation in the forecast. SEVP used the change in the numbers of payments received to provide the trend data used to forecast Form I–901 fee payments for each Form I–901 payment type separately. Table 10 reflects aggregate historical payment data for all three Form I–901 payment types.

Table 10: F, M, and J I-901 Payments 2007–2017

Fiscal Year	Total	Growth Rate*
2007	697,054	-
2008	753,065	8.0
2009	644,912	-14.4
2010	699,983	8.5
2011	749,082	7.0
2012	744,027	-0.7
2013	767,805	3.2
2014	829,636	8.1
2015	885,728	6.8
2016	866,623	-2.2
2017	796,820	-8.1
* Growth rate rounded to nearest tenth of a percent		

As indicated in Table 10, the level of payments received varied greatly over the past 10 years. This high degree of variation in the historical data, combined with the variables affecting demand for visas, called for a forecasting methodology that would capture and account for deviations.

SEVP selected a statistical forecasting method that uses trends in historical data to forecast future payments. SEVP selected ARIMA, an autoregressive integrated moving average model to forecast payments. An ARIMA model is a statistical model that uses historical time series data to predict future trends and movements. A non-seasonal model incorporates two major components: Trend and moving average. The autoregressive portion of the model, or trend, states that past values have an effect on current or future values and that values are estimated based on the weighted sum of past values. The second component is moving average which helps to smooth out the time series to filter out extreme fluctuations or outliers. In some cases, a third component is needed: Seasonality. Visa data from 2004 to the present shows extreme seasonality in the number of F, M, and J visas issued. Seasonality is factored into the model to account for the U.S. academic calendar.

SEVP evaluated alternative forecasting methods; however, SEVP rejected these methods due to inaccuracy, poor fit, and limited data. SEVP's chosen model provided a conservative forecast that will allow SEVP to operate with stability. The fee payment forecast, reflected in Table 11, places a balanced mix of emphasis on recent and historical data and still contains sufficient data points to smooth out some variability in the underlying data.

Table 11: Form I-901 Fee Payment Forecast FY 2019–FY 2020

I-901 Payment Type	FY 2019	FY 2020
Full Payments, F/M	418,393	407,933
Full payment, J-Full	157,550	153,612
Subsidized, J-Partial	158,945	158,945
TOTAL:	**734,888**	**720,490**

b. Certification Cost

SEVP uses historical data from FY 2012 to FY 2016 (Table 12) to find a three year moving average to forecast annual new initial certifications. SEVP predicts demand of approximately 426 initial certifications each year, which assumes the higher fee will not deter schools from applying for certification at a lower rate than the historical average. Historically, SEVP has used a forecasted increase in payments of approximately one percent annually due to the financial benefits schools derive from foreign student enrollment, but recent data on payments has led SEVP to apply a conservative zero percent growth.

Table 12: Three-Year Moving Average of the Number of School Certification Payments Received

Fiscal Year	Payments Received	3-Year Moving Average
2012	457	
2013	382	
2014	446	428
2015	469	432
2016	363	426

The total fee category budget is taken directly from the FY 2019 and FY 2020 SEVP ABC model, reflected in Table 13.

Table 13: FY 2019–FY 2020 Certification Fee-Recoverable Budget

Fiscal Year	Certification Payments Expected	Fee-Recoverable Budget
2019	426	$1,909,680
2020	426	$1,992,878
Total	**852**	**$3,902,558**

School certification fees are calculated by dividing the fee-recoverable budget by the anticipated number of payments. This results in a fee-recoverable amount from schools of $4,580 each. To arrive at the new fee, rounding was applied to the result of the fee algorithm. This results in a certification fee of $4,600 per school. Setting the certification fee at the $4,600 figure, however, leads to an increase of the current school certification fee by $2,900, resulting in a certification fee over twice the current fee amount. School certification is integral to SEVP—F and M nonimmigrant students can only attend SEVP-certified schools. While DHS is increasing the fee to ensure a more equitable distribution of costs, such a fee level could discourage potential new schools from seeking certification. At the same time, DHS considers that initial certification bestows upon the school a valuable asset, the ability to enroll F and M nonimmigrant students, and an increased fee amount is reasonable as the initial certification process becomes more extensive through the SEVIS modernization and other technological developments. Weighing these concerns, DHS decided to subsidize the Form I–17 school certification fee by increasing the payment by only $1,300 to $3,000. The remainder of the costs for Form I–17 school certification is subsidized by the Form I–901 F and M fee, which is addressed below.

c. Recertification Cost

To identify a fee level that would recover the full cost of recertification operations, SEVP determined the full cost of recertification (including level of effort and contract cost) and the approximate number of schools willing to recertify (Table 14). Because schools are required to recertify every two years, SEVP anticipates that approximately one-half of its certified schools—roughly 4,373 schools per year, given the current certified school population of 8,746—would recertify.

Table 14: FY 2019–FY 2020 Recertification Fee-Recoverable Budget

Fiscal Year	Recertification Payments Expected	Fee-Recoverable Budget
2019	4,373	$25,368,650
2020	4,373	$26,457,896
Total	**8,746**	**$51,826,546**

To calculate an anticipated school recertification fee, DHS divides the fee-recoverable budget by the anticipated number of payments. This results in a fee-recoverable amount from schools of $5,925.74 each. To arrive at the new fee, rounding was applied to the result of the fee algorithm. This resulted in a recertification fee of $6,000 per school. DHS desires to institute a recertification fee to more accurately assign the costs of recertification adjudication to those

stakeholders who are directly requesting the adjudication—the SEVP-certified schools—particularly since the costs of recertification continue to increase as the recertification process becomes more robust.

These increased costs are due to increased review of school records and other information submitted by schools as part of recertification to ensure that schools are remaining in compliance with all requirements. Ensuring compliance is a statutory requirement under EBSVERA that has been reaffirmed through the results of GAO audits and other Executive Branch reviews of SEVP operations. For example, as part of recertification, SEVP adjudicators independently verify state licenses, accreditation information, and other related information. SEVP is continuously trying to find ways to perform these checks more efficiently to reduce the burden. These reviews should become less burdensome as the modernization of SEVIS continues and more information becomes automated.

DHS considers that the recertification amount should be less than the initial certification amount so that schools are encouraged to seek recertification instead of allowing their SEVP certification to be withdrawn and applying for initial certification anew at some later date. Withdrawal of SEVP-certification not only leads to the school losing a valuable asset, but also leads to complications for F and M nonimmigrant students enrolled in the withdrawn school, who are then forced to transfer schools, leave the United States, or risk facing immigration law penalties for violating the terms of their nonimmigrant status. In such circumstances, the school may bear administrative costs to help students transfer to a certified school. Affected students bear costs as well. Weighing all these factors, DHS sets the Form I–17 recertification fee at $1,250. With this rule, DHS eliminates regulations that state that no fee is required for the school recertification process in order to recover part of this cost, as part of an effort to establish a more equitable distribution of costs and more sustainable level of cost recovery relative to services provided. The costs for Form I–17 school recertification not recovered by the new fee are subsidized by the Form I–901 F and M fee. The explanation for shifting responsibility of the fee adjustment to the Form I–901 fee is included below.

d. Site Visit Cost

Site visits consist of initial certification site visits, change of location visits, and new campus or location site visits (Table 15). The anticipated workload for these site visits is 600 per year, or 1,200 visits over a 2-year period.

Table 15: FY 2019–FY 2020 Site Visit Fee-Recoverable Budget

Fiscal Year	Site Visit Payments Expected	Fee-Recoverable Budget
2019	600	$385,674
2020	600	$389,689
Total	**1,200**	**$775,363**

The current fee amount is $655 as established in the 2008 Fee Rule that codified SEVP's authority to charge the fee when a school changes its physical location or adds new physical location or campus. Following this rule's effective date, SEVP will collect the fee when a certified school adds a new physical location or campus. Thus, in addition to the site fee(s) required upon initial certification, the site visit fee will now apply when a certified school updates its Form I–17 in SEVIS to indicate, pursuant to 8 CFR 214.3(h)(1)(ii), an added physical location or campus. The site visit fee is based on level of effort for both SEVP staff and contracts that cover the cost of operations.

e. Appeals and Motions Cost

Determining the full cost of processing an appeal is essential to improving the fee structure. The fee for filing an appeal or motion is calculated by determining the workload of appeals and motions over the FY 2019 and FY 2020 periods. Over the past two years, SEVP has processed 54 appeals and motions annually. To maintain conservative estimates, SEVP anticipates that number will remain constant over the FY 2019 and FY 2020 periods (Table 16).

Table 16: FY 2019–FY 2020 Appeals Fee-Recoverable Budget

Fiscal Year	Appeal and Motion Payments Expected	Fee-Recoverable Budget
2019	54	$1,956,375
2020	54	$2,198,825
Total	**108**	**$4,155,200**

BILLING CODE 9111–28–C

Fees for motions or appeals are calculated by dividing the fee-recoverable budget by the anticipated number of payments over the FY 2019 and FY 2020 periods. This results in a fee-recoverable amount of $38,474 for each appeal. The relative costs of seasoned federal employees involved in

rendering a decision and the few petitioners result in costs that SEVP felt should be subsidized. To arrive at the final cost, rounding was applied to the result of the fee algorithm. This results in a cost for a motion or appeal of $38,500. SEVP believes that this fee, while justified, is too high to impose on the affected schools as the first fee to be established and collected for the subject appeals and motions, and that some accommodation should be made to keep the fee at a more reasonable amount.[8] Instead, DHS is adding $4.76 to the Form I–901 F and M fees to counterbalance the unfunded costs of adjudicating appeals and motions. This will better ensure that cost is not a significant obstacle in pursuing an administrative appeal or motion. The Form I–290B fee when filed with SEVP is set at $675, which is currently the same amount charged when the form is filed with USCIS. *See* 8 CFR 103.7(b)(1)(i)(S).[9] The Form I–290B filed with USCIS is the same form used for appeals or motions related to any denial of school certification or recertification or a withdrawal of such certification. Although the appeal fee is not set at the amount necessary to recover the full costs of appeals and motions, by setting a fee of $675, schools that benefit from the appeal process bear some of its costs, and DHS more fairly balances allocation of the recovery of SEVP operational costs between beneficiary classes. DHS will charge the fee for all such appeals and motions.

4. Fee Levels

Viewing the SEVP fee structure and affected parties comprehensively, DHS is adjusting each fee in its fee structure based not only on cost of services, but also on the desire to spread the impact of fee increases reasonably among the various beneficiaries of SEVP services. Despite the ABC calculations' determination of the actual cost of each service, which is represented by each fee, DHS has determined that using the Form I–901 revenue to subsidize the costs of the SEVP's other fees is an appropriate course of action for two reasons. First, the number of F and M students paying the Form I–901 fee is substantially larger than the number of entities paying each of the school certification-related fees, allowing for SEVP to lessen the impact of fee increases in the aggregate. Second, the subsidization is reasonable because individuals paying the Form I–901 fee necessarily benefit from the continued certification of schools for their enrollment and prompt and accurate adjudication of appeals.

DHS is increasing the Form I–901 fee for F and M students from $200 to $350 and the full Form I–901 fee which applies to most J exchange visitors from $180 to $220. These fees have been unchanged since 2008. 73 FR 55683 (Sept. 26, 2008). In 2008, the first time these fees had been updated since SEVP's inception in 2004, the Form I–901 fee for F and M students increased from $100 to $200, and the Form I–901 J full fee increased from $100 to $180. *See id.* The Form I–901 fee for special J-visa categories (au pair, camp counselor, and summer work travel) remains at the current $35 level, consistent with the levels set by Congress in 8 U.S.C. 1372(e)(4)(A). IIRIRA also exempts from the Form I–901 fee J–1 exchange visitors who participate in Federal Government-sponsored J–1 exchange programs. 8 U.S.C. 1372(e)(3).

DHS is increasing the initial certification fee from $1,700 to $3,000. This fee was originally set at $230, effective in 2002, prior to the reorganization of the Immigration and Naturalization Service (INS) to become part of DHS. *See* 66 FR 65811 (Dec. 21, 2001). The fee was increased in 2008 to $1,700. *See* 73 FR 55683. This is the base fee for certification and does not include the site visit fee.

DHS is establishing a recertification fee at $1,250, maintaining the site visit fee of $655, and sets the Form I–290B fee at $675. The cost for SEVP recertification, site visits, and motions and appeals adjudication is determined by employing ABC principles, described in the proposed rule, balanced with SEVP's desire to prevent recertifications, site visits, appeals, and motions filings from becoming cost-prohibitive. *See* 83 FR 33762, 33771. DHS is setting a recertification fee and setting a Form I–290B fee for the first time, and SEVP believes that charging recertification and appeals fees sufficient to recover, on their own, the fee-recoverable amount for such services, may result in inordinately high fees from the perspective of entities who have regularly received the benefits of these SEVP services at no additional charge. As noted below, public comments received in response to the NPRM supported this assessment. Accordingly, DHS is setting these fees at amounts below the fee-recoverable cost. For the Form I–290B fee in particular, DHS is setting the amount at $675. DHS believes this amount best addresses concerns raised in public comments about entities paying a Form I–290B fee for the first time because it is less than both the fee for initial certification and the fee for recertification. Further, the amount $675 is already associated with the Form I–290B when filing it with USCIS. DHS believes $675 is a logical starting point, because this is the fee currently being charged by USCIS for motions and appeals. While the difference between the fee-recoverable amount (approximately $38,500) and the fee of $675 is substantial, subsidizing this fee by driving the additional costs to the Form I–901 fee results in an increase of only $4.76 to F/M students paying that fee. The program fee schedule for SEVP beginning in FY 2019 is shown in Table 17.

BILLING CODE 9111–28–P

[8] If a school is denied certification or withdrawn from certification, it can file an appeal with an independent Administrative Appeals Team (AAT). The AAT has sustained approximately 92 percent of decisions.

[9] Because the underlying rationale for the amount of the I–290B fee differs between SEVP and USCIS, DHS may change the I–290B fee for USCIS but not for SEVP, meaning the Form I–290B may have two different fees in the future.

Table 17: FY 2019 SEVP Fees

Category	Amount
I-901 Fees	
• I-901 Primary F/M visa holders (Full)	$350
• I-901 Primary J visa holders (Full)	$220
• I-901 Special J-visa categories (Subsidized payment)	$35
I-17 School Fees	
• Certification Fee	$3,000
• Recertification Fee	$1,250
• Site visit fee for initial certification (base fee to be multiplied by number of locations cited on the Form I-17), and for new physical locations	$655
Appeal or Motion Fee	
• Appeal or Motion Fee	$675

These fee amounts, the cost model outputs, and cost reallocation amounts are shown in Table 18. The cost reallocation amounts are negative for the fees that are subsidized. The cost reallocation amounts that are positive are the amounts per fee that subsidize the other fee categories.

Table 18: Fee Adjustment Amounts

Fee	Current Fee (a)	Activity Based Cost Model Output (b)	Cost Reallocation (c)	Final Fee (d = b + c)	Change in Fees (e)	% Change in Fee (f = (d / a) -1)
Appeal or Motion Fee: I-290B	N/A	$38,475	($37,800)	$675	$675	N/A
I-901 F/M	$200	$290	$60	$350	$150	75%
I-901 J-Full	$180	$130	$97	$220	$30	22%
I-901 J-Partial	$35	$130	($88)	$35	$0	0%
I-17 Initial Certification	$1,700	$4,600	($1,600)	$3,000	$1,300	76%
I-17 Recertification	N/A	$6,000	($4,750)	$1,250	$1,250	N/A
Site Visit – initial	$655	$650	$5	$655	$0	0%
Site Visit – new location	$0	$650	$5	$655	$655	N/A

Table 19 reflects the break-even analysis based on the fee schedule and the proportional fee volumes (rounded) required to generate sufficient revenue to offset projected program costs.

Table 19: Projected Revenue–FY 2019 and FY 2020

Fee Category	Fee Amount	Forecasted Volume	Forecasted Revenue
I-901 F/M	$350	826,326	$289,214,100
I-901 J-Full	$220	311,162	$68,455,640
I-901 J-Partial	$35	317,890	$11,126,150
I-901 Subtotal:			
Certification Fee	$3,000	852	$2,556,000
Recertification Fee	$1,250	8,746	$10,932,500
Site Visit	$655	1,200	$786,000
I-17 Subtotal:			
Appeal or Motion	$675	108	$72,900
Total:		1,466,284	$383,143,290

BILLING CODE 9111–28–C

IV. Technical Corrections to the Proposed Rule

DHS identified six sets of required technical corrections to the proposed rule, as follows.

First, DHS identified that in the NPRM's Table 7: *Form I–901 Fee Payment Forecast FY 2019–FY 2020,* contained a minor mathematical error due to rounding. On line three, column three, FY 2020 full payment, J-Full, stated as 153,611 is corrected to 153,612 in what is Table 11 of this final rule.

Second, DHS changed a corresponding number in the NPRM's Table 22: *Form I–901 Full J Fee Payments FYs 2010–2017* (Table 24 in this final rule), line 16, column 2 from 153,611 to the corrected 153,612. DHS also made two additional conforming corrections in the preamble text where the incorrect figure 153,611 was changed to 153,612 and in accordance corrected a sum of total increase in transfer payments from I–901 J-Full applicants from $12,446,440 to $12,446,480. These changes are minor and do not change the substance of the rule.

Third, DHS discovered that the NPRM's Table 17: *Projected Revenue—FY 2019 and FY 2020,* contained the following four errors:

- On line two, column four, a mathematical error indicating the forecasted I–901 F/M Full revenue as $289,214,144. The entry of $289,214,144 is corrected to $289,214,100.
- On line three, column four, a correlating mathematical error indicating the forecasted I–901 J-Full fee revenue as $68,455,584. The entry of $68,455,584 is corrected to $68,455,640.
- On line three, column two, a typographical error stating ''210'' for the Form I–901 fee the ''J-Full'' category. The correct amount, as included and discussed elsewhere in the proposed rule, is ''220.''
- On line eleven, column four, a correlating mathematical error indicating the total forecasted revenue as $383,143,278. The entry of $383,143,278 is corrected to $383,125,290. The proposed rule included and discussed the correct ''220'' figure at several points in the document, and no commenter expressed confusion over these proposed dollar amounts.

Fourth, DHS identified a section of the NPRM's proposed regulatory text at 8 CFR 103.7(b)(1)(ii)(B) that could be confusing to some readers. Though no commenters expressed confusion about the provision, DHS determined that the text, as published in the NPRM, made it appear as though a school going through recertification would be required to pay the $3,000 initial certification fee in addition to the $1,250 recertification fee, plus $655 per additional site. As previously noted throughout the preamble to the NPRM, the $1,250 recertification fee is charged in lieu of the full $3,000 fee for an initial certification, and an additional fee of $655 is charged when a certified school reports a new physical location where it provides education to international students and which was not previously reported on its Form I–17. *See, e.g.,* 83 FR 33762, 33771 (discussing the basis and purpose of DHS's intention to collect a site visit fee when a school changes or adds a new physical location or campus), 33773 (noting different costs for initial certification and recertification processes), 33776 (describing the fee-recoverable amount of recertification separately from initial certification), 33781–82 & 33788–89 (explaining the impact of the recertification fee). DHS amends the regulatory text at 8 CFR 103.7(b)(1)(ii)(B) to clarify this provision.

Fifth, DHS identified a section of the NPRM's proposed regulatory text at 8 CFR 103.7(b)(1)(ii)(H) that unnecessarily referred to fee remittance for ''certain'' F, J, and M nonimmigrants when all potential scenarios for fee remittance in these categories are in fact addressed. DHS amends the regulatory text at 8 CFR 103.7(b)(1)(ii)(H) to delete the word ''certain.''

Sixth, the NPRM's proposed regulatory text at 8 CFR 214.13(a)(2) inadvertently provided that the fee for certain J–1 status applicants is $210. The correct amount, as referenced elsewhere both in the regulatory text proposed in the NPRM and in its preamble, is $220. DHS amends the regulatory text at 8 CFR 214.13(a)(2) to correct this error. The revised regulatory text of this fee level does not change the intent of the proposed rule.

Last, the authority sections for the text of the CFR are amended to include additional references to relevant statutory authorities. Specifically, DHS is adding citations to 8 U.S.C. 1356 and 8 U.SC. 1372, which also serve as sources of authority relevant to 8 CFR parts 103 and 214.

V. Public Comments on the Proposed Rule

DHS provided a 60-day comment period for this rulemaking following publication of the NPRM. The comment period concluded on September 17, 2018. DHS received approximately 300 comments.

DHS has carefully reviewed all comments received during the comment period and summarizes and responds to all significant comments received in the following sections of this final rule preamble, with some additional responses to small entities-related comments in the Final Regulatory

Flexibility Analysis section below.[10] This final rule does not make any substantive revisions to the proposed rule based on the comments received.

A. General Comments

DHS received comments from a broad spectrum of individuals and organizations, including representatives of schools and universities, advocacy organizations, public policy groups and other interested persons. Most commenters expressed general opposition to the fee increases; others expressed concerns related to specific fees.

While most commenters opined the proposed fees were generally too high, many also expressed their understanding of the necessity of some fee increases. Some comments favored increasing fees, acknowledging the need to account for the costs of current SEVP services and planned enhancements without financially impacting the U.S. taxpayer. A few commenters expressed their appreciation for the fees having remained the same since 2008. Additionally, one commenter opined that the increase in fees may decrease the likelihood of visa overstays by curtailing visa applications. Another commenter expressed appreciation for the U.S. government policy related to assessing fees for the cost of government programs and opined that all costs associated with nonimmigrant students' presence in the United States should be paid by students rather than by U.S. taxpayers. Some commenters supported the fee increases but stated that the proposed fees were too low and that DHS should consider raising the fees further.

Some commenters suggested alternative methods to reduce costs and inefficiencies. DHS also received some comments on subjects that are not directly related to the proposed fee amounts and are outside the scope of the NPRM. For example, some commenters suggested that DHS should allocate funds from other areas of the department to address SEVP funding deficits rather than raise the fees.[11]

Overall, comments submitted to the docket for this rulemaking were dominated by concerns about the potential impact the increased Form I–901 fee would have on nonimmigrant student enrollments and concerns about the potential impact of the new recertification fee on a school's ability to continue being certified by SEVP. Commenters, particularly those representing institutions with few nonimmigrant students, specifically stated that the new recertification fee is excessive and would adversely affect their ability to remain an SEVP-certified school. Finally, several commenters observed that the fee changes will send a signal to nonimmigrant students that the United States intends to restrict access to its educational opportunities.

In response to these comments, SEVP notes that it supports international education. Nonimmigrant students typically have positive experiences while in the United States, and the goodwill engendered by all that the United States has to offer encourages mutually beneficial international relations. SEVP, by ensuring that individuals admitted to the United States as F, J, and M nonimmigrants are bona fide students and exchange visitors, reduces fraud, abuse, and potential terrorist threats, contributing to a safe environment for students and exchange visitors when they attend programs in the United States. In order for SEVP to continue to facilitate the benefits of U.S. educational and exchange experiences to F, J, and M nonimmigrants, SEVP must maintain its current systems and operational staff and make refinements now possible through progressive adaptions, both of which require appropriate funding.

B. Comments on Timing of Fee Increase

Several commenters expressed their understanding of the necessity to increase the fees; however, they suggested that instead of a one-time increase, a more consumer-friendly approach would be to raise fees incrementally over time to allow schools and students more time to budget and plan for the increase. DHS recognizes that the fees impose a burden on prospective students and schools. However, in order to ensure that fee levels are sufficient to recover the full cost of activities of the program immediately upon the effective date of the final rule, DHS calculations indicate that the fee amounts must remain, at a minimum, as proposed. If DHS does not adjust the current fees to recover the costs of processing the enrollment of F and M students, certification and recertification of schools, processing relating to J exchange visitors, appeals, and site visits, it will be forced to make reductions in oversight, security, and service as compared to current projections. Additional factors as to why DHS cannot implement such a tiered payment system at this time include the additional administrative burden and development costs such an incremental payment system would place on the program as well as time delays in development.

C. Comments on Enhancements

1. SEVIS Modernization

One commenter observed that since the NPRM was published, DHS has already implemented the SEVIS Student Portal, which the NPRM described as a part of the SEVIS modernization for which it required additional funding. In addition, a university expressed dissatisfaction with the current portal functionality and requested specific technical improvements. DHS acknowledges that the initial phase of the SEVIS Student Portal has now been launched. However, DHS clarifies that the proposed funding is intended to allow DHS to improve the portal and to expand the use of the portal to areas other than those currently online. DHS plans on building on the successes of and lessons learned from the initial Student Portal launch phase. Such expansion requires the additional revenue enabled by the fee increase.

One commenter also questioned the need for a DSO background check that is connected to SEVIS modernization and opined that such checks are duplicative as human resources offices in educational institutions already conduct their own background checks. DHS supports any school's initiative to conduct employee background checks when those employees will be accessing SEVIS but disagrees that the current DSO verification is a duplication of those efforts. FISMA, the Federal Information Security Management Act of 2002, as amended, requires that SEVP protect government information by applying appropriate suitability checks to non-government users. *See generally, e.g.,* 44 U.S.C. 3554(a). These checks are potentially substantively different than, and not replaceable by, those background checks used by private entities.

[10] Overall, the final rule does not address comments seeking changes in statutes, regulations, policy or processes unrelated to or not addressed by the proposed rule. It also does not respond to requests for changes in procedures of other DHS components or other agencies, or the resolution of any other issues not within the scope of the rulemaking.

[11] In addition to noting that it would be outside the scope of this rulemaking to artificially reduce the fee amounts in the hopes of receiving another lawful source of funding, DHS notes that such an approach would be irresponsible. As explained earlier in this preamble, by statute, SEVP is completely funded by the fees it collects. Congress specifically authorized SEVP to recover the full cost of agency operations, and has not indicated an intention to increase DHS appropriations to fund costs that SEVP could have recouped through fees. DHS cannot place SEVP operations at risk in the hopes of securing additional funding.

2. Increased SEVP Adjudication Personnel

Many commenters opined that current recertification processing times are too lengthy and observed that while the NPRM indicated that hiring additional SEVP adjudication personnel was a partial reason for the fee increases, there was no description of the impact such hiring would have on reducing adjudication times. Several SEVP-certified schools expressed support for the fee increase specifically on the condition that adjudications would become more expedited after new adjudicators were hired. Other comments noted that the quality and efficiency of SEVP adjudications needed to be assessed and asked that funds be directed to improve and expedite the adjudication process. As an alternative to increasing the number of adjudication personnel, an organizational commenter, supported by other commenters, opined that ''SEVP has opted to fully adjudicate nearly every change to Form I–17'' and questioned whether all such adjudications are necessary. The commenter further noted that by doing so, SEVP has created unnecessary work that has created a work backlog and delays.

SEVP agrees that its policy is to adjudicate most changes to the fields contained within the Form I–17. However, the lack of sound alternative methods to mitigate risks has necessitated such adjudications. SEVP notes that it continuously investigates and assesses opportunities for more streamlined, risk-based methods available, including opportunities that may arise due to new ways of analyzing school and student data. For purposes of this rulemaking, however, the underlying fee review, as described in the NPRM preamble, uses historical staffing and workload information for current SEVP functions and planned future initiatives to establish future revenue needs. SEVP lacks a methodology to reliably estimate downward adjustments in revenue needs based on workload adjustments that have yet to be made. To the extent that ICE makes such adjustments in the future, any efficiencies would be reflected in a subsequent fee rulemaking.

This change will allow SEVP to fund additional personnel needed to improve case processing, reduce backlogs, and move toward more expedited processing times. That being said, superseding priorities may arise, which could not have been known at the time fee cycle calculations were made, that may impact SEVP's ability to meet petitioner expectations at all times. It is possible that at times, SEVP will need to shift adjudicator workloads and priorities away from recertification to address emergent issues, which may impact case processing efficiency and backlogs.

D. Comments on Specific Fees

1. Fee for F, M and J Nonimmigrants

Almost all of the submitted comments voiced concern that the increase in the Form I–901 fee would adversely affect U.S. competitiveness in the international market for nonimmigrant student enrollment and exchange visitor participation. Some cited decreasing nonimmigrant student enrollments in the United States and corresponding increasing enrollments in other English-speaking countries, notably in Canada and Australia. Many commenters emphasized the importance of nonimmigrant student enrollment and exchange visitor participation to U.S. productivity and innovation and specifically identified the negative impact the decrease in enrollment would have on school programs, the U.S. economy and local jobs. While DHS acknowledges the potential for increased fees to theoretically lead to decreased enrollment and subsequent negative effects on the U.S. economy, these commenters provided no supporting facts or data to demonstrate that such broad effects are a likely outcome of this particular fee increase. Therefore, DHS determines that such concerns do not outweigh the Department's need to increase the Form I–901 fee.

Some commenters suggested that SEVP could decrease the burden on students by having the student fee increase gradually over a longer period of time, amortized annually based on the length of the student program, to minimize the potential impact on student enrollment.

One commenter criticized the decision to use the Form I–901 fee to effectively reallocate some of the costs of services for which SEVP has assessed a fee, such as recertification. The commenter stated that the cost reallocation undermined the consistency of the ABC approach, and that as a result of the cost reallocation, students would bear the burden of costs that are more fairly attributed to educational institutions.

As noted above, SEVP appreciates the importance of nonimmigrant student and exchange visitor enrollment to the U.S. culture and economy and is firmly committed to lawful admission of nonimmigrants for this purpose. SEVP also observes that while many of the comments provided historical data to show a recent decrease in nonimmigrant student enrollment, they neither cited nor provided a published study or other credible data supporting the suggestion that an increase in government fees charged to nonimmigrant students of the scale proposed in the NPRM would adversely affect their decision to choose the United States for academic or vocational study, or exchange visits. SEVP, likewise, has been unable to locate such a study. DHS thus has no objective basis for concluding that nonimmigrant students significantly base their decisions for attending educational institutions in the United States on government fees which, generally, are a small portion of the overall costs of attending these programs.

For instance, the increased Form I–901 fee represents approximately one percent of the average cost of yearly expenses for students in a four-year program.[12] DHS believes that amortizing these costs over the course of a student's stay in the United States would be administratively cumbersome and inappropriate, given the need to fund SEVP operations. For example, because many of the operational costs of nonimmigrant student enrollment associated with establishing an F or M student record in SEVIS occur prior to or at the beginning of the program of study (such as maintaining the SEVIS database and educating DSOs), amortization would result in ICE incurring costs years before it recovers such costs through fees.

In addition, there are a variety of types of educational institutions in the United States, such as community colleges and focused vocational educational programs of study that are relatively unique in the world. These United States institutions offer fields of study; academic, social, and geographic environments; and support services that cannot be found anywhere else. Noted American research facilities provide opportunities for advanced research and collaboration among an increasingly international community of scholars. Given the many variables that go into a nonimmigrant student's decision to study abroad, and the lack of validated data on this issue, there is no reliable basis to conclude that U.S. government fees represent a significant factor in

[12] *See* National Center for Education Statistics, Fast Facts: Tuition costs of colleges and universities, *https://nces.ed.gov/fastfacts/display.asp?id=76* (last visited Oct. 26, 2018) (showing the 2015–16 average total tuition, fees, room and board rates charged for full-time undergraduate students in degree-granting institutions).

persuading a student or exchange visitor to attend a school in the United States, or not. SEVP, consequently, cannot conclude at this time that the increase in the Form I–901 fee as a result of this rule would be directly or even indirectly related to a decrease in U.S. competitiveness for foreign students and exchange visitors.

Further, as discussed in the NPRM, after the fees were last increased in 2008 there was a brief decrease in the combined F, M, and J I–901 payments. However, the I–901 payment rate quickly recovered and ultimately reached record levels while the fees remained at the increased levels. *See* 83 FR 33762, 33775. Accordingly, an increase in fees does not necessarily precipitate a drop in enrollment. DHS acknowledges, however, that its analysis of the dropoff and subsequent increase in participants may not capture some applicants who forewent participation in SEVP due to the increased cost of application.

With respect to the comment about the use of cost reallocation, *i.e.,* the use of Form I–901 fee revenues to subsidize program integrity measures (such as mandatory biennial reviews) that would otherwise be funded through other fees (such as fees paid by schools), DHS notes that the benefits of program integrity measures accrue to F and M students and J exchange visitors, not just to institutions. DHS accordingly believes it reasonable for each F, M, and J nonimmigrant to share the cost by paying a small fee for this benefit rather than requiring SEVP-certified or Department of State (DOS)-designated institutions to bear the entire cost themselves. DHS also believes that such sharing of the costs, by lowering the respective costs of certification or designation, may be a contributing factor to the diversification of the type of schools that have sought SEVP certification and/or DOS designation thus benefiting F, M, and J nonimmigrants with a greater choice of schools.

In addition, as discussed above, 8 U.S.C. 1372 and 8 U.S.C. 1356(m) authorize a full range of SEVP activities and collection of fees related thereto, and not merely data collection. Also, inclusion of these costs is not inconsistent with the full cost concept as outlined in federal cost accounting guidance, generally applicable federal policy for user charges, and legal precedent.

Finally, DHS notes that even if a rise in the cost to F and M nonimmigrant students and J nonimmigrant exchange visitors were to cause a reduction in the demand by foreign students or exchange visitors for U.S. educational or exchange opportunities, that result would not alter this rulemaking. DHS and DOS must recoup the costs of administering the programs that manage F, M, and J nonimmigrants. The program cannot operate at a projected deficit based on a desire to attract a greater number of foreign students. If the rise in the cost causes a substantial reduction in the demand by foreign students or exchange visitors for U.S. educational or exchange opportunities, the lower revenue may not sustain the programs that manage the F, M, and J nonimmigrants. As stated previously, SEVP reviews its associated fees that are deposited into the IEFA biennially and, if necessary, will propose adjustments to ensure recovery of costs necessary to meet national security, customer service, and adjudicative processing goals at that time.

2. Impacts on Specific Applicant Groups

Several commenters voiced concern about the negative impact of the increased fee on all F, M, and J nonimmigrants, but particularly on students in short-term programs such as intensive English programs that are already reporting declines in enrollment. Several commenters expressed concern that specific groups of nonimmigrant students or specific programs could be disproportionately affected by the fee increases. For example, many commenters expressed concern that short-term programs of study, specifically English language training programs, would be negatively impacted by the increase in Form I–901 fees. These commenters noted that such programs are shorter than full degree programs and often cost less, making the fee increase relatively more burdensome than for students enrolled in multi-year programs of study.

For instance, some of these commenters suggested that the fee should be proportionate to the type of program of study a student is engaged in. Some of these comments suggested that students in short-term programs should be charged a lower fee than students in multi-year degree programs. One commenter suggested that for such short-term programs, the Form I–901 fee could account for 25 to 30 percent of the cost of a short-term program and stated that such a high percentage would be cost-prohibitive to many students to enroll in such programs. However, the commenter did not provide a clear basis for that 25 to 30 percent estimate, propose a specific amount for a short-term program fee, or explain how DHS would distinguish between ''short-term'' students and longer-term students. Some commenters requested that DHS establish a lower or a graduated fee for the student, exchange visitor and school fees to minimize negative impact specifically of potential declining enrollments.

DHS declines to establish a lower or graduated fee for specific subgroups of nonimmigrants, such as those who require shorter-term nonimmigrant status, for multiple reasons.

First, SEVP has reviewed its program costs for processing students in short-term nonimmigrant status versus those in long-term nonimmigrant status and can find no convincing basis for charging a lower fee for students on short-term status. As discussed above and in the proposed rule, DHS must establish a fee schedule that allows for recovery of the full costs of current SEVP services and planned enhancements. The proposed fee schedule was based on a fee model that captured the full cost of operations for current activities and planned enhancements and apportioned that full cost to the appropriate program activities. The model assigned costs to the appropriate fee category based on the nature of the activity. The model does not contain separate activity types for students in short-term programs as compared to long-term programs.

DHS nonetheless conducted a qualitative review of the activities and their associated costs, and found that students in short-term programs do not necessarily impose lower costs on SEVP than students in long term programs. For instance, as indicated in Table 7, significant portion of the costs assigned to the I–901 fee are for student and exchange visitor investigations and school and sponsor investigations. Such investigations are not significantly less likely for students in short-term programs, and in some cases, poor oversight of students by short-term program DSOs has resulted in a particular need for investigations of those students and programs. Similarly, SEVP system maintenance costs are not significantly lower for short-term students.[13]

Second, DHS would incur additional administrative costs associated with separate processing of these fees, increasing the costs for all participants.

Finally, as F–1 nonimmigrant students may easily transfer from one

[13] For instance, the creation of a SEVIS record, regardless of program affiliation or program length, has certain fixed costs shared by all nonimmigrant students. In addition, with respect to the increased fees on the schools themselves, SEVP notes that the costs of certification, recertification, maintaining SEVIS, and training DSOs do not necessarily vary based on program type.

type of a program of study to another without paying another I–901 fee, charging a lower fee for certain types of programs creates an opportunity for abuse of the transfer function in order to avoid paying a full fee.

Accordingly, DHS will charge a single set fee regardless of the student's anticipated program length or other considerations.

3. Continued Fee of $35 for Au Pairs, Camp Counselors and Summer Work Travel

One commenter asked why the $35 fee for au pairs, camp counselors, and summer work/travel programs was not included in the funding increase and why such a fee could not be increased to subsidize F and M nonimmigrant student fee.

For the J-visa for exchange visitors, Congress provided the Department of Homeland Security with the authority to set fees consistent with the Department's estimation of the cost per individual of providing services. In addition to that general authority, Congress also specifically indicated that the fee for au pairs, camp counselors, and participants in summer work travel programs should be $35. 8 U.S.C. 1372(e)(4)(A). Based on the clear Congressional intent that the fee for au pairs, camp counselors and summer work/travel programs remain set at $35, the Department has decided to keep the fee set at that level.

4. Recertification Fee

Many commenters objected to the introduction of a recertification fee, stating that it will disproportionately burden smaller institutions, because those schools obtain less revenue from F and M nonimmigrant students. Some representatives of small institutions commented that the proposed recertification fee increase would likely be cost-prohibitive to them and they would likely not seek to renew their SEVP certification. Other commenters voiced concerns over the timing of the increase in the middle of an academic budget cycle.

DHS declines to establish a lower fee for smaller institutions, because following a qualitative review of the fee model (which does not distinguish between institutions based on size), DHS could not identify a convincing basis for doing so. Many of the administrative costs associated with recertification are fundamentally similar regardless of school size or type. Universities, secondary schools, public or private schools, and F and M schools receive the same SEVP certification. The workload and cost of certification adjudications does not change for different types of schools. In addition, institutions with large nonimmigrant student populations typically require fewer resources in some respects, since they are more knowledgeable, have a stable professional pool of employees, and have better internal reporting systems to assist in their compliance efforts. By contrast, schools with smaller enrollments may require more frequent training of DSOs, or significant oversight if they are identified as higher risk.

With respect to the timing of the proposed fee increase, DHS appreciates this concern, but notes that DHS announced the likely publication of the proposed rule well in advance of the current academic year.[14] In addition, although the fee schedule will occur in the middle of a budget cycle, not all schools will be impacted during the current budget cycle.

Multiple commenters also opined that the interval of SEVP school recertification is too frequent at two years. One commenter suggested that the frequency of recertification should be decreased from two years to four or five years. DHS notes that EBSVERA, section 502, 8 U.S.C. 1762, and Homeland Security Presidential Directive–2 (HSPD–2) provided for DHS to periodically review all schools approved for attendance by F or M nonimmigrant students. Further, EBSVERA requires that DHS recertify all such schools within two years of enactment and conduct an additional recertification of these schools every two years thereafter. *See* 8 U.S.C. 1762(a). As the two-year recertification cycle is a statutory requirement, the frequency cannot be modified through rulemaking. Therefore, comments suggesting alternative recertification intervals are beyond the scope of this rulemaking.

5. Fee for Filing an Appeal or Motion

A few individuals and organizations commented on SEVP charging a fee to submit an appeal or motion following a denial or withdrawal of a school petition, the majority voicing their opposition to charging such a fee. Some questioned the meaningfulness of the fee when it covers only a fraction of the actual appeal cost and encouraged DHS to explore ways to increase efficiencies to decrease the cost of appeals and motions. DHS recognizes the potentially adverse impact of a high appeal fee, and therefore reallocated some of the costs of handling appeals to other SEVP fees. DHS notes that it is exploring ways to increase efficiencies to reduce the cost of adjudications. At this time, however, DHS feels that the benefits of charging a fee to recover some portion of the costs of reviewing appeals and motions remain compelling. One commenter stated that the fee was excessive as the appeal process is the only recourse or way for the applicant to engage with adjudicators for discussion. DHS notes that this notice comes at a point in the overall process during which the applicant or petitioner has had significant opportunities for dialogue (*see, e.g.,* 8 CFR 214.4(b)(3) (referencing a school's right to request a telephonic interview after receiving a notice of intent to withdrawal SEVP certification)), and so concerns about the impact of the appeal fee amount for this reason are overstated.

6. Site Visit Fee

Some commenters asked SEVP to reconsider charging a site visit fee when an SEVP-certified school adds a new physical location or a campus where it plans to enroll F and M students. In particular, an organizational commenter objected to DHS's statement in the proposed rule that under the 2008 Fee Rule, DHS must impose a site visit fee for each location listed on the initial SEVP certification, as well as each location added as part of an initial event, such as a SEVIS update requesting approval of a changed or new location or campus. *See* 83 FR at 33771. The commenter wrote that current regulations require site visits only in the context of initial school certification under 8 CFR 214.3(h)(1), and not in the context of recertification (8 CFR 214.3(h)(2)) and out-of-cycle reviews (8 CFR 214.3(h)(3)). According to the commenter, those provisions refer to ''on-site reviews,'' not to site visits. The commenter also suggested that the on-site review, when necessary, is a less costly endeavor than an initial school certification site visit and thus a school should not be charged for an on-site review but only for an initial site visit.

As an initial matter, DHS disagrees with the commenter's assessment of the scope of the site visit fee under existing regulations. When DHS established the site visit fee, DHS made clear that for initial SEVP certification petitions, a petition fee ($1,700) is required for each institution and a site visit fee ($655) is required for each campus. DHS also made clear that SEVP-certified institutions seeking approval for change

[14] *See, e.g.,* Spring 2018 Unified Agenda of Federal Regulatory and Deregulatory Actions, RIN 1653–AA74, *available at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201804&RIN=1653-AA74* (last visited Jan. 7, 2019) (indicating likely publication of a proposed rule in September of 2018).

of location must pay a site visit fee, and that SEVP-certified institutions seeking approval for a new campus must pay a site visit fee. 73 FR 55683, 55695.

These requirements are reflected in existing regulations, which provide as follows:

- The site visit fee applies to each location required to be listed on the form, and is not limited to the initial certification context. 8 CFR 103.7(b)(1)(ii)(B).
- As part of initial certification, SEVP will conduct a site visit for each petitioning school *and its additional schools or campuses.* 8 CFR 214.3(h)(1)(ii). As noted above, a fee is charged for each additional school or campus at the initial certification stage.
- The Form I–17 must include ''any physical location in which a nonimmigrant can attend classes through the school (*i.e.,* campus, extension campuses, satellite campuses, etc.).'' 8 CFR 214.3(a)(1)).
- Schools are subject to a continuing duty to update SEVIS school locations as changes arise, *i.e.,* even after initial certification, within 21 days of a change to a range of information types on the Form I–17, including school location and campus location. *See* 8 CFR 214.3(g)(2), (h)(3).

This makes amply clear that the intent of the 2008 Fee Rule was to apply the site visit fee whenever a school fulfills its duty to add a school or campus location in SEVIS.

DHS reaffirms that interpretation in this final rule. The site visit fee applies at the initial certification stage, and when a certified school updates its Form I–17 in SEVIS to indicate, pursuant to 8 CFR 214.3(g)(2)(i) and (h)(3), that it is changing its physical location or adding a new physical location or campus.

DHS emphasizes that the imposition of this fee is necessary to support the relevant operations. The revenue generated by the imposition of this fee assists in recovering the costs that DHS incurs for these site visits, which are necessary for program integrity purposes. Site visits are no less burdensome in the post-certification context, and warrant an equivalent fee, because SEVP must assess that the schools continue to possess the necessary facilities, personnel, and finances to conduct instruction regardless of the point in time at which the schools choose to use a location for the instruction of nonimmigrant students.

VI. Statutory and Regulatory Requirements

A. Executive Orders 12866, 13563, and 13771: Regulatory Review

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') 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, 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. Executive Order 13771 (''Reducing Regulation and Controlling Regulatory Costs'') directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget has designated this rule a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by OMB. This final rule imposes transfer payments between the public and the government with no new cost burdens. Thus, this rule is not subject to the requirements of Executive Order 13771.

No comments were received concerning the regulatory impact analysis contained in the proposed rule. With the exception of a minor technical amendment to Table 24, as described earlier in this preamble, there are no changes from the proposed to the final regulatory impact analysis. A final regulatory impact analysis follows.

1. Background and Purpose of the Rule

SEVP is a fee-funded program within ICE that provides oversight of certified schools and nonimmigrant students in the F and M visa category. SEVP uses SEVIS to monitor and track certified schools and F and M nonimmigrant students. DOS also uses SEVIS in the management of the Exchange Visitor Program for nonimmigrant exchange visitors in the J visa category. SEVIS is a web-based system administered by SEVP that retains data on nonimmigrant students and exchange visitors in the country. SEVP uses SEVIS to ensure accurate reporting and recordkeeping by schools and exchange visitor programs. SEVP also uses SEVIS to identify enforcement actions for students and exchange visitors who are out of status.

The purpose of this final rule is to generate the necessary revenue to recover the full cost of the FY 2019 and FY 2020 budgets. SEVP is authorized to recover the full cost of all resources and services provided. The costs of SEVP activities have increased, and the fees collected no longer cover the costs. The fee increase is needed to meet long-term cash flow needs and achieve solvency.

SEVP projects an annual budget of $186.6 million in FY 2019 and $188.4 million in FY 2020. SEVP forecasts $121.6 million in revenue for FY 2019 and FY 2020 without a fee change. The implementation of this rule would provide SEVP with additional fee revenue of $75.2 million in FY 2019 and $73.5 million in FY 2020. If DHS does not adjust the current fees to recover the costs of processing the enrollment of F and M students, certification and recertification of schools, processing relating to J exchange visitors, appeals, and site visits, it will be forced to make reductions in oversight, security, and service as compared to current projections.

To determine the full cost associated with SEVP and the management of SEVIS, SEVP used ABC methodology. ABC first identifies activities in an organization and then assigns the cost of each activity according to the resources they consume. SEVP identified the following as its primary activities: Collecting and retaining information on F, M, and J nonimmigrants; certifying schools; overseeing school compliance; recertifying schools; adjudicating appeals; investigating suspected violations of immigration law and other potential threats to national security by F, M, or J nonimmigrants; providing outreach and education to users; and performing regulatory and policy analysis. SEVP also recognizes management and overhead costs associated with the program.

With this rule, SEVP will collect five fees paid by two source categories: Individuals will pay the Form I–901 fee, and institutions will pay the Form I–17 certification fee, Form I–17 recertification fee, the fee for a motion or appeal, and the site visit fee. By tracing expenditures of the activities previously listed to the various fee categories, SEVP forecasted fee payments to determine the appropriate fee amount for each fee type in this rule.

Table 20 presents an accounting statement summarizing the annualized transfer amounts and qualitative benefits of the final rule. With this rule, schools will pay a higher fee for initial SEVP certification and will incur a fee

for recertification, a site visit when adding a new physical location or campus, and the filing of a motion or appeal. In addition, F and M nonimmigrant students and J nonimmigrant exchange visitors will pay higher fees.

BILLING CODE 9111–28–P

Table 20: Accounting Statement for FY 2019

Category	Primary Estimate	
Qualitative Benefits	SEVP will be able to maintain the current level of service. This rule will enhance SEVP's capability to support national security and counter immigration fraud through the continued development and implementation of critical system and programmatic enhancements. Enhancements to SEVIS, including the establishment of a student portal, will assist DSOs in their regulatory obligation to provide accurate and timely information and rebalance this reporting requirement by providing students an automated means to do so. Increased adjudication personnel will assist in reducing recertification processing times, while enhanced vetting protocols will ensure that only those eligible to enter and remain in the country do so.	
Transfers	7% Discount Rate $75,231,420 from schools and students to the government 3% Discount Rate $75,231,420 from schools and students to the government	
Category	**Effects**	**Source**
Effects on State, local, and/or tribal government	The final rule increases and establishes additional fees on state, local, and/or tribal government-funded educational institutions for support of SEVP operations. This rule increases the I-17 certification fee and creates the I-17 recertification fee and a fee for filing an appeal or motion. In addition, SEVP will collect a site visit fee when an SEVP-certified school adds a campus/location.	Final Rule, Executive Order 12866 analysis
Effects on small businesses	The final rule increases and establishes additional fees for educational institutions in support of SEVP operations. This final rule increases the I-17 certification fee and create the I-17 recertification fee and a fee for filing an appeal or motion. In addition, SEVP will collect a site visit fee when a school certified by SEVP adds a campus/location.	Final Regulatory Flexibility Analysis

2. Impacts of Regulatory Change

This rule amends the current fee levels for the individual student and exchange visitor application fee (Form I–901 fee) and school certification petition for initial certification. It maintains the current fee for site visits and makes clear that SEVP will impose it for any change of location or additional physical location or campus reported as an update by a certified school. It also institutes a fee for school recertification petitions and the filing of appeals and motions by schools. The amended fee structure reflects existing and projected operating costs, program requirements, and planned program improvements.

The current Form I–901 fee levels are based on a fee analysis performed when SEVP last increased the fees in 2008. *See* 73 FR 55683. Those cost calculations were established on the basis of projected workload. Since 2008, SEVP's program mission tasks have expanded significantly. The expansions of certification, recertification, and

appeals costs and the subsidization of excess costs not recovered by fees have led to the need for the fee increase. Additionally, SEVP now provides investigative analysis to support enforcement operations, has increased numbers of adjudication personnel, and is undergoing SEVIS Modernization. Concurrently, costs associated with these program tasks have been affected by increased costs due to inflation. This rule's fees will result in recovery of the full cost of SEVP analysis and support operations with fee-generated revenue; alignment of the fees with current and projected costs and processes that have been adjusted as the program has gained experience and sophistication; and the agency's adoption of more detailed and accurate data sources and improved management tools to align resources and workload.

a. Form I–901 F and M Fee

F nonimmigrants, as defined in INA section 101(a)(15)(F), 8 U.S.C. 1101(a)(15)(F), are foreign students who come to the United States to pursue a full course of academic study in SEVP-approved schools and their dependents. M nonimmigrants, as defined in INA section 101(a)(15)(M), 8 U.S.C.1101(a)(15)(M), are foreign nationals pursuing a full course of study at an SEVP-certified vocational or other recognized nonacademic program (other than language training programs) in the United States and their dependents. International F and M nonimmigrant students seeking temporary admission into the United States to attend a U.S. educational institution must pay the Form I–901 F and M fee. In this final rule, SEVP increases the Form I–901 F and M fee from $200 to $350.

From 2007 through 2017, SEVP received an average of 450,581 Form I–901 F and M fee payments per year. Table 21 shows the volume of Form I–901 F and M fee payments received and the annual average number of fee payments from 2007 to 2017. As previously discussed, SEVP has forecasted 418,393 Form I–901 F and M fee payments in FY 2019 and 407,933 FY 2020, respectively.

Table 21: Form 1-901 F and M Fee Payments FYs 2010–2017

Fiscal Year	Fee Payments
2007	358,666
2008	400,090
2009	348,815
2010	389,255
2011	431,180
2012	449,029
2013	469,986
2014	519,751
2015	574,158
2016	545,203
2017	470,261
Annual Average (2007–2017)	450,581
Forecasted 2019	418,393
Forecasted 2020	407,933

Table 22 illustrates the incremental increase DHS is finalizing with this rule for the Form I–901 F and M fee. Individuals who submit a Form I–901 will pay an additional $150 under this final rule, which is a 75 percent increase.

Table 22: Form I-901 F and M Incremental Fee Increase

Type	Current Fee	New Fee	Difference (New–Current)
I-901 F and M	$200	$350	$150

SEVP estimates that the fee increase will result in an annual increase of transfer payment from students who submit a Form I–901 to the government of approximately $62 million per year ($150 increase × 418,393 FY 2019 number of applicants = $62,758,950; $150 increase × 407,933 FY 2020 number of applicants = $61,189,950).

b. Form I–901 J—Full Fee

DOS generally oversees the exchange visitor program, which includes nonimmigrants who are charged the full Form I–901 J fee. J exchange visitors are nonimmigrant individuals approved to participate in an exchange visitor program in the United States and the spouse and dependents of the exchange visitors. This fee is associated with J–1 nonimmigrants participating in a designated exchange visitor program. Certain other J–1 categories are subject to a reduced fee or are exempt from a fee in accordance with 8 U.S.C. 1372(e). SEVP and DOS have a memorandum of reimbursable agreement. DOS sends

SEVP its actual expenditures, and SEVP reimburses them quarterly. Each year, SEVP and DOS review and update the memorandum. Table 23 displays the affected Exchange Visitor Program categories subject to the full Form I–901 J fee and the purpose of the visit.[15]

Table 23: J-1 Nonimmigrant Exchange Visitor Program Categories Subject to Form I-901 Full J Fee

Exchange Visitor Program Category	Purpose of Visit
Short-term Scholar	Lecture, observe, consult, training, demonstrate special skills.
Professor and Research Scholar	Research Scholar: Research, observe, or consult in connection with a research project. Professor: Teach or lecture at university, observe, or consult.
Physician	Pursue graduate medical education or training at accredited schools of medicine or scientific institutions.
Intern	Structured internship program that is in the student's field of study.
Trainee	Structured training program that is in the trainee's professional field.
Specialist	Observing, consulting, or demonstrating special skills.
Teacher	Teach full-time in an accredited primary, including pre- kindergarten, or secondary (K-12) public or private school.
Secondary School Student	Study in the U.S. at accredited public or private secondary schools for an academic semester or an academic year, while living with American host families.
College and University Student	Participate in a degree or nondegree program at an accredited postsecondary academic institution, or participate in a student internship program.
Government visitor (non-Federal)	Engage in observation tours, discussions, consultations, professional meetings, conferences, workshops and travel when selected by a state or local government agency

SEVP receives an average of 151,958 Form I–901 Full J payments per year (FYs 2007–2017). Table 24 displays the volume of Form I–901 Full J fee payments received and the annual average number of fee payments. SEVP has forecasted 157,550 Form I–901 Full J payments in FY 2019 and 153,612 in FY 2020.

[15] *See* Department of State, Exchange Visitor Program Category Requirements (June 2016), *https://j1visa.state.gov/wp-content/uploads/2017/06/Exchange-Visitor-Program-Category-Requirements.pdf (last visited Feb. 26, 2018).*

Table 24: Form I-901 Full J Fee Payments FYs 2010–2017

Fiscal Year	Fee Payments
2007	132,213
2008	137,173
2009	129,979
2010	139,534
2011	148,253
2012	155,008
2013	160,522
2014	172,530
2015	168,967
2016	164,401
2017	162,959
Average (2007–2017)	151,958
Forecasted 2019	157,550
Forecasted 2020	153,612

The difference between the final and current fees for the Form I–901 Full J applicants is $40, an increase of approximately 22 percent, as shown in Table 25.

Table 25: Form I-901 Full J Incremental Fee

Type	Current Fee	New Fee	Difference (New–Current)
I-901 J-Full	$180	$220	$40

The annual increase in transfer payments from Form I–901 Full J applicants to the government is expected to be $6,302,000 in FY 2019 and $6,144,480 in FY 2020 ($40 increase in fee × 157,550 FY 2019 and 153,612 FY 2020 forecasted number of applicants). The increase in J fees is meant to recover the full cost of J program operations for SEVP, which includes the reimbursement to DOS, SEVIS costs, and other adjudication services for J exchange visitors. For the purposes of calculating fees, SEVP isolates the costs specifically incurred by operating the J visa program. As it stands, the J visa program operates at a greater cost than the revenue that Form I–901 J fees bring to the program; therefore, SEVP increases the Form I–901 Full J fee to cover the $39.4 million full cost of operating the J visa program on an annual basis.

c. Form I–17 School Certification and Recertification Fee

For a U.S. school to enroll F and M nonimmigrant students, it is required to be certified by SEVP. A school petitions for SEVP certification to enroll these students by completing and submitting Form I–17, ''Petition for Approval of School for Attendance by Nonimmigrant Student,'' online through SEVIS.

All SEVP-certified schools are required to go through the recertification process every two years to ensure they remain qualified for certification and adhere to all requirements according to the regulations.

From FY 2012 to 2016, there has been an annual average of 423 schools applying for SEVP certification. As previously discussed, DHS calculated the three year moving average to minimize the variation in forecasting the population data. The Form I–17 initial certifications from FYs 2012 through 2016 are shown in Table 26.

Table 26: FYs 2012–2016 I-17 Initial Certifications

Fiscal Year	I-17 Certification Petitions	3-Year Moving Average
2012	457	-
2013	382	-
2014	446	428
2015	469	432
2016	363	426
Total	**2,117**	**-**

SEVP uses the three year moving average to predict that there will be 426 initial certifications in both FY 2019 and FY 2020, respectively.

As of May 2017, there were 8,746 SEVP-certified schools. DHS assumes that approximately half, or approximately 4,373 schools, will recertify each year, including the 1,728 schools with no active F or M nonimmigrant students. DHS assumes that a school would prefer to recertify for a $1,250 fee instead of allowing certification to lapse and thereafter having to again pay the initial certification fee of $3,000. The initial certification fee is a 76 percent increase from the current fee.

The current fee to apply for initial certification is $1,700, which has not changed since 2008. SEVP does not currently charge a recertification fee; the new fee amount is $1,250. The Form I–17 initial certification and Form I–17 recertification incremental fees are shown in Table 27.

Table 27: I-17 Incremental Fees

Type	New Fee	Current Fee	Difference (New–Current)
I-17 Initial Certification Fee	$3,000	$1,700	$1,300
I-17 Recertification Fee	$1,250	$0	$1,250

The annual increase in transfer payments from schools to the government from Form I–17 initial certifications is expected to be $553,800 ($1,300 increase in fee × 426 (FY 19 and FY 20 forecasted number of Form I–17 initial certifications)). The annual increase in transfer payments from schools to the government for Form I–17 recertification is expected to be $5,466,250 ($1,250 increase in fee × 4,373 (FY 2019 and FY 2020 forecasted number of recertifications)).

d. Fee for Motion or Appeal

When a school is denied certification or recertification, the school receives a denial letter through certified mail. The denial letter explains the reason for the denial and the steps to appeal. The school can appeal by filing the Form I–290B. This rule finalizes that SEVP impose a filing fee of $675, which is also the fee currently charged by USCIS upon submission of the Form I–290B.[16] SEVP does not currently collect a fee from a school that files a motion or appeal. DHS finalizes its regulations to institute this fee for a school filing an appeal or motion in order to establish a more equitable distribution of costs, improve services by decreasing an appeals or motions throughput time and a more sustainable level of cost recovery relative to the services provided.

SEVP processed an average of 54 motions and appeals from schools annually from 2013 to 2016. DHS assumes that there will be the same number of appeals or motions filed in FY 2019 and FY 2020.

The total annual increase in transfer payments from schools to the government for filing an appeal or motion is expected to be $36,450 ($675 fee × 54 (FY 2019 and FY 2020 forecasted number of fee payments)).

e. Site Visit Fee

As noted above, current regulations provide authority for SEVP to charge a site visit fee to schools that apply for initial certification or report a change of physical location, or addition of a physical location or campus. The site visit allows SEVP an opportunity to gather evidence on the school's eligibility, review school facilities, and interview personnel listed on the Form I–17 as a PDSO or DSO. SEVP currently collects the $655 fee when a school files a petition for certification to issue Forms I–20 or by a certified school when it physically moves to a new location. This final rule notifies the public that following completion of this rulemaking, SEVP plans to also collect the fee from any certified school that adds a physical location or campus, by updating its Form I–17 in SEVIS, consistent with the above authorities and the agency's longstanding interpretation.

SEVP performs 600 site visits annually. Of these 600 visits, 426 will be at schools that apply for initial certification and currently pay the $655 site visit fee. The remaining 174 site visits may include visits when a school adds a new physical location or campus. The site visit fee amount, $655, remains the same.

The annual increase in transfer payments from schools to the government due to site visits is expected to be $113,970 ($655 fee × 174 (FY 2019 and FY 2020 forecasted number of site visits)).

f. Conclusion

SEVP expects to have a total increase in fees of $68.7 million per year, discounted at seven percent, transferred from individuals and entities for the services they receive, to the government.

[16] USCIS Form I–290B, Notice of Appeal or Motion, Filing Fee of $675, *https://www.uscis.gov/i-290b.*

Table 28 shows the summary of the total annual number of payments, incremental fee amounts, and total fees transferred.

Table 28: Final Annual Incremental Fee Amounts, FY 2019

	Annual Number of Payments	Incremental Fee Amounts	Annual Fee Transfer to Government
I-901 F and M	418,393	$150	$62,758,950
I-901 J-Full	157,550	$40	$6,302,000
I-17 Initial Certification	426	$1,300	$553,800
I-17 Recertification	4,373	$1,250	$5,466,250
Site Visit – initial	426	$0	$0
Site Visit – new location	174	$655	$113,970
Appeal or Motion	54	$675	$36,450
Total			$75,231,420

3. Alternatives to Regulatory Change

SEVP examined several alternatives to the final fee structure, including no increase to any fee, only increasing the Form I–901 fee and Form I–17 SEVP school certification fee, and the unsubsidized results of the ABC model.

Without an increase in fees, SEVP will be unable to maintain the level of service for students and schools that it currently provides as well as the compliance and national security activities discussed above. SEVP considered the alternative of maintaining fees at the current level but with reduced services and increased processing times, but has decided that this would not be in the best interest of applicants and schools. SEVP seeks to minimize the impact on all parties, but in particular small entities. If SEVP followed this alternative scenario, there would be a shortfall of revenue of over $65.4 million in FY 2019 to cover expenses. SEVP rejected this alternative. SEVP must pay for the expenses of maintaining and improving SEVIS and adjudicating schools applying to be certified by SEVP in a timely manner.

SEVP also considered raising only the Form I–901 and Form I–17 certification fees instead of including a new fee for recertification and for filing an appeal or motion. If SEVP followed this scenario, the Form I–901 F and M fee would have increased to $350 to cover the shortfall in revenue, but the Form I–17 initial certification fee would have also increased to $4,200. This would have tripled the existing certification fee while allowing schools with zero foreign students to remain active SEVP schools that require SEVP effort for recertification. SEVP rejected this fee structure as it would have continued to add workload to SEVP's recertification branch. Without any disincentive to recertify, the list of schools recertifying would likely continue to grow. The new fees, however, establish a more equitable distribution of costs and a more sustainable level of cost recovery relative to the services provided.

SEVP also considered the unsubsidized results of the ABC model as an alternative, which allocated the Form I–901 F and M fee, school certification fees, and the fee to file an appeal or motion as shown in Table 29.

Table 29: Unsubsidized Fee Amounts

Fee Type	Unsubsidized Fee Amounts
I-901 F and M	$290
I-901 J-Full	$130
I-901 J-Partial	$130
I-17 Initial Certification	$4,600
I-17 Recertification	$6,000
Appeal or Motion	$38,475
Site Visit	$650

BILLING CODE 9111–28–P

SEVP rejected this alternative for several reasons. As a starting point, the current fee to file Form I–290B with USCIS is $675. The same form is required to file an appeal or motion with SEVP and using the existing USCIS fee is a consistent and reasonable means of implementing this new fee without discouraging schools from seeking an appeal. Setting the appeal fee at the amount that SEVP's standard methodology would dictate ($38,475) would result in a fee that is prohibitively expensive for many SEVP-certified schools, a significant portion of which have fewer than ten nonimmigrant students. Similarly, SEVP rejected the alternative to set the recertification fee at the ABC model output amount of $6,000. A recertification fee higher than the initial certification fee would also discourage schools from seeking recertification. SEVP instead sets the recertification fee at a level that is less than the initial certification fee. When schools can maintain their certification, F and M nonimmigrant students enrolled in the withdrawn school avoid complications such as being forced to transfer schools, leave the United States, or risk facing immigration law penalties for violating the terms of their nonimmigrant status.

SEVP also rejected the initial certification fee of $4,600, an increase of almost three times the current fee of $1,700. In the fee development, DHS balanced the challenge of minimizing the costs to schools and students while recovering funding to support SEVP services. The population of Form I–901 F and M nonimmigrant students relative to the population of Form I–17 schools allows for a minimal fee adjustment to be spread over the student population to reduce the cost burden on individual institutions seeking recertification.

B. Regulatory Flexibility Act

1. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) at 5 U.S.C. 604 generally requires Federal agencies to consider the economic impact of their rules on small entities. In accordance with the RFA, DHS has prepared a Final Regulatory Flexibility Analysis (FRFA) that examines the impacts of the rule on small entities. The term ''small entities'' encompasses small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of fewer than 50,000.

2. A Statement of the Need for, and Objective of, the Rule

This rule will adjust current fees and collect new fees to ensure that SEVP is able to recover the costs of the management and support of its program activities. DHS's objectives and legal authority for this final rule are further discussed throughout this final rule preamble. The objective of the final rule is to prevent an anticipated funding deficit in operating the SEVP. More specifically, this rule increases the SEVP funding stream by adjusting the Form I–901 F and M fee, Form I–901 J–Full fee, and Form I–17 certification fee, and by instituting the Form I–17 recertification fee and a fee for filing an appeal or motion. This final rule also announces the collection of a site visit fee when an SEVP-certified school adds a new physical location or campus at which it provides educational services to nonimmigrant students. The funding supports existing SEVP activities and planned enhancements critical to current SEVP oversight of schools and the monitoring of nonimmigrant students in the F, M, and J visa classifications for national security purposes. ICE continues to examine programmatic goals, which may include enforcement costs generated by SEVP information or compliance investigations. As such projections have not yet been completed, any related costs are beyond the scope of this rulemaking effort.

The legal basis for this final rule increasing the SEVP funding stream is grounded in the Homeland Security Act of 2002, which created DHS and imparted upon DHS the responsibility for SEVIS. DHS uses SEVIS to meet the monitoring and verification requirements under EBSVERA sections 501–02, 8 U.S.C. 1761–62), and to conduct a recertification of schools every two years following the date of EBSVERA's enactment. The Secretary of Homeland Security is authorized to collect fees for SEVP from prospective F and M nonimmigrant students and J nonimmigrant exchange visitors. IIRIRA section 641(e)(1), as amended, 8 U.S.C. 1372(e)(1). The Secretary is authorized to revise nonimmigrant fees on a periodic basis to account for changes in the cost of executing SEVP. IIRIRA section 641(g)(2), 8 U.S.C. 1372(g)(2). In addition, INA section 286(m), 8 U.S.C. 1356(m), provides that DHS may set fees ''at a level that will ensure recovery of the full costs of providing [adjudication] services.''

3. A Statement of Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis, a Statement of the Assessment of the Agency of Such Issues, and a Statement of Any Changes Made in the Proposed Rule as a Result of Such Comments

DHS published the Adjusting Program Fees for the Student Exchange Visitor Program NPRM which included the initial regulatory flexibility analysis on July 17, 2018 (83 FR 33762) with the comment period ending September 17, 2018. During the 60-day comment period, DHS received multiple comments that referred to the proposed rule's potential impact on small entities. These comments, however, did not result in any revisions to the established fee amounts for small entities in this final rule. DHS summarizes and responds to the significant issues raised by the public comments below.

Comments on Form I–17 Recertification Fee

Several commenters objected to the proposed Form I–17 recertification fee. Commenters specifically mentioned that the Form I–17 recertification will disproportionately burden smaller entities. Several commenters discussed concerns with the new Form I–17 recertification fee, because it is required every two years. One commenter said small rural public-school districts cannot afford the new expense of $1,250 to petition for recertification. A commenter who identified himself as affiliated with a rural high-need public school district, said the recertification fee will greatly inhibit the district's ability to continue a valuable program for its students.

One commenter wrote the proposed recertification fee would be cost-prohibitive to their international program and they would therefore be forced to pass on the additional expense incurred to the program onto international students. This commenter suggested applying a prorated fee schedule based upon the average number of Forms I–20 issued or the average number of attending students during the prior certification period.

A commenter stated that he or she was uncertain as to what information, statistics, guidance and studies were used to derive the proposed fees, but that it was not fair for a small institution to have to pay the same amount as an institution with high enrollment.

One commenter wrote that the recertification fee burden on small institutions may be the reason some institutions close their F–1 programs, which would negatively impact potential students who can no longer attend and domestic students who miss out on the opportunity for cultural and academic exchange. Overall, many commenters stated that it is not fair for a small institution to pay the same amount as an institution with larger enrollment numbers.

DHS Response to Comments on the Form I–17 Recertification Fee

Many commenters objected to DHS requiring small schools to petition for recertification and pay the fee every two years. DHS is mandated by EBSVERA section 502, 8 U.S.C. 1762(a), and HSPD–2 to periodically review all schools approved for admission of F or M students; EBSVERA specifically mandates a two-year review cycle. The recertification fee is used to support DHS's compliance with EBSVERA and HSPD–2 and to improve the recertification process.

Regarding the commenters' suggestion that DHS apply a gradual fee scale over time or base the fee on the number of international students attending the school, DHS considered this alternative but has ultimately decided not to institute a separate fee amount for small institutions. As DHS notes earlier under the section entitled, Recertification Fee, DHS declines establishing a lower fee for smaller institutions. Following a qualitative review of the fee model (which does not distinguish between institutions based on size), DHS could not identify a convincing basis for establishing a lower fee for small institutions. However, DHS identified two main reasons for keeping the recertification fee the same for all size schools. First, many of the administrative costs related to the recertification process are essentially similar irrespective of school type. The workload and cost of recertification adjudications does not change for different types of schools. Second, institutions with large nonimmigrant student populations typically require fewer resources in some respects, since they are more knowledgeable in the process, have a stable professional pool of employees, and have better internal reporting systems to assist in their compliance efforts. By contrast, schools with smaller nonimmigrant enrollment may require more frequent training of DSOs, or significant oversight if they are identified as higher risk.

Further, DHS conducted an analysis that compared the amount of the recertification fee to the overall revenue of affected small entities. DHS found that of the 7,037 small schools expected to apply for recertification and pay the final fee of $1,250, 50 schools, or less than one percent of all the small schools, will experience an impact greater than one percent, but less than three percent, of the school's annual revenue. See a detailed recertification fee regulatory flexibility analysis below.

With respect to the commenter who expressed uncertainty with respect to how the recertification and other fees are determined, DHS refers the commenter to the NPRM preamble, which described SEVP's current and future spend plans by organization and program category (Table 4), described future budget plans by initiative (Table 5), and allocated costs by activity type (Table 7). The NPRM also contained a comprehensive discussion of the basis for the individual fee calculations (see, e .g., 83 FR 33775 *et seq.*), as well as information about how to access the software used to calculate the fees (see 83 FR 33764).

Comments on Proposed Form I–901 Fees

Commenters objected that the proposed increase in the I–901 fees may lead to decreased enrollment at their small institutions from international students. Commenters raised objections that the increase in the I–901 fees made their small institutions less competitive with schools in other countries.

DHS Response to Proposed Form I–901 Fees

In response to these comments, SEVP reiterates from above that it supports international education. As stated above, nonimmigrant students typically have positive experiences while in the United States, and the goodwill engendered by all that the United States has to offer encourages mutually beneficial international relations. However, DHS must establish a fee schedule that allows for recovery of the full costs of current SEVP services and planned enhancements. Increasing the Form I–901 fees allows DHS to recover the costs of SEVP services and planned enhancements.

Comments on All Fee Adjustments and Potential Alternatives

Some commenters expressed concern that all the fee adjustments proposed would be burdensome to their small institutions and that DHS should charge its fees based on a scale of how many international students are enrolled.

DHS Response to Comments on All Fee Adjustments and Proposed Alternatives

DHS conducted an initial regulatory flexibility act analysis to consider how all the fee adjustments may cumulatively affect a small entity that is responsible for paying them. Commenters did not provide significant new data for DHS to consider in terms of impacts to small institutions. DHS rejects the alternative suggested by commenters to have a fee structure based on a scale of how many international students are enrolled at an institution. As stated above, since many of the costs associated with establishing an F or M student record in SEVIS occur prior to or at the beginning of the program of study (such as fixed costs of maintaining the system and educating DSOs), an equitable reduction in fees based on the number of students would be insignificant. SEVP reviews its fee structure biennially and will continue to explore additional means of configuring or tailoring the fees to better meet the needs of the stakeholders, including consideration of a tiered program if justified. In light of the significant adjustments in its fee structure, in its next biennial review SEVP will take into specific consideration any reductions in participation by small entities when determining a potential need for a tiered program.

4. The Response of the Agency To Any Comments Filed by the Chief Counsel for Advocacy of the Small Business Administration in Response to the Proposed Rule, and a Detailed Statement of Any Change Made to the Proposed Rule in the Final Rule as a Result of the Comments

DHS did not receive comments from the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule.

5. A Description and an Estimate of the Number of Small Entities to Which the Rule Will Apply or an Explanation of Why No Such Estimate Is Available

This analysis does not apply to increases in the Form I–901 F and M fees because these fees are paid by individuals who are not, for purposes of the RFA, within the definition of small entities established by 5 U.S.C. 601(6). DHS assumes that the Form I–901 J fees are also paid by individuals and did not receive comments on this assumption.

As of May 2017, there were a total of 8,746 SEVP-certified schools that would be subject to the Form I–17 recertification fee, site visit fee, and fee to file a motion or an appeal. New schools applying for SEVP certification will be subject to the Form I–17 initial certification fee. Of the 8,746 SEVP-certified schools, 2,013 have identified as public schools on their Form I–17 form. The remaining 6,733 schools have identified themselves on the Form I–17 as private for-profit, private nonprofit, or private unspecified entities.[17]

Of the 2,013 SEVP-certified public schools, DHS conducted a random sample of 100 [18] schools to approximate the number of public schools in governmental jurisdictions with a population of less than 50,000. Out of the 100 public schools, 22 are located in a city or school district with a population fewer than 50,000. Using this finding of 22 percent, DHS infers 443 SEVP-certified public schools are considered a small entity as defined by SBA.

DHS conservatively assumes that all 1,507 private nonprofit schools certified by SEVP are small entities because they are not dominant in their fields. DHS also conservatively assumes that the 4,755 schools that are private unspecified are small entities. DHS did not receive comments on this assumption.

To determine which of the remaining 471 private for-profit schools are considered a small entity, DHS references the Small Business Administration (SBA) size standards represented by business average annual receipts. Receipts are generally defined as a firm's total income or gross income. SBA's Table of Small Business Size Standards is matched to the North American Industry Classification System (NAICS) for industries.[19] DHS matches information provided by the schools in SEVIS regarding what programs of study it is engaged in with an appropriate NAICS industry description. NAICS is the standard classification used to categorize business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. economy.

DHS finds that the revenue of 332 of the 471 private, for-profit schools meet the SBA size standard of a small business according to their industry. DHS estimates each private school's annual receipts by multiplying the approximate annual cost of room, board, and tuition by the average annual number of total students, based on data provided by the schools on their Forms I–17. Every two years, as part of the recertification process, a school submits the approximate annual cost of room, board, and tuition per student and the average annual number of total students, both domestic and international. DHS acknowledges that this method to estimate receipts may be an incomplete account of a school's income, which may also include contributions from private individuals or other endowments. Since these data reflect a snapshot of all SEVP-certified schools as of May 24, 2017, DHS acknowledges there may be day-to-day changes in the status of a school's certification and that a school's revenue may differ from actual revenue due to a 2-year lag in school self-reporting before a school is required to recertify.

Given these assumptions, DHS estimates that 7,037 schools meet the SBA definition of a small entity. This is approximately 80 percent of the 8,746 of SEVP-certified schools included in this analysis.

Table 30 shows a summary by school type of the number of SEVP-certified schools and estimated small entities.

BILLING CODE 9111–28–P

[17] Prior to October 1, 2016, schools had two options in SEVIS to select their school type: Public or private unspecified. With the recent SEVIS update, schools can choose one of three options: public, private for-profit, or private nonprofit.

[18] The random sample helps ensure an accurate representation of the population with each school having an equal chance of being included. In determining the sample size DHS utilized a 90 percent confidence level (z-score), 10 percent margin of error (e), and a 50 percent population proportion (π) used as an unknown input and to maximize the estimate to overestimate sample size. The sample size equation used $n = (z \wedge (1 - \pi)) / e \wedge 2$ provided inputs $([1.65] \wedge 2(.5)(.5))/301 = 69$ and rounded up to 100 to over sample. DHS has revised the number of small public schools estimated in the Initial Regulatory Flexibility Analysis. DHS estimated the number of small public schools by first identifying that 61 of the 100 entities are state-administered entities are therefore not considered small entities under the RFA. For the remaining schools, DHS then identified geographic population data matched to the school district as provided in SEVIS, sourced from the U.S. Census Bureau, Small Area Income and Poverty Program, *https://www.census.gov/data/datasets/2016/demo/saipe/2016-school-districts.html* (last visited April 19, 2019) or to the school's city address provided in SEVIS, sourced from U.S. Census Bureau 2010–2016 Cities and Towns (Incorporated Places and Minor Civil Divisions), *https://www.census.gov/data/tables/2016/demo/popest/total-cities-and-towns.html* (last visited July 11, 2018).

[19] U.S. Small Business Administration, Tables of Small Business Size Standards Matched to NAICS Codes (Oct. 1, 2017), *https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.xlsx.*

Table 30: SEVP-Certified Schools by School Type

Description	Total	Small Entities
Public Schools	2,013	443
Private, nonprofit schools	1,507	1,507
Private, unspecified schools	4,755	4,755
Private, for-profit schools	471	332
Total Number of SEVP-Certified Schools	8,746	7,037

Table 31 provides a summary of the SEVP-certified schools by industry. Table 31 also shows the NAICS industry description, the NAICS code, and the number of small and large schools by industry. Note that the number of small schools includes all nonprofits and unspecified private schools. Most industries with SEVP-certified schools consist of a majority of small schools.

Table 31: Number of SEVP–Certified Schools by Industry

School Industry	NAICS Industry Description	NAICS Codes	Number of Small Schools	Number of non-small Schools	Total SEVP-Certified Schools	Percent Small Schools
Elementary and Secondary Schools (private)	Industry primarily engaged in providing academic courses and related course work that contain a basic preparatory education. A basic preparatory education generally starts kindergarten through 12th grade.	611110	3,472	18	3,490	99%
Junior Colleges	Industry primarily engaged in providing academic or technical courses and granting associate degrees, certificates, or diplomas below the baccalaureate level.	611210	11	2	13	85%
Colleges, Universities, and Professional Schools	Industry primarily engaged in providing academic courses and granting degrees at baccalaureate or graduate levels. The requirement for admission is at least a high school diploma or equivalent general academic training.	611310	2,150	57	2,207	97%
Computer Training	Industry primarily engaged in providing computer training (except computer repair), such as computer programming, software packages, computerized business systems, computer electronics technology, computer operations, and local area network management.	611420	13	0	13	100%

School Industry	NAICS Industry Description	NAICS Codes	Number of Small Schools	Number of non-small Schools	Total SEVP-Certified Schools	Percent Small Schools
Professional and Management Development Training	Industry primarily engaged in providing a collection of short interval courses and sessions for management and professional development. Training for career development may be provided directly to individuals or through employers' training programs, and courses may be customized or modified to meet the special needs of customers.	611430	18	0	18	100%
Cosmetology and Barber Schools	Industry primarily engaged in providing training in hair styling, barbering, or cosmetic arts, such as makeup or skin care.	611511	91	3	94	97%
Flight Training	Industry primarily engaged in providing aviation and flight training.	611512	199	1	200	100%
Apprentice-ship Training	Industry primarily engaged in providing apprenticeship training programs.	611513	39	1	40	98%
Other Technical and Trade Schools	Industry primarily engaged in providing job or career vocational or technical courses (except cosmetology and barber training, aviation and flight training, and apprenticeship training).	611519	183	6	189	97%
Fine Arts Schools	Establishments primarily engaged in offering instruction in the arts, including dance, art, drama, and music.	611610	79	3	82	96%

School Industry	NAICS Industry Description	NAICS Codes	Number of Small Schools	Number of non-small Schools	Total SEVP-Certified Schools	Percent Small Schools
Sports and Recreation Instruction	Industry primarily contains institutions such as camps and schools, primarily engaged in providing instruction in athletic activities to groups of individuals.	611620	10	0	10	100%
Language Schools	Industry primarily engaged in providing foreign language instruction (including sign language).	611630	286	44	330	87%
Exam Preparation and Tutoring	Industry primarily engaged in providing training for standardized examinations and/or educational tutoring services.	611691	8	4	12	67%
All Other Misc. Schools and Instruction	Industry primarily engaged in providing instruction (except academic schools, colleges and universities, business, computer, management, technical, trade, fine arts, athletic, language instruction, tutoring, and automobile driving instruction).	611699	32	0	32	100%
Educational Support Services	Industry primarily engaged in providing non-instructional services that support educational processes or systems.	611710	2	0	2	100%
Public Schools (Elementary, Secondary, and High School and post-secondary)	Industry primarily engaged in providing academic courses and related course work that contain a basic public education.	N/A	443	1,570	2,013	22%
Total			**7,037**	**1,709**	**8,746**	**80%**

Table 32 presents the type of schools with active F and M nonimmigrant students and the percent of students enrolled in small schools. Most F and M nonimmigrant students are enrolled at small schools. Of the 8,746 SEVP-

certified schools, DHS identified 1,728 with no active F or M nonimmigrant students and determined that 1,296 of these are considered small entities as defined by SBA. Note that although there are two SEVP-certified schools in the education support services industry (shown in Table 31), there are no active F and M nonimmigrant students in these schools. DHS applies the results of the sample of SEVP-certified public schools to the number of students in SEVP-certified public schools (619,295) to estimate that the number of students in small SEVP-certified public schools is 136,245.

Table 32: Total Number of Active F and M Students by Industry

School Industry	Total Active F and M Students in Small Schools	Total Active F and M Students	Percent of Students at Small Schools
Elementary and Secondary Schools (private)	60,990	63,491	96%
Junior Colleges	409	418	98%
Colleges, Universities, and Professional Schools	419,593	429,784	98%
Computer Training	404	404	100%
Professional and Management Development Training	217	217	100%
Cosmetology and Barber Schools	91	93	98%
Flight Training	6,598	6,605	100%
Apprenticeship Training	71	75	95%
Other Technical and Trade Schools	1,108	1,111	100%
Fine Arts Schools	1,736	2,030	86%
Sports and Recreation Instruction	13	13	100%
Language Schools	33,500	41,867	80%
Exam Preparation and Tutoring	1,469	1,984	74%
All Other Miscellaneous Schools and Instruction	218	218	100%
Educational Support Services	-	-	0
Public Schools (K-12 and post secondary)	136,245	619,295	22%

DHS estimated SEVP-certified public schools' revenue to examine the impact of the fee adjustments on small public schools. The tuition provided by public schools in SEVIS may not represent a public school's total revenue because most of the U.S. students would generally not pay the tuition provided to attend public schools. Instead, DHS assumes that a public school's school district, county, or city's tax revenue is the best revenue source against which to assess the impact of the fee adjustments. DHS collected local government revenue, expenditure, debt, and assets from the U.S. Census Bureau 2015 State and Local Government Survey [20] to examine the impact of the increased fees on the public schools included in the sample. A school district, county, or city's revenue may be an overestimation of a public school's capability to pay the fees related to SEVP-certification, appeals, or site visits for new locations. In other words, the use of revenue as a proxy for ability to pay may result in understating the impact of the fee increase on public schools.

Table 33 displays the range of annual revenue by each school industry and for public schools, from the small school

[20] United States Census, 2015 State & Local Government Finance Historical Tables, *https://www.census.gov/data/tables/2015/econ/gov-finances/summary-tables.html* (last visited Nov. 1, 2018).

with the lowest revenue to the median revenue of all the small schools to the small school with the largest revenue. It also shows the average revenue of all the small schools in that industry. The Colleges, Universities, and Professional Schools industry has the widest range from maximum to minimum revenue due to the assumption that all private, unspecified schools are small entities, while the Educational Support Services industry that only has two schools included has the smallest range of maximum to minimum revenue for any one industry.

Table 33: Range of Annual Revenue by School Industry

School Industry	Lowest Annual Revenue	Median Annual Revenue	Largest Annual Revenue	Average Annual Revenue
Elementary and Secondary Schools (private)	$28,800	$5,116,550	$1,680,000,000	$13,194,355
Junior Colleges	$44,400	$2,560,000	$15,255,000	$4,271,901
Colleges, Universities, and Professional Schools	$26,400	$28,432,500	$5,002,524,120	$96,761,518
Computer Training	$425,000	$3,000,000	$14,000,000	$3,881,631
Professional and Management Development Training	$129,600	$717,500	$2,904,625	$1,000,423
Cosmetology and Barber Schools	$70,000	$2,183,000	$66,907,200	$4,092,673
Flight Training	$36,000	$3,000,000	$60,000,000	$5,959,154
Apprenticeship Training	$132,000	$10,265,875	$106,080,000	$21,004,563
Other Technical and Trade Schools	$64,000	$2,800,000	$82,800,000	$7,570,939
Fine Arts Schools	$66,000	$2,895,000	$130,000,000	$9,425,304
Sports and Recreation Instruction	$276,800	$1,165,000	$9,312,500	$2,626,805
Language Schools	$118,500	$5,725,000	$108,000,000	$7,514,433
Exam Preparation and Tutoring	$3,150,000	$5,043,189	$27,000,000	$6,983,297
All Other Miscellaneous Schools and Instruction	$83,250	$845,000	$469,050,000	$18,359,767
Educational Support Services	$340,000	$521,750	$703,500	$521,750
Public Schools (K-12 and post secondary)	$2,948,000	$65,920,500	$8,352,908,000	$803,913,182

6. A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Final Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

The final rule will increase and establish additional fees for educational institutions in support of SEVP operations. DHS estimates the annual impact to small schools based on the school cost of compliance as represented as a percentage of their annual revenue. Table 34 displays the final fees, the current fees, and the difference in these amounts. This analysis examines the impact that the final incremental fee for the Form I–17 certification and the final fees for recertification, site visits to add a new physical location or campus, and the filing of a motion or an appeal would have on small SEVP-certified schools.

Table 34: Finalized School Fees by Type

Fee Type	Finalized Fee	Current Fee	Difference (Final –Current)	Percent Increase
I-17 Certification Fee	$3,000	$1,700	$1,300	76%
I-17 Recertification Fee	$1,250	$0	$1,250	N/A
Site Visit Fee – initial	$655	$655	$0	0%
Site Visit Fee – new location	$655	$0	$655	N/A
Motion or Appeal Fee	$675	$0	$675	N/A

I–17 Certification Fee

A school files a petition and pays a certification fee to become eligible to issue the Form I–20, Certificate of Eligibility for Nonimmigrant Student Status, to prospective international students after admitting them for a course of study. SEVP certification authorizes the school to enroll international students after they enter the country as F or M nonimmigrant students. Schools must initially go through the vetting process for authorization by DHS to enroll F and/or M nonimmigrant students and pay the Form I–17 school certification fee, which is currently $1,700 and determined to increase to $3,000. The incremental fee is the difference between the finalized fee ($3,000) and current fee ($1,700), or $1,300. From 2012 to 2016, DHS processed 2,117 Forms I–17 and payments. Out of the 2,117 schools, 1,151, or 54 percent, were identified as meeting the SBA definition of a small school, or estimated to be a small public school based on the sample conducted, as illustrated in Table 35.

Table 35: I-17 Initial Certifications FYs 2012–2016

Fiscal Year	Total I-17 Initial Certifications	Small School I-17 Initial Certifications	Percent of Small School I-17 Initial Certifications
2012	457	236	52%
2013	382	218	57%
2014	446	270	60%
2015	469	260	55%
2016	363	167	46%
Total	**2,117**	**1,151**	**54%**
2014–2016 3-year annual average	**426**	**232**	**55%**

SEVP forecasted the total Form I–17 initial certifications in FY 2019 and FY 2020 to be 426 using the three-year annual average of FY 2014 through 2016 initial certifications. Using that same methodology, 232 small schools applied for initial Form I–17 certification on average each year. DHS assumes the growth of small schools per industry seeking SEVP certification will remain constant in the future. DHS multiplied the annual average number of small schools applying for initial certification by the percent of small schools in each industry, as presented in Table 31. This calculation yields the number of small schools expected to petition for initial Form I–17 certification by industry. The results are presented in Table 36.

Table 36: Expected Annual Number of Small Schools to Initially Certify by School Industry

School Industry	Annual Number of Small Schools Applying for Initial Certification
Elementary and Secondary Schools (private)	103
Junior Colleges	0
Colleges, Universities, and Professional Schools	64
Computer Training	0
Professional and Management Development Training	1
Cosmetology and Barber Schools	3
Flight Training	6
Apprenticeship Training	1
Other Technical and Trade Schools	5
Fine Arts Schools	2
Sports and Recreation Instruction	0
Language Schools	8
Exam Preparation and Tutoring	0
All Other Miscellaneous Schools and Instruction	1
Educational Support Services	0
Public Schools (K-12 and post secondary)	12
Total Small Schools	**194**

This analysis examines the impact the $1,300 incremental fee has on small schools that might seek initial certification after this final rule is effective. DHS assumes that the range of revenue of the small schools that will apply for certification is similar to the range of revenue of current SEVP-certified small schools and uses this range to show the potential impacts. Table 37 shows the impact as a percentage for the schools with the lowest annual revenue, median annual revenue, and largest annual revenue, as well as the average annual revenue for all schools in that industry. From these results, DHS does not expect the Form I–17 certification incremental fee to have an impact greater than one percent on the average small school annual revenue. However, there is an expected impact greater than one percent for some small schools with the lowest annual revenue in their industry. On average the estimated 194 small schools that apply for initial Form I–17 certification annually and pay an incremental fee of $1,300 will experience an impact of less than one percent of their estimated annual revenue.

Table 37: Initial Certification Fee Impact for Small Schools by Type of School

Type of School	I-17 Initial Certification Incremental Fee Impact on the School with the Lowest Revenue	I-17 Initial Certification Incremental Fee Impact on the School with the Median Revenue	I-17 Initial Certification Incremental Fee Impact on the School with the Largest Revenue	I-17 Initial Certification Incremental Fee Impact on the Average School Revenue
Elementary and Secondary Schools (private)	4.5%	0.0%	0.0%	0.01%
Junior Colleges	2.9%	0.1%	0.0%	0.03%
Colleges, Universities, and Professional Schools	4.9%	0.0%	0.0%	0.00%
Computer Training	0.3%	0.0%	0.0%	0.03%
Professional and Management Development Training	1.0%	0.2%	0.0%	0.13%
Cosmetology and Barber Schools	1.9%	0.1%	0.0%	0.03%
Flight Training	3.6%	0.0%	0.0%	0.02%
Apprenticeship Training	1.0%	0.0%	0.0%	0.01%
Other Technical and Trade Schools	2.0%	0.0%	0.0%	0.02%
Fine Arts Schools	2.0%	0.0%	0.0%	0.01%
Sports and Recreation Instruction	0.5%	0.1%	0.0%	0.05%
Language Schools	1.1%	0.0%	0.0%	0.02%
Exam Preparation and Tutoring	0.0%	0.0%	0.0%	0.02%
All Other Miscellaneous Schools and Instruction	1.6%	0.2%	0.0%	0.01%
Educational Support Services	0.4%	0.2%	0.2%	0.25%
Public Schools (K-12 and post secondary)	0.0%	0.0%	0.0%	0.0%

I–17 Recertification Fee

SEVP-certified schools are required to file for recertification every two years to demonstrate that they have complied with all recordkeeping, retention, reporting, and other requirements when registering F and M students. There is currently no fee charged to schools for recertification, but this final rule establishes a new fee for that process.

To measure the impact on small schools, DHS first estimated the number of small schools that will recertify. DHS assumes 50 percent (4,373) of the total number of schools in this analysis (8,746) will recertify each year. DHS multiplies the recertification rate of 50 percent by the total number of small schools to generate the estimation that 3,519 [21] small schools will recertify annually. DHS examined all 7,037 small SEVP-certified schools to determine the impact of the recertification fee, as it is assumed that a significant number of the schools will pursue recertification within the next two years.

DHS assumes that the total number of SEVP-certified schools will remain static as new schools become certified and other schools' certifications are relinquished, withdrawn, or denied. DHS therefore assumes that the annual increase of total recertifications will be zero.

As previously discussed, DHS identified 1,296 SBA-defined small schools with no active F or M nonimmigrant students. DHS included these schools in this analysis and assumes they will opt to pay the recertification fee of $1,250 rather than reapplying for initial certification with a finalized fee of $3,000 at such time in the future that they enroll F or M nonimmigrant students.

Table 38 illustrates the number of small schools that will recertify by industry and the Form I–17 recertification incremental fee impact as a percent of the small school's annual revenue. From these findings, of the 7,037 small schools expected to apply for recertification and pay the finalized fee of $1,250, 50 schools, or 0.7 percent, will experience an impact greater than one percent but less than three percent of the school's annual revenue. For the remaining schools, DHS does not expect the incremental fee to have an impact of greater than one percent.

Table 38: Recertification Fee Impact for Small Schools by Type of School

School Industry	0% < Impact ≤ 1%	1% < Impact ≤ 2%	2% < Impact < 3%	Total
Elementary and Secondary Schools (private)	3,458	7	7	**3,472**
Junior Colleges	10	0	1	**11**
Colleges, Universities, and Professional Schools	2,135	12	4	**2,150**
Computer Training	13	0	0	**13**
Professional and Management Development Training	18	0	0	**18**
Cosmetology and Barber Schools	89	2	0	**91**
Flight Training	196	1	2	**199**
Apprenticeship Training	39	0	0	**39**
Other Technical and Trade Schools	175	8	0	**183**
Fine Arts Schools	76	3	0	**79**
Sports and Recreation Instruction	10	0	0	**10**
Language Schools	285	1	0	**286**
Exam Preparation and Tutoring	8	0	0	**8**
All Other Miscellaneous Schools and Instruction	30	2	0	**32**
Educational Support Services	2	0	0	**2**
Public Schools (K-12 and post secondary)	443	0	0	**443**
Total Small Schools	**6,987**	**36**	**14**	**7,037**

[21] 7,037 × 50 percent = 3,518.5 small schools recertifying each year.

Site Visit Fee

Current regulations provide authority for SEVP to charge a site visit fee to schools that apply for initial certification or add a new physical location or campus. The site visit allows SEVP an opportunity to gather evidence on the school's eligibility, review school facilities, and interview personnel listed on the Form I–17 petition as a PDSO or DSO. SEVP currently collects the $655 fee when a school files a petition for certification to issue Forms I–20 or by a certified school when it physically moves to a new location. This final rule notifies the public that SEVP will collect the fee from any certified school that adds a new campus or physical location by updating its Form I–17 in SEVIS, consistent with 8 CFR 214.3(h)(3) and the agency's description when it established the fee in 2008 that such a fee could apply to such an initial event. 73 FR 55683, 55691.

SEVP performs 600 site visits annually. Of these site visits, 426 would be performed as part of the forecasted initial certifications, leaving the capacity for 174 site visits to be performed when a school adds a campus. In order to estimate the impact on a school's revenue of the site visit fee for a new instructional campus, DHS assumes that any of the currently SEVP-certified schools could add a campus and require a site visit. Table 39 shows the finalized site visit fee impact on estimated annual revenue for all 7,037 small schools certified by SEVP and the type of school. Of the total 7,037 small schools, 7,022, or 99.8 percent, would have a site visit fee impact of less than or equal to one percent of their annual revenue. Twelve small schools, or 0.2 percent of small schools, would have an impact of greater than one percent but less than or equal to two percent of their annual revenue. Three small schools would have a site visit fee impact greater than two percent but less than three percent of their annual revenue.

Table 39: Site Visit Fee Impact on Estimated Annual Revenue

Type of School	0% < Impact ≤ 1%	1% < Impact ≤ 2%	2% < Impact < 3%	Total
Elementary and Secondary Schools (private)	3,465	5	2	**3,472**
Junior Colleges	10	1	0	**11**
Colleges, Universities, and Professional Schools	2,146	3	1	**2,150**
Computer Training	13	0	0	**13**
Professional and Management Development Training	18	0	0	**18**
Cosmetology and Barber Schools	91	0	0	**91**
Flight Training	197	2	0	**199**
Apprenticeship Training	39	0	0	**39**
Other Technical and Trade Schools	182	1	0	**183**
Fine Arts Schools	79	0	0	**79**
Sports and Recreation Instruction	10	0	0	**10**
Language Schools	286	0	0	**286**
Exam Preparation and Tutoring	8	0	0	**8**
All Other Miscellaneous Schools and Instruction	32	0	0	**32**
Educational Support Services	2	0	0	**2**
Public Schools (K-12 and post secondary)	443	0	0	443
Total Small Schools	**7,022**	**12**	**3**	**7,037**

Fee To File an Appeal or Motion

When a school is denied certification or recertification, the school receives a denial letter through certified mail. The denial letter explains the reason for the denial and the steps to appeal. The school can appeal by filing the Form I–290B. This final rule imposes a $675 filing fee for submission of the Form I–290B.[22] Currently no fee is imposed when a school submits the Form I–290B for a motion or appeal.

DHS processed 215 motions and appeals from schools from 2013 to 2016. Out of the 215 school motions and appeals, DHS determined that 74, or 34.4 percent, were filed by small schools. Among the 74 small schools, four schools had two appeals within the same year or over the four-year period. During the four-year period, there was an average of 19 appeals and motions filed by small schools annually.

DHS examined all 7,037 small schools to estimate the impact of the final appeal and motion fee on estimated

[22] USCIS, Form I–290B, Notice of Appeal or Motion, Filing Fee, *https://www.uscis.gov/i-290b.*

annual revenue. The impact is calculated by dividing the fee to file a motion or appeal by the school's estimated annual revenue. Of the 7,037 SEVP-certified small schools, 7,021, or 99.8 percent, would experience an impact less than or equal to one percent of their estimated annual revenue were the school to file an appeal or motion. DHS estimates 13 small schools, or 0.2 percent, would realize an impact between one percent and two percent of their estimated annual revenue. In addition, three small schools, or 0.04 percent, would experience an impact greater than two percent but less than three percent of estimated annual revenue. Table 40 shows the number of small schools within the range of impact to each school's estimated annual revenue.

Table 40: Appeal and Motion Fee Impact on Estimated Annual Revenue

Type of School	0% < Impact ≤ 1%	1% < Impact ≤ 2%	2% < Impact < 3%	Total
Elementary and Secondary Schools (private)	3,465	5	2	3,472
Junior Colleges	10	1	0	11
Colleges, Universities, and Professional Schools	2,146	3	1	2,150
Computer Training	13	0	0	13
Professional and Management Development Training	18	0	0	18
Cosmetology and Barber Schools	91	0	0	91
Flight Training	197	2	0	199
Apprenticeship Training	39	0	0	39
Other Technical and Trade Schools	182	1	0	183
Fine Arts Schools	78	1	0	79
Sports and Recreation Instruction	10	0	0	10
Language Schools	286	0	0	286
Exam Preparation and Tutoring	8	0	0	8
All Other Miscellaneous Schools and Instruction	32	0	0	32
Educational Support Services	2	0	0	2
Public Schools (K-12 and post secondary)	443	0	0	443
Total Small Schools	**7,021**	**13**	**3**	**7,037**

The possible total impact on small entities in any year can be determined by examining scenarios in which a school may pay more than one of the finalized adjustments in fees in the same year. DHS examines the following scenarios and determines that the impact on any small school's revenue is less than three percent on any school industry type: (1) A school appeals an initial certification or (2) a school appeals a recertification and adds a new location requiring a site visit.

A school may pay the initial certification fee and then it may appeal the results of the initial certification within the same year. DHS estimates that this would be an increase of $1,975 ($1,300 incremental fee for Form I–17 initial certification plus $675 fee for an appeal). More than 98 percent of schools would be impacted less than one percent in this scenario, as shown in Table 41. The impacts of this scenario would be greater than the impacts of a scenario where a school appeals a recertification, which would add to $1,925 in increased fees ($1,250 I–17 recertification fee plus $675 for an appeal).

Table 41: Impact of Initial Certification Fee Increase Plus an Appeal Fee

Type of School	0% < Impact ≤ 1%	1% < Impact ≤ 2%	2% < Impact < 3%	Total
Elementary and Secondary Schools (private)	3,440	21	11	**3,472**
Junior Colleges	10	0	1	**11**
Colleges, Universities, and Professional Schools	2,126	15	10	**2,151**
Computer Training	13	0	0	**13**
Professional and Management Development Training	15	3	0	**18**
Cosmetology and Barber Schools	89	1	1	**91**
Flight Training	192	4	3	**199**
Apprenticeship Training	37	2	0	**39**
Other Technical and Trade Schools	171	9	3	**183**
Fine Arts Schools	74	2	3	**79**
Sports and Recreation Instruction	10	0	0	**10**
Language Schools	282	4	0	**286**
Exam Preparation and Tutoring	8	0	0	**8**
All Other Miscellaneous Schools and Instruction	26	4	2	**32**
Educational Support Services	2	0	0	**2**
Public Schools (K-12 and post secondary)	443	0	0	**443**
Total Small Schools	**6,938**	**64**	**35**	**7,037**

A school may seek recertification in the same year it adds a new physical location or campus that requires a site visit and then it may appeal the findings of a recertification. A recertification fee would not include a site visit to a new location. DHS estimates that this would be an increase of $2,580 ($1,250 Form I–17 recertification fee plus $655 for a site visit at a new location plus $675 for an appeal). Under this scenario, the impact on small schools' revenue would be less than one percent for all but 139 small schools. The impact on these 139 schools' revenues would be less than three percent as shown in Table 42.

Table 42: Impact of Recertification Fee Plus a Site Visit – New Location Fee Plus an Appeal Fee

Type of School	0% < Impact ≤ 1%	1% < Impact ≤ 2%	2% < Impact < 3%	Total
Elementary and Secondary Schools (private)	3,426	28	18	**3,472**
Junior Colleges	10	0	1	**11**
Colleges, Universities, and Professional Schools	2,110	24	17	**2,151**
Computer Training	13	0	0	**13**
Professional and Management Development Training	15	3	0	**18**
Cosmetology and Barber Schools	87	2	2	**91**
Flight Training	191	5	3	**199**
Apprenticeship Training	37	2	0	**39**
Other Technical and Trade Schools	167	8	8	**183**
Fine Arts Schools	74	2	3	**79**
Sports and Recreation Instruction	10	0	0	**10**
Language Schools	279	6	1	**286**
Exam Preparation and Tutoring	8	0	0	**8**
All Other Miscellaneous Schools and Instruction	26	4	2	**32**
Educational Support Services	2	0	0	**2**
Public Schools (K-12 and post secondary)	443	0	0	**443**
Total Small Schools	**6,898**	**84**	**55**	**7,037**

7. A Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes, Including a Statement of the Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each One of the Other Significant Alternatives to the Rule Considered by the Agency Which Affect the Impact on Small Entities Was Rejected

SEVP examined several alternatives to the final fee structure, including no increase to any fee, only increasing the Form I–901 fee and Form I–17 initial school certification fee, not subsidizing the school fees with the Form I–901 F and M fees, and, as noted above, a graduated or sliding-scale fee structure based either on student population numbers or program length.

Without an increase in fees, SEVP will be unable to maintain the level of service for students and schools that it currently provides as well as the compliance and national security activities discussed above. SEVP considered the alternative of maintaining fees at the current level but with reduced services and increased processing times, but has decided that this would not be in the best interest of applicants and schools. SEVP seeks to minimize the impact on all parties, but in particular small entities. SEVP must pay for the expenses of maintaining and improving SEVIS and adjudicating schools in a timely manner. If SEVP followed this alternative scenario, there would be a shortfall of revenue to cover the expenses of over $65.4 million in FY 2019. SEVP rejected this alternative, as SEVP must pay for the expenses of maintaining and improving SEVIS and certifying and recertifying schools in a timely manner.

SEVP also considered only raising the Form I–901 fees and the Form I–17 initial certification fee instead of including new finalized fees for recertification and for filing an appeal or motion. If SEVP followed this scenario, while the Form I–901 F and M fee would increase to $350 to cover the shortfall in revenue, the Form I–17 initial certification fee would also increase to $4,200. This would triple the existing certification fee while continuing to allow schools with no foreign students to remain active SEVP schools that require SEVP effort for recertification. SEVP rejected this fee structure as it would continue to add workload to SEVP's recertification program. Without a disincentive to not recertify, the list of schools recertifying would never stop growing. SEVP rejected this alternative because the finalized fees would establish a more equitable distribution of costs and a more sustainable level of cost recovery relative to the services provided as compared to this alternative.

SEVP also considered the results of the ABC model as an alternative, which allocated the Form I–901 F and M fee, school certification fees, and the fee to file an appeal or motion as shown in Table 43.

Table 43: Unsubsidized Fee Amounts

Fee Type	Unsubsidized Fee Amounts
I-901 F and M	$290
I-901 J-Full	$130
I-901 J-Partial	$130
I-17 Initial Certification	$4,600
I-17 Recertification	$6,000
Appeal or Motion	$38,475
Site Visit	$650

BILLING CODE 9111–28–C

SEVP rejected this alternative for several reasons. Setting the fee at $38,475 may discourage schools from filing an appeal or motion.

Similarly, SEVP rejected the alternative of setting the recertification fee at $6,000. A recertification fee higher than the initial certification fee would discourage schools from seeking recertification as opposed to relinquishing certification or allowing certification to expire and subsequently applying again for initial certification.

SEVP instead sets the recertification fee at a level that is less than the initial certification fee. When schools can maintain their certification, F and M nonimmigrant students enrolled in the withdrawn school avoid complications such as being forced to transfer schools, leave the United States, or risk facing immigration law penalties for violating the terms of their nonimmigrant status.

SEVP also rejected the initial certification fee of $4,600 because it finds that an increase of almost three times the current fee of $1,700 is excessive. In the fee development, DHS balanced the challenge of minimizing the costs to schools and students while recovering funding to support SEVP services. The population of Form I–901 F and M nonimmigrant students relative to the population of Form I–17 schools allows for a minimal fee adjustment to be spread over the student population to reduce the cost burden on individual institutions seeking recertification.

C. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, 109 Stat. 48 (codified at 2 U.S.C. 1501 *et seq.*), requires federal agencies to assess the effects of their discretionary regulatory actions. In particular, UMRA addresses actions that may result in the expenditure by a State, local, or tribal government in the aggregate or by the private sector of $100 million (adjusted for inflation) or more in any one year. 2 U.S.C. 1532(a). Though this rule will not result in such an expenditure, DHS does discuss the effects of this rule elsewhere in this preamble. In addition, DHS maintains that this rulemaking is not a ''Federal mandate,'' as defined for UMRA purposes, 2 U.S.C. 658(6), as the payment of an SEVP certification fee by individuals, local governments, or other private sector entities is (to the extent it could be termed an enforceable duty) one that arises from participation in a voluntary Federal program (*i.e.,* applying for status as F–1, F–3, M–1, or M–3 students or as a J–1 exchange visitor in the United States or seeking approval from the United States for attendance by certain aliens seeking status as F–1, F–3, or M–1 students). 2 U.S.C. 658(7)(A)(ii). For these reasons, no additional actions were deemed necessary under the provisions of the UMRA.

D. Congressional Review Act

This rulemaking is not a major rule, as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking pursuant to the Congressional Review Act, Public Law 104–121, sec. 251, 110 Stat. 868, 873 (codified at 5 U.S.C. 804). This rulemaking would not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets. DHS will submit to Congress and the Comptroller General of the United States a report about the issuance of the final rule prior to its effective date, as required by 5 U.S.C. 801(a)(1).

E. Executive Order 13132: Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, 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. DHS has analyzed this final rule under that Order and has determined that it does not have implications for federalism.

F. Executive Order 12988: Civil Justice Reform

This rule meets the applicable standards set forth in 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

G. Energy Effects

DHS has analyzed this final rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. DHS has determined that it is not a ''significant energy action'' under that order because it is a ''significant regulatory action'' under Executive Order 12866 but is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

H. Environment

DHS Management Directive (MD) 023–01 Rev. 01 establishes procedures that DHS and its Components use to comply with the National Environmental Policy Act of 1969 (NEPA), Public Law 91–190, 83 Stat. 852 (codified at 42 U.S.C. 4321–4375),

and the Council on Environmental Quality. regulations for implementing NEPA, 40 CFR parts 1500 through 1508. The Council on Environmental Quality Regulations allow federal agencies to establish categories of actions that do not individually or cumulatively have a significant effect on the human environment and, therefore, do not require an Environmental Assessment or Environmental Impact Statement. 40 CFR 1508.4. The MD 023–01 Rev. 01 lists the Categorical Exclusions that DHS has found to have no such effect. MD 023–01 Rev. 01, Appendix A, Table 1.

For an action to be categorically excluded, MD 023–01 Rev. 01 requires the action to satisfy each of the following three conditions:

(1) The entire action clearly fits within one or more of the Categorical Exclusions.

(2) The action is not a piece of a larger action.

(3) No extraordinary circumstances exist that create the potential for a significant environmental effect. MD 023–01 Rev. 01 section V.B(1)–(3).

Where it may be unclear whether the action meets these conditions, MD 023–01 Rev. 01 requires the administrative record to reflect consideration of these conditions. MD 023–01 Rev. 01 section V.B.

DHS has analyzed this final rule under MD 023–01 Rev. 01. DHS has made a determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This final rule clearly fits within the Categorical Exclusion found in MD 023–01 Rev. 01, Appendix A, Table 1, number A3(a): ''Promulgation of rules . . . of a strictly administrative or procedural nature''; and A3(d): ''Promulgation of rules . . . that interpret or amend an existing regulation without changing its environmental effect.'' This rule is not part of a larger action. This rule presents no extraordinary circumstances creating the potential for significant environmental effects. Therefore, this rule is categorically excluded from further NEPA review.

I. Paperwork Reduction Act

All Departments are required to submit to OMB for review and approval any reporting or recordkeeping requirements inherent in a rule under the Paperwork Reduction Act of 1995, Public Law 104–13, 109 Stat. 163 (codified at 44 U.S.C. 3501 *et seq.*). Schools will be using SEVIS to petition for recertification. The recertification process requires schools to input data in SEVIS, print the Form I–17, and sign the form. The electronic data captured for the Form I–17 have been previously approved for use by OMB as one component of the data that are captured in SEVIS. The OMB Control Number for this collection is 1653–0038 (originally 1615–0066 before the collection was transferred from United States Citizenship and Immigration Services to ICE). With the regulatory implementation of SEVIS (67 FR 60107, Sept. 25, 2002), most schools enrolled in SEVIS were petitioning for DHS recertification, rather than initial certification (*i.e.,* enrolling F or M nonimmigrant students for the first time). The workload for both certification and recertification was included under OMB 1615–0066.

The changes to the certification and recertification fees, as well as the Form I–901 fees, would require changes to SEVIS and the Form I–901 software to reflect the updated fee amounts, as these systems generate the pertinent petition and application forms. DHS will submit a revision to OMB with respect to any changes to existing information collection approvals.

DHS's institution of the fee for a motion or appeal with regard to a denial of school certification or recertification, or a withdrawal of such certification, will not require a form amendment to reflect the charging of the fee. The instructions associated with the Form I–290B, which is currently used for such motions and appeals, contain information regarding the $675 fee.

List of Subjects

8 CFR Part 103

Administrative practice and procedure, Authority delegations (Government agencies), Freedom of Information, Immigration, Privacy, Reporting and recordkeeping requirements, Surety bonds.

8 CFR Part 214

Administrative practice and procedure, Aliens, Employment, Foreign officials, Health professions, Reporting and recordkeeping requirements, Students.

Accordingly, chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 103—IMMIGRATION BENEFITS; BIOMETRIC REQUIREMENTS; AVAILABILITY OF RECORDS

■ 1. The authority citation for part 103 is revised to read as follows:

Authority: 5 U.S.C. 301, 552, 552a; 8 U.S.C. 1101, 1103, 1304, 1356, 1356b, 1372; 31 U.S.C. 9701; Pub. L.107–296, 116 Stat. 2135 (6 U.S.C. 1 *et seq.*); E.O. 12356, 47 FR 14874, 15557, 3 CFR, 1982 Comp., p. 166; 8 CFR part 2; Pub. L. 112–54, 125 Stat 550.

■ 2. Amend § 103.7 by revising paragraphs (b)(1)(ii)(B) and (H) and adding paragraph (b)(1)(ii)(O) to read as follows:

§ 103.7 Fees.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(B) *Petition for Approval of School for Attendance by Nonimmigrant Student (Form I–17).* For filing a petition for school certification: $3,000, plus a site visit fee of $655 for each location required to be listed on the form. For filing a petition for school recertification: $1,250, plus a site visit fee of $655 for each new location required to be listed on the form.

* * * * *

(H) *Fee Remittance for F, J, and M Nonimmigrants (Form I–901).* The fee for Form I–901 is:

(*1*) For F and M students: $350.

(*2*) For J–1 au pairs, camp counselors, and participants in a summer work or travel program: $35.

(*3*) For all other J exchange visitors (except those participating in a program sponsored by the Federal Government): $220.

(*4*) There is no Form I–901 fee for J exchange visitors in federally funded programs with a program identifier designation prefix that begins with G–1, G–2, G–3, or G–7.

* * * * *

(O) *Notice of Appeal or Motion (Form I–290B) filed with ICE SEVP.* For a Form I–290B filed with the Student and Exchange Visitor Program (SEVP): $675.

* * * * *

PART 214—NONIMMIGRANT CLASSES

■ 3. The authority citation for part 214 is revised to read as follows:

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305, 1356, and 1372; section 643, Pub. L. 104–208, 110 Stat. 3009–708; Pub. L. 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note, and 1931 note, respectively, 48 U.S.C. 1806; 8 CFR part 2.

■ 4. Amend § 214.3 by revising paragraph (h)(2) introductory text to read as follows:

§ 214.3 Approval of schools for enrollment of F and M nonimmigrants.

* * * * *

(h) * * *

(2) *Recertification.* Schools are required to file a completed petition for SEVP recertification before the school's certification expiration date, which is 2 years from the date of their previous SEVP certification or recertification expiration date. The school must submit the proper nonrefundable recertification petition fee as provided in 8 CFR 103.7(b)(1)(ii)(B). SEVP will review a petitioning school's compliance with the recordkeeping, retention, and reporting, and other requirements of paragraphs (f), (g), (j), (k), and (l) of this section, as well as continued eligibility for certification, pursuant to paragraph (a)(3) of this section.

* * * * *

■ 5. Amend § 214.4 by revising the section heading and paragraphs (a)(1) and (h) to read as follows:

§ 214.4 Denial of certification, denial of recertification, or withdrawal of SEVP certification.

(a) *General*—(1) *Denial of certification.* The petitioning school will be notified of the reasons and its appeal rights if a petition for certification is denied, in accordance with the provisions of 8 CFR 103.3(a)(1)(iii). A petitioning school denied certification may file a new petition for certification at any time.

* * * * *

(h) *Appeals.* A school may file an appeal of a denial or withdrawal no later than 15 days after the service of the decision by ICE. The appeal must state the reasons and grounds for contesting the denial or withdrawal of the approval. The appeal must be accompanied by the fee as provided in 8 CFR 103.7(b)(1)(ii)(O).

* * * * *

■ 6. Amend § 214.13 by revising paragraph (a) to read as follows:

§ 214.13 SEVIS fee for certain F, J, and M nonimmigrants.

(a) *Applicability.* The aliens in paragraphs (a)(1) through (3) of this section are required to submit a payment in the amount indicated for their status to the Student and Exchange Visitor Program (SEVP) in advance of obtaining nonimmigrant status as an F or M student or J exchange visitor, in addition to any other applicable fees, except as otherwise provided for in this section:

(1) An alien who applies for F–1 or F–3 status in order to enroll in a program of study at an SEVP-certified institution of higher education, as defined in section 101(a) of the Higher Education Act of 1965, as amended, or in a program of study at any other SEVP-certified academic or language training institution, including private elementary and secondary schools and public secondary schools, the amount of $350;

(2) An alien who applies for J–1 status in order to commence participation in an exchange visitor program designated by the Department of State, the amount of $220, with a reduced fee for certain exchange visitor categories as provided in paragraphs (b)(1) and (c) of this section; and

(3) An alien who applies for M–1 or M–3 status in order to enroll in a program of study at an SEVP-certified vocational educational institution, including a flight school, in the amount of $350.

* * * * *

Kevin K. McAleenan,

Acting Secretary of Homeland Security.

[FR Doc. 2019–10884 Filed 5–22–19; 8:45 am]

BILLING CODE 9111–28–P

FEDERAL REGISTER

Vol. 84 Thursday,
No. 100 May 23, 2019

Part VI

The President

Federal Register
Vol. 84, No. 100
Thursday, May 23, 2019

Presidential Documents

Title 3—

The President

Proclamation 9893 of May 19, 2019

Adjusting Imports of Aluminum Into the United States

By the President of the United States of America

A Proclamation

1. On January 19, 2018, the Secretary of Commerce (Secretary) transmitted to me a report on his investigation into the effect of imports of aluminum articles on the national security of the United States under section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862). The Secretary found and advised me of his opinion that aluminum articles were being imported into the United States in such quantities and under such circumstances as to threaten to impair the national security of the United States.

2. In Proclamation 9704 of March 8, 2018 (Adjusting Imports of Aluminum Into the United States), I concurred in the Secretary's finding that aluminum articles were being imported into the United States in such quantities and under such circumstances as to threaten to impair the national security of the United States, and decided to adjust the imports of aluminum articles, as defined in clause 1 of Proclamation 9704, by imposing a 10 percent ad valorem tariff on such articles imported from most countries.

3. In Proclamation 9704, I further stated that any country with which we have a security relationship is welcome to discuss with the United States alternative ways to address the threatened impairment of the national security caused by imports from that country, and noted that, should the United States and any such country arrive at a satisfactory alternative means to address the threat to the national security such that I determine that imports from that country no longer threaten to impair the national security, I may remove or modify the restriction on aluminum articles imports from that country and, if necessary, adjust the tariff as it applies to other countries, as the national security interests of the United States require.

4. The United States has successfully concluded discussions with Canada and Mexico on satisfactory alternative means to address the threatened impairment of the national security posed by aluminum imports from Canada and Mexico. The United States has agreed on a range of measures with Canada and Mexico to prevent the importation of aluminum that is unfairly subsidized or sold at dumped prices, to prevent the transshipment of aluminum, and to monitor for and avoid import surges. These measures are expected to allow imports of aluminum from Canada and Mexico to remain stable at historical levels without meaningful increases, thus permitting the domestic capacity utilization to remain reasonably commensurate with the target level recommended in the Secretary's report. In my judgment, these measures will provide effective, long-term alternative means to address the contribution of these countries' imports to the threatened impairment of the national security.

5. In light of these agreements, I have determined that, under the framework in the agreements, imports of aluminum from Canada and Mexico will no longer threaten to impair the national security, and thus I have decided to exclude Canada and Mexico from the tariff proclaimed in Proclamation 9704, as amended. The United States will monitor the implementation and effectiveness of these measures in addressing our national security needs, and I may revisit this determination as appropriate.

6. In light of my determination to exclude, on a long-term basis, these countries from the tariff proclaimed in Proclamation 9704, as amended, I have considered whether it is necessary and appropriate in light of our national security interests to make any corresponding adjustments to such tariff as it applies to other countries. I have determined that, in light of the agreed-upon measures with Canada and Mexico, it is necessary and appropriate, at this time, to maintain the current tariff level as it applies to other countries.

7. Section 232 of the Trade Expansion Act of 1962, as amended, authorizes the President to adjust the imports of an article and its derivatives that are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security.

8. Section 604 of the Trade Act of 1974, as amended (19 U.S.C. 2483), authorizes the President to embody in the Harmonized Tariff Schedule of the United States (HTSUS) the substance of statutes affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States of America, including section 232 of the Trade Expansion Act of 1962, as amended, section 301 of title 3, United States Code, and section 604 of the Trade Act of 1974, as amended, do hereby proclaim as follows:

(1) Clause 2 of Proclamation 9704, as amended, is further amended in the second sentence by deleting the ''and'' before ''(c)'' and inserting before the period at the end: '', and (d) on or after 12:01 a.m. eastern daylight time on May 20, 2019, from all countries except Argentina, Australia, Canada, and Mexico''.

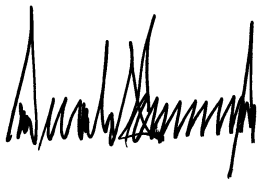
(2) The ''Article description'' for heading 9903.85.01, in subchapter III of chapter 99 of the HTSUS, is amended by replacing ''of Australia'' with ''of Australia, of Canada, of Mexico''.

(3) The modifications made by clauses 1 and 2 of this proclamation shall be effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on May 20, 2019, and shall continue in effect, unless such actions are expressly reduced, modified, or terminated.

(4) Any imports of aluminum articles from Canada and Mexico that were admitted into a U.S. foreign trade zone under ''privileged foreign status'' as defined in 19 CFR 146.41, prior to 12:01 a.m. eastern daylight time on May 20, 2019, shall not be subject upon entry for consumption made after 12:01 a.m. eastern daylight time on May 20, 2019, to the additional 10 percent ad valorem rate of duty imposed by Proclamation 9704, as amended.

(5) Any provision of previous proclamations and Executive Orders that is inconsistent with the actions taken in this proclamation is superseded to the extent of such inconsistency.

IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of May, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-third.



[FR Doc. 2019–10999
Filed 5–22–19; 11:15 am]
Billing code 3295–F9–P

Presidential Documents

Proclamation 9894 of May 19, 2019

Adjusting Imports of Steel Into the United States

By the President of the United States of America

A Proclamation

1. On January 11, 2018, the Secretary of Commerce (Secretary) transmitted to me a report on his investigation into the effect of imports of steel articles on the national security of the United States under section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862). The Secretary found and advised me of his opinion that steel articles were being imported into the United States in such quantities and under such circumstances as to threaten to impair the national security of the United States.

2. In Proclamation 9705 of March 8, 2018 (Adjusting Imports of Steel Into the United States), I concurred in the Secretary's finding that steel articles, as defined in clause 1 of Proclamation 9705, as amended by clause 8 of Proclamation 9711 of March 22, 2018 (Adjusting Imports of Steel Into the United States), were being imported into the United States in such quantities and under such circumstances as to threaten to impair the national security of the United States, and decided to adjust the imports of these steel articles by imposing a 25 percent ad valorem tariff on such articles imported from most countries.

3. As stated in the Proclamation dated May 16, 2019 (Adjusting Imports of Steel Into the United States), the Secretary has now advised me that the domestic industry's capacity utilization has improved to approximately the target level recommended in the Secretary's report. This target level, if maintained for an appropriate period, will improve the financial viability of the domestic steel industry over the long term.

4. In Proclamation 9705, I further stated that any country with which we have a security relationship is welcome to discuss with the United States alternative ways to address the threatened impairment of the national security caused by imports from that country, and noted that, should the United States and any such country arrive at a satisfactory alternative means to address the threat to the national security such that I determine that imports from that country no longer threaten to impair the national security, I may remove or modify the restriction on steel articles imports from that country and, if necessary, adjust the tariff as it applies to other countries, as the national security interests of the United States require.

5. The United States has successfully concluded discussions with Canada and Mexico on satisfactory alternative means to address the threatened impairment of the national security posed by steel articles imports from Canada and Mexico. The United States has agreed on a range of measures with Canada and Mexico to prevent the importation of steel articles that are unfairly subsidized or sold at dumped prices, to prevent the transshipment of steel articles, and to monitor for and avoid import surges. These measures are expected to allow imports of steel articles from Canada and Mexico to remain stable at historical levels without meaningful increases, thus permitting the domestic industry's capacity utilization to continue at approximately the target level recommended in the Secretary's report. In my judgment, these measures will provide effective, long-term alternative means to address the contribution of these countries' imports to the threatened impairment of the national security.

6. In light of these agreements, I have determined that, under the framework in the agreements, imports of steel articles from Canada and Mexico will no longer threaten to impair the national security, and thus I have decided to exclude Canada and Mexico from the tariff proclaimed in Proclamation 9705, as amended. The United States will monitor the implementation and effectiveness of these measures in addressing our national security needs, and I may revisit this determination as appropriate.

7. In light of my determination to exclude, on a long-term basis, Canada and Mexico from the tariff proclaimed in Proclamation 9705, as amended, I have considered whether it is necessary and appropriate in light of our national security interests to make any corresponding adjustments to such tariff as it applies to other countries. I have determined that, in light of the agreed-upon measures with Canada and Mexico, it is necessary and appropriate, at this time, to maintain the current tariff level as it applies to other countries.

8. Section 232 of the Trade Expansion Act of 1962, as amended, authorizes the President to adjust the imports of an article and its derivatives that are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security.

9. Section 604 of the Trade Act of 1974, as amended (19 U.S.C. 2483), authorizes the President to embody in the Harmonized Tariff Schedule of the United States (HTSUS) the substance of statutes affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States of America, including section 232 of the Trade Expansion Act of 1962, as amended, section 301 of title 3, United States Code, and section 604 of the Trade Act of 1974, as amended, do hereby proclaim as follows:

(1) Proclamation 9705, as amended, is further amended by revising clause 2 to read as follows:

''(2)(a) In order to establish certain modifications to the duty rate on imports of steel articles, subchapter III of chapter 99 of the HTSUS is modified as provided in the Annex to this proclamation and any subsequent proclamations regarding such steel articles.

(b) Except as otherwise provided in this proclamation, or in notices published pursuant to clause 3 of this proclamation, all steel articles imports covered by heading 9903.80.01, in subchapter III of chapter 99 of the HTSUS, shall be subject to an additional 25 percent ad valorem rate of duty with respect to goods entered for consumption, or withdrawn from warehouse for consumption, as follows: (i) on or after 12:01 a.m. eastern daylight time on March 23, 2018, from all countries except Argentina, Australia, Brazil, Canada, Mexico, South Korea, and the member countries of the European Union; (ii) on or after 12:01 a.m. eastern daylight time on June 1, 2018, from all countries except Argentina, Australia, Brazil, and South Korea; (iii) on or after 12:01 a.m. eastern daylight time on August 13, 2018, from all countries except Argentina, Australia, Brazil, South Korea, and Turkey; (iv) on or after 12:01 a.m. eastern daylight time on May 20, 2019, from all countries except Argentina, Australia, Brazil, Canada, Mexico, South Korea, and Turkey; and (v) on or after 12:01 a.m. eastern daylight time on May 21, 2019, from all countries except Argentina, Australia, Brazil, Canada, Mexico, and South Korea. Further, except as otherwise provided in notices published pursuant to clause 3 of this proclamation, all steel articles imports from Turkey covered by heading 9903.80.02, in subchapter III of chapter 99 of the HTSUS, shall be subject to a 50 percent ad valorem rate of duty with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on August 13, 2018, and prior to 12:01 a.m. eastern daylight time on May 21, 2019. All steel articles imports covered by heading 9903.80.61,

in subchapter III of chapter 99 of the HTSUS, shall be subject to the additional 25 percent ad valorem rate of duty established herein with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on the date specified in a determination by the Secretary granting relief. These rates of duty, which are in addition to any other duties, fees, exactions, and charges applicable to such imported steel articles, shall apply to imports of steel articles from each country as specified in the preceding three sentences.''

(2) The ''Article description'' for heading 9903.80.01, in subchapter III of chapter 99 of the HTSUS, is amended by deleting ''of South Korea, of Brazil, of Turkey'' and inserting ''of Brazil, of Canada, of Mexico, of South Korea, of Turkey''.

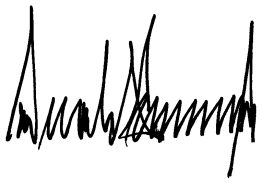
(3) The modifications made by clauses 1 and 2 of this proclamation shall be effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on May 20, 2019, and shall continue in effect, unless such actions are expressly reduced, modified, or terminated.

(4) The Proclamation dated May 16, 2019 (Adjusting Imports of Steel Into the United States), is amended by revising clause 5 to read as follows: ''The 'Article description' for heading 9903.80.01 in subchapter III of chapter 99 of the HTSUS is amended by replacing 'of South Korea, of Turkey' with 'of South Korea'.''.

(5) Any imports of steel articles from Canada and Mexico that were admitted into a U.S. foreign trade zone under ''privileged foreign status'' as defined in 19 CFR 146.41, prior to 12:01 a.m. eastern daylight time on May 20, 2019, shall not be subject upon entry for consumption made after 12:01 a.m. eastern daylight time on May 20, 2019, to the additional 25 percent ad valorem rate of duty as imposed by Proclamation 9705, as amended.

(6) Any provision of previous proclamations and Executive Orders that is inconsistent with the actions taken in this proclamation is superseded to the extent of such inconsistency.

IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of May, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-third.



[FR Doc. 2019–11002

Filed 5–22–19; 11:15 am]

Billing code 3295–F9–P

Reader Aids

Federal Register

Vol. 84, No. 100

Thursday, May 23, 2019

CUSTOMER SERVICE AND INFORMATION

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, MAY

CFR PARTS AFFECTED DURING MAY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

110.....18697
114.....18697

12 CFR

204.....20541
208.....21691
211.....21691
Ch. VI.....21693

Proposed Rules:

43.....23644
217.....21988
225.....21634, 21988
231.....18741
238.....21634, 21988
243.....21600
252.....21988
381.....21600
Ch. X.....21732
1003.....20049, 20972
1005.....21729
1006.....23274

13 CFR

Proposed Rules:

124.....21256
127.....21256

14 CFR

25 .....18701, 20021, 23456
39 .....18704, 18707, 19709, 20242, 20246, 20248, 20252, 20542, 20772, 22693, 22695, 22697, 23458, 23461, 23703
71 .....20256, 20257, 20258, 20774, 22362, 22363, 22364, 22365, 22366, 22699, 22701, 22959
97 .....18971, 18973, 23710, 23712

Proposed Rules:

25 .....18997, 20053, 21733
39 .....19745, 19879, 19881, 19885, 19888, 19891, 20054, 20057, 20300, 20303, 20822, 20823, 21268, 21270, 21273, 21276, 21279, 22075, 22738, 22740, 22743, 22986, 23740, 23742
71 .....20306, 22078, 22745, 22746, 22747

15 CFR

744 .....21233, 22961, 23468
762.....23468
774.....23886

Proposed Rules:

960.....21282

16 CFR

18.....20776
433.....18711
460.....20777
640.....23471
680.....23471
698.....23471

Proposed Rules:

Ch. I.....18746

17 CFR

Proposed Rules:

1.....22226
23.....21044
39.....22226
43.....21044
45.....21044
49.....21044
140.....22226

18 CFR

35.....23902

20 CFR

655.....20005

21 CFR

886.....22702
1308.....20023

Proposed Rule:

73.....20060
101.....22749
102.....22749
1308.....18423

22 CFR

40.....19712
41.....22968

24 CFR

Proposed Rules:

5.....20589
204.....19748

26 CFR

1.....20790, 23716
300.....20801

Proposed Rules:

1 .....18652, 18999, 21198, 22751, 22987

29 CFR

1602.....18383, 18974
1904.....21416
1910.....21416
1915.....21416
1926.....21416
4022.....21698
4041A 18715
4245.....18715
4281.....18715

Proposed Rules:

548.....21300
778.....21300
791.....21301
1910.....22756

30 CFR

250.....21908
916.....20259
934.....20264

Proposed Rules:

913.....18428
917.....18430, 20595
925.....18433, 20597
935.....20599
938.....18435

31 CFR

Proposed Rules:

33.....19000

32 CFR

151.....18383

Proposed Rules:

199.....18437
200.....18437

33 CFR

100 .....18727, 18974, 19715, 20027, 20028, 20270, 21699, 22969, 23486
117.....22702, 23488
165 .....18387, 18389, 18975, 20028, 20029, 20034, 20035, 20544, 20546, 20547, 21701, 21703, 21704, 22367, 22369, 22704, 22706, 22708, 22971, 22972, 23490, 23492, 23494, 23496, 23719, 23720, 23721
326.....18979

Proposed Rules:

100 .....20060, 20307, 20602, 22079
165 .....18452, 19003, 20307, 20318, 20825, 21302, 22403, 22405, 22988, 23748
175.....20827

36 CFR

Proposed Rules:

7.....21738

37 CFR

201.....20273

Proposed Rules:

201.....22762
202.....22762

38 CFR

0.....22709
17.....21668
21.....22370

Proposed Rules:

17.....22990
62.....22407

39 CFR

111 .....18731, 21238, 22710
233.....20804
3020.....18982
3050.....20806

Proposed Rules:

3020.....21304
3050.....22994
3060.....23503

40 CFR

49.....21240
52 .....18392, 18736, 18738, 18989, 18991, 19680, 19681, 20274, 20808, 21253, 22049, 22374, 22376, 22711, 22972, 22982, 22984, 23723, 23725
63.....23727
81.....21253
158.....18993
180 .....18398, 20037, 21706
271.....20549, 22378
282.....22727
300.....20550, 21708
1552.....21714

Proposed Rules:

1.....20062
52 .....19005, 19007, 19750, 19893, 20070, 20071, 20318, 20604, 20838, 22082, 22084, 22087, 22091, 22093, 22768, 22771, 22774, 22786, 22787, 22995, 22996, 23504, 23750
63 .....18926, 20208, 22642
80.....21305
81 .....19007, 19893, 22093, 22101
131.....18454
174.....20320
180.....20320, 20843
282.....22805
300.....20073

41 CFR

Proposed Rules:

51.....23005
52.....23005
53.....23005
54.....23005
55.....23005
56.....23005
57.....23005
58.....23005
App. C Ch. 301.....19895
304–2.....19895
304–3.....19895
304–5.....19895
304–6.....19895

42 CFR

403.....20732
405.....19855
422.....23832
423.....19855, 23832
447.....19718
484.....20810
1001.....20810

Proposed Rules:

410.....18748
412.....19158
413.....19158
414.....18748
424.....18748
488.....18748
493.....18748
495.....19158

43 CFR

3160.....22379

44 CFR

64.....18403, 22049

45 CFR

88.....23170
1181.....22943
1182.....22943
1184.....22943

Proposed Rules:

155.....19000

46 CFR

401.....20551
404.....20551

Proposed Rules:

25.....20827
355.....18468
356.....18469

47 CFR

2.....20810
25.....20810, 22733
27.....23498
30.....18405, 20810
52.....19874
54.....19874
64.....19874
73.....21718
76.....18406

Proposed Rules:

1 .....18757, 20077, 23508
2.....20088, 23508
27.....23508
30.....20077
73.....19897
95.....20088

48 CFR

Ch.1 .....19834, 19847
1 19839
2 .....19835, 19839
3 19839
4 .....19837, 19839
5 19839
6 19839
7 19839
8 .....19837, 19839
9 19839
10 19835
11 19839
12 19835
13 19835
16 .....19837, 20292
17 .....19837, 19839
18 19835
19 19839
22 19839
26 .....19835, 19839
30 19839
31 19839
35 19837
45 19839
50 19839
52 19839
53 19839
501 22381
515 22381
538 22381
552 22381

Proposed Rules:

2 20607

49 CFR

10 23728
209 23730
213 23730
214 23730
215 23730
217 23730
218 23730
219 23730
220 23730
221 23730
222 23730
223 23730
224 23730
225 23730
227 23730
228 23730
229 23730
230 23730
231 23730
232 23730
233 23730
234 23730
235 23730
236 23730
237 23730
238 23730
239 23730
240 23730
241 23730
242 23730
243 23730
270 23730
272 23730
1002 20292
1312 20292

Proposed Rules:

225 22410
240 20472
571 21309
576 21741

50 CFR

17 .....19877, 23644
229 22051
300 18409
622 .....19728, 22073, 22383, 22389
635 .....20296, 22734, 23519
648 .....20820, 21723, 22392
660 .....19729, 20578, 23737

Proposed Rules:

17 .....19013, 21312
218 21126
635 23014
648 .....18471, 20609, 22104, 22426

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List May 14, 2019

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.